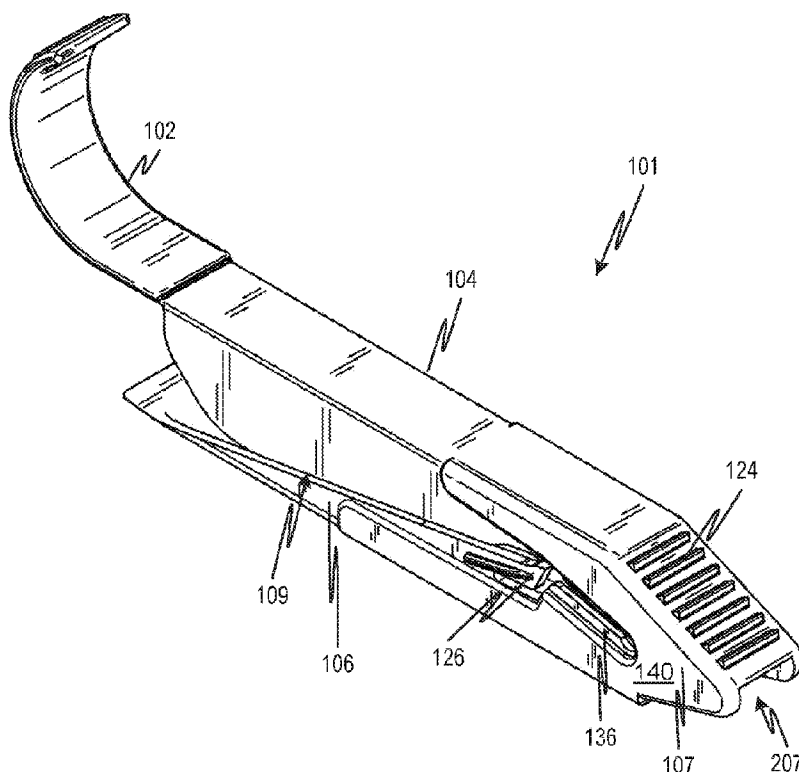




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(57) Abrégé/Abstract:

A needle set includes a needle guard with upper and lower jaws each defining a channel and joined at a hinge. Each edge of the jaws is aligned with and spaced from a respective edge of the opposite jaw defining slots alongside walls of the jaws. A winged needle has a cannula, a hub with a pair of wings with a tube connected to the cannula by the hub. The hinge portion has an opening into which the tube is received, and the side walls are spaced apart to permit the hub to be received between the jaws with the wings in the slots. The slots progressively narrow to a first spacing that is narrower than a thickness of each wing at a point thereof, and thereafter expand linearly to a second spacing that is substantially equal to the thickness of the wings.

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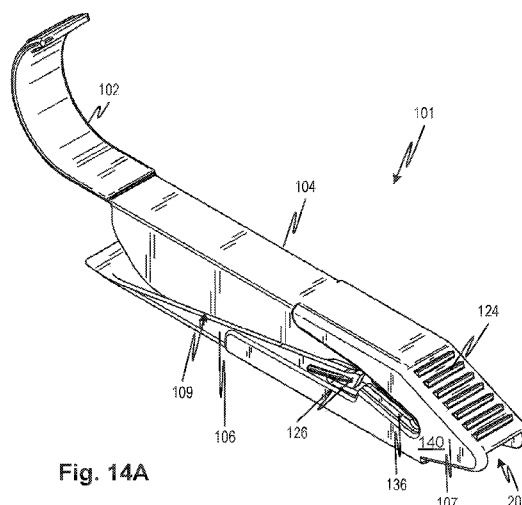


Fig. 14A

(57) **Abstract:** A needle set includes a needle guard with upper and lower jaws each defining a channel and joined at a hinge. Each edge of the jaws is aligned with and spaced from a respective edge of the opposite jaw defining slots alongside walls of the jaws. A winged needle has a cannula, a hub with a pair of wings with a tube connected to the cannula by the hub. The hinge portion has an opening into which the tube is received, and the side walls are spaced apart to permit the hub to be received between the jaws with the wings in the slots. The slots progressively narrow to a first spacing that is narrower than a thickness of each wing at a point thereof, and thereafter expand linearly to a second spacing that is substantially equal to the thickness of the wings.

NEEDLE GUARD

[0001] This application claims priority to U.S. Provisional Application Number **62/202,792** filed on August 8, 2015. The entire content of this application is hereby incorporated by reference as if it was repeated herein.

Background

[0002] After a needle is used in medical care it is desirable to quickly cover the needle and render it incapable of subsequent punctures, especially for needles that are used in contact with blood. Utterberg et al. U.S. Pat. Nos. 5,112,311 and 5,562,637 disclose a sliding body or sheath carried on a tubular set such as a fistula set for hemodialysis, having a winged needle at the end. The sliding sheath or guard of the cited patent can be brought forward to enclose the needle as the needle is retracted from the patient, so that the needle is immediately secured against accidental needle punctures by the sliding needle guard. The wings of the needle, which are commonly used in conjunction with a variety of intravenous needles, slide within opposed slots of the needle protector of the cited patent, and are locked in place when the needle is fully withdrawn into the sliding sheath as described.

[0003] Figs. **1A** and **1B** show a needle guard **1** according to the prior art. A needle guard **1** (also referred to as guard **1**) has an upper jaw **4** and a lower jaw **6** joined at a hinge **7** formed in a monolithic structure defining a cavity **12** with slots on either side. The front slots **9** are defined by bottom edges **8** of the upper jaw side walls **13** and top edges **10** of the lower jaw side walls **14**. The rear end of guard **1** is defined as the rounded wedge shape on the left side of Fig. **1A** and the front end of guard **1** is defined as the end of upper jaw **4** shown on the right side of Fig. **1A**. Side walls **13** and **14** have uniform thickness from the front end to the rear end. The front slots **9** define the cavity **12**. As may be seen in the drawing, the front slots **9** (one on either side) are tapered such that the bottom edges **8** of upper jaw side wall **13** and top edges **10** of the lower jaw side wall **14** form an acute angle (indicated by the projecting lines **18** and **19**). Further, the size of the slots is large, larger at the opening of cavity **12** than the thickness of the wings of a winged needle **90** shown in Figs. **2A-2C**, as indicated by the spacing between projecting lines **18**

and **19**. This facilitates easy capture of needle wings when the winged needle **90** is drawn into the guard **1**, but it also makes it possible for tube **60** and the cannula **52** of the winged needle to pass somewhat sideways through the slot as shown in Fig. **2C**. In a clinical environment where the process is repeated many times a day, there is a substantial risk of inattention or hasty withdrawals leading to a partially sideways pull on the needle tubing and consequent misalignment of the guard.

[0004] A rear slot **35** is defined between edges **34** and **36** that also taper as indicated by projections **30** and **32** that are aligned with the edges **34** and **36**. The rear slot **35** receives wings of a winged needle as discussed below. The edges **34** and **36** form an acute angle as indicated by the projections **30** and **32** of the edges **34** and **36**.

[0005] A resilient latch **26** is formed to catch the wings of a winged needle drawn into the rear slot **35**. The latch **26** has a straight edge facing toward the upper jaw **4**. A finger shield **2** extends forward from the front end **20** of the upper jaw **4** and curls up as shown in Figs. **1A** and **1B**. The finger shield **2** has a uniform thickness through its entire length, except for a small drum shaped portion at its front end caused as a remnant of casting or molding. The finger shield **2** facilitates holding the guard **1** in position while the needle is drawn into it and further protects the user from the sharp needle point passing below the finger shield **2** when the tube **60** is pulled through needle guard **1**. A front end **22** of the lower jaw **6** ends behind (*i.e.*, extending less toward the front than) a front end **20** of the upper jaw **4** as highlighted by the angle formed between a line **17** that is perpendicular to the guard **1** major axis and a line **16** connecting the front end **22** of the lower jaw **6** that ends behind a front end **20** of the upper jaw **4**.

[0006] A winged needle **90** includes a hub **49** which holds cannula **52**, as illustrated in Fig. **2A**. The hub has wings **53** each of which includes a thin wing portion **51** transitioning to thick wing portions **50** which are thicker than thin wing portions **51**.

[0007] Figs. **2A – 2C** illustrate a method of use of a prior art needle guard **1**. When the cannula **52** is to be withdrawn from the patient, the guard **1** is held in place as the tube **60** is pulled back drawing the cannula **52** through the cavity **12** and the wings **53** into the slots **9** as shown in Fig. **2B**. Thin wing portions **51** of wings **53** are supposed engage vertically with the front

slot **9** while thick wing portions **50** are supposed remain horizontally outside the front slot **9** and provide horizontal stabilization. However, this is not always the case, given the large opening of the front slot **9**.

[0008] If the tube **60** is pulled at an angle relative to the prior art needle guard **1**, the cannula **52** can protrude through one of the slots **9** as shown in Fig. **2C** thereby causing the needle to remain exposed and defeating the effect and purpose of the guard **1**.

[0009] Even when the needle guard of the prior art is used properly, there is also a risk that a fingertip or other part of a user's or third party's body may be inadvertently pushed into or otherwise enter the tip creating a risk of an accidental puncture. The body part does not need to enter very far because the housed needle tip is not far from the front of the device.

Summary

[0010] A needle guard reduces the risk of misalignment and concomitant protrusion of a needle due to imprecise use. In comparison to previous configurations, the inventive device may have narrowed slots that receive the wings of a winged needle. The slots may further be about as narrow as the wings are thick. The slots may further be narrower than the wings are thick. The slots may have parallel edges such that they have a uniform width over a substantial length thereof. The slots may have parallel edges such that they have a uniform width over a majority thereof.

[0011] In embodiments, the sides and/or rear end are reinforced to prevent the relative lateral movement of upper and lower jaws which may permit the needle to slip out the side through one of the slots once drawn into the guard. The resistance to this mode of movement may be further increased by forming the guard of high density polyethylene (HDPE). In embodiments, the HDPE has a flexural modulus of over **300 Mpa**. In embodiments, the HDPE has a flexural modulus of over **1000 Mpa**. In embodiments, the HDPE has a flexural modulus of at least **1200 Mpa**.

[0012] In embodiments, the lower jaw extends beyond the upper jaw. This helps to protect against use with slightly longer needles due to manufacturing variability and incomplete retraction of the needle within the guard. It also facilitates holding and stabilizing the guard

against the skin of the patient when the needle is retracted. The lower jaw may have a rounded forward edge or straight. The rounded edge may increase comfort while the straight forward edge may improve ease of manipulation.

[0013] In embodiments, a home slot that receives the needle wings in a locked position thereby retaining the needle within the guard, has a substantially constant width. In variants, the home slot is tilted further than prior art embodiments to push the needle up against the upper interior wall of the upper jaw.

[0014] In embodiments, ribs are molded into on the back end to facilitate use. The back end may be held rather than using an integral finger shield or guard to hold the shield or guard during the drawing of the needle into the guard.

[0015] In embodiments, a resilient latch by virtue of its shape and the use of HDPE provides a more distinct tactile feedback upon engagement of the wings.

[0016] Objects and advantages of embodiments of the disclosed subject matter will become apparent from the following description when considered in conjunction with the accompanying drawings. The foregoing summary does not comprehend all the embodiments or inventive aspects of the disclosed subject matter and serves merely to assist the reader.

Brief Description of the Drawings

[0017] The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate exemplary embodiments of the disclosure, and, together with the general description given above and the detailed description given below, serve to explain the features of embodiments of the disclosed subject matter. The accompanying drawings have not necessarily been drawn to scale. Where applicable, some features may not be illustrated to assist in the description of underlying features.

[0018] Figs. **1A** and **1B** show a needle guard according to the prior art.

[0019] Figs. **2A** and **2B** illustrate a method of using a prior art needle guard.

[0020] Fig. **2C** illustrates an improper engagement of a needle with a needle guard according to the prior art.

[0021] Figs. **3A** and **3B** illustrate a needle guard according to embodiments of the disclosed subject matter.

[0022] Fig. **4A** illustrates a view of a winged needle according to embodiments of the disclosed subject matter.

[0023] Fig. **4B** illustrates a view of the winged needle of Fig. **4A** being drawn into a needle guard according to embodiments of the disclosed subject matter.

[0024] Fig. **4C** shows a front view of the needle guard shown in Fig. **4B**.

[0025] Figs. **5A** and **5B** illustrate features of a needle guard as well a method of use of a needle guard according to embodiments of the disclosed subject matter.

[0026] Figs. **5C** and **5D** illustrate a feature of an extended lower jaw of the disclosed embodiments by comparing an embodiment **5C** of the disclosed subject matter with a prior art needle guard **5D**.

[0027] Figs. **6A** and **6B** show an abstract illustration of a needle guard whose features are exaggerated to illustrate the engagement between a needle guard and wings of a needle hub according to embodiments of the disclosed subject matter.

[0028] Figs. **7A** and **7B** show an abstract illustration of a needle guard whose features are exaggerated to illustrate the shape of the guard and the engagement between the guard and needle according to embodiments of the disclosed subject matter and wings of a needle hub.

[0029] Fig. **7C** illustrates a cross-sectional view across plane C-C' in Fig. **7B**.

[0030] Figs. **7D** and **7E** illustrate aspects of the molding operation for a needle guard according to embodiments of the disclosed subject matter.

[0031] Figs. **8A-8J** illustrate the progression of a needle hub wing through a needle guard with a bridge slot according to embodiments of the disclosed subject matter.

[0032] Fig. **9** illustrates a cut-away view of a needle guard with a resilient plug according an embodiment of the disclosed subject matter.

[0033] Fig. **10** illustrates a cut-away view of a needle guard with an absorbent surface according to embodiments of the disclosed subject matter.

[0034] Figs. **11A** and **11B** illustrate a needle guard according to embodiments of the disclosed subject matter with Fig. **11A** showing the configuration after being freed from a mold and Fig. **11B** showing the configuration after being put in an operating state.

[0035] Fig. **12** illustrates a finger shield of a needle guard according to embodiments such as disclosed in Figs. **11A** and **11B**.

[0036] Figs. **13A**, **13B**, and **13C** illustrate a method of using a finger shield of a needle guard according to embodiments of the disclosed subject matter.

[0037] Figs. **14A** and **14B** illustrate a needle guard according to embodiments of the disclosed subject matter.

[0038] Embodiments will hereinafter be described in detail below with reference to the accompanying drawings, wherein like reference numerals represent like elements.

Detailed Description of the Embodiments

[0039] Embodiments will hereinafter be described in detail below with reference to the accompanying drawings, wherein like reference numerals represent like elements.

[0040] Needle guards and needle sets according to embodiments of the disclosure prevent accidental punctures of users of the needle guard or caretakers of the users. In particular, features are provided to further protect against incorrectly sheathed needles, accidental contact with sheathed needles, and other problems with prior art needle guards.

[0041] Referring to Fig. **4A**, a winged needle **90** includes a hub **49** which holds cannula **52**. The hub **49** has wings **53** each of which includes two thin wing portions **51** extending laterally on substantially opposite sides of the hub **49**. The thin wing portions **51** attach the hub **49** to thick wing portions **50**, which are thicker than the thin wing portions **51**. In embodiments the thickness difference is a factor of **2** or **3** or a number approximately in that range. The thin wing portion **51** may transition to the thick wing portion **50** progressively forming an inclined ramp **85** as

shown in Fig. 7C. Alternatively, the transition may be abrupt forming a step (not shown). In either case, a valley 93 is defined between the side of the hub 49 and the thick wing portion 50. A similar valley may be formed on the bottom side of the winged needle 90 (not shown). The valley 93 may facilitate the retention and proper alignment of the hub 49 by providing interfering engagement between the step or ramp and the edges of the side walls 114 of the lower (and/or upper if such a valley is present) jaw 106 according to the respective embodiment.

[0042] The bottom of the hub 49 and may include a nub 54 projecting downward as shown in Fig. 4A. The nub 54 is illustrated with a flat bottom surface and has a height measured down and away from the hub 49. Even though nub 54 is illustrated with a flat bottom surface, the bottom surface may have a more curved shape. The bottom surface shape of the nub 54 can be shaped to fit the space between side walls 114 of the lower jaw 106 of needle guard 101 as illustrated in Figs. 3A-3B and discussed in more detail *infra*. Other shapes for a protrusion such as nub 54 may be provided, its function being to help align the winged needle 90 with a needle guard such as needle guard 101 discussed presently by providing an interfering engagement of the protrusion with the side wall 114 edge leading portion 77 on the lower jaw which may be inserted underneath the hub 49 to initially align the hub 49 with the needle guard 101. These features are shown in Fig. 4C.

[0043] Referring to Figs. 4B and 4C, Fig. 4B illustrates the needle guard 101 in relation to the needle hub 49 at an initial time during a withdrawal procedure according to embodiments of the disclosed subject matter. A tube 60 passes through a rear opening 207 of the needle guard 101 and exits through the cavity 112 at the front end. This is a configuration of a needle set 89 that includes the winged needle 90 and needle guard 101 as part of the needle set 89. The user does not need to establish this configuration except for initially positioning the needle guard 101 with respect to the winged needle 90 by sliding the needle guard 101 along the tube 60. The tube 60 is connected to the winged needle 90. The winged needle 90 includes hub 49 and cannula 52. The cannula 52 is normally inserted at an appropriate site such as a patient's blood vessel, and the wings 53 of the hub 49 are attached to the patient with tape. When the cannula 52 is to be withdrawn from the patient, the needle guard 101 is manually held in place using the finger shield 102, raised ribs 124 located at the hinge region thereof, or a combination of these. The

finger shield's **102** position, shape, and size are selected to permit pressure to be applied at the puncture site where the cannula **52** enters the patient's skin. When the needle guard **101** is in this position, the lower jaw **106** front edge **122** may be placed under the hub **49**. If a protrusion such as nub **54** is present, it may be guided by the side wall **114** edge leading portion **77** as shown in Fig. **4C**. As the tube **60** is pulled back, drawing the cannula **52** through the cavity **112** the wings **53** are guided into the slots **109** as shown, for example, in Fig. **4B**, **7A**, and **7B**. Thin wing portions **51** engage vertically with the front slot **109** while thick wing portions **50** remain horizontally outside the front slot **109** and provide horizontal stabilization due to interfering engagement with top edge **110** and/or bottom edge **108**. In other words, the valley **93** may trap the bottom edge **108** of the upper side wall **113** and/or top edge **110** of the lower side wall **114** within it thereby steering the winged needle **90** straight (aligned with its axis parallel to the longitudinal axis of the needle guard **101**) with respect to the needle guard **101**. Again, at the same time, at least initially, the nub **54**, in embodiments where present, may also be guided by the side wall **114** edge leading portion **77**. Note that nub **54** is shown in Fig. **4C** merely to show its position relative to the needle guard **101** when the lower jaw is inserted under the hub **49** having a nub **54**. The drawing is not intended to show a disembodied nub or suggest that it is part of the lower jaw.

[0044] Note that in embodiments, the needle may be horizontally confined by a respective step or ramp in each of the wings as illustrated in Fig. **7C**. That is the left inclined ramp **85** may prevent movement in the right direction and the right inclined ramp **85'** may prevent movement in the left direction. Again the ramps may be steps and the limitation of movement is due to interfering engagement with the top edges **110**.

[0045] The needle guard **101**, according to embodiments of the disclosed subject matter, reduces the chances of cannula misalignment or other contact with a needle by providing a variety of features discussed herein, including:

- a. narrow slots that positively and interferingly engage the needle from an initial point of entry to the slots;
- b. increased lateral rigidity of the needle guard housing to prevent misalignment or failure of the slot edges to engage the needle;

c. a lower jaw that protrudes beyond the upper jaw to facilitate the ability to plate the lower jaw beneath the needle hub prior to drawing the needle;

d. an aperture at the front end that faces away from the needle tip as a result of an upward facing angle between the extended lower jaw and the upper jaw;

as well as other features.

[0046] Figs. **3A** and **3B** show a needle guard **101** substantially as described with reference to Figs. **4A** through **4C**. The needle guard **101** may prevent accidental punctures even when the user pulls the tubing at an angle relative to the needle guard **101**. The needle guard **101** has slots defined by top **110** and bottom **108** edges that may be substantially parallel or linearly converging from a position near the back of the needle guard **101** to the front of the needle guard **101**. Figs. **4A** and **4B** show an embodiment in which the top **110** and bottom **108** edges are parallel. Figs. **3A** and **3B** show an embodiment where these edges are not parallel but define a converging slot that defines a gap that is zero at the front end and the thickness of a wing of the winged needle at the other end. Either type of slot converging or parallel, may be provided in any of the embodiments. The upper and lower jaws may be such that the edges overlap, touch, converge but rest just short of touching, depending on the degree of convergence. Some degree of lateral offset of the edges of the upper jaw relative to the lower may be permitted to allow overlap, such as by making one of them slightly wider.

[0047] The slot may be made to converge by the structure of the guard and the process of cooling the part from a mold where the thickening of the needle guard **101** at the hinge end causes the upper and lower jaws to close due to slower cooling at the back part of the hinge portion than the front part of the hinge portion. This difference in cooling may be caused by the additional reinforcement provided by the thickened region **140**. The needle guard **101** is also made rigid through thickening of certain portions that affect the flexibility of the needle guard **101**. The narrower slot and the increased rigidity make it more difficult for the tubing of the needle assembly to fit between the lower jaw and the upper jaw. Thus the combination of the thicker rear portion of the needle guard **101** and the parallel or converging slots prevent escape of the needle by providing rigidity that keeps edges defining the slots aligned laterally and causing

cooling of the front side of the hinge region faster than the heavier rear side of the hinge region. Further the limited width of the slot as compared to the prior art prevents the escape of the needle as well. It is more difficult for the needle to become wedged into the slot than in the prior art configuration. To further enhance the rigidity, the choice of materials may be suitably limited. In embodiments the material may be a rigid polymer as indicated herein. The increased rigidity and narrower slot guides and secures the needle wings **53** during the entire removal of the needle, from the initial point of contact between thin wing portion **51** and the jaws until the wings **53** are securely locked in the rear slot **135**, to avoid the sharp needle tip extending out the slot opening, avoiding an accidental needle puncture.

[0048] The needle guard **101** has an upper jaw **104** and lower jaw **106** joined at hinge **107** and formed in a monolithic structure, defining a cavity **112** with slots on either side. The slots include a front slot **109** and rear slot **135** being defined by the bottom edge **108** of the side wall **113** of the upper jaw **104** and the top edge **110** of the side wall **114** of the lower jaw **106**. The front slot **109** may be called the receiving slot.

[0049] As may be seen in the drawing, the front slots **109** (one on either side) have a constant, or nearly constant width such that the upper jaw side wall **113** bottom edges **108** and lower jaw side wall **114** top edges **110** are parallel (indicated by the projecting lines **118** and **119**). Further, the size of the slots is narrow as indicated by the spacing between projecting lines **118** and **119**. In embodiments, the slot spacing can be as narrow, or narrower than, the thickness of the thin wing portion **51**, which keeps the cannula **52** contained between the slots.

[0050] Upper jaw **104** includes a substantially flat roof **115** and two opposed side walls **113** extending down from the roof **115**. Though roof **115** is illustrated as flat, it may be curved or have a triangular cross-section in different embodiments which may be combined with all of the embodiments discussed below. The curved roof or the triangular cross-section roof may guide the sharp point of the cannula to a point and resist sideways movement of the cannula point.

[0051] Each side wall **113** has a substantially straight upper edge integral with the roof **115** and extending down from roof **115**. The front end of the side wall **113** is curved from the

front end **120** to a straight bottom edge **108**. The bottom edge **108** extends to and abuts the bridge slot **138** as illustrated in Figs. **3A** and **8A**.

[0052] Side wall **113** does not have a uniform thickness. Instead, the side wall has a one thickness at the front end and includes a thickened region **140** at the rear end (toward the rear of the needle guard **101** shown on the left side of Fig. **3A**). The thickened region **140** extends from the upper jaw side wall **113** through the hinge **107** to the lower jaw side wall **114**. The thickened region has a thickness that is greater than the thickness of the side wall **113** and side wall **114** at the front end. The thickened region **140** of the needle guard **101** increases the stiffness of the part and minimizes the lateral bending of the upper and lower jaws. This lateral movement can cause the slot to open, allowing the needle tubing to wedge open the slot and thus creates the aforementioned condition of the cannula being exposed. The thickness of the wall may be greater than 1 mm. In embodiments, the wall is 1.25 mm in the thickened rear section of the guard. In embodiments, the thin and thick sections are 0.8 mm and 1.4 mm, respectively.

[0053] The roof **115** of the upper jaw extends from the front of the needle guard **101** toward the hinge **107**, joining the roof of the hinge **107**. The hinge **107** has two side walls and two rear slots **135** on opposite sides, as shown in Figs. **3A** and **3B**. The rear slot **135** is defined between edges **134** and **136** that also taper as indicated by projections **130** and **132** that are aligned with the edges **134** and **136**. The rear slot **135** receives wings of a winged needle as discussed below. The edges **134** and **136** form an acute angle as indicated by the projections **130** and **132** of the edges **134** and **136**. The rear end of rear slot **135** terminates in a partial circle. A resilient latch **126** is formed on the lower jaw side wall **114** to catch the wings of a winged needle drawn into the rear slot **135**.

[0054] The edges **134** and **136** have a height (measured in the direction substantially perpendicular to roof **115**) which is substantially equal or greater than the thickness of the thick wing portion **50**. This enables the edges **134** and/or **136** to mate with the valley **93** formed above thin wing portion **51**. The thick wing portions **50** remain on the outside of the edges **134** and **136** acting as fences to maintain the correct alignment of the needle inside the needle guard **101**.

The rear slot **135** abuts a bridge slot **138** which in turn abuts the front slot **109**, as shown in Figs. **3A**, **3B**, and **8A**.

[0055] The bridge slot **138** projects beyond the point where the extension of the bottom edge **108** and the extension of edge **134** would intersect, as shown in Fig. **8A**. The bridge slot **138** thus creates an enlarged space, void, recess, or cavity above the resilient latch **126**. The bridge slot **138** has a length d from one end (where it abuts the rear slot **135**) to an opposite end (where it abuts the front slot **109**) that is at least as long as the length of the cross-section of thin wing portion **51**, as shown in Fig. **8A**. The bridge slot **138** creates a recess at a location between the front slot **109** and the rear slot **135** that provides more space for the thin wing portion **51** to traverse from the front slot **109** to the rear slot **135**. The process of the thin wing portion **51** traversing the slots is illustrated in Fig. **8A-8F**, showing the thin wing portion **51** progressing through positions as it moves from the front slot **109** at the front of the needle guard **101** to the rear slot **135** at the rear of the needle guard **101**.

[0056] The recess created by the bridge slot **138** is an open space or a void above the resilient latch **126**. This void has a large aspect ratio such that the length d is greater than the height of the void measured from the top of the resilient latch **126** to the roof of the bridge slot **138**. In an embodiment of the disclosed subject matter the aspect ratio of the recess or void created by the bridge slot **138** above the resilient latch **126** is **2**. In an embodiment the aspect ratio is greater than **2**. In an embodiment the aspect ratio is greater than or equal to **3**. In an embodiment the aspect ratio is greater than or equal to **4**.

[0057] In an embodiment, the height of the open space created by the bridge slot **138** measured from the top of the resilient latch **126** (at the base of barb **127**) is greater than the height of the thin wing portion **51**, as shown by the free space above and below the thin wing portion **51** in Fig. **8A**. In an embodiment, the height of the open space above the upper tip of barb **127** is equal to or smaller than the height of the thin wing portion **51**, so that the thin wing portion **51** causes the resilient latch **126** to deflect downward when the thin wing portion **51** traverses the bridge slot **138** and presses on the barb **127**.

[0058] The bridge slot **138** has serpentine shape helps to resist the needle wings moving forward out of the rear slot **135** by bypassing the resilient latch **126**. The bridge slot **138** allows the front slot **109** and the rear slot **135** to be narrow, while allowing the thin wing portion **51** to smoothly make the turn from the front slot **109** to the rear slot **135**. The shape of the recess formed by the bridge slot **138** provides for a smooth and consistent pull of the winged needle **90** through the needle guard **101**. In an embodiment, the force required to be exerted on the tube **60** to pull the winged needle **90** through the needle guard **101** is constant through the pull from the point where the thin wing portion **51** first engages the front slot **109** until the thin wing portion **51** arrives at the rear end of the rear slot **135** and its progress is blocked by the rounded end of the rear slot **135**. The pulling force is based on the coefficient of friction between the straight bottom edge **108** and the top edge **110** pinching the thin wing portion **51** and on the force required to deflect the resilient latch **126** when the thin wing portion **51** traverses the bridge slot **138**. When the thin wing portion **51** first enters the front slot **109**, the pinching force of the straight bottom edge **108** and the top edge **110** is the only force contributing to the pulling force on the tube **60**. When the thin wing portion **51** reaches the bridge slot **138**, as shown in Fig. **8A**, the pinching force of the straight bottom edge **108** and the top edge **110** is exerted on only a small trailing portion of the thin wing portion **51**. At that point, the force to depress the resilient latch **126** compensates for the decrease of the pinching force exerted by the straight bottom edge **108** and the top edge **110**, providing for a substantially constant pulling force on the tube **60**. Providing a substantially constant pulling force provides a smooth and easily repeatable motion for the user of the needle guard **101**. It is safer to use a needle guard **101**, or any sharp object for that matter, when jarring or jerking movements are avoided.

[0059] Resilient latch **126** is partially an extension of the top edge **110** of the side wall **114** of the lower jaw **106**, as shown in Fig. **8A**. The resilient latch **126** includes a barb **127** at its rear end, as shown in Fig. **8A**. Thus, the upper edge of the resilient latch **126** is not straight, but has a bend or a kink upward to the tip of barb **127**. The upper edge of the resilient latch **126** has a hockey stick shape. The hockey stick shape creates a larger space between the bridge slot **138** and the resilient latch **126** as compared to an embodiment that lacks the hockey stick shape. Although Fig. **8A** illustrates the upward kink of barb **127** as having straight sides, the kink can be

formed with an upward curving edge, curving up from an extension of the top edge **110** toward the sharp tip or point of the barb **127**.

[0060] The resilient latch **126** is capable of movement down toward the lower jaw in response to force from the direction of the upper jaw, but it springs back. The resilient latch **126** is positioned such that the cross section of thin wing portion **51** can pass through the bridge slot **138** while the thin wing portion **51** depresses the resilient latch **126**, as shown in Figs. **8A-8F**. In Figs. **8A-8F**, a cross section of thin wing portion **51** is shown in sequence as it presses down on the resilient latch **126** and passes through bridge slot **138**. The bridge slot **138** creates a clearance space for the thin wing portion **51** above the upper edge of the resilient latch **126**.

[0061] In Fig. **8C** the resilient latch **126** is pressed down, but it springs back to its original position once the thin wing portion **51** slides beyond the resilient latch **126**, as shown in Fig. **8F**. The resilient latch **126** is resilient and springy such that it springs back with speed and force once the thin wing portion **51** passes beyond it. This springing back is like strumming a guitar string and creates an audible and also palpable sensation (a click) for the user of the needle guard **101**. The audible and palpable feedback confirm to the user that the needle **90** has been correctly retracted, improving the safety of the device. If the user does not hear and/or feel the expected feedback, the user will check closely to ensure that the needle has been retracted and reduce the likelihood of an accidental puncture.

[0062] The audible and palpable feedback is increased by barb **127** which makes the resilient latch **126** effectively taller, causing the thin wing portion **51** to press the resilient latch **126** down farther than if there was no barb. The additional depressing of the latch causes the latch to spring back with more force and increases the feedback for easier perception by the user. The barb **127** also provides a taller obstacle for the thin wing portion **51** once it has passed into the rear slot **135**. Any reverse movement (*i.e.*, from the rear of the needle guard **101** toward its front) is blocked by the barb **127**. Moreover, the use of barb **127**, instead of making the entirety of the resilient latch **126** taller, allows the resilient latch **126** to maintain springiness and maintain a smooth and continuous pulling motion for pulling winged needle **90** into the needle guard **101**. If the resilient latch **126** were made taller in its entirety, it would become more difficult for the thin wing portion **51** to deform the latch **126** as thin wing portion **51** travels through the slot.

[0063] Referring now to Fig. **8G**, a projection of the rear slot **135** is indicated by lines **139A** and **139B**. It will be observed that the tip portion **137** spans the entire of this projection indicating that the path for exit of the thin wing portion **51** is effectively blocked by it. Since there is no path guide that can deform the thin wing portion **51** such as a curved wall that could guide a leading edge of thin wing portion **51** over the latch **126**, the thin wing portion **51** is effectively blocked by the latch **126**. This contrasts with the prior art rear slot **35** which is only partially blocked. Also, the rear slot **135** is approximately the same width as the thin wing portion **51**. This is compared to the rear slot **35** which is substantially larger than the thin wing portion **51**. In addition, the bridge slot **138** transition to the rear slot **135** has a wall section **153** that curves down forming an acute angle with the walls of the rear slot **135**. The thin wing portion **51** is thus guided down toward the rear slot **135** (See Fig **8C**) in a direction lateral to the walls of the rear slot **135** defining a relaxed S-curve or chicane in the path defined by the front slot **109**, bridge slot **138**, and rear slot **135**. The wall section **153** pushes the thin wing portion **51** against the latch **126** causing it to retract (Figs. **8B** to **8C**).

[0064] Referring again to Fig. **8G**, it may also be observed that the front slot **109**, bridge slot **138**, and rear slot **135** have respective axes front slot axis **171**, bridge slot axis **172**, and rear slot axis **173**. The front slot axis **171** and bridge slot axis **172** are parallel but not collinear. It may also be observed that the transition from the bridge slot **138** to the rear slot **135** defines an S-shaped path around the latch **126** tip portion **137**. In terms of paths, the transitions through front slot **109**, bridge slot **138**, and rear slot **135** may be described as a jog followed by an S-shaped bend as shown in Fig. **8J**.

[0065] As shown in Figs. **3A** and **3B**, the edges **134** and **136** are of a reduced thickness (measured in the direction perpendicular to the side walls **113** and **114**) relative to the thickened region **140**, which bounds the edges **134** and **136**. One effect of this difference in thickness is that upon molding or casting of the needle guard out of a polymer material, the material at edges **134** and **136** cools faster than the material in the thickened region which surrounds edges **134** and **136**. The material that cools faster shrinks and creates tension in the surrounding material which, due to cooling more slowly, is still soft and pliable. The tension in the thinner material pulls on the still-pliable material, causing the hinge to partially close as it cools. The partial closing

of the hinge pulls the lower jaw against the upper jaw, biasing them against each other. Once the thickened portion cools, the material solidifies, setting its shape, and the bias of the upper jaw against the lower jaw persists. This process may be characterized as one where the jaws close slightly. This effect may create the converging shape of the slots. Note also that as a result of this jaw-closing, the draft of the inside of the needle guard **101** may be reduced and even be negative. That is, the hollow inside of the needle guard is formed in molding by a three-part mold including two molds that converge toward the longitudinal axis of the molded part (i.e., the needle guard **101**) and a core that fits inside and is drawn out of the front. In the embodiments shown, the core may have a zero or positive draft such that it can be pulled out of the molded part. If the part cools in the manner described, the internal draft angles will be reduced and may even be negative. As shown in Fig. **3A**, this biasing causes the upper jaw and the lower jaw to come in contact at least at the front end of the needle guard **101**.

[0066] To illustrate the terms and concepts described consider a molded hollow part **214** as shown in Fig. **7D**. The mold **210** may be a two-part mold that releases the part **214** (with legs **218A** and **218B**) in a direction normal to a plane of the page. A core **212** is inserted making the assembly a three-part mold with two actions (the splitting of the mold parts **210** and the withdrawal of the core **212**). In order for the core to be removable from the part **214** the core **212** has to be shaped with a neutral (angle $p=0$) or positive (angle $a = \text{a positive number}$) draft. If the part **214** is a needle guard of any of the embodiments, and the core has a neutral or near-zero draft, then the opening may be characterized by a negative draft after cooling it causes the legs **218A** and **218B** to converge (angle n) as shown by converging rays **217** in Fig. **7E**. Thus, the part **214** may have an internal draft angle (or shape) that is negative as a result of being cooled in a manner that causes its shape to change in this way. In embodiments, the needle guard **101** is molded and the mold shape configured such that the part cools after release from the mold such that the thicker walled hinge portion is still somewhat plastic as portion of the hinge portion toward the front cools and shrinks. The part **214** is a simplified version of the needle guard molded part. In part **214** the hinge portion would correspond the portion indicated at **229** and the front of the hinge portion would be the portion at **230**. If the front of the hinge portion is thinner or otherwise cools faster after release from the mold (or is cooled differently inside the

mold such as by heat transfer mechanism) so that the front part cools and shrinks first, then the negative draft (or more negative draft than a positive draft of the mold core itself) would be obtained. Other ways to make the jaws “close” are also possible such as by mechanically deforming while the part is still plastic or placing an external spring or other urging mechanism on the part after molding.

[0067] In other embodiments, it possible to make the separation between the upper jaw and the lower jaws for a needle guard correspond to the thickness of the wings or such portion thereof that fits into the slot such that there is a tight but reasonably low friction engagement between the needle guard edges and the wings. In such embodiments the jaws might not touch at the front end, but the front slot may taper away from the hinge toward the front end. When the thin wing portion **51** is at least as thick as the height of the front slot **109** at its front end and also at least as thick as the maximum height of the front slot **109**, the upper jaw **104** and the lower jaw **106** will grip the winged needle **90** firmly but without producing significant friction as it is pulled through the needle guard **101**, avoiding sideways misalignment of the winged needle **90**. The tightness need only be sufficient to ensure positive interfering engagement and does not need to actually grip the wings if the interfering engagement, such as between the inclined ramp **85** (or step – not shown) and the edge **110**. Note also that the interfering engagement between the slot edge and wing can be provided between the top edge and a feature such as a step or inclined ramp on the upper surface of the wing, between the bottom edge and a feature such as a step or inclined ramp on the lower surface of the wing, or both.

[0068] Figs. **6A** and **6B** illustrate a simplified representation of a needle guard **101** with front slot **209** and rear slot **335**. The front slot **209** has an opening that is large enough to accommodate the winged needle **90** without it being pried open. However, a step or inclined ramp **85** may engage the edges and guide the winged needle **90** throughout a length of the front slot **209** and rear slot **335**. A progressively narrowing entrance **290** to the front slot **209** is shown which provides for a smooth capture (Fig. **6B**) and engagement of the winged needle thin wing portion **51**.

[0069] Fig. **7A** shows a simplified representation of the front slot **109** and the rear slot **135** of an embodiment of the disclosed subject matter as a single slot, with a front end of the

upper and lower jaws coming into contact. While Fig. **7A** is not drawn to scale and omits the resilient latch **126** and bridge slot **138** for clarity, it illustrates the biasing of the two jaws against each other. Tube **60** of the winged needle passes freely through cavity **112**. Fig. **7A** shows a cross-section of thin wing portion **51** which extends from winged hub **49** to the thick wing portion **50**. The thin wing portion **51** is shown as a cross-section but it is understood that the thick wing portion **50** may be present as in the other embodiments. Note that the wings can be of any configuration depending on the embodiment, and preferably the wings have an engagement edge suitable to confine the hub to a central path through the needle guard.

[0070] As tube **60** is pulled in the direction from the front end of the needle guard **101** toward the rear end of the needle guard **101**, the thin wing portion **51** comes into contact with the lower jaw **106** and with upper jaw **104** and pries them apart as shown in Fig. **7B**. Because the jaws are biased against each other, they exert a force from opposed sides on the thin wing portion **51**, keeping the winged needle **90** properly aligned with the front slot **109** for the entire traversal of the winged needle **90** through the front slot **109** and the rear slot **135**.

[0071] Fig. **7C** shows a cross-sectional view between points C and C', looking into cavity **112** when the thin wing portion **51** has pried apart the upper jaw **104** and the lower jaw **106**. As seen in Fig. **7C**, the jaws maintain contact with the thin wing portion **51**. The thick wing portion **50** is thicker than the thin wing portion **51** and thus creates a wall on the outside of the front slot **109**, avoiding sideways translation or rotation of winged needle **90**, so the cannula **52** remains safely within cavity **112**.

[0072] As shown in Fig. **3A**, the top outer surface of the hinge **107** includes raised ribs **124** extending generally perpendicularly to the longitudinal axis of the needle guard **101**. The raised ribs **124** provide a secure grip for a user of the needle guard **101**. A user may press on raised ribs **124** to hold the needle guard **101** in place while pulling on tube **60** to retract the winged needle **90**. Although parallel ribs are illustrated in the figures, a different pattern that improves the user's comfort and provides a more secure grip can be used, including cross hatches, stippling, and a roughened surface. The raised ribs **124** address the needs of different user approaches to holding the needle guard **101** in place as the needle is drawn back. Some users prefer the safety of keeping fingers away from the front of the needle guard **101** and therefore avoid using the

finger shield **102**. To provide such users with a more secure grip on the needle guard **101**, the raised ribs **124** are provided which not only increase grip, but also provide feedback to the user of the position of the user's fingers relative to the needle guard **101**. The positioning of the raised ribs **124** at the back end on a sloping surface makes it easier for the user to locate the position by feel. Also, the security provided by pressing on the sloping surface is increased because the surface faces away from the traction forces that need to be applied to pull the winged needle through the slots and the latch (described below).

[0073] As mentioned above, the hinge **107** abuts the lower jaw **106**. Lower jaw **106** includes two opposed side walls **114** joined to floor **125**. As shown in Figs. **3A** and **3B**, front end **122** of the lower jaw **106** extends beyond the front end **120** of the upper jaw **108** as indicated by the angle formed between a line **117** that is perpendicular to the needle guard **101** major axis and a line **116** connecting the front end **122** of the lower jaw **106** to front end **120** of the upper jaw **104**. The front end **122** may have rounded shape for increased comfort when the lower jaw is pressed against a patient's skin. The front end **122** may also be straight. In embodiments, the front end **122** has a notch in the center of the front end, resulting in a two-pronged fork that can straddle the cannula **52** from two sides when the cannula **52** is withdrawn from the patient and help guide the winged needle **90** into cavity **112**. Preferably such a front edge would be rounded, for example defining a "B" shaped front end **122A** as indicated at **177**. The extended lower jaw has the additional effect of reducing the intensity of the force to the skin at the front end **122** resulting from leveraged forces applied to the finger shield **102**. In the prior art needle guard **1** and the disclosed embodiments **101**, the magnitude of leverage applied against the skin is greater than unity due to the significant overhang of finger shield **102**. In the disclosed embodiments, the lower jaw **106** is extended to the point where it underlies region where the finger is placed for removal of the winged needle **90**. Comfort may further be increased by providing that there is a convex bevel **1401** at the forward end of the lower jaw as shown in Fig. **14B**.

[0074] The side wall **114** of the lower jaw **106** may have a non-uniform thickness with a thickened region **140** discussed above. The thickened region **140** improves resistance to lateral movement of the lower jaw **106** relative to the upper jaw **104** so that a thinner region forward thereof may permit greater economy in the use of polymer where the flexion is less of an issue.

The shape of the thickened region is indicated at **147**, which is not intended to indicate that it is a separate part but merely an outline to highlight the boundaries of the portion indicated at **140**. The thickened region **140** is located at the rear end (hinge end) because the weakest point in the lateral movement of the upper and lower jaws is the hinge region. The channel shaped upper and lower jaws form trusses that have reasonably good resistance to bending even if the walls are thin over at least a portion thereof. The upper jaw has higher depending walls and can tolerate a longer thin span indicated at **149**. The lower wall having lower depending walls is reinforced by thickened region **140** further toward the front end of the needle guard **101** so that there is a shorter thin region **145**. The hinge arc in back experiences a torsional twisting moment about a vertical axis **133** which is harder to resist with the hollow structure especially with the presence of the opening **207** (See Fig. **4B**). Thus, the hinge portion **143** is reinforced by thickened walls.

[0075] Referring also to Figs. **5A** and **5B**, the extended lower jaw **106** of the needle guard **101** permits the convenient placement of the front end **122** of the lower jaw under the needle hub **49** adjacent a needle puncture site **141** of a patient's body **131**. This allows the positioning the finger shield **102** above the puncture site **141**. This helps to ensure the hub (nub **54** or equivalent, if present) is, prior to drawing, positioned between the **122A** side wall **114** edge leading portion **77** as indicated at **122A** as indicated at **177**, as shown in Fig. **3B**. The extended length of the lower jaw **106** facilitates the accurate placement of the finger shield **102** directly over the needle puncture site **141**, providing for precise placement of gauze holding pressure fingers over the needle puncture site **141** to control bleeding. The front end **122** of the lower jaw **106** may be positioned immediately adjacent, and optionally beneath, gauze bandage covering the needle puncture site such that side walls **114** provide stabilization for the thick wing portion **50** and thin wing portions **51** immediately when the needle is pulled out and pulled through the needle guard **101**, as shown in Fig. **5B**. Further, the extended length places the needle wings in the precise position for guiding needle wings into the slots.

[0076] Additionally, the extended lower jaw reduces ease with which a user can inadvertently insert the finger into the cavity **112** within close proximity of the locked needle tip. Referring to Figs. **5C** and **5D**, the needle guard **101** with an extended lower jaw **106** is shown in

Fig. **5C** and a needle guard **1** of the prior art with a shorter lower jaw **6** is shown in Fig. **5D**. The aperture defined by the relationship between the upper **104** and lower **106** jaws of needle guard **101** of the disclosed subject matter faces upwardly as indicated by the plane **79A** which extends into the page. A soft body part **81** pressed against this aperture, such as the tip of a finger, may extend past the aperture but it extends in a direction away from the tip of the cannula **52** in its stored position. The aperture defined by the relationship between the upper **4** and lower **6** jaws of needle guard **1** of the prior art faces downwardly as indicated by the plane **79B** which also extends into the page. A soft body part **81** pressed against this aperture, such as the tip of a finger, may extend past the aperture in a direction toward from the tip of the cannula **52** in its stored position. This creates a risk of inadvertent needle stick or contact with the needle or fluids thereon. Thus, by extending the lower jaw relative to the upper jaw and the degree to which the lower jaw extends beyond the upper jaw, the disclosed subject matter defines an aperture that points at least partially away from the position of the tip of a needle in the locked and stored position.

[0077] Referring to Figs. **5A** and **5B**, the finger shield **102** extends from the front end **120** of upper jaw **104**. The finger shield **102** may be integrally formed with the roof **115** of the upper jaw **104** or may be attached to the upper jaw **104** as a separate component. The finger shield **102** facilitates holding the needle guard **101** in position while the needle is drawn into it. As shown in Figs. **5A** and **5B**, the shield **102** has a thin portion **1022** and a thick portion **1021**. The thick portion **1021** is thicker than the thin portion **1022**, and is thus less flexible. This allows the finger shield **102** to maintain its shape so that it curls around a user's fingertip even when the user presses down into the curve of the finger shield **102** toward a gauze place above the cannula **52** puncture site. This helps to ensure the finger shield **102** continues to hook the finger of the user to help resist the traction forces applied to the needle guard **191** as the winged needle **90** is drawn into it.

[0078] Referring to Figs. **14A** and **14B**, the finger shield **102** in an embodiment has a uniform thickness. In another embodiment, the upper surface of finger shield **102** may have ribs akin to ribs **124** on hinge **107**, though these ribs are not illustrated on finger shield **102** and only on hinge **107**. The embodiment also has a fixed width of front slot **109** but as indicated above

the embodiment may be modified to have the narrowing slot as in Fig. **7A**. The present figures show specific details such as surfaces and transitions between surfaces that improve the usability of the needle guard **101**. These details include the smooth flat roof **115**, shape and relative size of the opening **207**, and relative thickness of the thickened region **140**. The drawings also show a to-scale embodiment. Note also that details of the drawing indicate aspects that are essential for molding in a three part dual action injection molding process as will be appreciated by those of skill in the art.

[0079] Referring to Fig. **11A**, in another embodiment, the finger shield **102** has a uniform thickness but may also be non-uniform as described with reference to Figs. **5A** and **5B**. In an embodiment, a needle guard **501** is substantially as needle guard **101** in all respects except that as a molded piece **501'** as released from the mold, the finger shield **102** and a safety flap **1023** are molded as shown in Fig. **11A**. It will be confirmed by inspection that the shape of molded piece **501'** permits the use of two mold halves and a core that can be drawn out of the internal space of the molded unit shown. Thus, as shown in Fig. **11A**, the finger shield **102** is molded in the position shown above the roof **115** with a safety flap **1023** extending away from roof **115** in the direction from the rear of the molded piece **501'** toward the front of the molded piece **501'** to permit the withdrawal of a mold core in a single-shot, three-part molding operation. After molding, the finger shield **102** carrying the safety flap **1023** may be pivoted about a living hinge **1027B** which is illustrated in Fig. **12**, to its final position for use shown in Fig. **11B**.

[0080] Fig. **12** illustrates a cross sectional view of finger shield **102** with safety flap **1023** integrally connected to roof **115** of the upper jaw **104**. As shown in Fig. **12**, portions of material adjacent to the finger shield **102** are molded so they are thinner to form living hinges to enable the finger shield **102** to rotate into position and to allow the safety flap **1023** to flex passively when the winged needle **90** is pulled past it. Thus, when the needle guard **101** is used, the finger shield **102** is rotated down about the front end **120** of the upper jaw as shown in Fig. **11B**, which also rotates safety flap **1023** into the opening of cavity **112**, as shown in Fig. **11B**. The safety flap **1023** may be thin enough to permit the winged needle **90** to pass by when it is drawn into the needle guard **101**, and still overly an inserted needle to protect a user inserting a finger or other body part into the cavity **112**, thus further reducing the possibility of an accidental puncture.

Alternatively, the flexibility that permits the safety flap **1023** to permit the winged needle to pass may be provided (if the safety flap **1023** itself is thick or otherwise inflexible) or facilitated by means of a further living hinge **1027A**. The safety flap **1023** may be coated with an absorbent material and/or may be made hydrophilic through a surface treatment such as electrical discharge machining. This will help prevent blood that may be in or on the cannula **52** from leaking out of the front opening of the needle guard **101**. An absorbent material block can also be attached to the safety flap **1023**, similar to the block **802** in Fig. **9**. When the finger shield **102** is put into use, the block **802** would be on the inner side of the safety flap **1023** and in position to absorb stray blood from the cannula **52**. It should be evident that the safety flap **1023** covers the tip of a cannula in the stored position after it is fully retracted and locked so even if a body part were pushed into the front end of the needle guard **501**, the safety flap **1023** isolates the body part from the tip of the cannula **52**.

[0081] In yet another embodiment, after use, the finger shield **102** can be folded and locked in engagement with the lower jaw **106** to block cavity **112**, as shown in Figs. **13A-13C**. Fig. **13A** illustrates the needle guard **101** after the winged needle **90** has been fully pulled into the needle guard. The pointed end of the needle is pressed against roof **115** of the upper jaw **104**. Though the needle is now safely stored, it is advantageous to further prevent a user, such as a child, from inserting a finger into the cavity **112**. To this end, finger shield **102** has an opening that mates with the front end **122** of the lower jaw. Fig. **13B** illustrates the finger shield **102** being bent down toward lower jaw **106**, and Fig. **13C** illustrates the final position where the finger shield **102** is mated to the lower jaw **106**, closing off the cavity **112**.

[0082] Another risk from stored cannulae is leaking blood or other bodily fluids that remain in the cannula after storage in the needle guard. A mechanism to reduce or prevent or loss of such fluid from a stored cannula provides further utility. To this end, the cavity **112** may be provided with various devices or coatings to absorb or block the flow of blood. Fig. **9** shows a cut-away view of needle guard **101** with a resilient block **801** and **802** placed inside the cavity **112**. The block **801** may have two parts indicated at **801** and **802** and may be of foam or other material and may be absorbent, hydrophilic, or hydrophobic. The block parts **801** and **802** may be connected by a thin tearable sheet (not shown) to permit them to be stuffed into the front

end of the needle guard **101** after molding in a single operation. Alternatively, they may be emplaced by a fixture that aligns them with respect to each other. They may be held in place by adhesive or locked by engagement features in the interior of the needle guard such as a roughened surface or pins or some other suitable mechanism. The space between the two block parts **801** and **802** allows the winged needle **90** to pass but helps to block blood or other fluid from escaping. The block parts **801** and **802** may have other suitable shapes that do not interfere with wings **50** when winged needle **90** is pulled through the needle guard. Block parts **801** and **802** may be of foam, gauze, or other material. In further embodiments, only a single block part **801** is used. Absorbent material blocks **801** and **802** can be made of a material that not only absorbs stray blood, but is firm enough to also prevent accidental needle punctures if a user presses a finger firmly into the front opening of the cavity **112** of the needle guard after the needle has been retracted to attempt to force the jaws apart through brute force.

[0083] Fig. **10** shows a cut-away view of another embodiment of needle guard **101** where cavity **112** has an inner surface **901**. The inner surface **901** is the inner surface of side walls **113** and **114** and the inner surface of roof **115** and floor **125**. The inner surface is coated with an absorbent coating or hydrophilic surface treatment. The inner surface **901** may be textured to provide a hydrophilic surface that attracts stray blood drops and causes them to cling to the inner surface of cavity **112** rather than falling out. The embodiment of Fig. **9** will be combined with the embodiment of Fig. **10**, where an absorbent coating is provided on inner surface **901** and absorbent material blocks **801** and **802** are provided in the cavity **112**.

[0084] The needle guard **101** according to embodiments of the disclosed subject matter is made of high density polyethylene (HDPE) which has thermal properties that can bias the upper jaw against the lower jaw as described above. HDPE has a flexural modulus of over **300** Mpa. In embodiments, the HDPE has a flexural modulus of over **1000** Mpa. In embodiments, the HDPE has a flexural modulus of at least **1200** Mpa. The high flexural modulus of HDPE increases the needle guard's resistance to twisting. HDPE use also facilitates sterilization because it is compatible with gamma irradiation sterilization. HDPE also provides a low coefficient of friction between the wings and the needle guard, making it easy to withdraw the needle into the needle

guard with a smooth and continuous motion. Other suitable materials include polypropylene and low density polyethylene.

[0085] An exemplary embodiment of the disclosed subject matter includes a needle set that has a needle guard (101) and a winged needle (90). The needle guard (101) has elongate upper and lower jaws (104, 106) each defining a channel (109, 135) and joined at a hinge portion (143), each jaw having depending side walls (113, 114) with elongate edges parallel to a longitudinal axis of each channel, each edge (108, 110) of each jaw being aligned with and spaced from a respective edge of the other jaw defining elongate slots along the side walls. The winged needle has a cannula (52), a hub (49), and a pair of wings (53). A tube (60) is connected to the cannula (52) by the hub (49). The hinge (107) has an opening (207) into which the tube (60) is received. The side walls (113, 114) are spaced apart to permit the hub (49) to be received between the jaws (104, 106) with the wings (50, 51, 53) in the slots (109, 135). Each elongate slot has an open end opposite the hinge portion and the elongate slots progressively narrow to a first spacing that is narrower than a thickness of each wing portion (51) at a point thereof that is aligned with a respective pair of the edges, and thereafter expands linearly to a second spacing that is substantially equal to the thickness of each wing portion (51).

[0086] In an embodiment, the side walls (113, 114) are thicker at the hinge portion (143) than at the open end.

[0087] In an embodiment, a cross-section of a cylindrical space between the jaws (104, 106) and in a plane perpendicular to the longitudinal axis is constant along a majority of a length of the needle guard, except for a vertical dimension thereof that diminishes progressively from a maximum dimension at the hinge portion (143) to a minimum dimension at the open end (120, 122), the maximum and minimum dimensions differing by the difference between the first and second spacings.

[0088] In an embodiment, a cross-section of a cylindrical space between the jaws (104, 106) and perpendicular to said longitudinal axis is uniform in a horizontal direction and progresses, in the vertical direction, from a maximum dimension at the hinge portion to a minimum dimension at the open end, the maximum and minimum dimensions differing by the

difference between the first and second spacings. In an embodiment the first spacing may be zero.

[0089] In an embodiment, the jaws (**104**, **106**) define a space therebetween that has a negative draft. The negative draft allows a center mold piece to be removed from the space between the jaws after the needle guard **101** is manufactured. In an embodiment the magnitude of the negative draft is equal to the difference between the first and second spacings.

[0090] In an embodiment the channels defined by the jaws (**104**, **106**) have C-shaped cross-sections.

[0091] In an embodiment of the disclosure, a method of guarding a needle includes drawing a winged needle (**90**) into a cylindrical guard (**101**) having sidewalls (**113**, **114**) with elongate slots (**109**, **135**) therein, the drawing including forcing a respective wing (**50**, **51**, **53**) of said winged needle into a respective one of the slots. The drawing progressively forces the elongate slots open to a width equal to a thickness of the wings (**50**, **51**, **53**) against an urging force generated by a hinge portion (**143**) of the channel. During the drawing, a non-parallel orientation of the axes of the winged needle and the cylindrical guard is prevented by interferingly engaging the wings (**50**, **51**, **53**) with edges of the elongate slots during the drawing.

[0092] In an embodiment the forcing includes prying the cylindrical guard apart by urging the wings (**50**, **51**, **53**) into progressively narrowing entrances of the elongate slots (**109**).

[0093] In an embodiment the interferingly engaging includes interferingly engaging steps in the surface of the wings (**50**, **51**, **53**) with the edges (**134**, **136**).

[0094] In an embodiment, the method may include positioning a lower portion (**106**) of the cylindrical guard underneath the winged needle (**90**) prior to said drawing.

[0095] In an embodiment, the preventing may include, prior to the forcing, guiding a central hub (**49**) of the winged needle (**90**) between barriers (**114**) on either side of said lower portion.

[0096] In an embodiment, the drawing may include drawing the wings (**50**, **51**, **53**) into expanded slot segments (**138**) of the elongate slots (**109**, **135**) where the width of the slots

expands and thereafter, proceeding further, bends where an edge of each slot defines a deflectable portion (126), the drawing further causing the wings to be urged against the deflectable portion as both the deflectable portion and the wings deform, the expanded slot segments being sized such that tail ends of the wings move across the expanded slot segments without friction in an initial stage of passing the deflectable portion.

[0097] In an embodiment, the drawing may include drawing the wings (50, 51, 53) into expanded slot segments (138) of the elongate slots (109, 135) where the width of the slots expands and thereafter, proceeding further, bends where an edge of each slot defines a deflectable portion (126), the deflectable portion having hook shapes (127) over which a leading edge of the wings rides after it enters the expanded slot segments, drawing further causing the wings to be urged against the deflectable portion as both the deflectable portion and the wings deform in order to follow the elongate slots through the bends.

[0098] In an embodiment, a needle set includes a needle guard (101), a winged needle (90) with a cannula (52) that has a hub (49) with a pair of wings (50, 51, 53), and a tube (60) connected to the cannula by the hub. The needle guard has elongate upper and lower jaws (104, 106) each defining a channel and joined at a hinge portion (143), each jaw having depending side walls with elongate edges parallel to a longitudinal axis of each channel, each edge of each jaw being aligned with and spaced from a respective edge of the other jaw defining elongate slots (109, 135) along the side walls. The hinge has an opening 207 into which the tube (60) is received and the side walls are spaced apart to permit the hub (49) to be received between the jaws (104, 106) with the wings (50, 51, 53) in the slots (109, 135). The lower jaw (106) extends beyond the upper jaw (104).

[0099] In an embodiment, the lower jaw (106) is C-shaped at its distal end defining sloping barriers on each side thereof to permit the lower jaw (106) to be positioned beneath the hub (49) while the cannula (52) is inserted in a patient.

[0100] In an embodiment, the hub (49) has a protrusion or a raised nub (54) that fits between the barriers when the lower jaw is positioned beneath the hub.

[0101] In an embodiment, the lower jaw (106) has a rounded front edge.

[0102] In an embodiment, the lower jaw has a rounded surface at its front edge (122) having a center of curvature that runs parallel to a front edge thereof.

[0103] In an embodiment, a method of guarding a needle includes drawing a winged needle into a cylindrical guard having sidewalls with elongate slots therein, the drawing including guiding a respective wing of the winged needle into a respective one of the slots. Prior to the drawing, the method includes positioning a lower portion of cylindrical guard between a hub of the winged needle and the skin of a patient to at least partially support and guide the hub as it is drawn. During said drawing, the method also includes preventing a non-parallel orientation of the axes of the winged needle and the cylindrical guard by interferingly engaging the wings or a hub of the winged needle with edges defining the elongate slots during said drawing.

[0104] In an embodiment, the drawing includes forcing effective to pry the cylindrical guard apart by urging the wings into progressively narrowing entrances of the elongate slots until the wings hold the slots open and the wings can slide therethrough.

[0105] In an embodiment, the interferingly engaging includes interferingly engaging steps in the surface of the wings with the edges.

[0106] In an embodiment, the preventing includes, prior to said forcing, guiding a central hub of the winged needle between barriers on either side of said lower portion.

[0107] In an embodiment, the drawing further includes drawing the wings into expanded slot segments of said elongate slots where the width of the slots expands and thereafter, proceeding further, bends where an edge of each slot defines a deflectable portion, the drawing further causing the wings to be urged against the deflectable portion as both the deflectable portion and the wings deform, the expanded slot segments being sized such that tail ends of the wings move across the expanded slot segments without friction in an initial stage of passing the deflectable portion.

[0108] In an embodiment, the drawing further includes drawing the wings into expanded slot segments of the elongate slots where the width of the slots expands and thereafter, proceeding further, bends where an edge of each slot defines a deflectable portion, the deflectable portion having hook shapes or barbs over which a leading edge of the wings rides

after it enters said expanded slot segments, drawing further causing the wings to be urged against the deflectable portion as both the deflectable portion and the wings deform in order to follow the elongate slots through the bends.

[0109] In an embodiment, a needle set includes a winged needle (90) and a channel member (104, 106) having a longitudinal axis. The winged needle includes a hub (49), a cannula (52), and wings (50, 51, 53). The channel further has sidewalls (113, 114) with slots opposite each other and parallel to said axis. The slots are open at an open end of the channel member and closed at a hinge end of the channel member. Each slot has a first portion (109) beginning at the open end where it has a constant width or a width that increases linearly from the open end toward the hinge end. Each slot has a progressively narrowing entry at the open end leading to the first portion (109). Each slot has a transition portion (138) at an end thereof near the hinge end (143) with a width greater than a maximum width of the first portion, the transition having a length that is a minor fraction of the first portion. Each slot has a narrow terminal portion that forms an angle with the first portion and transition portion such that there is a bend in each slot with the terminal portion on one side and the transition and first portions on the other side. The transition portion (138) having, along one edge thereof, a latch (126) with a concave niche formed by a corner in said one edge.

[0110] Another embodiment includes a needle guard (101) for protecting a user from a needle (90) pulled from a front end of the needle guard to a rear end of the needle guard. The needle guard includes an upper jaw (104), a hinge (107), and a lower jaw (106). The upper jaw includes a roof (115), two opposed upper side walls (113) extending down from the roof, where each upper side wall includes an upper edge integral with the roof, a curved side edge at the front end, and a substantially straight bottom edge (108) abutting a bridge slot (138) at a rear end of the bottom edge. The upper jaw abuts the hinge (107), which in turn abuts the lower jaw (106). The hinge includes an upper hinge edge (134) and a lower hinge edge (136) defining a rear slot (135). The lower jaw abuts the hinge and includes a floor (125), two opposed lower side walls (114) extending up from the floor toward the upper jaw. Each lower side wall includes a bottom edge integral with the floor, a top edge (110) facing the bottom edge (108) of the upper side wall and extending toward the front end to meet the bottom edge of the lower side wall.

The top edge of the lower side wall and the bottom edge of the upper side wall define a front slot (109). A latch (126) extends from the lower side wall opposite the bridge slot, wherein the front slot defines a cavity (112) opening at the front end of the needle guard, the front slot (109) connects to the rear slot (135), and the latch (126) bends down in response to a winged needle (90) passing through the front slot (109) and the bridge slot (138). The latch (126) rises to block the winged needle (90) from pulling out of the rear slot once the winged needle passes beyond the latch.

[0111] In another exemplary embodiment disclosed above, the upper side wall (113), the lower side wall (114), and the hinge (107) include a thickened region (140) that has wall thickness greater than the wall thickness at other regions of the needle guard.

[0112] In another exemplary embodiment disclosed above, the thickened region of the upper side wall abuts the hinge.

[0113] In another exemplary embodiment disclosed above, the thickened region of the lower side wall abuts the hinge.

[0114] In another exemplary embodiment disclosed above, the thickened region of the hinge abuts the upper jaw and the lower jaw.

[0115] In another exemplary embodiment disclosed above, the roof is flat or has a triangular cross-section, like a gable roof of a house.

[0116] In another exemplary embodiment disclosed above, the upper edge of the upper side wall is substantially straight.

[0117] In another exemplary embodiment disclosed above, the floor is substantially flat.

[0118] In another exemplary embodiment disclosed above, the lower jaw extends in the front beyond the upper jaw.

[0119] In another exemplary embodiment disclosed above, the floor includes a front edge (122) that has a rounded shape.

[0120] In another exemplary embodiment disclosed above, a finger shield (102) extends from a front end of the roof of the upper jaw, the finger shield including a curved strip extending up from the front end of the roof.

[0121] In another exemplary embodiment disclosed above, the finger shield (102) includes a thin portion (1022) immediately abutting the roof of the upper jaw, and a thick portion (1021) having a thickness greater than the thickness of the thin portion abutting the thin portion.

[0122] In another exemplary embodiment disclosed above, the width of the finger shield (102) measured perpendicularly to the upper side wall is substantially same as the width of the roof (115) of the upper jaw.

[0123] In another exemplary embodiment disclosed above, the finger shield (102) is configured to fold toward the lower jaw after the winged needle is pulled into the needle guard, to engage the lower jaw to close the front end of the needle guard.

[0124] In another exemplary embodiment disclosed above, finger shield (102) also includes a safety flap (1023) extending from the roof toward the floor when the finger shield is pressed toward the lower jaw.

[0125] In another exemplary embodiment disclosed above, the rear slot (135) of the hinge is bounded by a region of material having a first thickness that is smaller than the thickness of the thickened region of the hinge. The region of the material having the first thickness cools faster than the thickened region of the hinge when the needle guard is molded or cast. The difference in cooling time pulls the upper jaw (104) toward the lower jaw (106). This may result in a positive draft of the needle guard 101 even when the mold or cast has a negative draft.

[0126] In another exemplary embodiment disclosed above, the upper jaw (104) is biased against the lower jaw (106) by the hinge (107), and the top edge (110) of the lower side wall is in contact with the bottom edge (108) of the upper side wall at least at the front end of the needle guard.

[0127] In another exemplary embodiment disclosed above, the top edge (110) of the lower side wall is parallel to the bottom edge (108) of the upper side wall.

[0128] In another exemplary embodiment disclosed above, the front slot (109) tapers from the front end of the needle guard toward the rear end of the needle guard.

[0129] In another exemplary embodiment disclosed above, the latch (126) includes a barb (127) protruding from latch toward the bridge slot. The barb (127) forms a kind of a hockey-stick shape on the upper edge of the latch (126).

[0130] In another exemplary embodiment disclosed above, the winged needle (90) strums the latch when the winged needle passes over and clears the barb (127), producing an audible and palpable click.

[0131] In another exemplary embodiment disclosed above, a safety needle set includes a winged needle (90) having a hub (49) with wings (50, 51, 53) extending in opposite directions, a cannula (52) held in the center of the hub, and a tube (60) extending from the hub on a side opposite the needle. The safety needle set also includes a needle guard (101) according to any combination of the exemplary embodiments disclosed above.

[0132] As used herein, the term “cylinder” or “cylindrical” may refer to a hollow structure and is not limited to a structure with a circular cross-section. For example, a hollow elongate prism or one elongate structure with an elliptical cross-section or piece-wise closed cross-section may be identified by the term “cylinder.” Note that any of the embodiments may be modified by providing additional openings, for example the floor of the needle guards 101 may be opened (U-shaped) to permit a snap-on type of arrangement that allows the user to emplace the needle guard over a winged needle and tube set.

[0133] Features of the **disclosed** embodiments may be combined, rearranged, omitted, etc., within the scope of the disclosed subject matter to produce additional embodiments. Furthermore, certain features may sometimes be used to advantage without a corresponding use of other features. It is, thus, apparent that there is provided, in accordance with the present disclosure, a needle guard and associated manufactures, components, systems, and methods of use. Many alternatives, modifications, and variations are enabled by the present disclosure. While specific embodiments have been shown and described in detail to illustrate the application of the principles of the disclosure, it will be understood that the disclosed subject matter may be

embodied otherwise without departing from such principles. Accordingly, Applicants intend to embrace all such alternatives, modifications, equivalents, and variations that are within the spirit and scope of the present disclosure.

Claims

1. A needle guard for protecting a user from a needle pulled from a front end of the needle guard to a rear end of the needle guard, the needle guard comprising:

an upper jaw that includes
a roof,
two opposed upper side walls extending down from the roof, each upper side wall including
an upper edge depending from the roof,
a curved side edge at the front end, and
a substantially straight bottom edge abutting a bridge slot at a rear end of the bottom edge, the upper jaw abutting a hinge;
the hinge abutting the upper jaw and a lower jaw, the hinge including an upper hinge edge and a lower hinge edge defining a rear slot, wherein the bridge slot projects beyond a point where an extension of the bottom edge and an extension of the upper hinge edge would intersect; and
the lower jaw abutting the hinge and including a floor,
two opposed lower side walls extending up from the floor toward the upper jaw, each lower side wall including a bottom edge depending from the floor,
a top edge facing the bottom edge of the upper side wall and extending toward the front end to meet the bottom edge of the lower side wall, said top edge of the lower side wall and said bottom edge of the upper side wall defining a front slot, and
a latch extending from the lower side wall opposite said bridge slot, wherein
the front slot defines a cavity opening at the front end of the needle guard,
the front slot connects to the rear slot,
the latch has a tip portion that together with the bridge slot defines an S-shaped path through which a winged needle passes from the front slot to the rear slot and the tip portion blocks the winged needle from pulling out of the rear slot along the S-shaped path.

2. The needle guard according to claim 1, wherein
the upper side wall, the lower side wall, and the hinge include a thickened region that has wall thickness greater than the wall thickness at other regions of the needle guard.

3. The needle guard according to claim 2, wherein the thickened region of the upper side wall abuts the hinge.

4. The needle guard according to claim 2, wherein the thickened region of the lower side wall extends from the hinge to half way along the lower jaw.

5. The needle guard according to claim 2, wherein the thickened region of the hinge abuts the upper jaw and the lower jaw.

6. The needle guard according to claim 1, wherein the roof is flat.

7. The needle guard according to claim 1, wherein the upper edge of the upper side wall is substantially straight.

8. The needle guard according to claim 1, wherein the lower jaw extends in the front beyond the upper jaw.

9. The needle guard according to claim 8, wherein the floor includes a front edge that has a rounded shape.

10. The needle guard according to claim 1, further comprising:
a finger shield extending from a front end of the roof of the upper jaw, the finger shield including a curved strip extending up from the front end of the roof.

11. The needle guard according to claim 10, wherein the finger shield includes a thin portion immediately abutting the roof of the upper jaw, and

a thick portion having a thickness greater than the thickness of the thin portion abutting the thin portion.

12. The needle guard according to claim 10, wherein the finger shield is configured to fold toward the lower jaw after the winged needle is pulled into the needle guard, to engage the lower jaw to close the front end of the needle guard.

13. The needle guard according to claim 10, wherein the finger shield further comprises a safety flap extending from the roof toward the floor when the finger shield is pressed toward the lower jaw.

14. The needle guard according to claim 2, wherein the rear slot of the hinge is bounded by a region of material having a first thickness that is smaller than the thickness of the thickened region of the hinge, and,

wherein the region of the material having the first thickness cools faster than the thickened region of the hinge when the needle guard is molded or cast.

15. The needle guard according to claim 14, wherein a difference in cooling time pulls the upper jaw toward the lower jaw.

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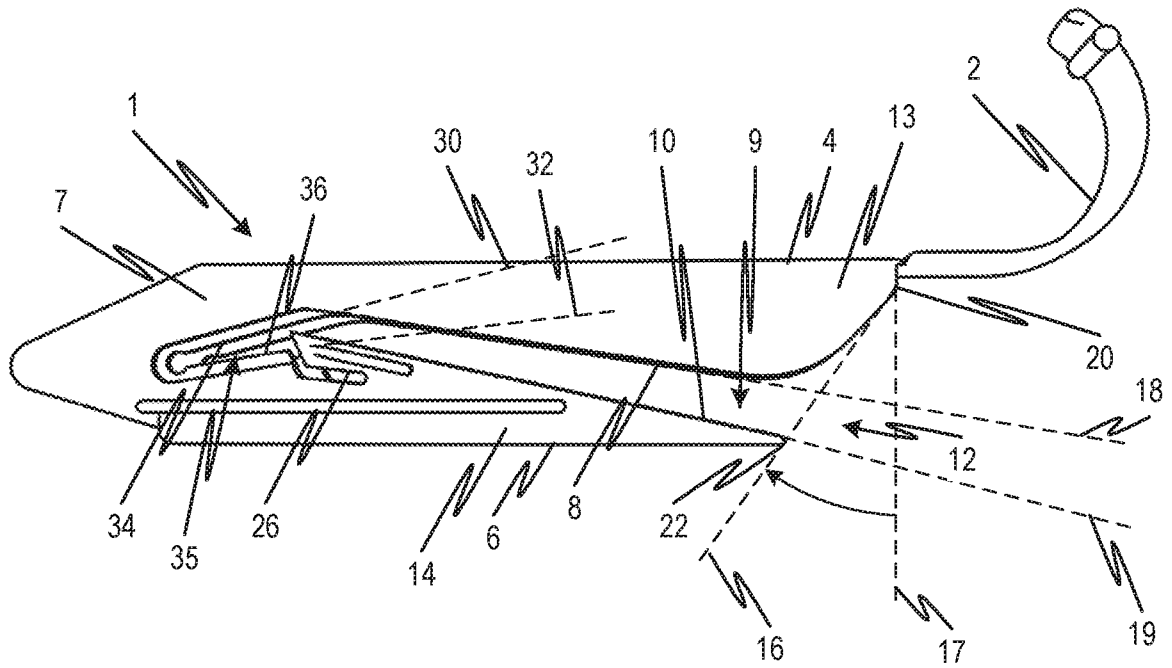


Fig. 1A
Prior art

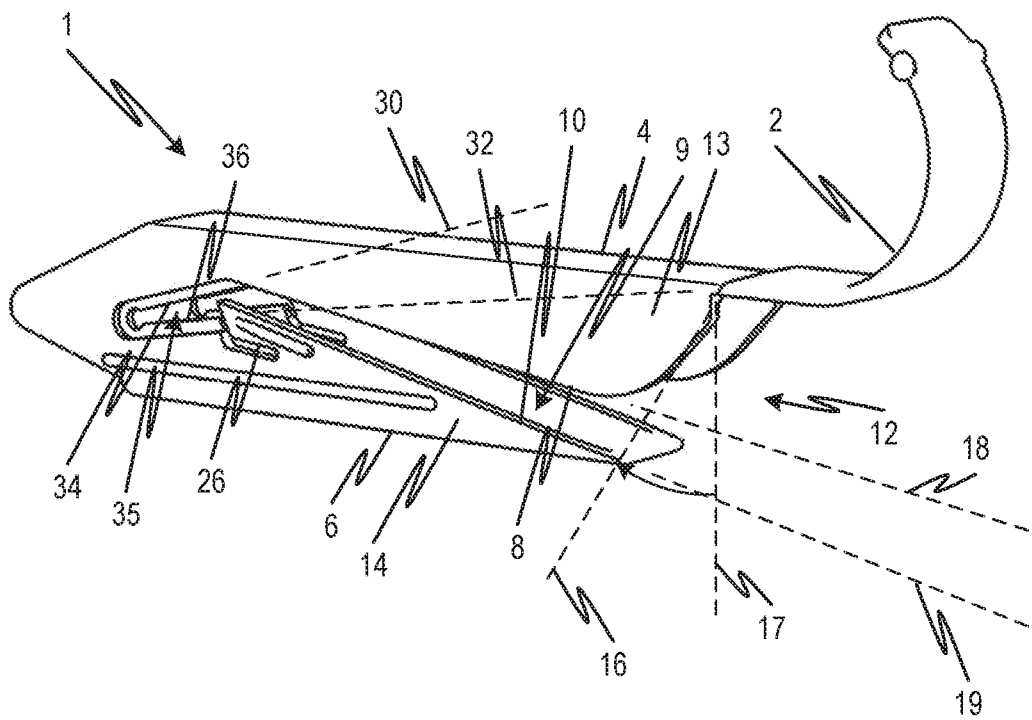


Fig. 1B
Prior art

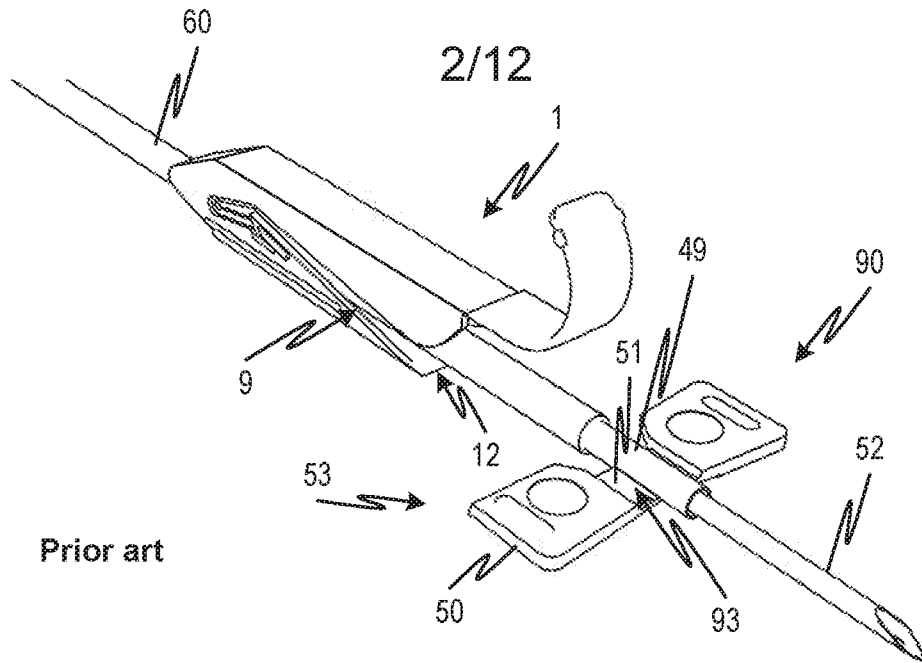


Fig. 2A

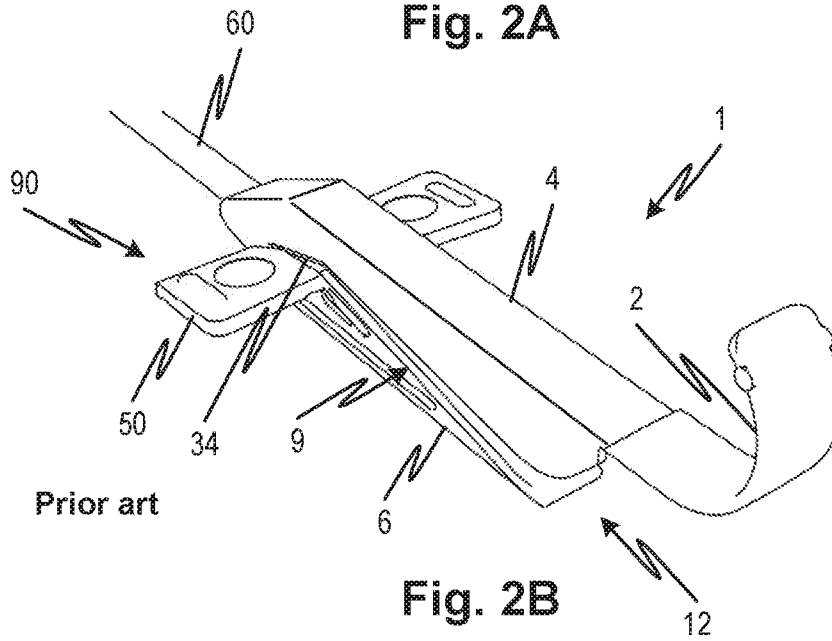


Fig. 2B

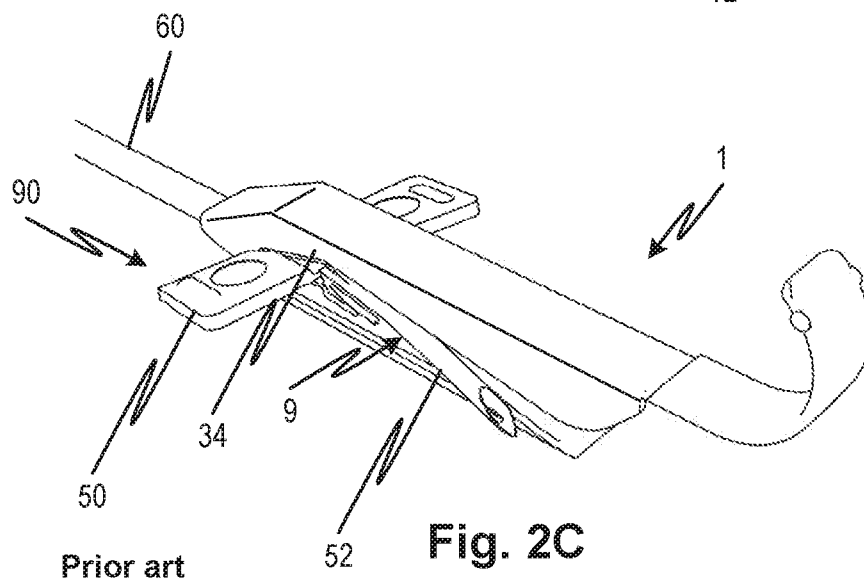


Fig. 2C

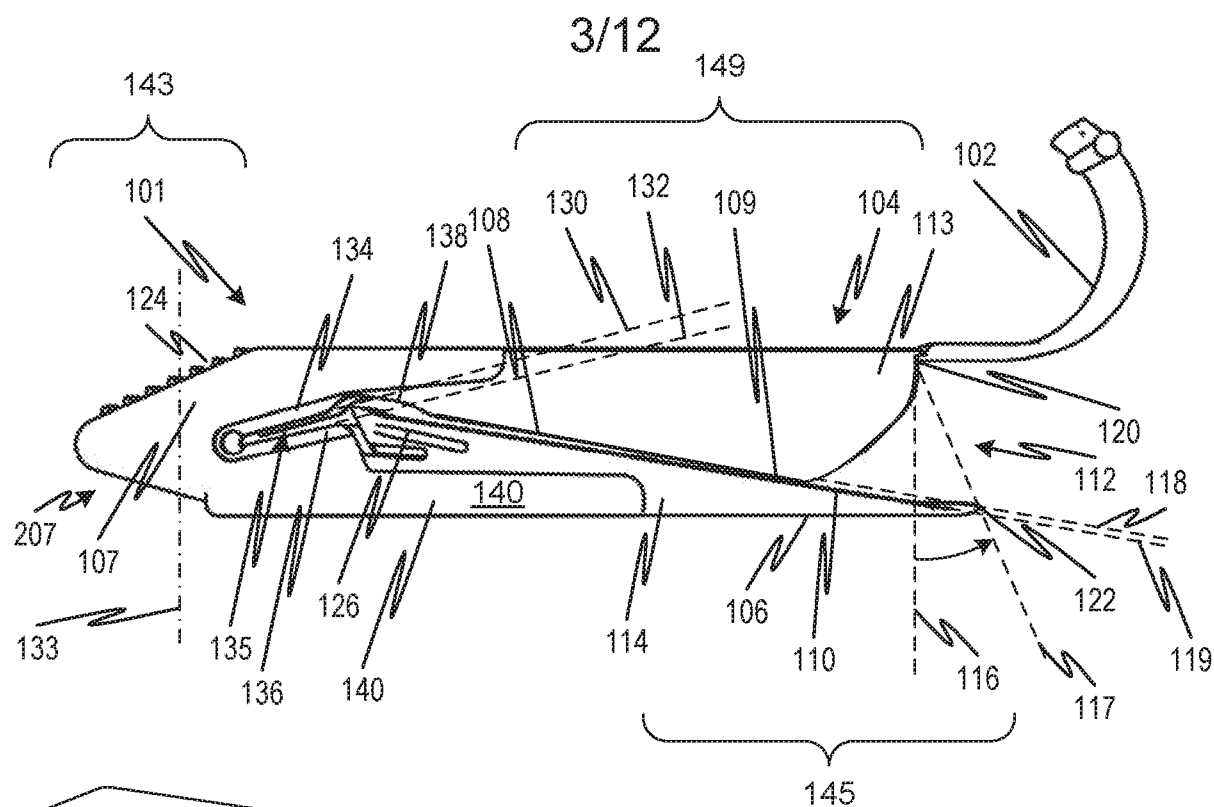
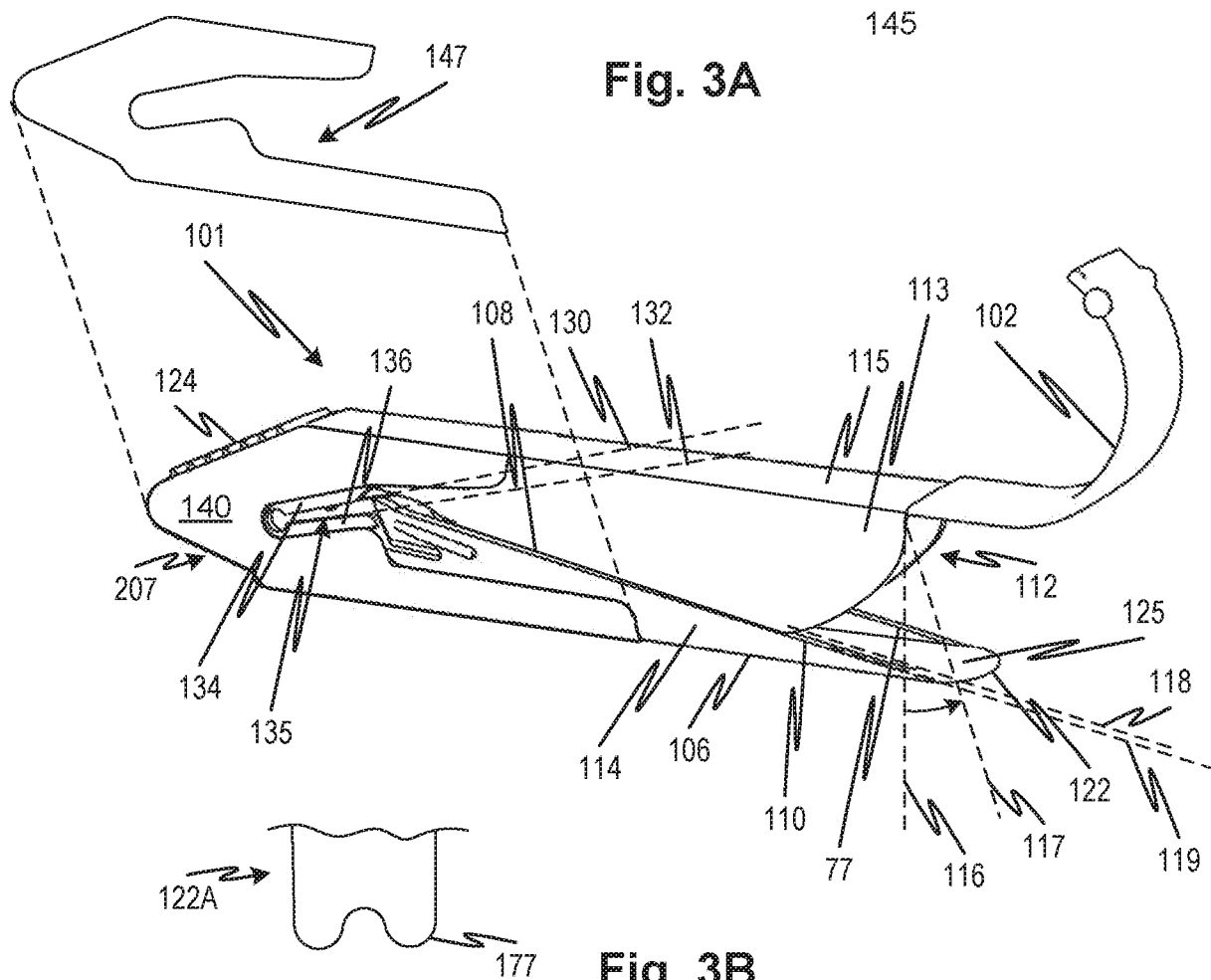


Fig. 3A



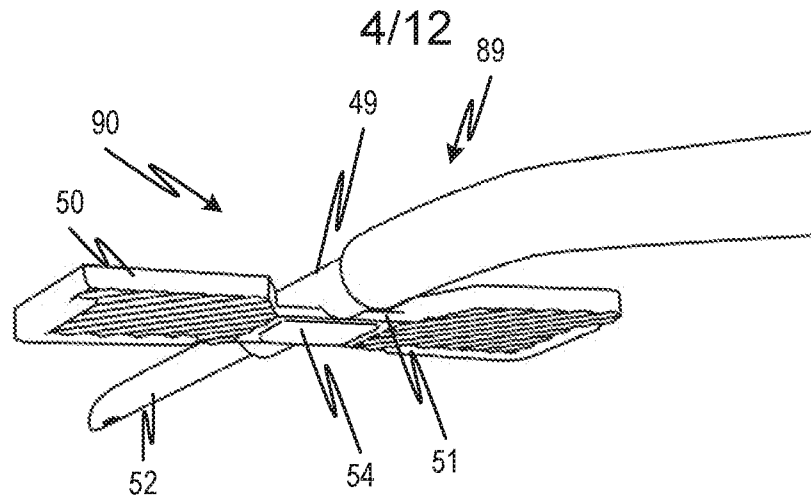


Fig. 4A

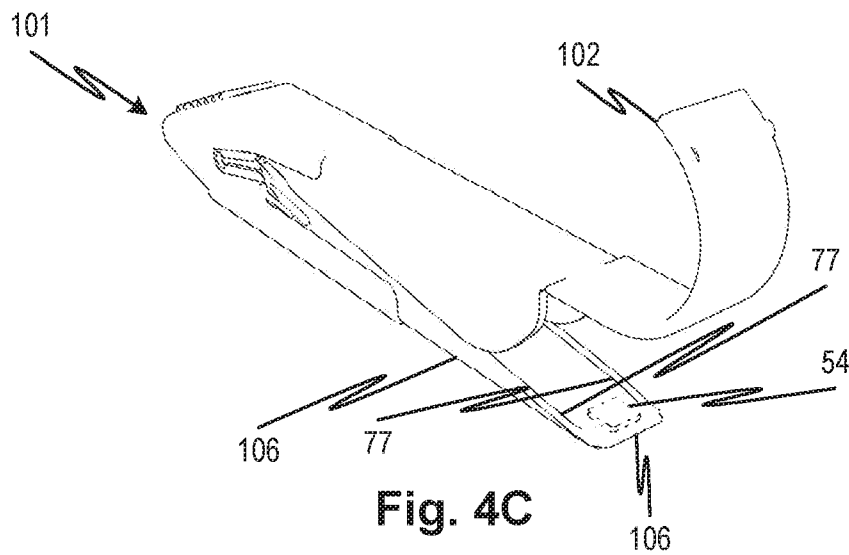


Fig. 4C

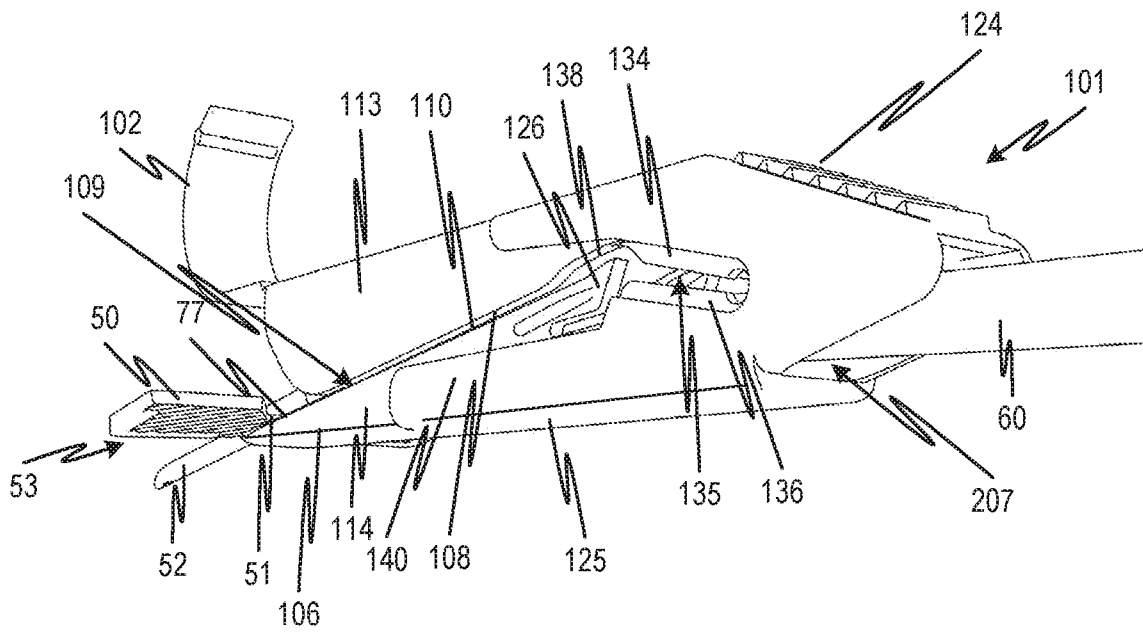


Fig. 4B

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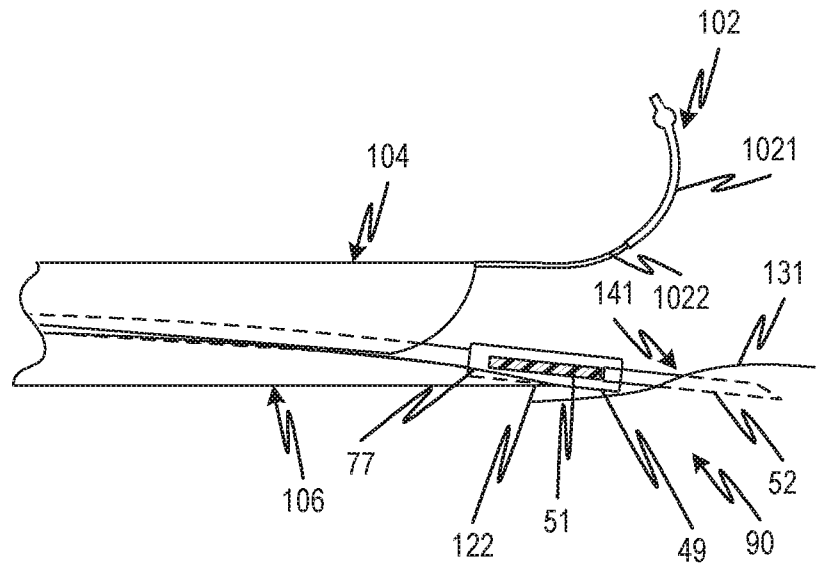


Fig. 5A

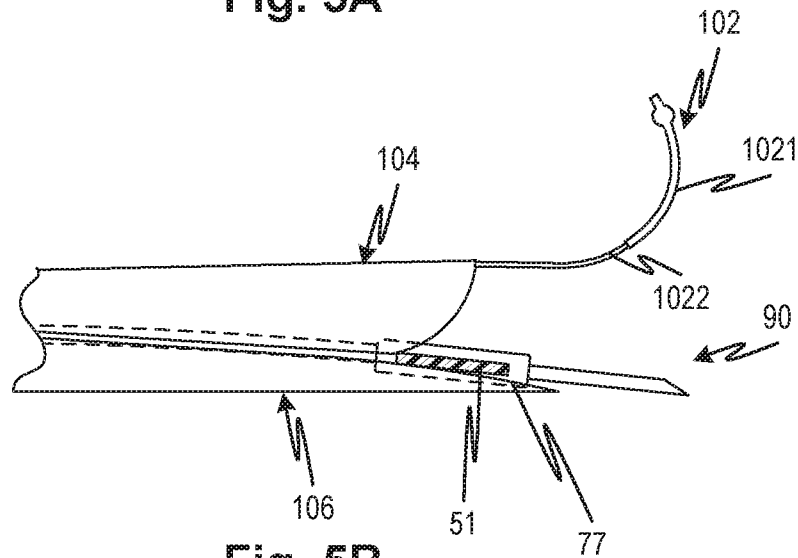


Fig. 5B

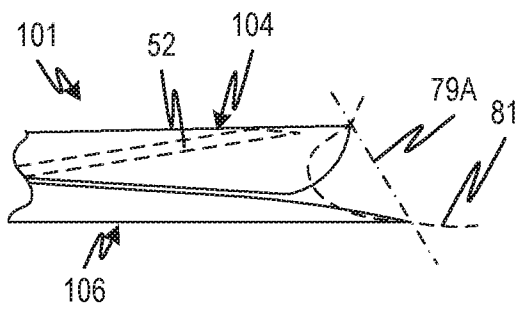


Fig. 5C

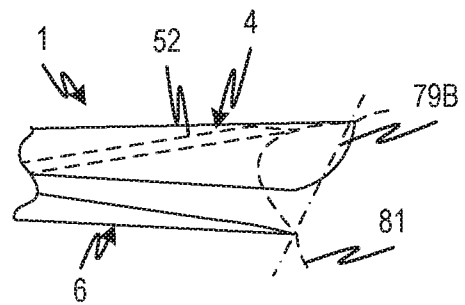


Fig. 5D

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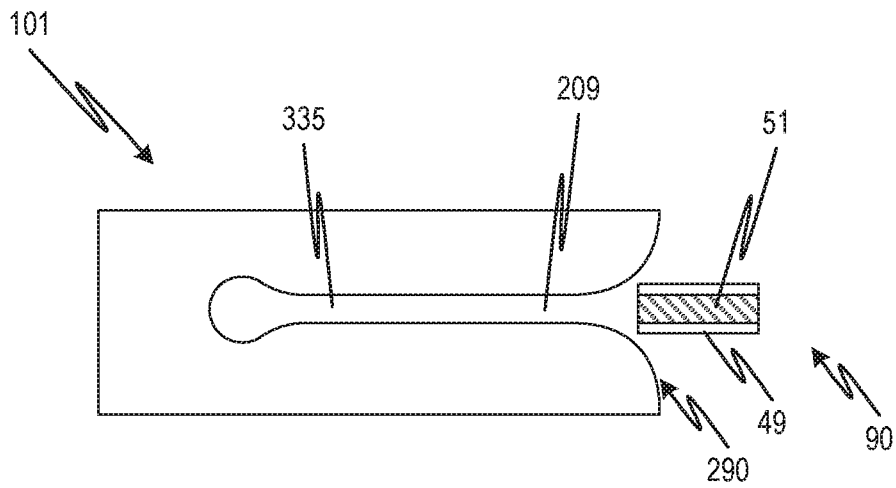


Fig. 6A

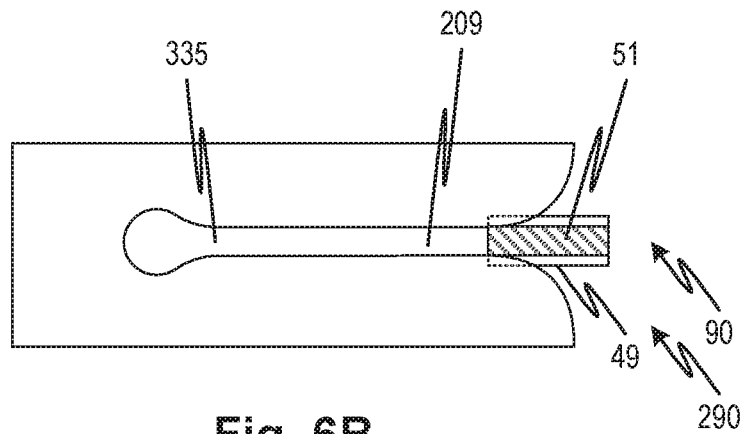


Fig. 6B

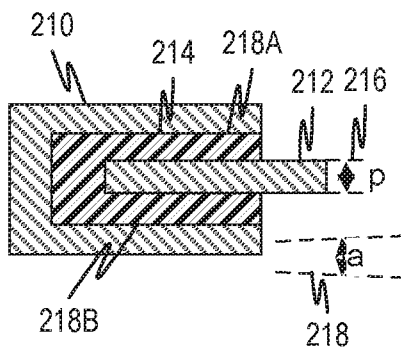


Fig. 7D

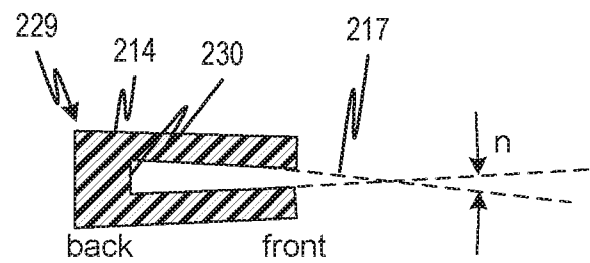


Fig. 7E

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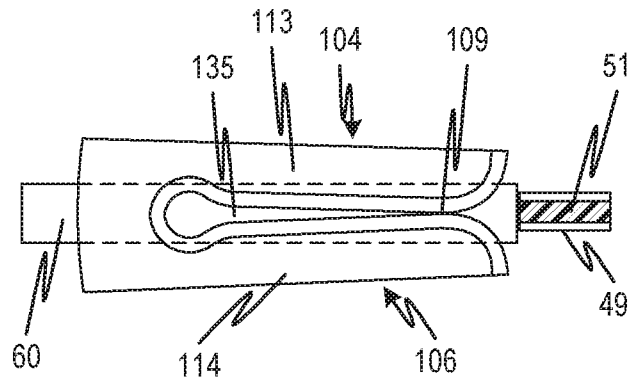


Fig. 7A

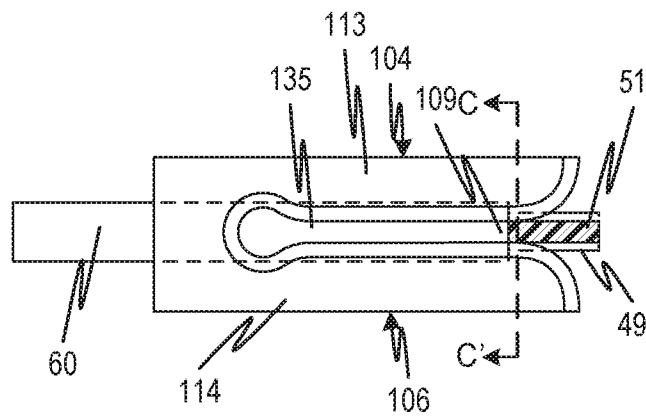


Fig. 7B

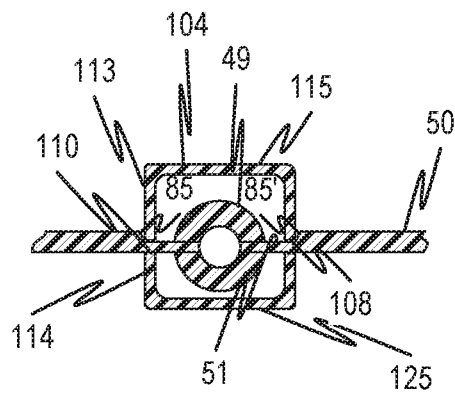


Fig. 7C

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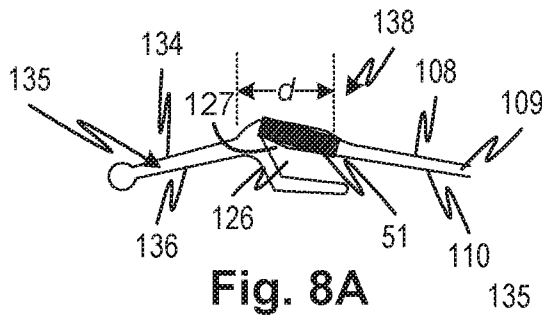


Fig. 8A

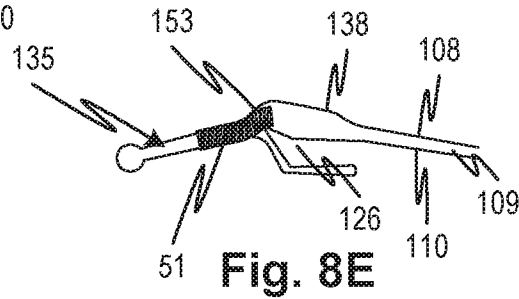


Fig. 8E

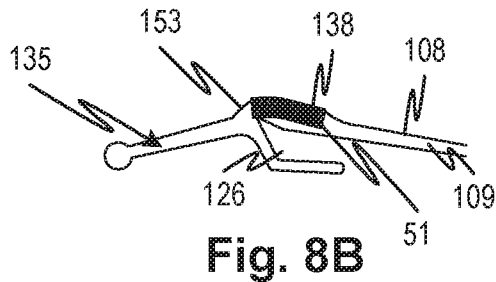


Fig. 8B

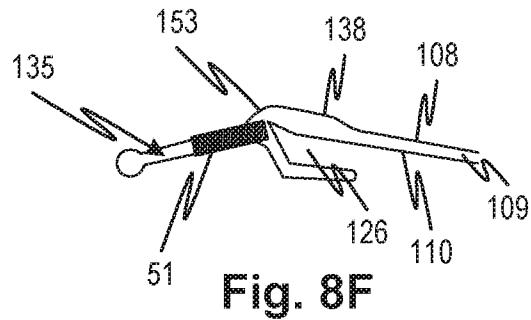


Fig. 8F

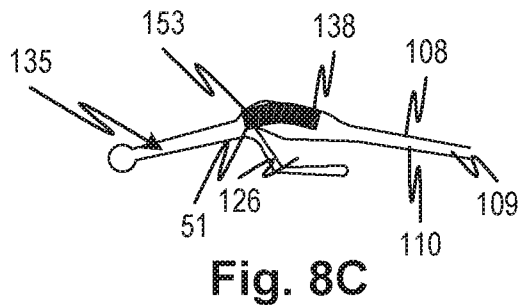


Fig. 8C

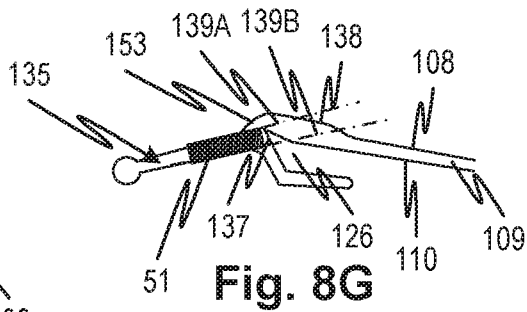


Fig. 8G

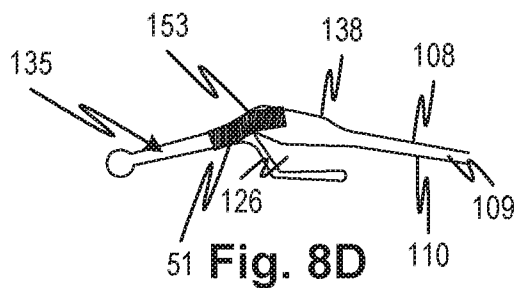


Fig. 8D

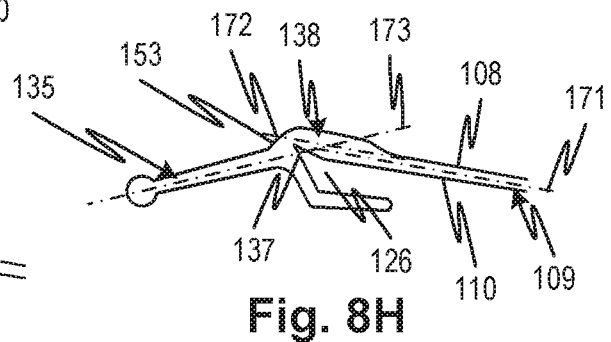


Fig. 8H

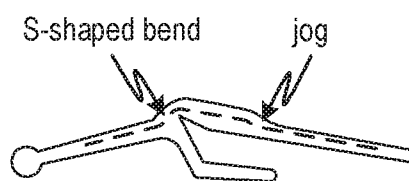


Fig. 8J

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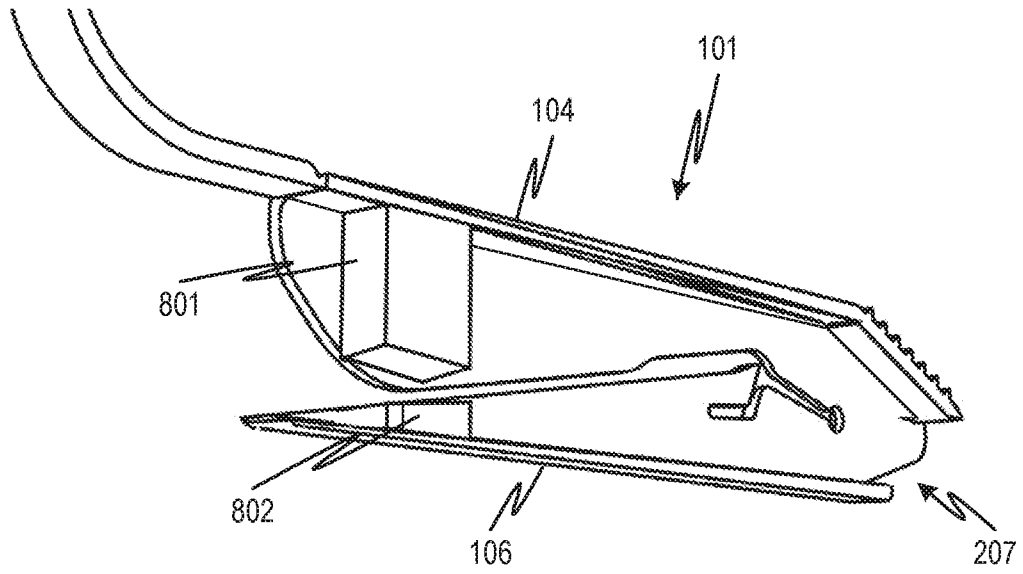


Fig. 9

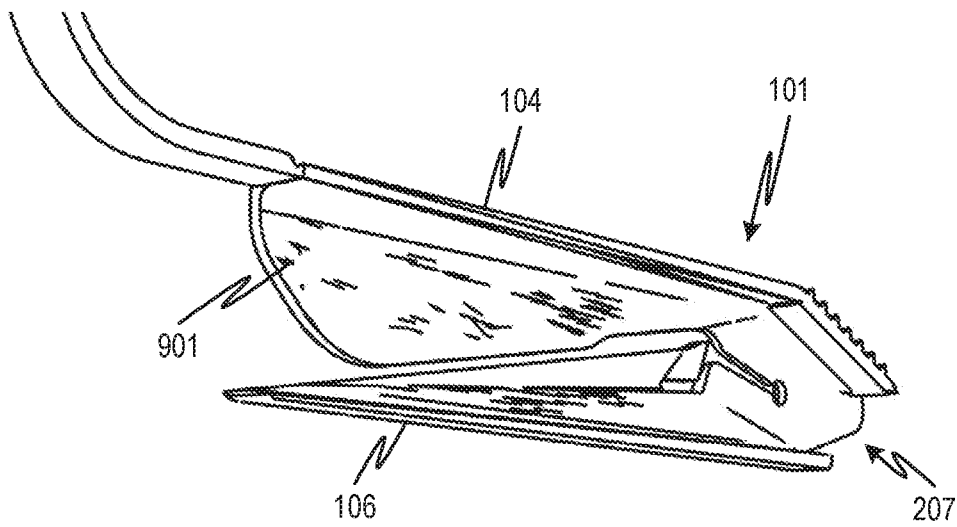
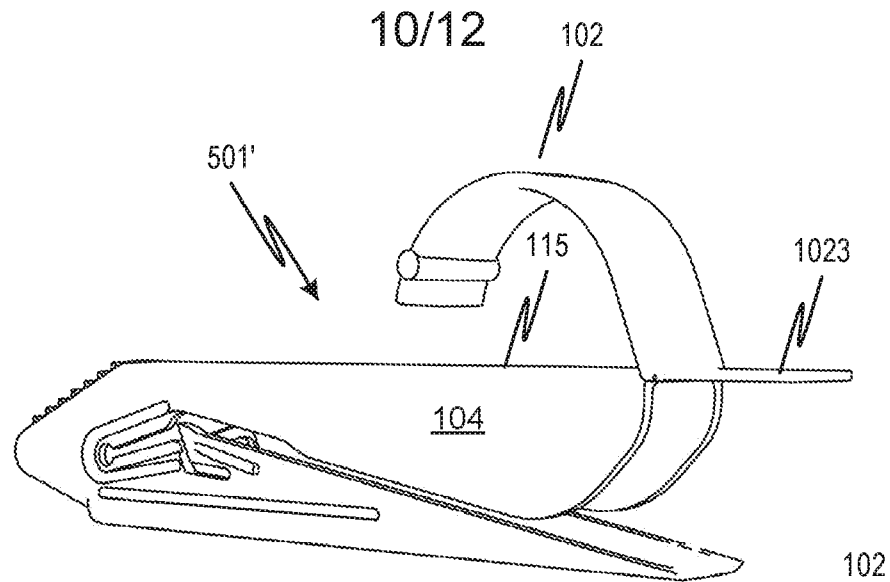
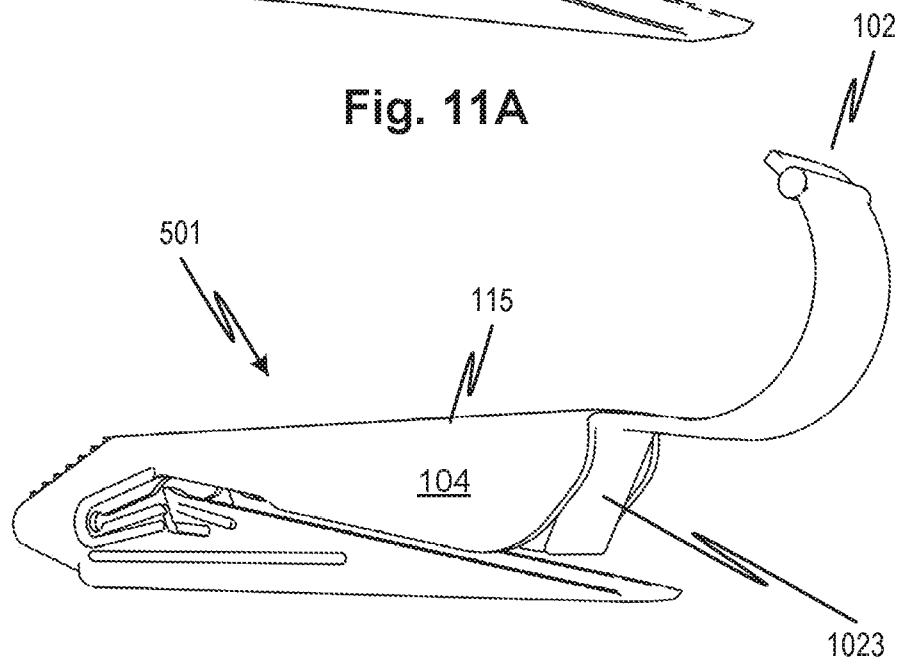
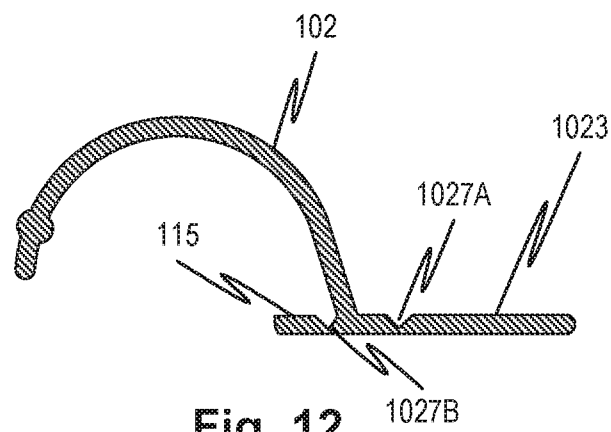
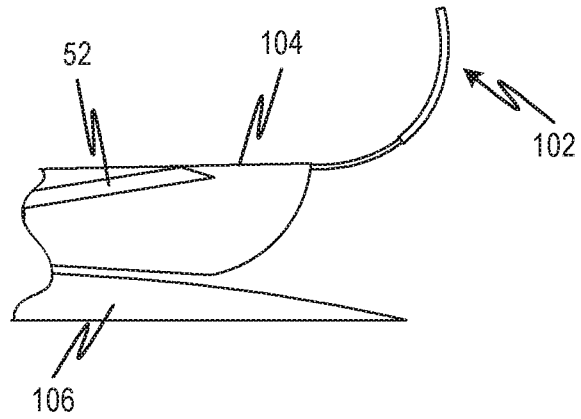
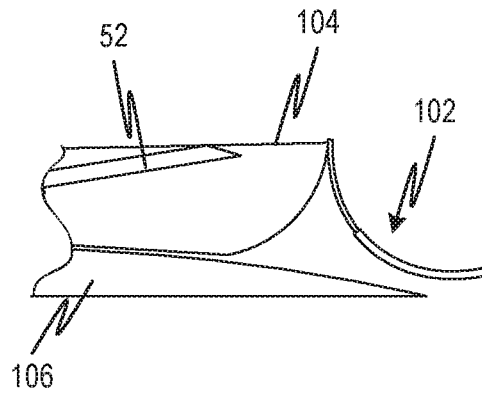
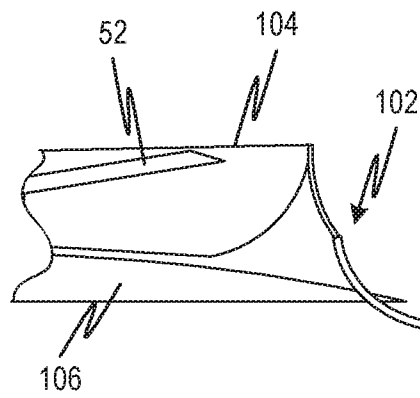


Fig. 10

**Fig. 11A****Fig. 11B****Fig. 12**

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**Fig. 13A****Fig. 13B****Fig. 13C**

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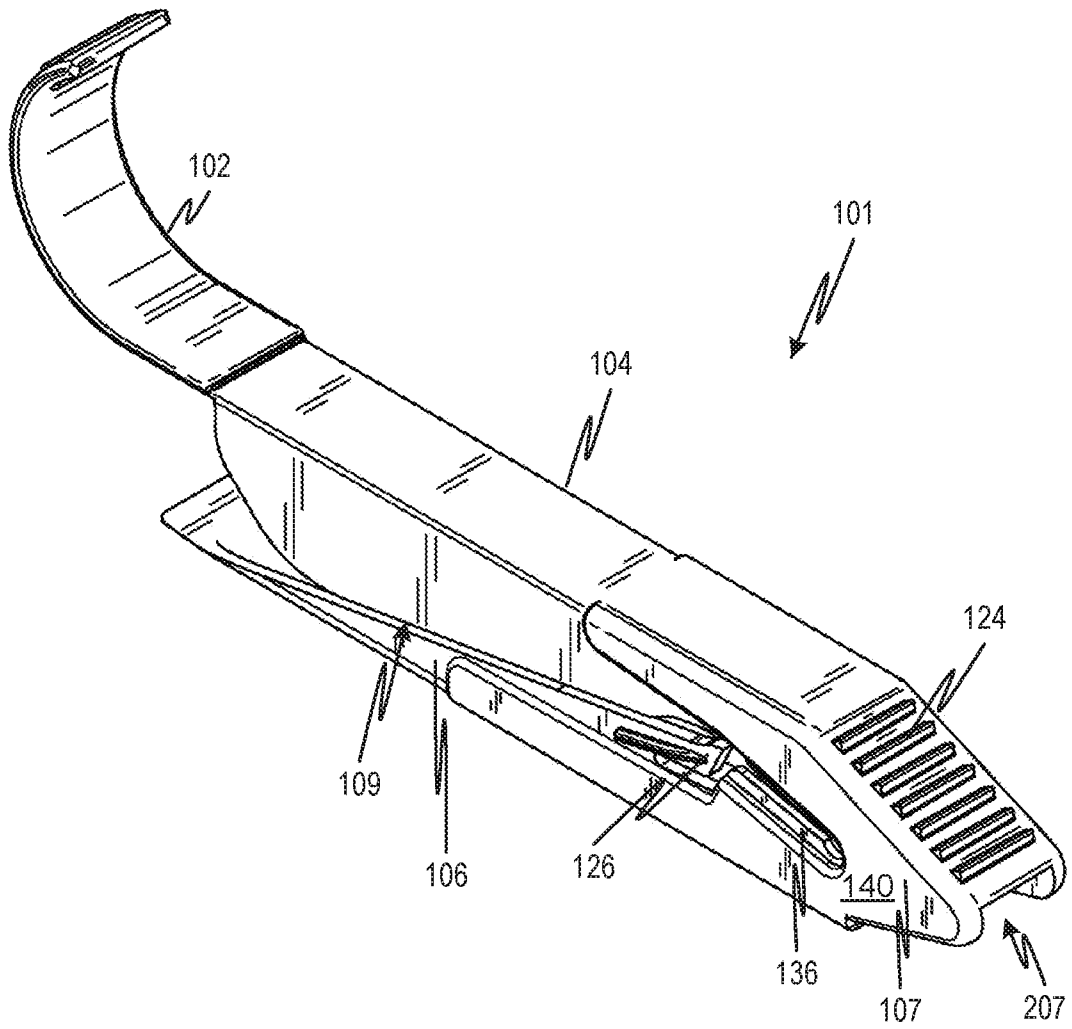


Fig. 14A

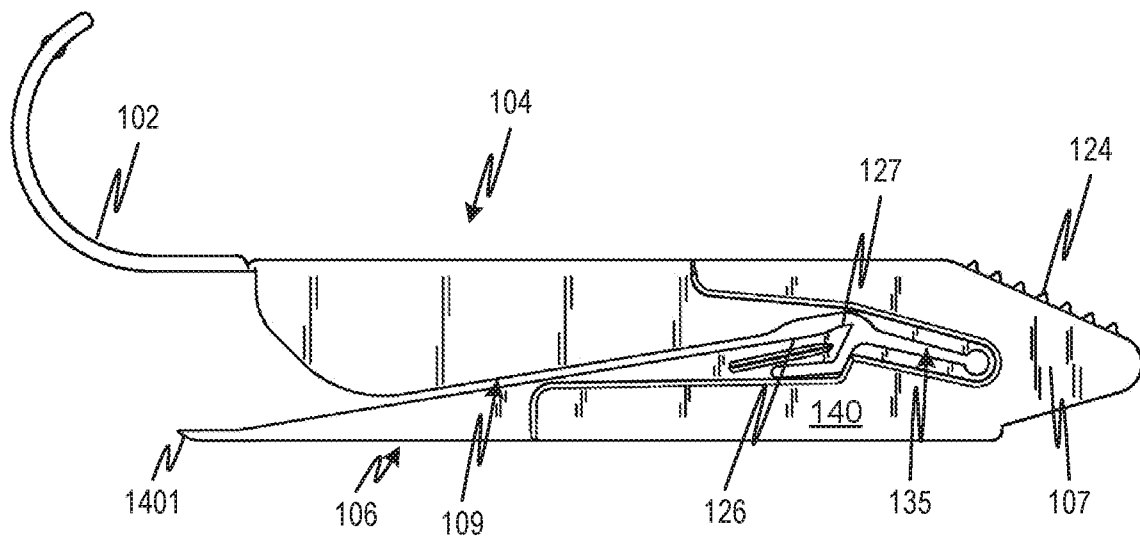


Fig. 14B

