

Injection Molded Cannula System

Field of disclosure

The present invention lies in the field of infusion technology. More particularly, it is related to infusion site interfaces and infusion pumps, as well as manufacturing methods for cannula
5 systems for infusion site interfaces.

Background, prior art

Infusion pumps are used for parenterally providing patients with liquid medicaments over longer time periods. Nowadays, infusion pumps with very small dimensions are available that can be carried by the patient on the body. Such small-sized ambulatory infusion pumps are particularly
10 useful for metering small doses of highly effective liquid medicaments, such as insulin for the treatment of diabetes, or analgesics for pain therapy, which are conveyed through a cannula into the tissue of a patient.

In one approach, an infusion pump, carried somewhere on the body, e.g. attached to a belt, is fluidly connected via flexible tubing to an infusion site interface, also called insertion head, that
15 is attached to the body of the patient. The infusion site interface comprises a cannula system with a cannula to be inserted into the body tissue, a housing and connector means for fluidly connecting the cannula with the flexible tubing connected to the upstream infusion pump. The tubing can be repeatedly connected and disconnected from the infusion site interface. The connector means may for example comprise a septum sealingly closing the fluid system of
20 cannula and housing. The septum can be penetrated by a hollow needle, for reversibly establishing a fluid connection. The cannula is preferably made of a flexible material and is thus a soft cannula. Such cannulas are more comfortable for their users, particularly during body

movements. Since flexible cannulas cannot be inserted directly into the tissue, an additional piercing device, e.g. in the form of a rigid piercing needle made from metal, is arranged inside the flexible cannula. A pointed end of the piercing device protrudes from the proximal end of the cannula, the cannula that will be open toward the interstitial fluid. After inserting the
5 piercing device and the stabilized cannula into the body tissue, the rigid piercing device is removed from the flexible cannula. The flexible cannula remains in the body tissue. Generally, a piercing needle is arranged in such a way that it penetrates a septum, which after withdrawal of the piercing needle sealingly closes the distal end of the now open cannula fluid path.

In another approach, the infusion pump device is directly fluidly connected with the infusion
10 site interface. The fluid connection between pump and cannula is established by a hollow connector needle of the pump, reversibly penetrating a septum of the cannula unit that sealingly closes the distal end of the cannula fluid path. Advantageously, the pump can be repeatedly connected and disconnected from the infusion site interface.

In a common method for manufacturing infusion site interfaces with soft and flexible cannulas,
15 a stabilizing pin is introduced in a first step into the flexible cannula, for simplifying the handling of the flexible cannula during the manufacturing process. The temporary structural unit prepared in this manner is inserted into a previously manufactured housing, the flexible cannula and the housing are permanently connected, for example by a thermal process. The stabilizing pin is then drawn out of the flexible cannula, and is replaced by the actual piercing device. The insertion of
20 the piercing devices sometimes damages the flexible cannulas, which results in comparably high rejection rates during manufacturing.

WO 2018 033 614 A1 discloses a cannula unit comprising a housing and a flexible cannula. The flexible cannula is provided with an end area that deviates from the shape of the rest of the flexible cannula. The end area of the flexible cannula has for example a funnel-like shape or the

shape of a flange. Furthermore, the housing comprises two parts, between which the end area of the flexible cannula is positively locked to the housing by clamping. The two parts of the housing are ultimately connected by welding, particularly laser welding.

Summary of disclosure

5 Cannula units and systems known in the state of the art suffer from certain drawbacks. For example, if the cannula unit comprises a housing with two parts, which are separately produced and only subsequently connected during the manufacturing process, certain restrictions are imposed. Firstly, the materials have to be suitable for welding or gluing, such that the two housing parts can be connected. Secondly, the connecting step represents an additional step,
10 which increases the manufacturing time and cost of the production. Thirdly, the two parts of the housing must be strictly complementary to each other, thus allowing only minor material tolerances, as otherwise leakage becomes a problem. This is a severe problem in the state of the art, as the amount of deficient products due to non-complementary housing parts is significantly high.

15 It is therefore an overall objective of the present invention to improve the state of the art regarding the design and use of cannula systems in the context of infusion of liquid drugs, thereby preferably avoiding disadvantages of the prior art fully or partly.

In advantageous embodiments, a cannula unit is provided, in which the occurrence of leakage is avoided or at least significantly reduced.

20 In further favorable embodiments, a cannula unit is provided, which can be manufactured in a time and cost efficient manner.

In additional favorable embodiments, the amount of deficient products during the manufacturing process and thus the rejection rate is reduced.

According to a first object of the invention, the overall objective is achieved by a method for manufacturing a cannula system with a body unit and a compressing unit. The method comprises
5 providing the body unit comprising a mounting structure, the body unit being mounted onto a molding core pin. Subsequently, a soft cannula is threaded on the mounting structure of the body unit. In a following step, the compressing unit is injection molded on the soft cannula and at least on parts of the body unit. The compressing unit circumferentially surrounds the mounting structure, at least parts of the soft cannula and at least parts of the body unit. Furthermore, the
10 injection-molded compressing unit is cooled, thereby providing an internal material tension of the compressing unit. The cooling typically entails shrinking of the compressing unit. In addition, the molding core pin is removed. It is understood by the skilled person that the molding core pin can be removed either directly after injection molding of the compressing unit, i.e. before cooling of the compressing unit, after cooling the compressing unit or even during cooling
15 of the compressing unit.

Optionally, the body unit is also produced by injection molding. For example, the body unit may be provided by injection molding onto the molding core pin. However, the body unit may also be produced by another suitable method. Particularly, if the body unit is produced by injection molding, the two injection molding steps may be conducted as two separate injection molding
20 steps.

Using injection-molding technology for manufacturing the compressing unit and optionally the body unit has the advantage that only a reduced number of tools is required. Furthermore, no additional connection step such as welding or gluing, is required. In addition, as the compressing unit is injection molded on the body unit and the cannula and subsequently cooled, shrinking

induces an internal material tension, which significantly increases the fixture of the soft cannula within the cannula system. The shrinking and the thus associated internal material tension can be increased, if cooling is performed in the mold. Furthermore, injection molding of both the body unit and the compressing unit has the advantage that the two parts are necessarily
5 complementary to each other and thus the amount of material deficient parts is significantly reduced.

It is understood that the term “circumferentially” does not necessarily require that the mounting structure, the cannula and or the body unit have a round cross section and/or a cylindrical shape. These components may independently of each other comprise a round, elliptical or angular cross
10 section and further have any shape suitable for an infusion set.

In some embodiments the compressing unit is injection molded such that it circumferentially surrounds at least $1/3$, preferably $1/2$ of the outer surface of the body unit, thereby providing a particular tight and safe connection between the body unit and the compressing unit.

In further embodiments, only a distal end area of the soft cannula is threaded on the mounting
15 structure of the body unit. The compressing unit preferably circumferentially surrounds only the distal end area of the soft cannula. As the skilled person understands, the distal end area is facing away from the patient in an operative state. Thus, the distal end area is closer to the body unit as the proximal end area. Upon insertion into the patient’s tissue, the proximal end area is therefore first inserted into the tissue.

20 In other embodiments, the distal end area is provided with a locking structure for establishing a positive locking (form closure) and/or an adhesive bond between the soft cannula, in particular the distal end area, and the compressing unit. A locking structure establishing a form lock is advantageous, as during injection molding of the compressing unit on the soft cannula, the

material is provided into and/or around the locking structure, thereby providing an improved cannula system, in which the cannula is tightly secured to avoid that the cannula is separated from the compressing unit and the body unit when the cannula system is withdrawn from the skin. The improved cannula system improves the sealing of the cannula system thus avoiding the
5 occurrence of leakage of the infusion fluid.

In further embodiments, prior to threading the soft cannula in the mounting structure of the body unit, a locking structure is generated at the distal end area of the soft cannula. The locking structure may be either adhered to the distal end area or a through bore may be generated by drilling. Alternatively, the protruding locking structure such as a nipple may be adhered or
10 welded to the distal end area of the soft cannula.

In some embodiments, the locking structure includes at least one protrusion protruding from the distal end area. For example, the locking structure may be a collar extending from the distal end area of the soft cannula. Preferably, the collar is arranged at the most distal part of the distal end area, i.e. the collar may be a flange. The protrusion may also be a nipple, a hook or a barb.
15 Additionally, or alternatively, the locking structure may be at least one hole. Preferably, the hole is a through bore or a blind hole.

In further embodiments, the distal end area of the soft cannula has a larger diameter than the rest of the cannula before the cannula is threaded on the mounting structure. Thus, the cannula is, when pushed over the mounting structure, not or only slightly laterally expanded, which will
20 result in no or less material creep and potentially leads to less leakage.

In further embodiments, the internal material tension of the compressing unit exerts a compression force which is directed radially inwards. Such a force is particularly advantageous,

as the risk of leakage between the cannula and the mounting structure and/or between the cannula and the compressing unit is further decreased.

In some embodiments, the internal material tension of the compressing unit compresses the parts of the soft cannula threaded on the mounting structure. In such embodiments, at least the part
5 of the cannula which is circumferentially surrounded by the compressing unit, preferably the distal end area, is compressed. Thus, the wall thickness of the cannula of this part is smaller than the wall thickness of the rest of the cannula which is not circumferentially surrounded by the compressing unit.

In further embodiments, the body unit and the compressing unit and/or the compressing unit
10 and the soft cannula form a bonded connection during injection molding of the compressing unit.

In some embodiments, the methods may in general consist of two separate injection molding steps, thereby reducing the required amount of manufacturing steps and the overall production time and costs even further.

15 According to a second aspect of the invention, the overall objective is achieved by a cannula system comprising a soft cannula and a cannula unit for holding the soft cannula. The cannula unit comprises or alternatively may also consist of a compressing unit and a body unit, wherein the body unit contains a mounting structure and a cavity for holding a septum. The soft cannula is threaded on the mounting structure of the body unit. Furthermore, the compressing unit
20 circumferentially surrounds the mounting structure and at least parts of the body unit. The compressing unit also comprises an internal material tension for exerting a compression force on the soft cannula and the mounting structure.

For example, such a cannula system may be manufactured by a method as described herein. Furthermore, the body unit and/or the compressing unit are typically injection molded.

In some embodiments, the mounting structure may be a protuberance, in particular a cylindrical or cubical protuberance.

- 5 In further embodiments, only a distal end area of the soft cannula is threaded on the mounting structure and the compressing unit circumferentially surrounds the distal end area of the soft cannula.

In some embodiments, the distal end area of the soft cannula comprises a locking structure providing a positive locking and/or an adhesive bond between the soft cannula and the
10 compressing unit. Both form lock and/or an adhesive bond between the soft cannula and the compressing unit provide a tight fit of the compressing unit and the soft cannula, which avoids the occurrence of leakage. A locking structure for establishing positive locking (form closure) between the soft cannula and the compressing unit may be a protruding locking structure or a recessed locking structure. An adhesive bond may for example be provided by attachment of an
15 external adhesive, for example a glue. Such cannula systems of the invention provide an improved cannula system, in which the cannula is tightly secured to avoid that the cannula is separated from the compressing unit and the body unit when the cannula system is withdrawn from the skin. The improved cannula system also improves the sealing of the cannula system thus avoiding the occurrence of leakage of the infusion fluid.

- 20 In further embodiments the locking structure includes at least one protrusion protruding from the distal end area. For example, the locking structure may be a collar extending from the distal end area of the soft cannula. Preferably, the collar is arranged at the most distal part of the distal end area, i.e. the collar may be a flange. The protrusion may also be a nipple, a hook or a barb.

Additionally, or alternatively, the locking structure may be at least one recessed locking structure, such as a hole. Preferably, the hole is a through bore or a blind hole. The locking structure may also be formed by the wall of the soft cannula, in particular by a waved or stepped wall.

- 5 In some embodiments, the distal end area of the soft cannula has a larger diameter than the rest of the soft cannula. Thus, in these embodiments, the whole distal area has a larger diameter than the rest of the soft cannula.

Typically, the distal end area of the soft cannula is free of an internal material tension.

- In some embodiments, the wall thickness of the distal end area of the soft cannula is smaller than
10 the wall thickness of the rest of the soft cannula.

In other embodiments, the compressing unit compresses at least the distal end area of the soft cannula. In these embodiments, a particular fluid tight system is achieved and the risk of leakage is reduced.

- In further embodiments, the body unit and the compressing unit are connected by a bonded
15 connection and/or the soft cannula and the compressing unit are connected by a bonded connection.

- It is understood that such a bonded connection is typically only formed by the body unit, the compressing unit and/or the soft cannula itself. Thus an external adhesive, for example a glue, is neither required nor present, except for embodiments in which adhesive bond between the soft
20 cannula and the compressing unit is provided, for example by a glue.

In some embodiments, the cannula system does not comprise additional connection means, particularly form-lock means, for coupling and/or connecting the compressing unit and the body unit such as for example barbs, nipples, snap fits and the like. The cannula system may also not comprise any additional housing parts or adapters, which are not integral parts of the cannula
5 unit and/or the soft cannula and/or the body unit. Thus, preferred cannula systems may comprise a soft cannula, which is only held in place by the body unit and the compressing unit and consequently not by an additional component not being integral to the body unit or the compressing unit. Thereby, the rejection rate and production effort and cost are reduced.

In further embodiments, the body unit may comprise a septum within the cavity for holding the
10 septum. The septum may be fixed by crimping. Such a septum is typically continuously closed, i.e. free of a slit, prior to insertion of a piercing needle. In particular, such a septum may not comprise a slit elongated in both the lateral and the vertical piercing direction of the septum.

According to another aspect of the invention, the overall objective is achieved by the use of a cannula system according to any of the embodiments described herein in an infusion set.

15 **Brief description of the figures**

Figure 1 shows a cross-sectional view of a cannula system in accordance to an embodiment of the invention.

Figures 2a to 2c schematically show the manufacturing method of a cannula system according to an embodiment of the invention.

20 Figure 3 shows a cross-sectional view of a cannula system in accordance to another embodiment of the invention.

Figure 4 shows a cross-sectional view of a cannula system in accordance to another embodiment of the invention.

Exemplary embodiments

Figure 1 shows an advantageous embodiment of a cannula system 1 according to the invention.

- 5 Cannula system 1 comprises soft cannula 10 and a cannula unit for holding soft cannula 10. The cannula unit comprises compressing unit 20 and body unit 30. Body unit 30 further comprises mounting structure 31 and cavity 32 for receiving a septum. Distal part 11 of soft cannula 10 is threaded on mounting structure 31. The diameter of distal end area 11 of soft cannula 10 is larger than the diameter of the rest of the soft cannula. Compressing unit 20 circumferentially surrounds distal end area 11 of soft cannula 10, mounting structure 31 and also an additional part of body unit 30. As shown in Figure 1, more than 1/3 of the outer surface of the body unit are circumferentially surrounded by compressing unit 20.
- 10

- As indicated by the arrows, the compressing unit 20 has an internal material tension, thereby exerting a radially inwards directed compression force on the distal end area of the soft cannula and the mounting structure. As a result, a particular tight connection between soft cannula 10, mounting structure 31 and compressing unit 20 is achieved. Furthermore, as can be readily seen in Figure 1, the wall thickness of distal end area 11 of soft cannula 10 is smaller than the wall thickness of the rest of soft cannula 10. In addition, as indicated by the arrows, distal end area 11 of soft cannula 10 is compressed by the compression force exerted by compressing unit 20.
- 15
- 20 Compressing unit 20 and body unit 30 are connected by a bonding connection at their contact area. As a result, a reliable and sealingly tight connection is established.

Figures 2a to 2c depict certain steps of a method of manufacturing a cannula system according to an advantageous embodiment of the invention. As shown in Figure 2a, body unit 30 with

mounting structure 31 is injection molded onto a molding core pin 40 (mold not shown). In a following step, distal end area 11 of soft cannula 10 is threaded on mounting structure 31 (Figure 2b). Afterwards, compressing unit 20 is injection molded on the distal end area of the soft cannula, on the mounting structure and also on further parts of body unit 30 (Figure 2c, mold
5 not shown). As the compressing unit is at least partially injection molded on body unit 30, any production imprecision of the proximal face of the body unit is less relevant, as the compressing unit is necessarily complementary to those parts of the body unit 30. Once compressing unit has been injection molded, molding core pin 40 can be removed and the compressing unit be cooled, upon which an internal material tension is established, thereby exerting a force on distal end
10 area 11 of soft cannula 10 and mounting structure 31. Generally, the cooling can be performed in the mold and/or the cooling may be achieved by active cooling. Thus, the compressing unit is not allowed to cool to room temperature by itself, but actively cooled, particularly by using a cooling medium. Such rapid cooling enhances the internal material tension. The two-step injection molding sequence can be performed significantly faster as the methods for
15 manufacturing cannula unit as known in the state of the art.

Figure 3 shows another advantageous embodiment of a cannula system 1 according to the invention. Cannula system 1 comprises soft cannula 10 and a cannula unit containing compressing unit 20 and body unit 30. Body unit 30 comprises mounting structure 31 on which distal end area 11 of the soft cannula 10 is threaded. In the particular embodiment shown, distal
20 end area 11 comprises two holes 12a as locking structures, which are provided as through bores. The dimension of holes 12a are drawn in exaggeration for demonstrative purposes only. Even though the arrows indicating the compressing force are not shown in Figure 3 (see Figure 1), also in this embodiment with holes 12a, a compressing force is exerted by the compressing unit on soft cannula 10. As can be seen, parts of the compressing unit 20 enter holes 12a during injection
25 molding. After the compressing unit is cooled, a tighter sealing between compressing unit 20 and

soft cannula 10 is achieved. Additionally, the fixation of soft cannula 10 within thin cannula system is improved.

Figure 4 depicts another embodiment of cannula system 1, with soft cannula 10 and a cannula unit comprising compressing unit 20 and body unit 30 with mounting structure 31. In general,
5 the mounting structure may be a protrusion of the body unit, such as a nipple. Distal end area 11 of soft cannula 10 comprises collar 12b as a locking structure, which establishes a form lock between soft cannula 10 and compressing unit 20. Collar 12b is circumferentially arranged at the most distal part of distal end area 11. During injection molding of compressing unit 20, the material is provided around collar 12b. As a result, soft cannula 11 is anchored within
10 compressing unit 20, thereby both increasing fixation of the cannula within the cannula system and the sealing between the cannula and the compressing unit.