

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (*day/month/year*)
31 July 2020

Applicant's or agent's file reference
P5797PC00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/AU2020/050545

International filing date (*day/month/year*)

29 May 2020

Priority date (*day/month/year*)

31 May 2019

International Patent Classification (IPC) or both national classification and IPC

A61M 5/32 (2006.01)

Applicant

METIER MEDICAL LIMITED

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| ☒ | Box No. I | Basis of the opinion |
| ☐ | Box No. II | Priority |
| ☐ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☐ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☐ | Box No. VII | Certain defects in the international application |
| ☐ | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA

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Date of completion of this opinion

31 July 2020

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2020/050545

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ The international application in the language in which it was filed
 - ☐ A translation of the international application into, , which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account **the rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b))
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed:
 - ☐ in the form of an Annex C/ST.25 text file.
 - ☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
 - ☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
 - ☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY		International Application No. PCT/AU2020/050545									
Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement										
1. Statement <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; vertical-align: top;"> Novelty (N) </td> <td style="width: 40%; vertical-align: top;"> Claims NONE Claims 1 to 21 </td> <td style="width: 30%; vertical-align: top; text-align: center;"> YES NO </td> </tr> <tr> <td style="vertical-align: top;"> Inventive step (IS) </td> <td style="vertical-align: top;"> Claims NONE Claims 1 to 21 </td> <td style="vertical-align: top; text-align: center;"> YES NO </td> </tr> <tr> <td style="vertical-align: top;"> Industrial applicability (IA) </td> <td style="vertical-align: top;"> Claims 1 to 21 Claims NONE </td> <td style="vertical-align: top; text-align: center;"> YES NO </td> </tr> </table>			Novelty (N)	Claims NONE Claims 1 to 21	YES NO	Inventive step (IS)	Claims NONE Claims 1 to 21	YES NO	Industrial applicability (IA)	Claims 1 to 21 Claims NONE	YES NO
Novelty (N)	Claims NONE Claims 1 to 21	YES NO									
Inventive step (IS)	Claims NONE Claims 1 to 21	YES NO									
Industrial applicability (IA)	Claims 1 to 21 Claims NONE	YES NO									
2. CITATIONS AND EXPLANATIONS: <u>CITATIONS</u> D1: WO 2018/109470 A2 (STAR SYRINGE LIMITED) 21 June 2018 D2: WO 2017/129968 A2 (STAR SYRINGE LIMITED) 03 August 2017 D3: EP 0832660 A2 (BECTON, DICKINSON AND COMPANY) 01 April 1998 D4: US 2017/0258990 A1 (WEI) 14 September 2017 D5: US 2002/0161336 A1 (CRAWFORD et al.) 31 October 2002 D6: EP 2397181 A1 (F. HOFFMANN-LA ROCHE AG et al.) 21 December 2011 D7: WO 2010/059415 A2 (B. BRAUN MELSUNGEN AG) 27 May 2010 D8: WO 2008/076459 A1 (MELSUNGEN AG, B., BRAUN) 26 June 2008 D9: GB 2532979 A (OWEN MUMFORD LIMITED) 08 June 2016 D10: US 5643219 A (BURNS) 01 July 1997 D11: WO 2009/007718 A1 (STAR SYRINGE LIMITED) 15 January 2009 D12: EP 0724890 A1 (BECTON, DICKINSON AND COMPANY) 07 August 1996 D13: US 2012/0323216 A1 (KOH) 20 December 2012 D14: WO 2010/059345 A2 (B. BRAUN MELSUNGEN AG) 27 May 2010 D15: US 5490841 A (LANDIS) 13 February 1996 <u>NOVELTY (N)</u> <u>Claims 1 to 5 and 10 to 21:</u> The invention defined in these claims is not novel when compared with the following prior art document that discloses all the features of the invention claimed: D2 = WO 2017/129968 A2 (STAR SYRINGE LIMITED) 3 August 2017. D2 discloses (See: Abstract; Figures and related text; claims) a needle cover including: a mounting portion for mounting a needle; and a lid portion hingedly connected to the mounting portion, the lid portion movable to: an open position; a first cover position, wherein the lid portion is releasably docked with the mounting portion; and a second cover position, wherein the lid portion is irreversibly docked with the mounting portion, wherein the mounting portion and the lid portion include corresponding docking elements that engage to provide the first and second cover positions. D2 (Figures 1 to 31) discloses a needlestick prevention device (1, 100) for an injection needle carried by a needle-bearing member (2, 102) of a syringe (102) is formed as a one-piece moulding and comprises a first part (3, 103) adapted to be attached to the needle-bearing member (2, 1) and a second part (4, 104) providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use. The device is adapted to adopt a first position in which the needle is protected for transport of the device prior to use, a second position in which the needle is exposed for filling of the syringe and injection, a third position in which the needle is protected after filling of the syringe but before injection and a fourth position in which the needle is locked in the device following injection. In one embodiment the shield (104) has a transport recess (124) and a locking recess (125) connected by a gate device (126) at least at the base of the needle (130), the arrangement being such that in the third position the needle (130) is in the transport recess (124) and is able to move into the second position, and in the fourth position the needle moves through the gate device (126) into the locking recess (125), with the gate device (126) preventing movement out of the fourth position. It is virtually impossible to remove the needle from the locking recess without significant damage. The first and second parts of the device are preferably connected by a living hinge. The hinge provides the force to move the second part between the first and second positions, and between the second and third positions, once movement is initiated by the user. Further manual force is required to move the second part into the fourth position. The hinge also retains the second part in the first and third positions. The gate device preferably comprises a projection formed in the second part to define a partition between the transport recess and a locking recess and a curved or labyrinthine path connecting the transport recess											

Form PCT/ISA/237 (Box V) (revised January 2019)

and the locking recess. When the needle is moved into the third position from the second position, it is retained in the transport recess by the projection, but can follow the labyrinthine path into the locking recess when the further manual force is applied. Once in the locking recess, the base of the needle does not have sufficient flexibility to return along the labyrinthine path round the projection. In another embodiment the first and second parts of the device are preferably connected by a living hinge, and a retaining means. In the first position the needle is accommodated in the second part, and the retaining means is engaged to maintain the relative positions of the first and second parts. In the second position the retaining means is disengaged and the second part is pivoted away from the first part, with the assistance of the hinge, to expose the needle. The second part can be moved back into the first position, and maintained there by the retaining means with the needle covered, to be in the third, transport position. Then the second part can be moved into the operative position again when the injection is to be given. Following injection, the second part is moved back, through the first position such that the retaining means engages in a position where a permanent locking arrangement is actuated. The retaining means may comprise a pair of detents on one of the first and second parts, adapted to engage in a recess on the other part respectively in the third and fourth positions. Alternatively the retaining means may comprise a co-operating pin and hole arrangement, with a pin being provided on one of the first and second parts, and a hole on the other part, in which the pin engages in the fourth position. The second part may also include a secondary locking mechanism for the needle in the locked position. The secondary locking mechanism may comprise at least a pair of opposing hooks, arranged such that the needle can pass over them in one direction, but not return. The U-shaped shield member 26 has an open face allowing passage of the needle. It is formed with a lip 35 at its free end and flat faces 36 to allow the strip 7 to be sealed to it. The shield member 26 also has a secondary locking mechanism 37 for the needle, in the form of tongues 38 projecting inwardly from the side wall 39 of the shield member 26. Three tongues 38 are shown in the drawings, two provided on one side of the needle and one on the other. It is essential to have at least two opposing tongues; more may be provided according to the length of the needle. The tongues are of different lengths to ensure that the needle is held securely, whatever its length. It will be appreciated that in the initial position the needle may contact the tongues but is free to move out of the shield member 26. In the locking position the needle contacts and deflects the tongues 38, which then return to their original position and trap the needle in the shield member 26. For use, the assembled device 100 and hub 101 are removed from any packaging and attached to a syringe 102, as shown in Figure 23. The lid portion includes a beveled tip (Figures 4 and 6). Therefore, the subject matter of claims 1 to 5 and 10 to 21 is not new and does not meet the requirements of Article 33(2) of the PCT with regard to novelty.

Claims 1 to 2 and 15 to 21: The invention defined in these claims is not novel when compared with the following prior art document that discloses all the features of the invention claimed: D4 = US 2017/0258990 A1 (WEI) 14 September 2017.

D4 discloses (See: Abstract; Figures and related text; claims) a needle cover including: a mounting portion for mounting a needle; and a lid portion hingedly connected to the mounting portion, the lid portion movable to: an open position; a first cover position, wherein the lid portion is releasably docked with the mounting portion; and a second cover position, wherein the lid portion is irreversibly docked with the mounting portion, wherein the mounting portion and the lid portion include corresponding docking elements that engage to provide the first and second cover positions. D4 (Figures 1 to 10) discloses a protective cover type safety device for syringes includes a first buckle seat, a second buckle seat which can be engaged with the first buckle seat, and a protective cover which is pivotably connected with the first buckle seat. The first buckle seat and the second buckle seats are clamped and positioned to a needle seat of a syringe, and the protective cover is able to swing between a first position and a second position, and limited at a third position. The protective cover at the third position covers a needle body of the syringe to prevent the needle body from being exposed or piercing or hurting people. The protective cover is pivotably connected to the first buckle seat by the round shaft and can swing reciprocally between a first position and a second position about the round shaft. The protective cover is pushed from the first position and latched to a third position by an external push, and thus unable to return to the first position. The protective cover at the second position embraces the needle cover of the syringe by the two hugging arms. The protective cover swings outwardly from the second position to the first position. The protective cover is offset from the needle cover of the syringe, so as to remove the needle cover and the needle body is ready for injection. After the needle body is used, an external pushing force is applied to the protective cover. The protective cover swings from the first position to the third position, and the protective cover of the third position is latched to the bottom of the limiting members by passing the two hugging arms through the limiting members of the second buckle seat. The protective cover accommodates the needle body and needle seat of the syringe by the first accommodating space and the second accommodating space. In an embodiment, the fastener of the first buckle seat is a square fastener with a square hole and the fastener of the second buckle seat is a protruding member which is combined with the fastener. As shown in FIG. 7, the protective cover 5 can swing freely between the first position P1 and the second position P2. Preferably, at the second position P2, the protective cover 5 holds the plastic needle cover 68 by the two hugging arms 59. The friction between the plastic hugging arms 59 and the plastic needle cover 68 is sufficient to restrict the protective cover 5 from easily overturning outward and getting separated from the needle cover 68. Therefore, the subject matter of claims 1 to 2 and 15 to 21 is not new and does not meet the requirements of Article 33(2) of the PCT with regard to novelty.

Claims 1 to 21: The invention defined in these claims is not novel when compared with the following prior art document that discloses all the features of the invention claimed: D8 = WO 2008/076459 A1 (MELSUNEN AG, B., BRAUN) 26 June 2008.

D8 discloses (See: Abstract; Figures and related text; claims) a needle cover including: a mounting portion for mounting a needle; and a lid portion hingedly connected to the mounting portion, the lid portion movable to: an open position; a first cover position, wherein the lid portion is releasably docked with the mounting portion; and a second cover position, wherein the lid portion is irreversibly docked with the mounting portion, wherein the mounting portion and the lid portion include corresponding docking

elements that engage to provide the first and second cover positions. D8 (Figures 1 to 27) discloses a hinged cap device for use with a syringe includes a base defining an interior cavity for mounting onto a tip and a cap connected to the base by a living hinge. cap (14) is connected to the base by a living hinge (18), and is movable from a ready position to an open position to expose a needle (16) i.e. hypodermic needle, and from the open position to a secured position to prevent relative rotation between the cap and the base. A latching mechanism (24) is locatable on two sides of the needle respectively in the ready position, and secured position. The needle is disengageable from the mechanism in the ready position, and is not disengageable from the mechanism in the secured position. An integral ear, lever, or tab 40 extends into the channel 22, the tabs being generally located toward a lower, proximal portion of each fin 39. The tabs 40 are configured to abut corresponding tabs 38 extending from the base 12 to prevent relative movement between the cap 14 and the base in the ready position. More specifically, the tabs 38 extend from the second cylinder 12b and have a flat bottom surface adapted to abut a flat top surface of the tabs 40. The two sets of tabs provide a temporary lock state and function as an added security feature when in the ready position. The base 12 is connected to the cap 14 by a living hinge 18 located between a base segment 54 and a cap segment 56. As shown in FIGS. 1 and 5, the cap segment 56 extends proximally from a proximal end of the base wall 28 and is generally parallel to a longitudinal axis of the cap 14. The base segment 54 extends at an angle from a wall surface of the base 12 towards the cap segment 56 with the living hinge 18 integrally joined therebetween such that the living hinge not only allows rotation of the cap 14 relative to the base 12, but also allows for limited axial movement of the cap relative to the base to enable the tabs 38, 40 to be disengaged. With reference now to FIGS. 4-6, and initially to FIG. 6, a wedge 42 extends from a wall surface of the base 12, the wedge having a slightly arcuate configuration. The wedge 42 is dimensioned to fit between two spaced gripping plates 44 which extend from the base wall 28 of the cap 14 (FIG. 6). More specifically, the wedge 42 is located on the base 12 such that when the cap 14 is rotated by a certain amount about the living hinge 18 with respect to the base, the wedge engages the gripping plates 44 to temporarily retain the cap in the open position. In one exemplary embodiment, the engagement between the wedge 42 and the gripping plates 44 is a frictional engagement. However, one of ordinary skill in the art will appreciate that toothed surfaces or detents may be used without deviating from the spirit and scope of the present invention. IG. 12 is a top or plan view of the hinged cap assembly 210 of FIG. 11, looking down at the base wall 230, the coupling well 220, and a channel 222 defined by the two side walls 228. Assuming that a needle is attached to the coupling well 220, the hinged cap assembly 210 is shown in an open or exposed position with the cap 214 pivoted away from the needle to expose the needle tip. A round detent 240, which resembles a half-cylinder, is molded to one of the side walls 228. A second detent 242 is incorporated near the distal end of the cap, closer to the rounded end 232 and on the other side of the living hinge 236. The second detent 242 resembles a downward leaf spring having one end integrally molded to the same side wall 228 as the round detent and a free end pointed downward into the channel 222. As further discussed below, the round detent 240 is configured to temporarily engage the cap 214 to the needle, such as during transport and prior to use. After use, the second detent 242 in combination with the living hinge 236 is configured to more permanently secure the cap to the needle to prevent needle stick injuries. FIG. 15 is a perspective view of yet another exemplary hinged cap device 254 provided in accordance with aspects of the present invention, attached to a syringe 255. The hinged cap device 254 incorporates a cap 256 connected to a needle hub 258 by a living hinge 259. The hinged cap device 254 is moveable between a semi-locked or start position (FIG. 16), in which the cap temporarily covers a needle 252, to an open position wherein the needle is exposed (FIG. 15), from the open position to a capped position (FIG. 17), and from the capped position to a locked position (FIG. 18) in which the needle 252 is permanently trapped within the cap 256. In one exemplary embodiment, the cap 256 defines a generally U-shaped channel 262 adapted to house the needle 252. A catch mechanism 260 is incorporated in the channel 262 defined by the cap 256. In one exemplary embodiment, the catch mechanism 260 is made from a metal material and is attached to the cap in a snap lock arrangement, such as detent, dove-tail, or tongue-and-groove lock arrangement. FIG. 16 is a perspective view of the hinged cap device 254 of FIG. 15 in the semi-locked or start position, that is also a packaged or shipped position. As shown, the lock mechanism 260 comprises an anchor plate 200, that is similar to a tongue for engaging a groove located on the cap. A cantilevered member 202 extends from the anchor plate 200, or to another section that extends from the anchor plate, and comprises an arcuate joint 203 and a hook arm 270, (more clearly shown on FIG. 19) that comprises an inactive surface 204 and an active surface 206, located on the hook arm facing in the opposite direction from the inactive surface 204. A plurality of ribs 208 are optionally incorporated in the cap for enhancing the structural rigidity of the cap. With reference now to FIG. 20, another exemplary embodiment of a hinged cap device 272 mountable on a syringe is shown. The hinged cap device 272 may include any of the latching mechanism. The hub 274 incorporates a flange 276, including a lock lever 278 for locking a needle hub 280 having the 252 needle attached thereto and a socket 282 for receiving a boss 284 on the cap 286. The cap 286 further includes a gripping lever 288 for pushing or pulling on the cap to engage the boss 284 to the socket 282. In one exemplary embodiment, the hinged cap device includes two sockets 282, two bosses 284, and two gripping levers 288 located on opposite sides of the needle hub 274 and the cap 286. As shown in FIG. 21, the cap 286 may be rotated from the open position to a semi-locked position in which the cap 286 is aligned over the needle and the boss 284 is engaged in a first groove of the socket 282. In the semi-locked position, the cap can be pivoted away from the needle to an open position or the gripping lever 288 may be pulled or pushed to move the boss to the second groove of the socket 282 to a locking position. The hinge 290 is an articulating hinge, capable of both pivoting and translating to move the boss to a fully locked position. Yet another exemplary embodiment of a hinged cap device 310 of the present invention is shown in FIGS. 23-27. With reference now to FIG. 23, the hinged cap device comprises a base 312 connected to a cap 314 by a living hinge 18, the living hinge being biased toward an initial packaged or ready position. Similarly to previously described embodiments, the cap can be rotated from the ready position to an open position (FIG. 24), in which a needle 316 is exposed and from the open position to a secured position in which the needle 316 is secured within the cap by the first latching mechanism 24. A push tab 346 is provided to aid in rotation of the cap 314 between various positions, the push tab including a gripping surface 347, for example, a plurality of raised protrusions or bumps, to provide a user with a more secure hold on the cap. The push tab 346 may also be contoured to generally conform to a user's finger, thereby providing a comfortable feel for the user. Additionally, the base 312 includes a base engagement prong 348 having a detent or hook 350 at an

end adapted to engage a detent or hook 354 on a cap engagement prong 352 to temporarily lock the cap 314 in the open position. D8 further discloses that although limited hinged cap embodiments and their components have been specifically described and illustrated, many modifications, combinations, and variations of the embodiments will be apparent to those skilled in the art. For example, the length, size, colours, and other appearances of the hub may be modified, and the needle may be attached directly to the hub on the hinged cap or as a separate hub attached via a luer fitting. Furthermore, it is understood and contemplated that features specifically discussed for one hinged cap embodiment may be adopted for inclusion with another hinged cap embodiment provided the functions are compatible. For example, the cap living hinge of FIGS. 11-14 may be incorporated into the caps of the various other embodiments. Accordingly, it is to be understood that the hinged cap devices and their components constructed according to principles of this invention may be embodied other than as specifically described herein. The lid portion includes a beveled tip. Therefore, the subject matter of claims 1 to 21 is not new and does not meet the requirements of Article 33(2) of the PCT with regard to novelty.

INVENTIVE STEP (IS)

Claims 1 to 21: These claims also lack an inventive step for the reasons given above. An invention is necessarily obvious in the light of its disclosure.

Claims 1 to 21: These claims do not meet the criteria for inventive step. The invention claimed in these claims does not involve an inventive step in light of document: D1 = WO 2018/109470 A2 (STAR SYRINGE LIMITED) 21 June 2018.

D1 discloses (See: Abstract; Figures and related text; claims) a needle cover including: a mounting portion for mounting a needle; and a lid portion hingedly connected to the mounting portion, the lid portion movable to: an open position; a first cover position, wherein the lid portion is releasably docked with the mounting portion; and a second cover position, wherein the lid portion is irreversibly docked with the mounting portion. The claimed invention differs from the cited art in that D1 does not disclose wherein the mounting portion and the lid portion include corresponding docking elements that engage to provide the first and second cover positions. I consider that the differences between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Appended claims 2 to 21 do not involve an inventive step. These features are disclosed in D1 or are part of the common general knowledge in the art. For example, D1 discloses (Figures 1 to 7) a needlestick prevention device 100 for an injection needle carried by a needle-bearing member such as a syringe barrel or a needle hub. Figures 8 to 11 show the device 100 attached to a needle hub 101 and a syringe 102. The first and second parts 103, 104 are connected by a hinge 105. This allows the first and second parts 103, 104 to adopt three stable positions. The first position is an initial position and a transport position can be seen in Figure 9. The second position, shown in Figures 1 and 2, as well as Figure 10, is an open or operative position, in which the needle is exposed for use. The third position, shown in Figure 11, is a locking position, in which the two parts 103, 104 are held firmly, and the needle is trapped in the second part 104. The first part 103 has a pair of diametrically opposed axial ribs 112 extending from the end 108 and terminating short of the free end 107. As best seen in Figures 5 and 6, each rib 112 has an internal projection 113, which is used to attach the device 100 to a needle-bearing member (Figure 8). Each projection 113 has a substantially triangular profile, having a face inclined to the axis, and an abutment face 114 perpendicular to the axis. The second part 104 is a substantially U-shaped shield member. As best seen in Figure 3, the outline is indented at 115 adjacent the open side 116 and the closed part 117 is slightly bulbous. The open side 116 allows for passage of the needle between the initial position and the open position, and between the open position and the transport position. The open side 116 is formed with a funnel 123 leading to a transport recess 124 which in turn leads to a locking recess 125 through a gate device 126. The transport recess 124 extends along the axis of the device 100 so that it accommodates the needle in the initial and transport positions. The gate device 126 comprises a projection 127 defining a position between the recesses 124 and 125 and a curved or labyrinthine path 128 between them. The projection extends all the way along the axial length of the second part 104; but could be provided only at the end adjacent the first part 103, that is, adjacent the base of the needle. In a further modification (not shown), the gate device 126 may be modified by changing the profile of the projection 127 adjacent the base of the needle to ensure that the needle cannot return from the locked position. Therefore, the claimed invention does not involve an inventive step. Therefore, the subject matter of claims 1 to 21 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

Claims 6 to 9: These claims do not meet the criteria for inventive step. The invention claimed in these claims does not involve an inventive step in light of document: D2 = WO 2017/129968 A2 (STAR SYRINGE LIMITED) 3 August 2017.

D2 discloses claims 1 to 5 and 10 to 21 (see NOVELTY). The claimed invention differs from the cited art in that D2 does not disclose the features of appended claims 6 to 9, namely: wherein the docking port includes one or more resiliently deformable elements that deform to allow entry of the hook portions, and engage with the hook portions to provide the first and second cover positions; wherein the docking port includes an aperture with resiliently deformable elements in the form of internally projecting tabs; wherein, in the first cover position, the docking projection is engaged with the docking port such that the distal hook portion thereof is inserted beyond the tabs and the proximal hook portion is not, and, the tabs are configured to resist withdrawal of the distal hook portion; wherein, in the second cover position, the docking projection is engaged with the docking port such that the distal hook portion and the proximal hook portion are both inserted beyond the tabs, and, the tabs are configured to prohibit withdrawal of the proximal hook portion. I consider that the differences between the claimed invention and the citation constitutes

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no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Therefore, the subject matter of claims 6 to 9 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

Claims 1 to 21: These claims do not meet the criteria for inventive step. The invention claimed in these claims does not involve an inventive step in light of document: D3 = EP 0832660 A2 (BECTON, DICKINSON AND COMPANY) 1 April 1998.

D3 discloses (See: Abstract; Figures and related text; claims) a needle cover including: a mounting portion for mounting a needle; and a lid portion hingedly connected to the mounting portion, the lid portion movable to: an open position; a first cover position, wherein the lid portion is releasably docked with the mounting portion; and a second cover position, wherein the lid portion is irreversibly docked with the mounting portion. The claimed invention differs from the cited art in that D3 does not disclose wherein the mounting portion and the lid portion include corresponding docking elements that engage to provide the first and second cover positions. I consider that the differences between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Appended claims 2 to 21 do not involve an inventive step. These features are disclosed in D3 or are part of the common general knowledge in the art. For example, D3 discloses (Figures 1 to 23) a needle assembly comprising: an elongate needle having a proximal end, a distal end and a passageway therethrough defining an axis; a needle hub having a proximal end, a distal end and an exterior surface, said needle hub having an axial bore therethrough to receive and hold said needle with said distal end of said needle projecting axially therefrom, said proximal end of said needle hub further including means for releasably mounting said needle hub on a fluid handling device; an elongate shield having an open proximal end, a distal end and a sidewall with an inside surface defining a cavity, said sidewall having an elongate aperture into said cavity from about said distal end to said proximal end; hinge means including a mount for retaining said shield onto said hub, said mount including an opening therein sized and shaped to receive at least a portion of said needle hub, said shield being movable about said hinge means by an off-axis pivotal movement between an initial closed position wherein inadvertent access to said needle is substantially prevented, an open position wherein at least said distal point of said needle is exposed and a latched position wherein said shield is in contact with said needle, is latched to said mount and substantially prevents access to said distal point of said needle; a removable cover, said cover disposed over said elongate aperture in said shield and engaging said shield to hold said shield in said initial closed position, said cover being removable by a distal axial movement to open said shield, to disengage said cover from said shield and to expose at least said distal point of said needle; and latch means for latching said shield to said mount when said shield is in said latched position. Shield 32 also includes two proximal raised retention areas 70 on an exterior surface 72 of sidewall 38 adjacent to aperture 44. Raised retention areas 70 are disposed to be engaged by two rails 69 on an inside surface 51 of cover 50 to retain the cover on the shield when the assembly is in the initial closed position as seen in Figs. 2 and 6. Cover 50 further includes at least one inward protuberance 73 that is disposed to engage a proximal edge 74 of raised retention area 70 so that when cover 50 is axially moved distally, the engagement of protuberance 73 and proximal edge 74 cause shield 32 to pivot about hinge 46 and move to the open position, as seen in Fig. 3. Once cover 50 is removed, it cannot easily be replaced with the shield in the initial closed position, because once shield 32 is moved from the initial closed position, cantilever spring 66 provides a resistance to the shield being closed unless it is sufficiently closed to engage pawls 54 with slots 58 and latch the shield onto the mount. However, cover 50 may be replaced on the mount to cover needle 12 after a syringe has been opened and filled to allow the assembly to be transported to a remote dosage location. The ability to remount cover 50 with shield 32 open is particularly useful in hospital pharmacy applications where a dosage is prepared for a patient at a location remote from the administration location. Once the dosage is administered, the practitioner then may proceed with latching the shield. Therefore, the claimed invention does not involve an inventive step. Therefore, the subject matter of claims 1 to 21 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

Claims 3 to 14: These claims do not meet the criteria for inventive step. The invention claimed in these claims does not involve an inventive step in light of document: D4 = US 2017/0258990 A1 (WEI) 14 September 2017.

D4 discloses claims 1 to 2 and 15 to 21 (see NOVELTY). The claimed invention differs from the cited art in that D4 does not disclose the features of appended claims 3 to 14, namely: wherein the corresponding docking elements include at least one docking projection and docking port pair, the docking projection configured for engagement with the docking port; wherein the docking projection includes a distal hook portion and a proximal hook portion, the distal hook portion for engagement with the docking port to provide the first cover position, and the proximal hook portion for engagement with the docking port to provide the second cover position; wherein the hook portions are provided by lateral expansions on the docking projection; wherein the largest lateral radius of the proximal hook portion is larger than the largest lateral radius of the distal hook portion; wherein the docking port includes one or more resiliently deformable elements that deform to allow entry of the hook portions, and engage with the hook portions to provide the first and second cover positions; wherein the docking port includes an aperture with resiliently deformable elements in the form of internally projecting tabs; wherein, in the first cover position, the docking projection is engaged with the docking port such that the distal hook portion thereof is inserted beyond the tabs and the proximal hook portion is not, and, the tabs are configured to resist withdrawal of the distal hook portion; wherein, in the second cover position, the docking projection is engaged with the docking port such that the distal hook portion and the proximal hook portion are both inserted beyond the tabs, and, the tabs are configured to prohibit withdrawal of the proximal hook portion. I consider that the differences between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker

in the art would be expected to make directly and without difficulty and by routine steps alone. Therefore, the subject matter of claims 3 to 14 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

Claims 1 to 21: These claims do not meet the criteria for inventive step. The invention claimed in these claims does not involve an inventive step in light of document: D5 = US 2002/0161336 A1 (CRAWFORD et al.) 31 October 2002.

D5 discloses (See: Abstract; Figures and related text; claims) a needle cover including: a mounting portion for mounting a needle; and a lid portion hingedly connected to the mounting portion, the lid portion movable to: an open position; a first cover position, wherein the lid portion is releasably docked with the mounting portion; and a second cover position, wherein the lid portion is irreversibly docked with the mounting portion. The claimed invention differs from the cited art in that D5 does not disclose wherein the mounting portion and the lid portion include corresponding docking elements that engage to provide the first and second cover positions. I consider that the differences between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Appended claims 2 to 21 do not involve an inventive step. These features are disclosed in D5 or are part of the common general knowledge in the art. For example, D5 discloses (Figures 1 to 15A) that preferably, the hinged shield is capable of pivoting from a first position, where the intravenous end of the needle is exposed and bevel up, to an intermediate position where the needle is partially covered, to a second position where the needle is contained by the shield. Preferably, the hinged shield is connected to the collar by a hanger bar that engages with a hook arm on the collar so that the hinged shield may be pivoted with respect to the collar into several positions. It is within the purview of the present invention to include any structure for connecting the hinged shield to the collar so that the shield may be pivoted with respect to the collar. These structures include known mechanical hinges and various linkages, living hinges, or combinations of hinges and linkages. The hinged shield preferably includes at least one cannula finger lock for locked engagement with the cannula when the hinged shield is in the second position around the needle cannula. The cannula finger lock preferably projects obliquely from one sidewall of the hinged shield angularly toward the opposed sidewall and the top wall of the shield. The cannula finger lock is dimensioned, disposed and aligned to contact the needle cannula when the hinged shield approaches the second position. Contact between the cannula and the cannula finger lock will cause the cannula finger lock to resiliently deflect toward the sidewall from which the cannula finger lock extends. Sufficient rotation of the hinged shield will cause the needle cannula to pass the cannula finger lock. As a result, the cannula finger lock will resiliently return to or toward its undeflected condition for securely trapping the needle cannula in the hinged shield. As shown in FIGS. 12-15, when the venipuncture is complete the user easily rotates hinged shield 140 from the open position towards the intravenous needle to an intermediate position and then the user pushes on the shield at the top finger guide area to move the shield into a second position whereby the needle is trapped in the longitudinal opening. More particularly, needle 40 contacts cannula finger lock 167. The engagement of needle 40 with cannula finger lock 167 causes cannula finger lock 167 to deflect toward top wall and toward the sidewall 162 from which cannula finger lock 167 projects. Sufficient rotation of hinged shield 140 will cause needle 40 to pass cannula finger lock 167. As a result, cannula finger lock 167 will return resiliently to an undeflected condition. Thus, needle 40 will be trapped above cannula finger lock 167. Alternatively, the safety shield assembly of the present invention may be used in conjunction with a syringe, as illustrated in FIGS. 18A-C. Therefore, the claimed invention does not involve an inventive step. Therefore, the subject matter of claims 1 to 21 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

Claims 1 to 21: These claims do not meet the criteria for inventive step. The invention claimed in these claims does not involve an inventive step in light of document: D6 = EP 2397181 A1 (F. HOFFMANN-LA ROCHE AG et al.) 21 December 2011.

D6 discloses (See: Abstract; Figures and related text; claims) a needle cover including: a mounting portion for mounting a needle; and a lid portion hingedly connected to the mounting portion, the lid portion movable to: an open position; a first cover position, wherein the lid portion is releasably docked with the mounting portion; and a second cover position, wherein the lid portion is irreversibly docked with the mounting portion. The claimed invention differs from the cited art in that D6 does not disclose wherein the mounting portion and the lid portion include corresponding docking elements that engage to provide the first and second cover positions. I consider that the differences between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Appended claims 2 to 21 do not involve an inventive step. These features are disclosed in D6 or are part of the common general knowledge in the art. For example, D6 discloses (Figures 1 to 14) a needle cover 42 that is pivotably mounted 424 on the handle structure. In the shown embodiment the cover 42 is realized as a sleeve closed at one end, forming a cap 425, and with a longitudinal access slot 422. The cover 42 can be pivoted 51 between a first position and a second position, whereas the insertion needle 41 does not change its position and passes through the access slot 422 of the needle cover 42. The needle cover 42 is provided with a grip 421 that allows a user to actuate the cover by pulling the grip 421 toward the handle frame 45. In the first position, as it is shown in Figure 2, the insertion needle 41 with infusion cannula 12 is located inside the cover 42. The needle tip 412 is not accessible, and there is no risk for a user or patient of getting inadvertently stung. In the second position, as shown in Figure 6, the needle 42 is ready for insertion into the body tissue of a patient. For being pivotably movable in regard to the frame 45, the cover 42 is connected by hinge 424 to a sliding element 441, slidably mounted in the handle structure 45. In the shown embodiment the hinge is realized as a living hinge. The sliding element 441 is part of a translational lock 44 realized as a linear ratchet mechanism. To safely dispose the insertion device 4 with the now exposed insertion needle 41, the user now pivots the needle cover 42 back over the needle 41, arriving back at the first position as shown in Figure 9. However, in contrast to the state of the device in Figure 2, where the spring element 43 in its first configuration is unbiased, the spring element 43 in its second

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configuration is now elastically deformed and biased and exerts a force. The rotational lock 46 comprises a tongue 462 connected to the handle structure 45, and a slot 461 in the cover 42. As long as the cover is in the first position of Figure 2, the tongue 462 is located outside of the slot 461, and the rotational movement 51 of the cover 42 around the pivotal point 424 is not hindered. In the situation of Figure 9, however, a spring force is directed toward the handle structure (to the right in Figure 9). Therefore, in the moment the cover 42 reaches the first position, the sliding element 41 will shift from the left to the right along translational direction 52, and the tongue 462 will lock to the slot 461, thereby establishing the rotational lock 46. The cover 42 can no longer pivot 51 back to its second position. This becomes clearer in the detailed view provided in Figure 11, where the tongue 462 has reached its final position in the lock mechanism 46. The needle cover 42 of the device 4 is now locked in a position where the needle is located within the needle cover. The needle 41 is no longer exposed, and the device according to the invention can now be safely disposed. Therefore, the claimed invention does not involve an inventive step. Therefore, the subject matter of claims 1 to 21 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

Claims 1 to 21: These claims do not meet the criteria for inventive step. The invention claimed in these claims does not involve an inventive step in light of document: D7 = WO 2010/059415 A2 (B. BRAUN MELSUNGEN AG) 27 May 2010.

D7 discloses (See: Abstract; Figures and related text; claims) a needle cover including: a mounting portion for mounting a needle; and a lid portion hingedly connected to the mounting portion, the lid portion movable to: an open position; a first cover position, wherein the lid portion is releasably docked with the mounting portion; and a second cover position, wherein the lid portion is irreversibly docked with the mounting portion. The claimed invention differs from the cited art in that D7 does not disclose wherein the mounting portion and the lid portion include corresponding docking elements that engage to provide the first and second cover positions. I consider that the differences between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Appended claims 2 to 21 do not involve an inventive step. These features are disclosed in D7 or are part of the common general knowledge in the art. For example, D7 discloses as shown in FIG. 1, a hypodermic syringe 102 including a body portion or syringe barrel 106 configured to receive a plunger 110 at one end and includes a hypodermic needle 112 coupled at the opposite end or discharge end. The shield 104 includes a coupling member 122 for mounting a cap 118 which defines an interior cavity therein for shielding needle 112 preceding or following an injection and a plug 120. Cap 118 and plug 120 may be made by injection moulding or similarly known procedures. As will be described in more detail below, shield 104 is rotatable or pivotable with respect to coupling member 122 from between a packaged or ready position (FIG. 5A) to an open position (FIG. 1) and from the ready position to a secured position (FIG. 5B). In one embodiment, shield 104 includes a cap 118 formed in a telescoping arrangement with a plug 120. Referring to FIG. 2A, cap 118 generally is configured to shield and contain needle 112 in the ready and secured positions, to be easily manipulated between the ready and open positions; and to be easily manipulated between the open and secured positions. Cap 118 includes a base wall 208a and two side walls 208b and 208c, defining a generally U-shaped or otherwise open cavity or recessed space 208 therebetween, also known as a channel. Recessed space 208 is configured and dimensioned to have an internal clearance sized and shaped to allow a needle of a given length to pass unobstructed when cap 118 is pivoted to substantially align and envelop needle 112. In one embodiment, cap 118 may include a retaining means 214 for temporarily holding cap 118 in the ready position relative to needle 112. Retaining means 214 may include any suitable means for temporarily retaining needle in the ready position. In one exemplary embodiment, a pair of detentes, such as rounded members, fingers or other projections may be positioned in cap 118 to hold needle 112 in a temporarily fixed position within recessed space 208. For example, as needle 112 is received into recessed space 208, projections 214a may be brought in line with corresponding recesses disposed on needle hub 114c of needle 112, such that, projections 214a fall partially into the recesses, thus, holding needle 112 temporarily in position. Alternatively, friction may be used between projections 214a and needle hub 114c to hold needle 112 in position. To open the cap 118 from the temporary lock position, a force may be applied to cap 118 directed away from the needle, to separate the needle hub 114c from the projections 214a. In one embodiment, needle hub 114c is connected to shield 104 using a coupling member 122, which has a living hinge 124 located thereon. Therefore, the claimed invention does not involve an inventive step. Therefore, the subject matter of claims 1 to 21 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

INDUSTRIAL APPLICABILITY (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.