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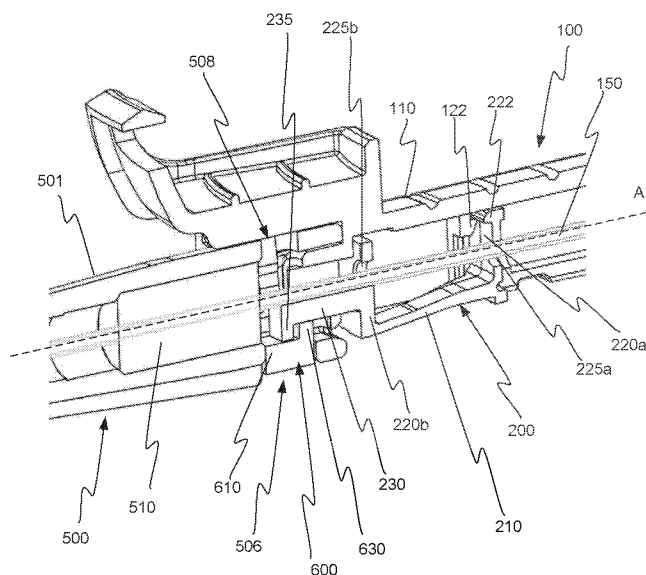


Fig. 2A

(57) Abstract: The present invention discloses a catheter instrument extending in a proximodistal direction along a centre axis (A). The catheter instrument (1000) comprises a catheter assembly (500) having a catheter hub (501) with a distal end (514), comprising a high pressure clip (600) provided with an engagement socket (630), and a needle shielding device (100) having a proximal end (112) comprising a needle protection clip (200) having a proximal engagement portion (235). The proximal engagement portion (235) engages the socket (630) when the catheter assembly (500) and the needle shielding device (100) are connected to each other. Further, the present invention relates to a method for assembling such a catheter instrument, a high pressure clip and a catheter hub.



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**A CATHETER INSTRUMENT COMPRISING A CATHETER ASSEMBLY HAVING A CATHETER HUB, COMPRISING A HIGH PRESSURE CLIP, AND A NEEDLE SHIELDING DEVICE. A METHOD FOR ASSEMBLING SUCH A CATHETER INSTRUMENT**

5                   **TECHNICAL FIELD**

The present invention relates to a catheter instrument comprising a high pressure clip and a needle clip. Further, the invention relates to a method for manufacturing said catheter instrument, a high pressure clip and a catheter hub.

10                   **BACKGROUND**

Intravenous catheters are used to administer fluids and/or drugs to patients regularly. Fluids are supplied through the catheter through an extension tube, coupled to the catheter through an extension tube coupling present and extending from the catheter hub body. When a catheter instrument is to be applied to a patient, by for instance a  
15 caretaker, a needle extending through the catheter tube is used to insert the catheter intravenously. Once the catheter tube is in place, the needle is extracted and the catheter tube remains intravenously.

To protect caretakers and patients from infections caused by potential damages from the needle during the extraction of the needle once the catheter tube is in place,  
20 many catheter instruments comprise a needle shield of some sort. The needle shield protects the needle tip and sometimes also covers the needle to avoid spillage of body fluids such as blood.

A common issue with needle shields known in the art is that the needle shielding devices are too long in an axial direction, causing difficulties for the user since  
25 the devices are often operated using one hand only. Furthermore, many needle guards rely on automatic mechanisms, e.g. snapping mechanisms, to activate the needle protective shield. The automatic mechanism relies on tensions within the device to trigger the automatic response of the shield. A lot of devices comprises poorly tuned tensions within the device, resulting in a discomforting experience for the patient during  
30 use. In addition, several devices have a complex manufacturing process.

Hence, there is an apparent need for an improved catheter instrument having a needle shield which is easier to use, comfortable for the patient and more simple to manufacture.

## SUMMARY

It is an object of the present invention, considering the disadvantages mentioned above, to provide a catheter instrument extending in a proximodistal direction along a centre axis A. The catheter instrument comprises a catheter assembly comprising a catheter hub, having a distal end comprising a high pressure clip provided with an engagement socket, and a needle shielding device having a proximal end comprising a needle protection having a proximal engagement portion. The proximal engagement portion engages the socket when the catheter assembly and the needle shielding device are connected to each other. This catheter instrument is advantageous in that it is shorter in a longitudinal direction than if a high pressure clip was not part of the catheter instrument. The catheter instrument also provides a more controlled fastening of the needle protection clip to the catheter hub, causing tensions within the needle protection clip to be under control. Further, it is easy to use and to assemble.

In a second aspect, there is provided a method for manufacturing a catheter instrument extending in a proximodistal direction along a centre axis A. The method comprises the steps of providing a catheter assembly comprising a catheter hub having a distal end and providing a needle shielding device having a proximal end, and comprising a needle and a needle protection clip having a proximal engagement portion. The method further comprises joining the catheter assembly and the needle shielding device by mating the proximal end together with the distal end, and inserting a high pressure clip provided with an engagement socket into the catheter hub through an incision provided in the catheter hub. The proximal engagement portion engages the socket when the high pressure clip has been inserted, whereby the catheter assembly and the needle shielding device are connected to each other. This method is beneficial since it provides a catheter instrument having the advantages presented above, and the assembling of the device is facilitated using this method.

In a third aspect, there is provided a high pressure clip comprising a pressure clip base part provided with a socket, and a leg extending from said pressure clip base part. This high pressure clip has the advantage that it provides a dual function. Not only will it provide a socket, which can engage a needle protection clip of a needle shielding device, but the leg extending from the base will also hold a needle septum in place in the catheter hub of a catheter instrument.

In a fourth aspect, there is provided a catheter hub extending along a proximodistal axis A, comprising a distal end provided with an incision in connection with a lumen. This catheter hub is advantageous in that the lumen can hold a high

pressure clip as disclosed above, which may be securely fastened by engaging the incision in connection with said lumen.

Further features of the invention and its embodiments are set forth in the appended claims.

5

### **BRIEF DESCRIPTION OF THE DRAWINGS**

These and other aspects, features and advantages of which the invention is capable will be apparent and elucidated from the following description of non-limiting embodiments of the present invention, reference being made to the accompanying  
10 drawings, in which

Fig. 1 is an isometric view of a catheter instrument comprising a needle shielding device and a catheter assembly;

Fig. 2A is a transversal cross-section of a portion of the catheter instrument disclosed in Fig. 1;

15 Fig. 2B is an isometric view of a high pressure clip connected to a needle protection clip;

Fig. 3A is a transversal cross-section of a catheter assembly and a needle shielding device detached from each other;

20 Fig. 3B is an isometric view of the high pressure clip disconnected from the needle protection clip shown in Fig. 2B;

Fig. 3C and 3D show alternative versions of needle protection clips;

Fig. 4 shows the catheter assembly from a distal perspective;

Fig. 5 shows the high pressure clip from a distal perspective;

Figs 6A and 6B shows isometric views of two embodiments of catheter hubs;

25 and

Fig. 7 shows a flow chart of a method for assembling the catheter instrument.

### **DETAILED DESCRIPTION OF THE EMBODIMENTS**

Embodiments of the present invention will be described in more detail below  
30 with reference to the accompanying drawings in order for those skilled in the art to be able to carry out the invention. The invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art.  
35 The embodiments do not limit the invention, but the invention is only limited by the

appended patent claims. Furthermore, the terminology used in the detailed description of the particular embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention.

Embodiments of the present invention will now be described below with  
5 reference to Figs. 1 to 7.

Referring to Fig. 1, there is provided a catheter instrument 1000 comprising a  
needle shielding device 100, and a catheter assembly 500. The needle shielding device  
100 shown in Fig. 1 is a part of a telescopic needles shielding device. The catheter  
instrument 1000 and its parts thereof extend along a longitudinal centre axis A in a  
10 proximodistal direction.

The catheter assembly 500 comprises a catheter hub 501, a coupling for an  
extension tube 502, a pair of wings 504 and an opening 505 configured to hold a hollow  
catheter tube. The part of the needle shielding device 100 comprises an encapsulation  
tube 110, a proximal push tab 120 and has a proximal end 112 and a distal end 114.  
15 When a needle 150 (shown in Figs 2A, 3A and 3B) is extracted from the catheter  
assembly 500, the encapsulation tube 110 encloses the needle 150.

Fig. 2A shows a longitudinal cross-section of a portion of the assembled  
catheter instrument 1000 shown in Fig. 1. The section shown in Fig. 2A is the interface  
between the catheter assembly 500 and the needle shielding device 100 where the  
20 catheter assembly 500 and the needle shielding device 100 are connected to each other.  
The interior of the catheter assembly 500 comprises a needle septum 510 and a high  
pressure clip 600. The interior of the proximal end 112 of the needle shielding device  
100 comprises a needle protection clip 200 in connecting engagement with the high  
pressure clip 600. The high pressure clip 600 may also be referred to as a U-lock or  
25 septum U-lock herein.

The needle protection clip 200 comprises a lower base part 210, having a  
transversal distal wall 220a and a transversal proximal wall 220b, each comprising a  
distal and a proximal through hole 225a, 225b, respectively. Further, the clip 200 has a  
proximally extending arm 230, which in turn comprises a proximal engagement portion  
30 235. The proximal engagement portion 235 is also referred to as a proximal hook 235  
herein. Further, the proximal hook 235 extends radially in a lateral direction  
(substantially perpendicularly to the axis A) away from the centre axis A. Further, the  
needle shielding device 100 is provided with an internal latch 122 in connecting  
engagement with a distal wall latch 222 on the protection clip 200. The distal wall latch  
35 222 is arranged on an upper edge of the distal wall 220a.

The high pressure clip 600 has a pressure clip base portion 610 from which a distal socket 630 extends centrally towards the centre axis A. As shown in Fig. 2A, the proximal hook 235 of the proximal arm 230 engages the distal socket 630 of the high pressure clip 600. The high pressure clip 600 is fitted into the catheter hub 501 and has  
5 been inserted into the catheter assembly 500 from below through a lower incision 506 and two upper incisions 508 in the catheter hub 501 at the catheter assembly distal end 514. The mounting of the catheter instrument 1000 will be explained more in the following with reference to the figures 5, 6A and 6B.

In Fig. 2A (and Fig. 2B) the through holes 225a, 225b of the distal wall 220a, and the proximal wall 220b are transversally aligned. A needle 150 extends along the  
10 axis A through the aligned through holes 225a, 225b of the needle protection clip 200, the high pressure clip 600 and the septum 510.

Fig. 2B shows an isometric view of the high pressure clip 600 and the needle clip 200 in engagement with each other. The high pressure clip 600 is arranged in  
15 contact with the septum 510 and is fitted in the lower and upper incisions 506, 508 of the catheter assembly 500. The through holes 225a, 225b of the respective transversal wall 220a, 220b of the clip 200 are aligned and the proximal hook 235 of the proximally extending arm 230 engages the high pressure clip 600. The needle septum 510 is held in place by the high pressure clip 600, which will be explained in more detail with  
20 reference to Fig. 5.

More specifically, the high pressure clip 600 has a protruding socket 630 extending centrally from the high pressure clip base 610. The hook portion 235 of the proximal arm 230 engages the socket 630 when the high pressure clip 600 and the needle clip 200 are attached to each other.

25 Additionally, the protective needle clip 200 is provided with a needle recess 237 which is configured to hold the needle (shown in Fig. 2A) when it extends through the catheter instrument 1000. Such a needle recess 237 decrease the friction when moving the needle 150 in an axial direction and facilitates the sliding of the needle 150. The high pressure clip 600 further comprises two transversally extending legs 615a,  
30 615b. Each leg 615a, 615b is provided with an upper protrusion 618a, 618b, respectively.

The engaging configuration of the protective needle clip 200 in Figs 2A and 2B is not the resting state of the protective clip 200. The needle clip 200 is made of a resilient, flexible material. Preferably, the clip 200 may be made of a polymer, such as a  
35 plastic material, or a metal since these materials provide a satisfying flexibility and

strength. In the resting state of the protective needle clip 200, the through holes 225a, 225b are not aligned along the longitudinal axis A, but off-centred transversally in relation to each other.

The needle 150 extending through both through holes 225a, 225b forces the  
5 though holes 225a, 225b into alignment along the centre axis A, as show in Figs 2A and 2B. This is possible due to the flexibility of the protective needle clip 200. Since the distal wall 220a is connected to the needle shielding device 100 through the distal wall latch 222, the lower base part 210 is forced downwards when the needle 150 is inserted through both the distal and proximal through holes 225a, 225b.

10 With reference to Fig. 3A, the catheter assembly 500 and the needle shielding device 100 have been disconnected from each other. As shown in Fig. 3A, the needle 150 has been retracted from the catheter assembly 500, and has been retracted further distally past the proximal through hole 225b of the protective needle clip 200.

Due to that the protective needle clip 200 is formed from a flexible material  
15 having a resting state in which the through holes 225a, 225b are not aligned, the removal of the needle 150 from the proximal through hole 225b causes the lower base part 210 to flex towards the centre axis A. This causes misalignment of the through holes 225a, 225b, which in turn prevents the possibility of the needle 150 being pushed back outside the needle shielding device 100. When the base part 210 moves towards  
20 the axis A, the proximal wall 220b will abut the tip of the needle 150 if the needle 150 is subsequently pushed in a proximal direction towards the catheter assembly 500.

In addition, the movement of the base part 210 towards the centre axis A cause the hook portion 235 on the arm 230 to disengage from the socket 630 provided on the pressure clip base portion 610 in the interior of the catheter assembly 500. Hence, the  
25 needle shielding device 100 detaches from the catheter assembly 500 while at the same time the needle 150 is protected and cannot harm the patient or the caretaker.

Furthermore, below the push tab 120, the proximal end 112 of the needle shielding device 100 is provided with an arm encapsulation part 130, which circumvents the arm 230 of the needle protection clip 200. The push tab 120 is further equipped with  
30 side walls, each of which has an inner groove 125, both configured to engage a longitudinal protrusion 525 (shown in Fig. 4) provided on a housing 520 at a distal end 514 of the catheter assembly 500.

One of the legs 615b of the high pressure clip 600 is shown in Fig. 3A. The legs 615a, 615b provide means for connecting the high pressure clip 600 to the catheter  
35 assembly 500. In addition, the high pressure clip 600 holds the needle septum 510 in

place. These properties of the high pressure clip 600 will be explained in more detail with reference to Fig. 5.

Fig. 3B shows the high pressure clip 600 and the protective clip 200 disengaged from each other. The needle 150 has been retracted distally through the septum 510, the high pressure clip 600 and past the proximal through hole 225b. The removal of the needle 150 has caused the arm 230 to flex upwards such that the proximal hook 235 no longer engages the socket 630 on the pressure clip base part 610.

In addition, if the needle 150 is pushed forward in a proximal direction towards the proximal wall 220b, the area of the wall 220b below the through hole 225b will obstruct the needle 150 since the distal through hole 225a is no longer aligned with the proximal through hole 225b.

Hence, the protective needle clip 200 in the present disclosure has a dual function, it both protects potential users from the needle 150 once it is withdrawn from the catheter assembly 500 and it provides an engagement feature (the proximal hook 235) for connecting the needle shielding device 100 to the catheter assembly 500.

The septum 510 may lack a preformed perforation and may instead be formed from a malleable material which the needle 150 can penetrate, but which will automatically seal when the needle 150 is removed from the septum 510. However, any septum known in the art may be used in the catheter instrument 1000 according to the present disclosure. The needle recess 237 configured to fit the needle 150 facilitates a smooth extraction of the needle 150. The needle recess 237 has a concave shape to hold and fit the needle 150 and decreases the friction between the needle 150 and the proximally extending arm 230.

Optionally, the protective needle clip 200 may be an alternative protective needle clip 200' provided with a lower base part 210' and an upper base part 210'' as shown in Fig. 3C. Further, in Fig. 3D yet another protective needle clip 200''' is shown. The protective needle clips 200', 200''' in Figs 3C and 3D both have a lower base part 210', 210'', a distal wall 220a', 220a'', a proximal wall 220b', 220b'', a distal through hole 225a', 225a'', a proximal through hole 225b', 225b'', an arm 230', 230'' and a proximal hook 235''.

Further, the protection needle clip 200 may comprise side walls in connection with the base 210 and may be attached to the catheter assembly 500 using other attachment mechanisms or adhesives. The protective needle clip 200' may also be provided with a distal wall latch as the needle protection clip 200 (not shown).

The needle protection clips 200, 200', 200'' disclosed herein may be attached to the needle shielding device 100 using an adhesive and the latch 122 and distal wall latch 222 may be arranged on an opposite side of the distal wall 220a. Further, the needle protection clips 200, 200', 200'' disclosed herein may be attached using any  
5 other attachment mechanism suitable within the art.

Fig. 4 shows the catheter assembly 500 viewed from its distal end 514. The distal end 514 of the catheter hub 501 is provided with the housing 520, having two longitudinal protrusions 525 extending along the exterior of said housing 520. The protrusions 525 fit the recesses 125 provided on the interior surface of the side walls  
10 below the push button 129 (shown in Fig. 3A). Also, the housing 520 with enclose the arm encapsulation part 130 (also shown in Fig. 3A) when the catheter assembly 500 and the needle shielding device 200 are attached to each other.

Arranged proximally of the housing 520 is the high pressure clip 600, of which the base part 610, the socket 630 and legs 615a, 615b are visible. Arranged even further  
15 inside the catheter hub 501, proximally of the high pressure clip 600, is the needle septum 510.

With reference to Fig. 5, a detailed figure of the high pressure clip 600 in its resting state is shown. The high pressure clip 600 is substantially U-shaped and is made of a slightly flexible material such that the legs 615a, 615b may flex inwards towards  
20 the centre of the U-shaped clip 600. As mentioned with reference to the foregoing Figs 1-4, the high pressure clip 600 comprises a base part 610, a socket 630, a pair of legs 615a, 615b and an upper protrusion 618a, 618b each arranged on one of the legs 615a, 615b, respectively. The pressure clip legs 615a, 615b each has a proximal flange 616a, 616b, which together lock the septum 510 and hold it in its position proximal of the  
25 high pressure clip 600.

Hence, arranging the high pressure clip 600 in the catheter hub 501 has several functions. Firstly, it provides the socket 630 which engages the needle protection clip 200 of the needle shielding device 100, and it locks the needle septum 510 inside the catheter hub 501. In addition, arranging the high pressure clip 600 in the lumen 515  
30 (shown in Fig. 6A) of the catheter hub 501 improves the assembling process of the catheter instrument 1000 to become more simple.

Each upper protrusion 618a, 618b has an upper side surface 619a, 619b which are angled downwards in opposite directions, to conform and align with the concave upper surface of the catheter hub 501 when the high pressure clip 600 is assembled in  
35 the catheter hub 501. Further, the slightly curved formation of the upper side surfaces

619a, 619b facilitates the centrally directed flexion of the legs 615a, 615b when the high pressure clip 600 is pressed against the upper incisions 508. Alternatively, the upper protrusions 618a, 618b engage on the internal walls of the catheter hub 501. This will be further elaborated with reference to Fig. 6B.

5 In addition, the high pressure clip 600 comprises two lower protrusions 612a, 612b extending from the base part 610, in a direction perpendicular to the axis A. Each lower protrusion 612a, 612b of the base part 610 has a centrally facing upper side surface 617a, 617b.

10 Preferably, the high pressure clip 600 is made of a polymeric material (such as a plastic) or a metal material.

In Fig. 6A, an isometric view of the catheter hub 501 is shown. The catheter hub 501 comprises a distal end 514 and has a width  $W_C$ . The exterior of the catheter hub 501 is provided with the two longitudinal protrusions 525 and the lower incision 506. The lower incision 506 has a lower incision upper edge 507, and the upper incisions 508  
15 are arranged separately from each other and are aligned transversally perpendicularly of the axis A.

The upper incisions 508 are configured to fit and engage the upper protrusions 618a, 618b of the high pressure clip 600. The width  $W_B$  of the pressure clip base part 610 corresponds to the width  $W_C$  of the catheter hub distal end 514. Further, the area  
20 between the lower incision 506 and the upper incisions 598 forms the lumen 515, where the high pressure clip 600 is arranged in the assembled state of the catheter instrument 1000. Further, when the high pressure clip 600 is inserted into the lower incision 506 and forced transversally upwards, the lower protrusions 612a, 612b of the base part 610 will prevent the high pressure clip 600 from being pushed too far into the lumen 515.  
25 The centrally facing upper side surfaces 617a, 617b will engage the lower incision upper edge 507 and thus prevent the high pressure clip 600 from being forced further into the lumen 515.

Fig. 6B shows a catheter hub 501' according to another embodiment disclosed herein. The catheter hub 501' comprises a distal end 514', exterior protrusions 525' and  
30 a lower incision 506'. However, the catheter hub 501' does not comprise the upper incisions as the catheter hub 501. Instead, the high pressure clip 600 when it is present in the lumen 515 is connected to the catheter hub 501' by other means, for instance the upper protrusions 618a, 618b each engage in an internal recess inside the catheter hub 501' and is snip-fitted into secure attachment in the lumen 515.

When arranged in the catheter hub 501, the pressure clip base part 610 extends transversally at the bottom of the catheter hub 501 and is fitted in the lower incision 506. The legs 615a, 615b extends from the base part 610 centrally and further past the central axis A in a lateral direction, along the interior side walls of the catheter hub 501.

5 The upper leg protrusions 618a, 618b secure the high pressure clip 600 in the catheter hub 501 and prevent extraction of the high pressure clip 600 from the upper incisions 508, the lumen 515 and the lower incision 506.

The use of the high pressure clip 600 in the catheter instrument 1000 disclosed herein provides a catheter instrument 1000 having a more controlled locking mechanism  
10 between the needle protection clip 200 and the catheter hub 501 of the catheter assembly 500. This results in controlled tension levels within the needle protection clip 200, which in turn results in a comfortable experience for a patient and a device which is easy to use.

In addition, an effect of the design and arrangement of the high pressure clip  
15 600 in the catheter instrument 1000 disclosed herein is that the needle protection clip 200 can be shortened axially compared to known protection clips. Due to the shorter dimensions of the needle protection clip 200, the length along the axis A of the device is decreased. A shorter device is easier to handle and thus more simple to use, even with a one handed grip.

20 A method for assembling the catheter instrument 1000 will now be explained with reference to the Figs 1-6. A flow scheme indicating the steps of the method is shown in Fig. 7. Firstly, the method comprises the step of providing 830 a needle shielding device 100 comprising a needle protection clip 200 and a needle 150. (If the needle shielding device 100 is a telescopic needle shielding assembly as disclosed in SE  
25 2050266-2, the needle 150 is attached to a needle hub in a grip part, which is connected to a telescopic middle part).

Secondly, the method 800 comprises providing 850 a catheter assembly 500. The lumen 515 formed between the lower incision 506 and the upper incision 508 of the catheter assembly 500 is vacant. The catheter assembly 500 may or may not comprise  
30 an internal needle septum 510, which has been inserted into the needle hub 501.

The steps of providing 850 a catheter assembly 500 and providing 830 a needle shielding device 100 may occur simultaneously or the step of providing 830 a needle shielding device 100 may be performed before or after the step 850 of providing a catheter assembly 500, as indicated with the arrows between the steps 830 and 850 in  
35 Fig. 7.

Optionally, the method comprises a step of engaging 810 the needle 150 with the needle protection clip 200 by threading the needle 150 through the distal and proximal through holes 225a, 225b in the distal and proximal walls 220a, 220b before providing 820 the needle shielding device 100.

5 In yet another optional step, the method 800 comprises attaching 820 (from below in Fig. 2A) the needle protection clip 200 holding said needle 150 into the needle shielding device 100 such that the distal wall latch 222 engages the internal latch 122 with a snip-fit function. (If the needle shielding assembly 100 is a telescopic needle shielding assembly as disclosed in SE 2050266-2, the needle protection clip 200 is  
10 inserted into the encapsulation tube 110, which is then moved distally to engage the middle part of the telescopic needle shielding device).

Further, the method 800 may comprise an optional step of mounting 840 a needle septum 510. This step may be performed either by inserting the needle septum 510 inside the catheter hub 501 of the catheter assembly 500 or by threading the needle  
15 septum 510 onto the needle 150. If the needle septum 510 is threaded onto the needle 150, the step 840 is performed after the needle protection clip 200 has been threaded onto the needle 150.

The step of mounting 840 the needle septum 510 may occur after or before the step of providing 830 the needle shielding device 100 and/or the step of attaching 840  
20 the needle protection clip 200 in the encapsulation tube 110.

Subsequently, the method comprises joining 860 the needle shielding device 100 and the catheter assembly 500 by pressing the proximal end 112 of the needle shielding device 100 together with the distal end 514 of the catheter assembly 500. The protrusions 525 on the catheter assembly 500 will each engage one of the grooves 125  
25 arranged on the side walls of the push tab 120. Further, the arm encapsulation part 130 will be fitted into the housing 520.

The final step of the method 800 to complete the assembling of the catheter instrument 1000 comprises inserting 870 the high pressure clip 600 into the lower catheter assembly incision 506. The high pressure clip 600 is forced from below  
30 through the lower incision 506 transversally upwards such that the leg upper protrusions 618a, 618b reach the upper incisions 508. The distance between the upper incisions 508 correspond to the width  $W_A$  between the legs 615a, 615b of the high pressure clip 600.

Hence, when the upper protrusions 618a, 618b reach the upper incisions 508 from below, the legs 615a, 615b will flex inwards, towards the centre axis A. When the  
35 upper protrusions 618a, 618b are forces through the upper incisions 508, the legs 615a,

615b will spring back to their resting state. As a result, the upper side surface 619a, 619b of the upper protrusions 618a, 618b aligns with the upper surface of the catheter hub 501. Thus, the upper protrusions 618a, 618b engage the upper incisions 508 with a snip fit mechanism, whereby the high pressure clip 600 is securely attached to the  
5 catheter hub 501.

The width of the lower incision 506 fits and corresponds to the width  $W_B$  between the base part lower protrusions 612a, 612b. The upper incision 506 corresponds to the width  $W_A$  between the legs 615a, 615b. Therefore, when the high pressure clip 600 is inserted into the lower incision 506, and when the leg protrusions  
10 618a, 618b reach the upper incisions 508, the legs 615a, 615b will flex inwardly towards the centre axis A. When the leg protrusions 618a, 618b are forced further upwards passed the upper incisions 508 of the catheter hub 501, the legs 615a, 615b will spring back outwardly to its resting state such that the leg protrusions 618a, 618b engage in a snip fitting securement with the side edges of the upper incision 508.

15 Alternatively, the catheter hub 501' is provided with other means for attaching the high pressure clip 600 to the catheter assembly 500.

Optionally, the method further comprises a step of inserting 870 a needle 150 through the catheter instrument 1000, through the proximal and distal through holes 225a, 225b of the transversal walls 220a, 220b, the needle septum 510 and the opening  
20 505 into a catheter tube (not shown) as shown in Fig. 2A.

The arrangement of the high pressure clip 600 in the lumen 515 of the catheter hub 501 as disclosed herein facilitates the manufacturing and assembling process. In addition, the length of the overall catheter instrument 1000 is decreased and the tension in the catheter instrument 1000 is relaxed.

25 For instance, if the catheter instrument 1000 did not comprise the high pressure clip 600, the catheter hub 501 would include a ledge/socket corresponding to the socket 630 of the high pressure clip 600. This would cause the need of flexing the proximally extending arm 230 centrally during the assembling process, which increases the risk of creating fatigue in the arm 230. To avoid fatigue in the material of the arm 230, the arm  
30 230 of the needle protection clip 200 would have to be longer, resulting in an overall longer catheter instrument 1000, which is a disadvantage. By using the high pressure clip 600, the tensions in the needle protection clip 200 is transferred to the lower base part 210, and the risk of causing fatigue in the proximally extending arm 230 is reduced.

The disclosed catheter assembly 500 is a closed system, i.e. a system wherein a  
35 septum 510 (shown in Figs 2A-3B) is provided in the catheter hub 501, and fluids are

withdrawn or introduced through an extension tube (not shown) attached to the extension tube coupling 502. However, the high pressure clip 600 is equally applicable on an open catheter assembly, wherein fluid can be introduced or withdrawn longitudinally from a distal end of the catheter hub, to form a catheter instrument 1000 as disclosed herein.

The needle shielding device 100 disclosed in Fig. 1 is a portion of a telescopic encapsulation shielding assembly, as disclosed in the applicants patent application SE 2050266-2. However, the needle protection clip 200 and high pressure clip 600 may be arranged in other types of needle shielding device.

Further, the high pressure clip 600 may be mounted from a top down direction instead from a bottom up direction, as explained with reference to the figures. Optionally, incisions are present in the side walls of the catheter hub 501 and the legs 615a, 615b extend from the base part 610 such that the upper protrusions 618a, 618b are in level transversally with the side wall incisions, and engage said incisions with a snip fit mechanism.

Optionally, the high pressure clip 600 comprises only one laterally extending leg 615a, 615b. In such case, the single leg 615a, 615b holds the septum 510 in place. Further, the protrusions 618a, 618b may be arranged as lower protrusions which attach the high pressure clip to the catheter hub 501 at another position than in the protrusions upper 508.

In the claims, the term “comprises/comprising” does not exclude the presence of other elements or steps. Furthermore, although individually listed, a plurality of means, elements or method steps may be implemented by e.g. a single unit or processor. Additionally, although individual features may be included in different claims, these may possibly advantageously be combined, and the inclusion in different claims does not imply that a combination of features is not feasible and/or advantageous. In addition, singular references do not exclude a plurality. The terms “a”, “an”, “first”, “second” etc. do not preclude a plurality. Reference signs in the claims are provided merely as a clarifying example and shall not be construed as limiting the scope of the claims in any way.

## CLAIMS

1. A catheter instrument extending in a proximodistal direction along a centre  
5 axis (A), wherein the catheter instrument (1000) comprises:
- a catheter assembly (500) comprising a catheter hub (501) having a distal  
end (514) comprising a high pressure clip (600) provided with an engagement socket  
(630);
  - a needle shielding device (100) having a proximal end (112) comprising  
10 a needle protection clip (200) having a proximal engagement portion (235); and  
wherein the proximal engagement portion (235) engages the socket (630)  
when the catheter assembly (500) and the needle shielding device (100) are connected  
to each other.
- 15 2. The catheter instrument according to claim 1, wherein the high pressure clip  
(600) is arranged in a lumen (515) of the catheter hub (501).
3. The catheter instrument according to claim 1 or 2, wherein the high pressure  
clip (600) is connected to the catheter hub (501) through a snap fit mechanism.  
20
4. The catheter instrument according to any one of claims 1 to 3, wherein the  
catheter hub (501) has a lower incision (506) and wherein the high pressure clip (600) is  
arranged in said incision (506).
- 25 5. The catheter instrument according to claim 4, wherein the high pressure clip  
(600) has been inserted into the catheter hub (501) from below through said lower  
incision (506).
- 30 6. The catheter instrument according to claim 4 or 5, wherein the catheter hub  
further comprises upper incisions (508) and wherein the high pressure clip (600) is  
arranged in said upper incisions (508).

7. The catheter instrument according to any one of the preceding claims, wherein the high pressure clip (600) has a U-like shape comprising a pressure clip base part (610) and pair of flexible transversally extending legs (615a, 615b).

5

8. The catheter instrument according to claim 7, wherein each leg (615a, 615b) comprises an upper protrusion (618a, 618b), and wherein said upper protrusions (618a, 618b) each engages an upper incision (508) of the catheter hub (501).

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9. The catheter instrument according to claim 7, wherein each leg (615a, 615b) comprises an upper protrusion (618a, 618b), and wherein said upper protrusions (618a, 618b) each engages an internal recess inside the catheter hub (501)

15

10. The catheter instrument according to any one of the preceding claims, wherein needle protection clip (200) comprises a distal through hole (225a) and a proximal through hole (225b) holding a needle (150) in an assembled state of the catheter instrument (1000), and wherein a base part (210) of the needle protection clip (200) move towards the centre axis (A) when the needle (150) is extracted passed the proximal through hole (225b), whereby the proximal engagement portion (235) detaches from the socket (630).

20

11. A method for manufacturing a catheter instrument extending in a proximodistal direction along a centre axis (A), the method (800) comprising the steps of:

25

- providing (830) a needle shielding device (100) having a proximal end (112), and comprising a needle (150) and a needle protection clip (200) having a proximal engagement portion (235);

- providing (850) a catheter assembly (500) comprising a catheter hub (501) having a distal end (514);

30

- joining (860) the catheter assembly (500) and the needle shielding device (100) by mating the proximal end (112) together with the distal end (514); and

- inserting (870) a high pressure clip (600) provided with an engagement socket (630) into the catheter hub (501) through an incision (506) provided in the catheter hub (501);

5 wherein the proximal engagement portion (235) engages the socket (630) when the high pressure clip (600) has been inserted, whereby the catheter assembly (500) and the needle shielding device (100) are connected to each other.

12. The method according to claim 11, wherein the method further comprises a step of engaging (810) the needle (150) comprised in the needle shielding device (100) with the needle protection clip (200), preferably by threading the needle (150) through 10 distal and proximal through holes (225a, 225b) in distal and proximal walls (220a, 220b) of the needle protection clip (200).

13. The method according to claim 12, further comprising attaching (820) the 15 needle protection clip (200) holding said needle (150) into the needle shielding device (100), preferably such that a distal wall latch (222) of the needle protection clip (200) engages an internal latch (122) in the needle shielding device (100) with a snip-fit function.

20 14. The method according to any one of the claims 11 to 13, further comprising a step of mounting (840) an internal needle septum (510) inside the catheter hub (501) of the catheter assembly (500) or onto the needle (150) comprised in the needle shielding device (100).

25 15. A high pressure clip comprising a pressure clip base part (610) provided with a socket (630), and a leg (615a) extending from said pressure clip base part (610).

16. The high pressure clip according to claim 15, wherein the high pressure clip (600) comprises a plurality of, preferably two, legs (615a, 615b).

30

17. A catheter hub extending along a proximodistal axis (A), comprising a distal end (514) provided with an incision (506) in connection with a lumen (515).

18. The catheter hub according to claim 17, wherein the lumen (515) holds a high pressure clip (600) comprising a pressure clip base part (610) provided with a socket (630), and a leg (615a) extending from said pressure clip base part (610), and wherein said pressure clip base part (610) fits in the incision (506).

5

19. The catheter hub according to claim 17 or 18, wherein the incision (506) is a lower incision (506) arranged in a bottom of the catheter hub (501).

20. The catheter hub according to any one of claims 17 to 19, wherein the catheter hub (501) further comprises an upper incision (508) or two upper incisions (508).

10

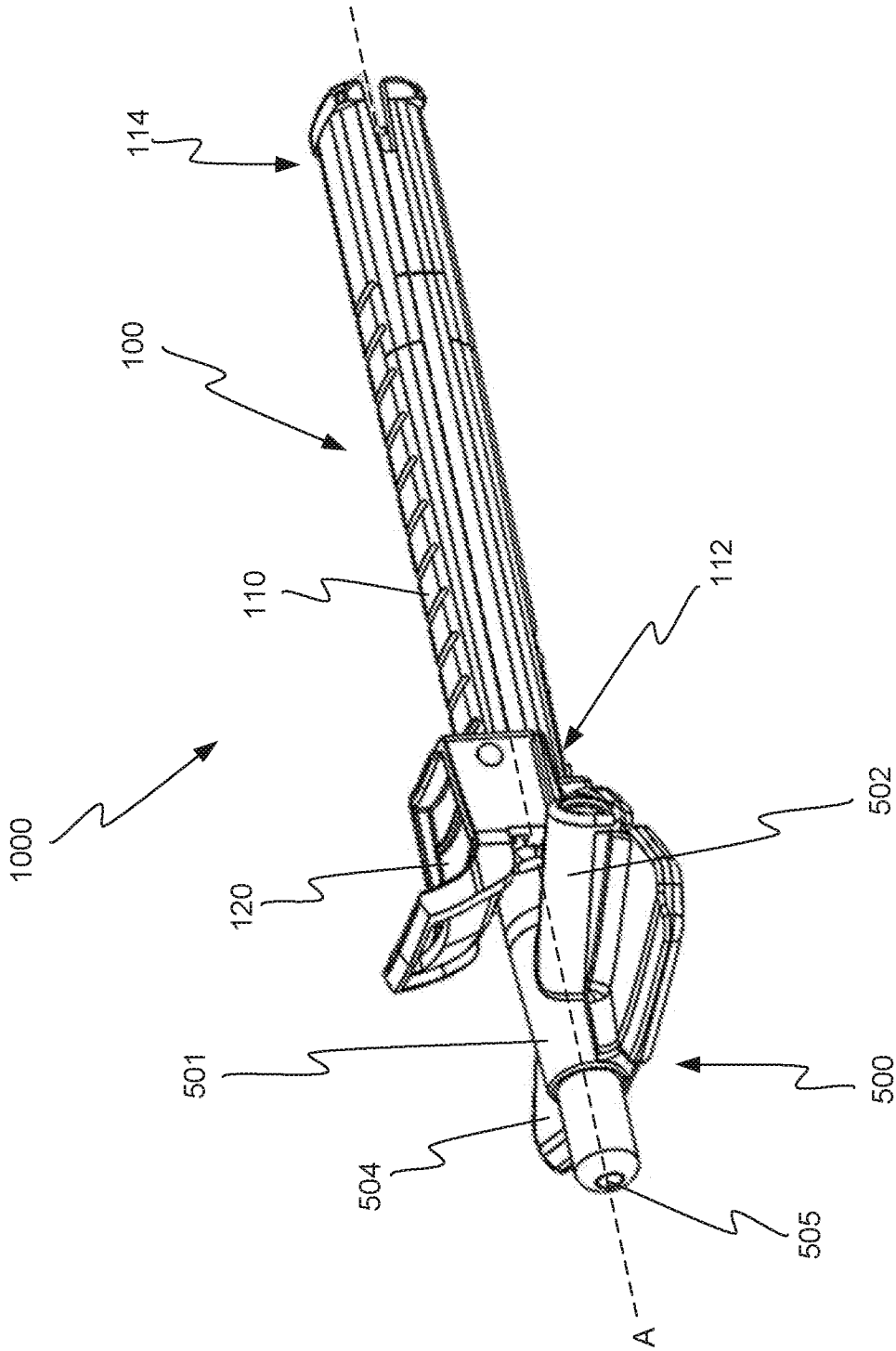


Fig. 1

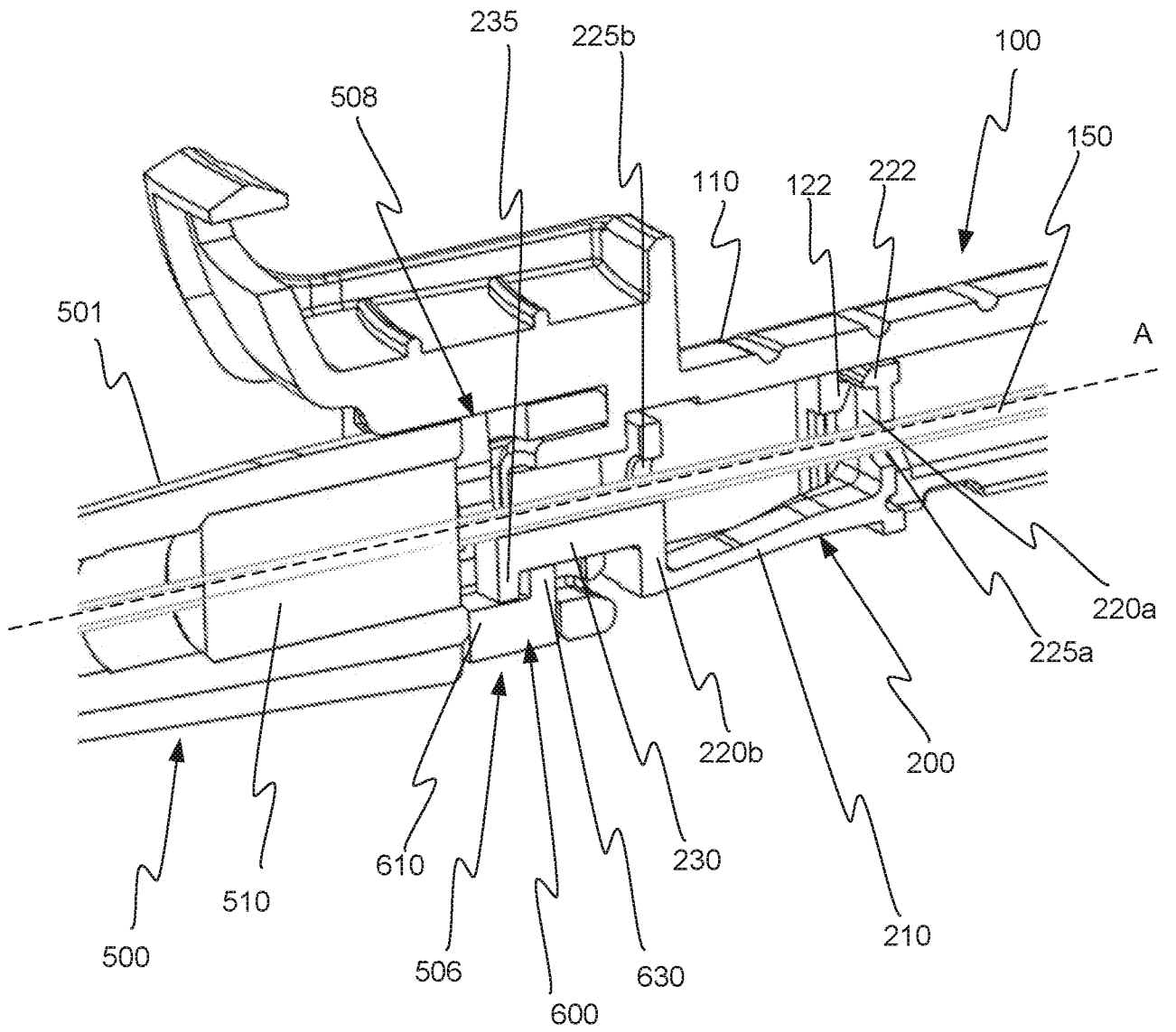


Fig. 2A



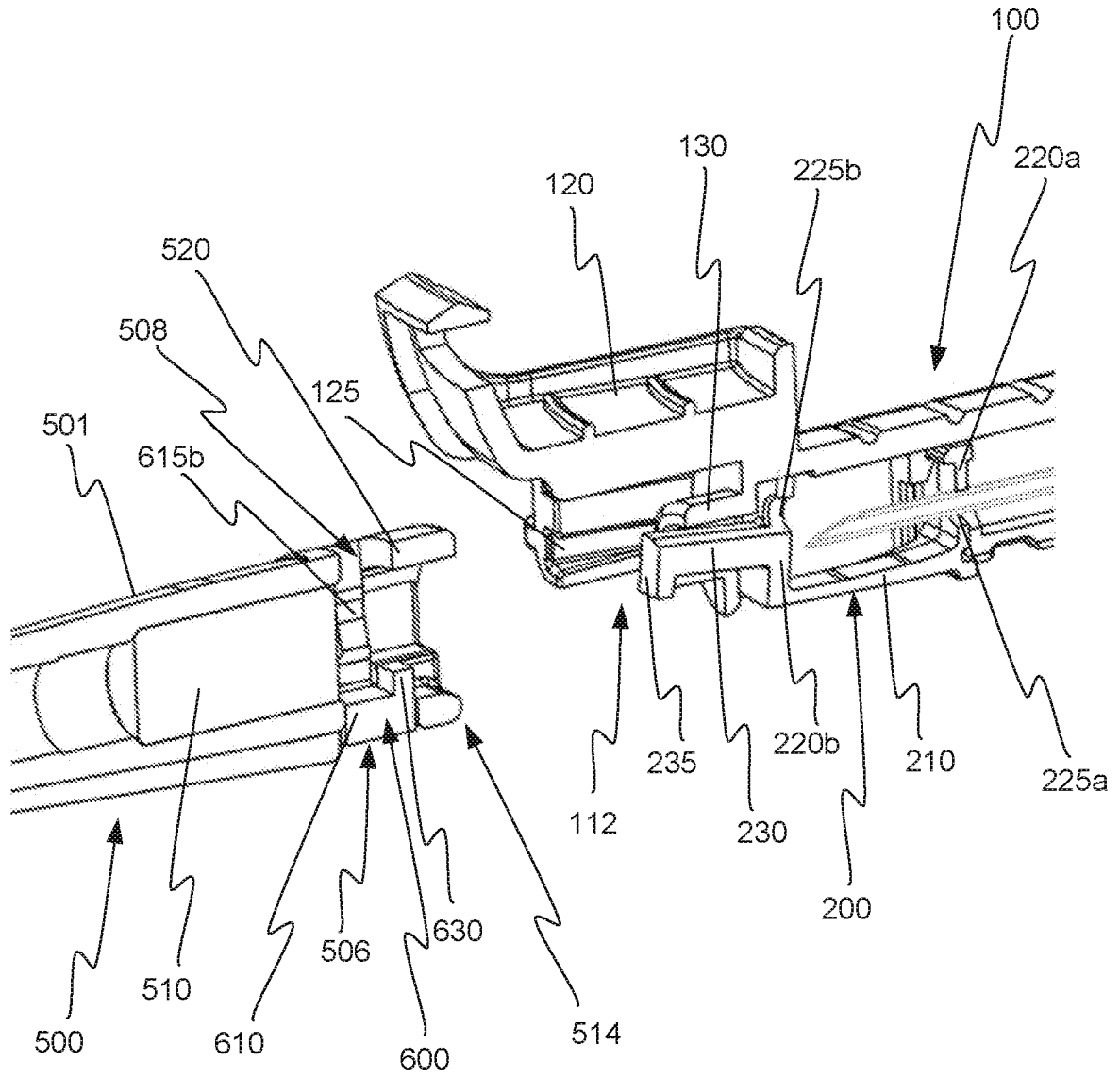


Fig. 3A

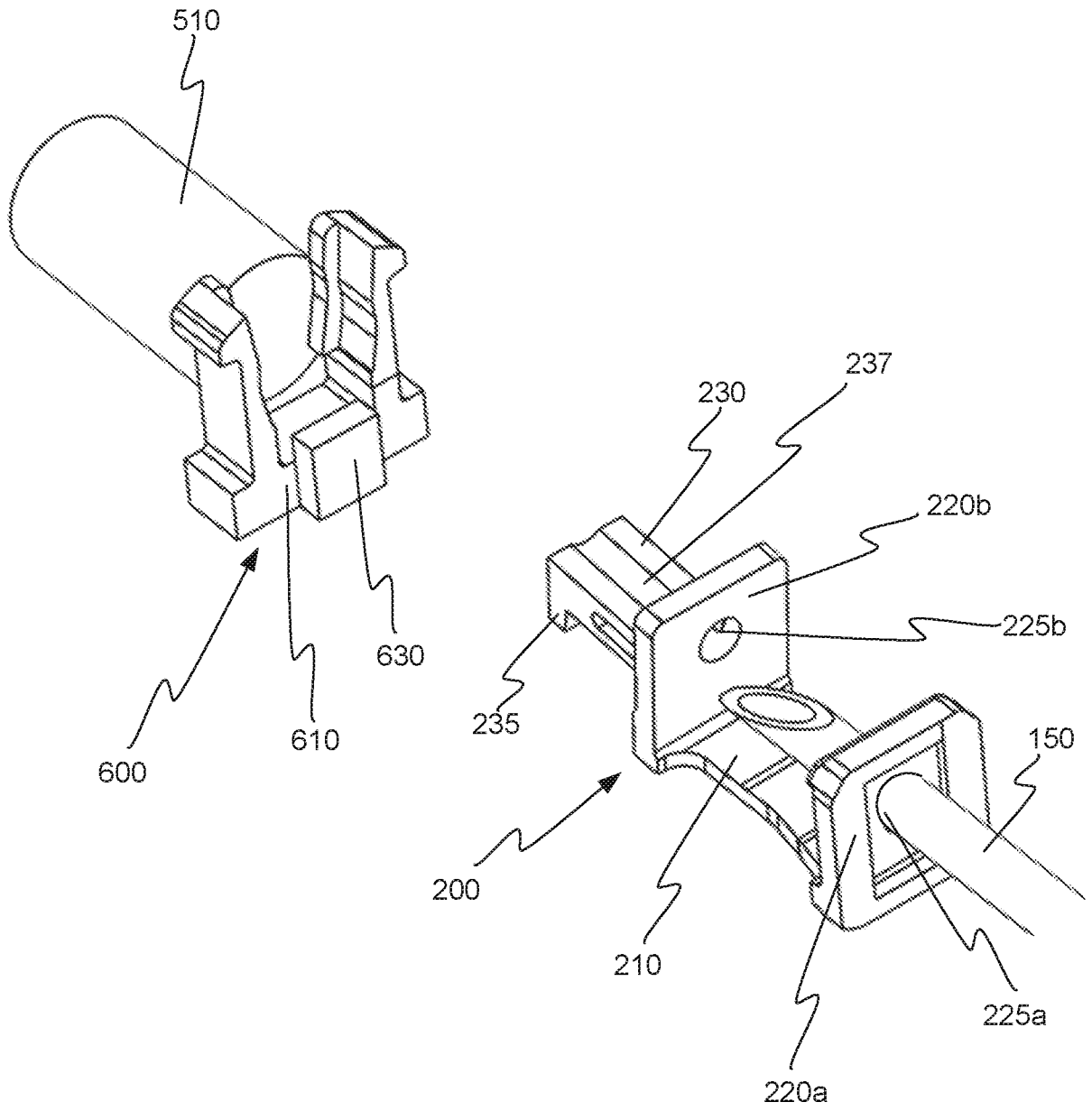
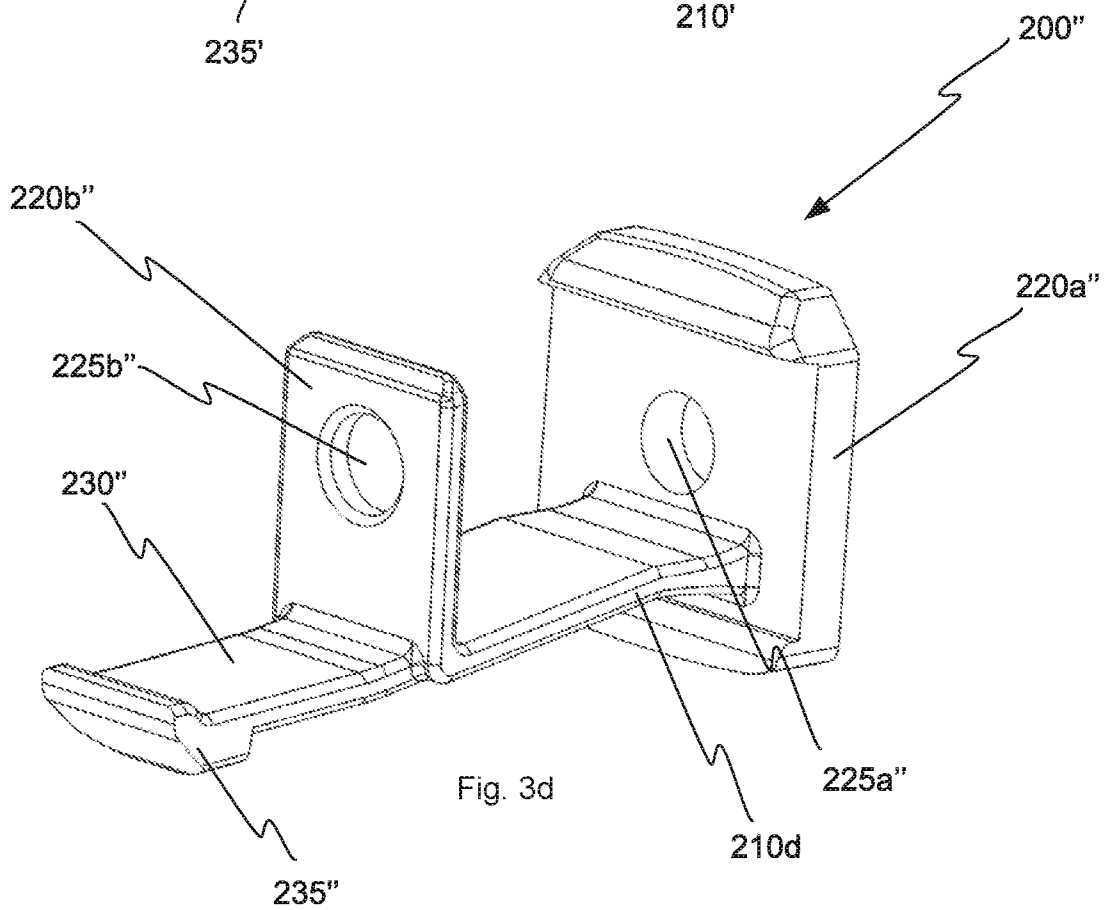
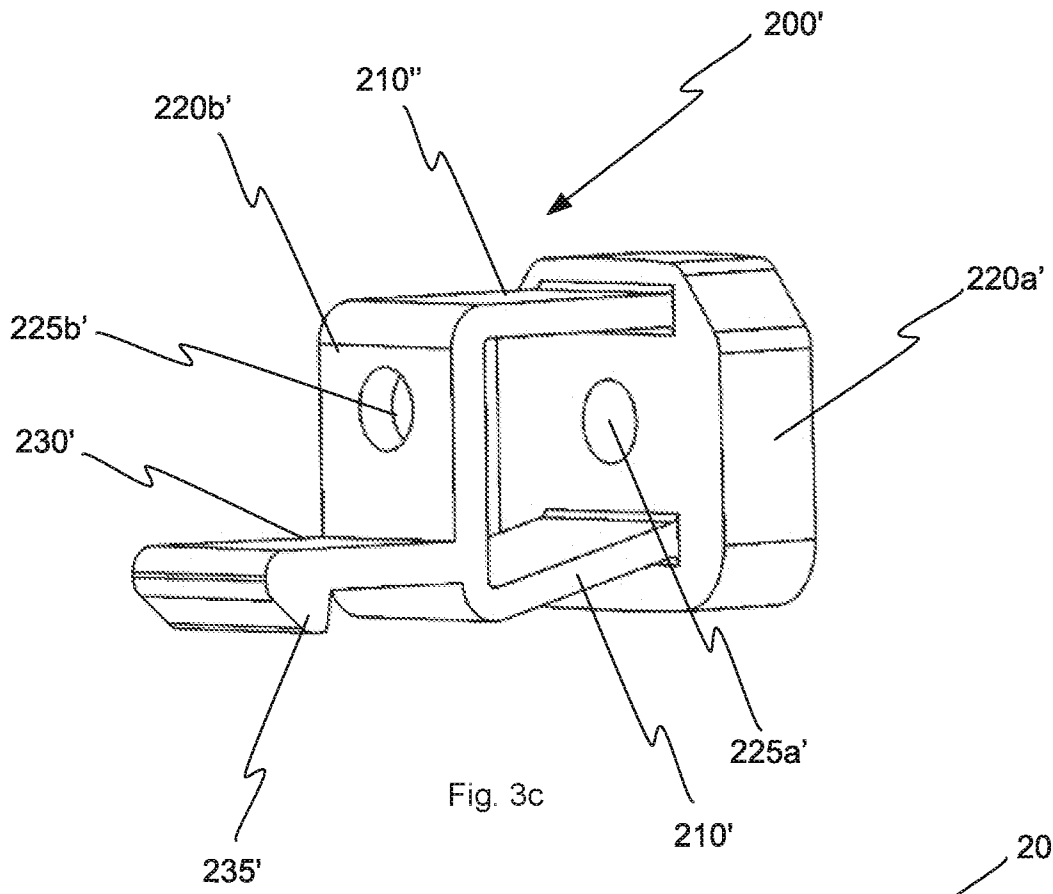


Fig. 3B



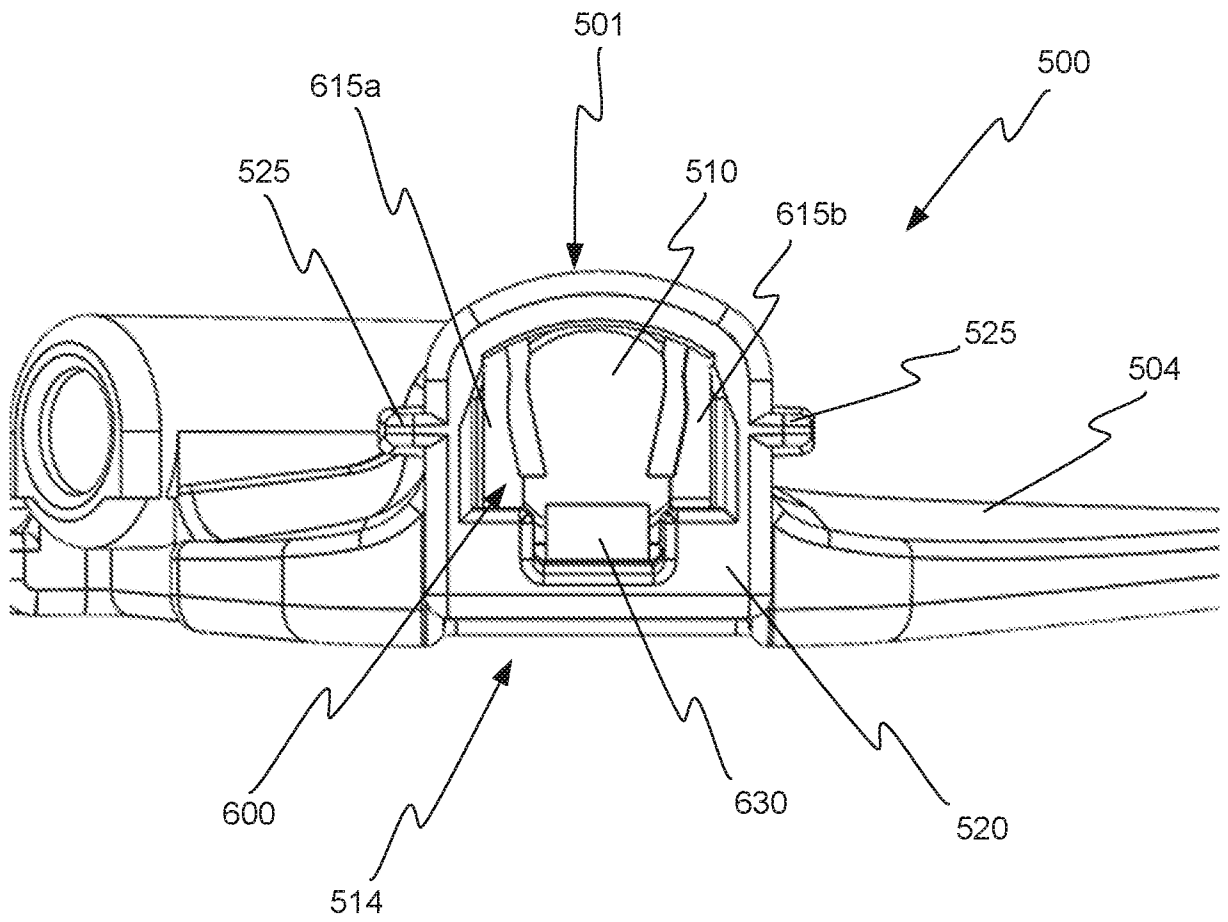


Fig. 4

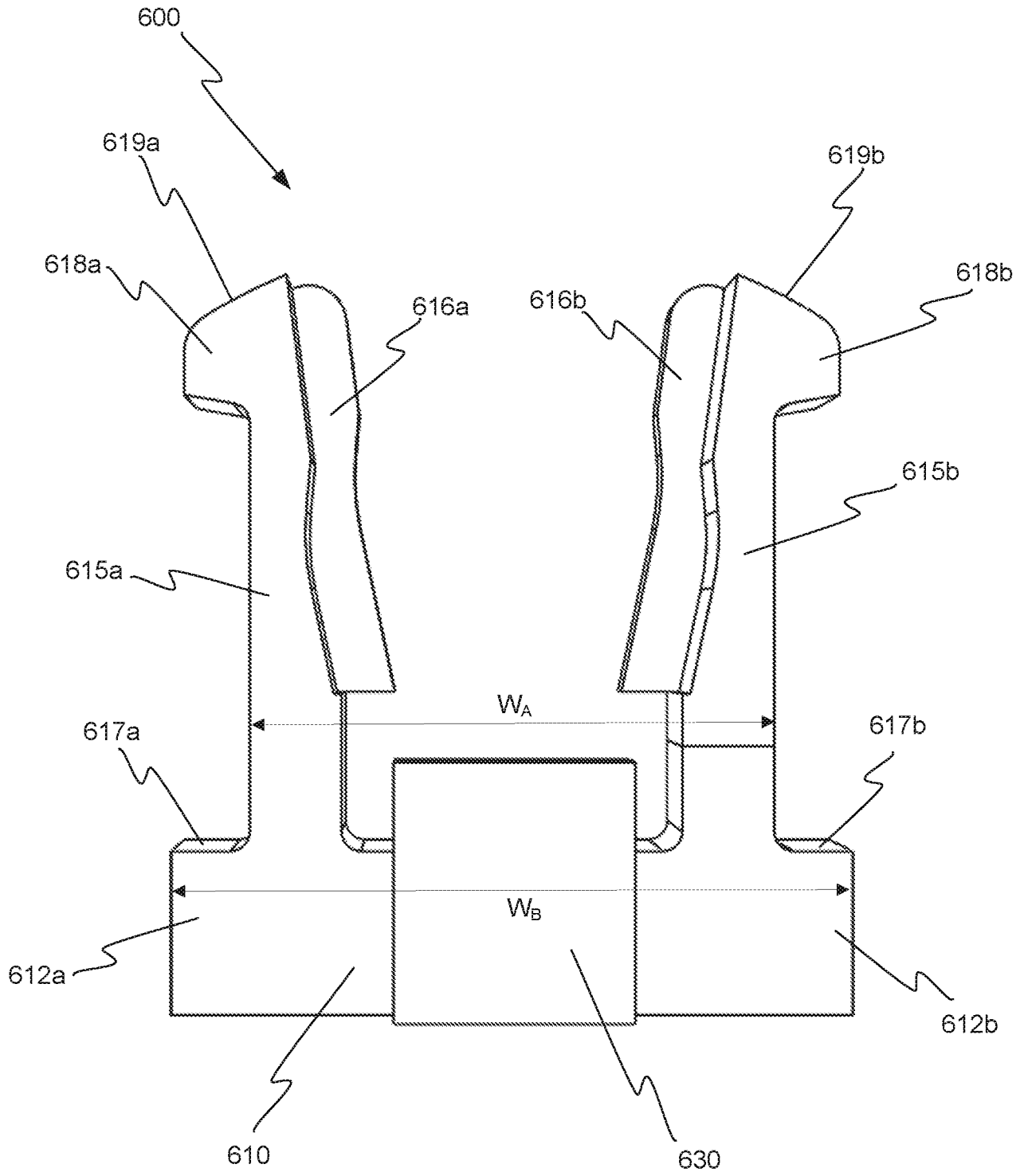


Fig. 5

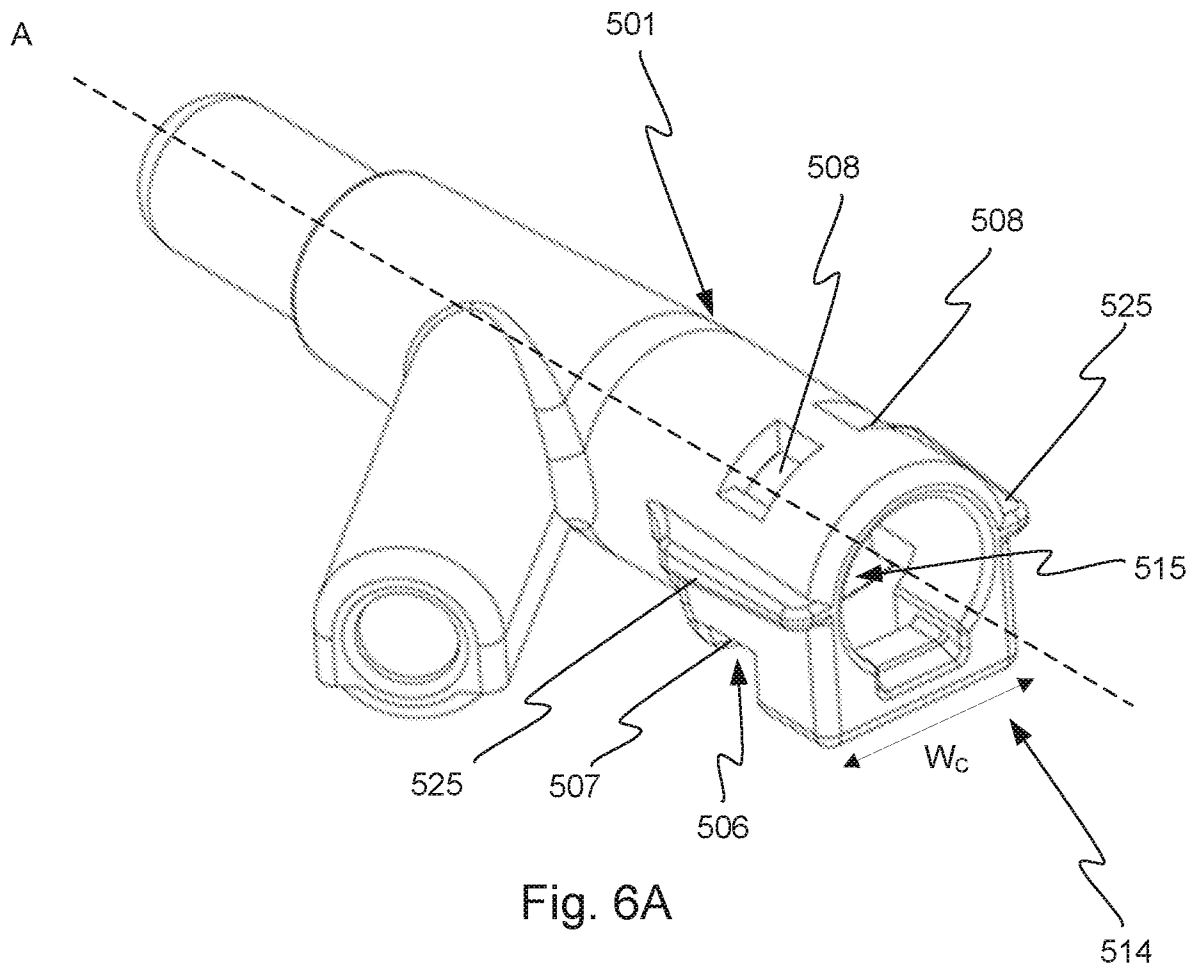


Fig. 6A

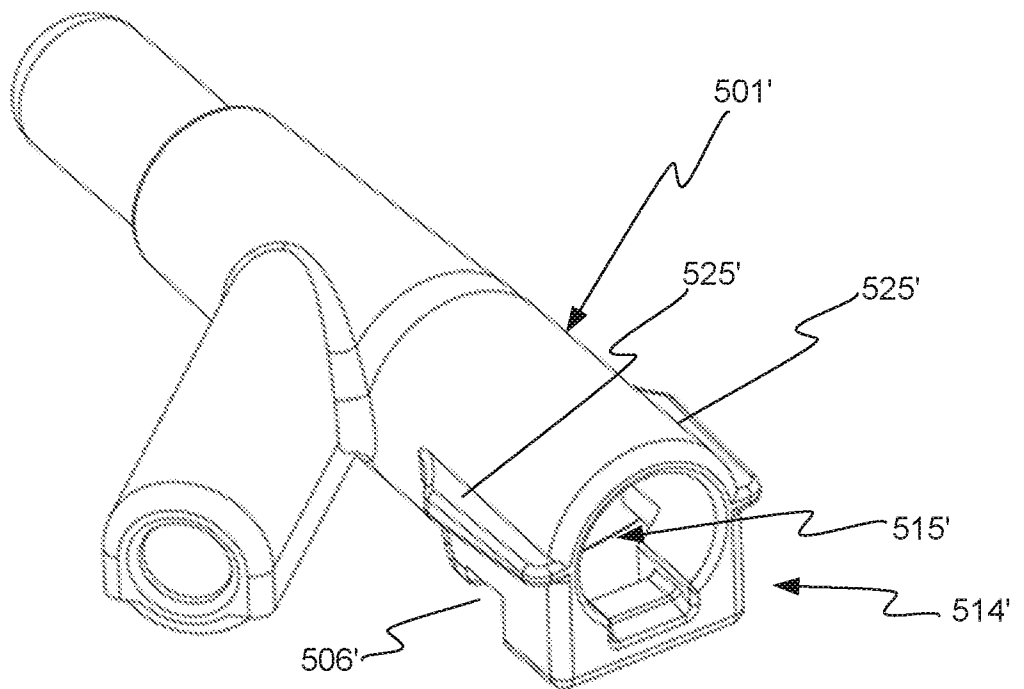


Fig. 6B

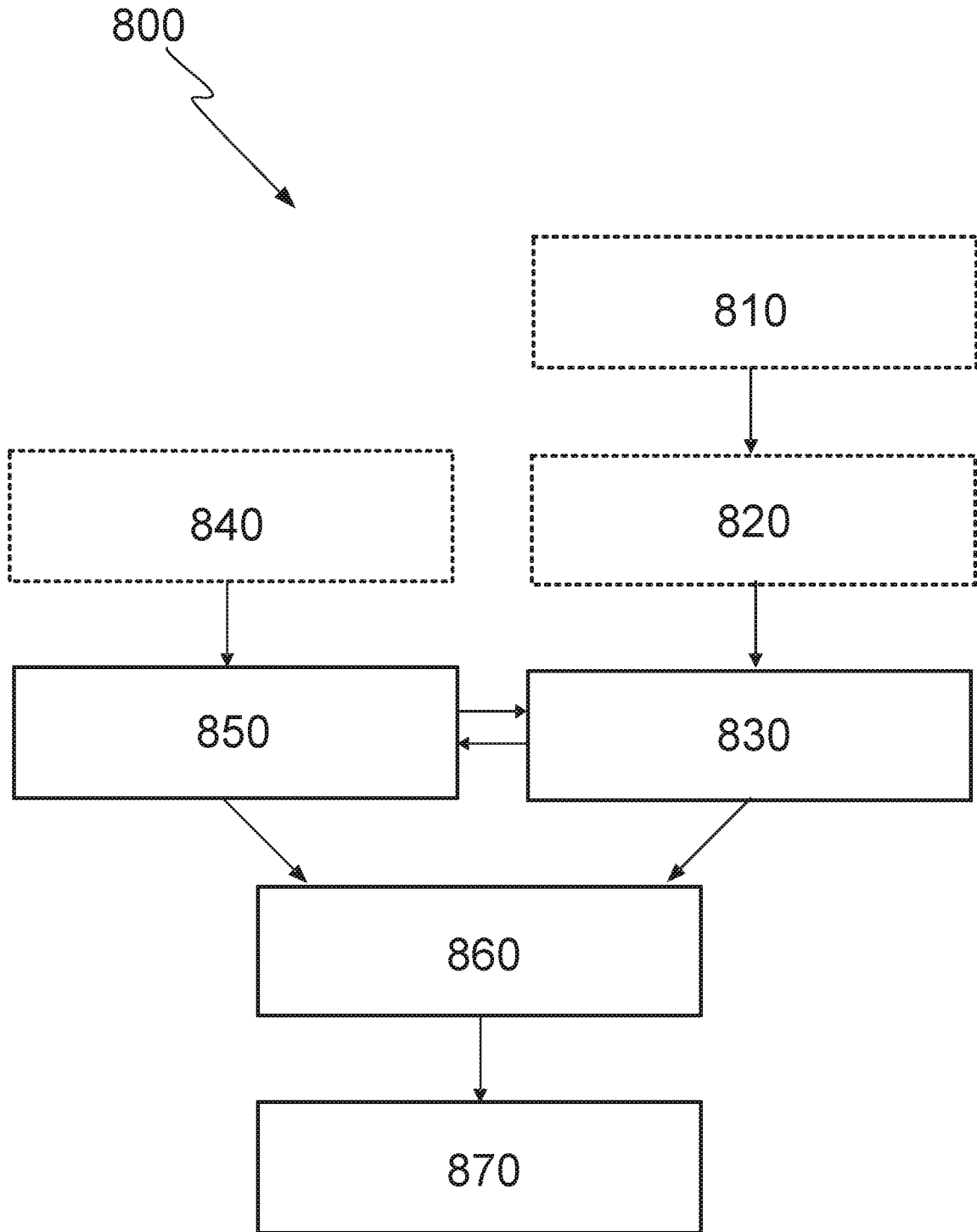


Fig. 7

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/SE2021/050596

A. CLASSIFICATION OF SUBJECT MATTER		
IPC: see extra sheet		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC: A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE, DK, FI, NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
EPO-Internal, PAJ, WPI data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2018077748 A1 (BRAUN MELSUNGEN AG), 3 May 2018 (2018-05-03); abstract; page 31, line 3 - line 6; page 32, line 6 - page 33, line 3; figures 2, 3a-3c	1-10
A	--	11-14, 17-20
X	US 20080140004 A1 (THORNE JOHAN FREDRIK ET AL), 12 June 2008 (2008-06-12); abstract; paragraphs [0034]-[0039]; figures 2, 5b	1, 17-20
A	--	2-14
<input checked="" type="checkbox"/>	Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/> See patent family annex.
* Special categories of cited documents:		
"A" document defining the general state of the art which is not considered to be of particular relevance		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"D" document cited by the applicant in the international application		"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date		
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)		"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		"&" document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report	
23-08-2021	24-08-2021	
Name and mailing address of the ISA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer Kristina Jern Telephone No. + 46 8 782 28 00	

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/SE2021/050596

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	--	1-14
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A	--	2, 14, 17-20
X	WO 2018156148 A1 (BECTON DICKINSON CO), 30 August 2018 (2018-08-30); abstract; paragraphs [0023]-[0026]; all figures	1
A	--	2, 14, 17-20
A	WO 0245786 A2 (BECTON DICKINSON CO ET AL), 13 June 2002 (2002-06-13); abstract; all figures	1-14, 17-20
A	--	
A	EP 3238770 A1 (NIPRO CORP), 1 November 2017 (2017-11-01); abstract; all figures	1-14, 17-20
A	--	
A	WO 2016142410 A1 (BRAUN MELSUNGEN AG), 15 September 2016 (2016-09-15); abstract; all figures	1-14, 17-20
	-- -----	

**Continuation of:** second sheet

**International Patent Classification (IPC)**

**A61M 25/06** (2006.01)

**A61M 5/32** (2006.01)

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/SE2021/050596**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1-14 and 17-20**

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

**Continuation of:** Box No. III

According to Rule 13.1 PCT, an international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

According to Rule 13.2 PCT when a group of inventions is claimed, the requirement of Rule 13.1 PCT shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. In this context, "special technical features" means those technical features with which each invention contributes over the prior art.

The following separate inventions were identified:

- 1: Claims 1-14 directed to a catheter instrument and a method for manufacturing a catheter instrument.
- 2: Claims 15-16 directed to a high pressure clip.
- 3: Claims 17-20 directed to a catheter hub.

The present application has been considered to contain 3 inventions which are not linked such that they form a single general inventive concept, as required by Rule 13 PCT for the following reasons:

Invention 1 relates to the problem of administering drugs or fluid to a patient. This problem is solved by providing a catheter instrument comprising a catheter assembly and a needle shielding device where the catheter assembly and the needle shielding device can be connected to each other. This is realised by an engagement portion on the needle shielding device engaging an engagement socket on the catheter assembly.

Invention 2 relates to the problem of connecting two parts of the catheter instrument. This problem is solved by providing a high pressure clip comprising a pressure clip base part provided with a socket, and a leg extending from said pressure clip base part.

Invention 3 relates to the problem of accessing a catheter lumen. This problem is solved by providing a catheter hub comprising a distal end provided with an incision in connection with a lumen.

As both the problems and solutions are technically different, no single general concept can be formulated based on the technical features of the inventions. Consequently, the requirements of Rule 13.1 PCT are not met.

It was investigated under Rule 13.2 if any further feature, either in the claims or derivable from the description, could be considered as a same or corresponding feature, and could be considered a special technical feature establishing a technical link between the 3 groups of inventions.

No such features were identified.

.../...

**Continuation of:** Box No. III

Consequently, the 3 groups of inventions are not so linked as to form a single general inventive concept as required by Rule 13.1 PCT.

The ISA did not consider it necessary to request an additional fee for invention 3. However, the ISA considers that an additional search fee is required for invention 2.

A partial search has been carried out, which relates to the inventions 1 and 3 mentioned above.

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

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## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

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