

Cannula System with Rigid Cannula

Field of disclosure

The invention lies in the field of infusion technology. More particularly, it is related to a cannula system comprising a rigid cannula and the use of such a cannula system in an infusion system.

5 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 useful for metering small doses of highly effective liquid medicaments, such as insulin for the
10 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 is attached to the body of the patient. The infusion site interface comprises a cannula system
15 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 infusion site interface may be attached to the patient via an infusion pump cradle. The tubing can be repeatedly connected and disconnected from the infusion site interface. The connector means may for example comprises a septum sealingly closing the fluid system of cannula and
20 housing. The septum can be penetrated by a hollow needle, for reversibly establishing a fluid connection. The cannula may be made of a flexible material and thus be 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 piercing device and the stabilized cannula into the body tissue, the rigid piercing device is removed from the flexible cannula. The
5 cannula remains in the body tissue. Generally, a piercing needle is arranged in such a way that it penetrates the 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 site interface. The fluid connection between pump and cannula is established by a hollow connector
10 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.

Summary of disclosure

While the use of soft or flexible cannulas is in general preferred due to the increased wearing
15 comfort for the user, these can also be problematic for certain patients suffering from intolerances against the soft cannula material, for example latex, silicone or rubber, leading to skin irritation and/or infections. For such patients, metallic cannulas, for example steel cannulas, provide a favorable alternative. The overall setup for rigid cannulas is typically less complicated, as the piercing needle is typically dispensed with.

20 It is therefore an overall general objective of the present invention to advance the state of the art regarding cannula systems with a rigid cannula as used in the context of liquid drug infusion, thereby preferably avoiding disadvantages of the prior art fully or partly.

In advantageous embodiments, a cannula system with increased compatibility for the patient, in particular for a patient with an intolerance against silicone, rubber or the like is provided.

In further advantageous embodiments, a cannula system is provided in which the locking of the rigid cannula is improved and/or the occurrence of leakage is diminished.

According to an aspect of the invention, the overall objective is achieved by a cannula system comprising a rigid cannula, a cannula unit to which the rigid cannula is connected, preferably directly connected, and an insertion unit. The cannula unit comprises a septum, which is mounted to a mounting structure of the cannula unit. The mounting structure may for example be a groove or recess formed by inner walls of the cannula unit. For example, the septum may be crimped or clamped to the mounting structure, thereby establishing a tight sealing between the septum and the inner walls of the cannula unit. The cannula unit further comprises a connecting structure for reversibly or irreversibly connecting the cannula unit to a cannula unit holder. The cannula unit holder may typically be an infusion pump cradle for attaching the cannula unit to the patient's body. Additionally, the cannula unit comprises a cavity for receiving the liquid medicament when the cannula unit is connected to an infusion pump by piercing the septum with an infusion pump cannula. The cavity is at least partially formed by the septum. The rigid cannula is in fluidic communication with the cavity. In order to establish a releasable but also stable connection between the cannula unit and the insertion unit, the insertion unit contains a rigid needle, which at least partially penetrates the septum of the cannula unit. Thus, the rigid needle prevents essentially any lateral movement of the insertion unit with respect to the cannula unit, with the exception of any movement enabled by the elastic nature of the septum. The rigid needle preferably extends up to the cavity. The rigid needle preferably does not extend into rigid cannula, preferably the tip of the rigid needle does not extend into the lumen of the rigid cannula. Due to its rigidity, the rigid cannula is able to penetrate and insert into the skin without help of an enveloping or enveloped rigid insertion needle. This is contrary to soft cannulas which require a rigid insertion needle that either envelops the soft cannula or is enveloped by the soft cannula for stabilization of the soft cannula at least during insertion of the soft cannula into the skin. This difference is associated with the advantage that it simplifies the design of the cannula system and the rigid cannula insertion process when compared to systems

using a soft cannula and a rigid insertion needle. For example with the prior arts' soft cannula and rigid insertion needle combinations it is necessary to insert and withdraw the rigid insertion needle while leaving the inserted soft cannula in place. Such devices are complex since the insertion needle and the soft cannula are in direct mechanical contact with each other during
5 insertion into the skin whereas in the case of the present invention there is no need for such a complex insertion needle withdrawal process since the rigid insertion needle is not in direct mechanical contact with the rigid cannula. The insertion unit further comprises an attachment structure configured to reversibly attaching the insertion unit to the cannula unit.

As used herein, the term "septum" is readily understood by those skilled in the art and is typically
10 an engineered element, for example in the form of a membrane or plug, for sealingly separating a first side and second side in a fluid, i.e. gas and/or liquid, tight seal, which can be pierced by a needle or a cannula. Typically, a septum does not comprise an opening or a puncture, which passes through the septum from the first side to the second side, before a needle or a cannula has been pierced through the septum. Thus, the septum may be referred to as a puncture-less
15 septum. Consequently, a stump needle cannot be easily pierced through the septum without exerting high forces. Apart from the first surface being shaped as explained above and further below, the first and second surface may preferably be coplanar.

The rigid cannula may be made from any suitable metal, preferably steel, particularly stainless steel. Additionally, at least the cannula unit may be injection molded, preferably directly injection
20 molded onto the rigid cannula. It is understood that the rigid needle is typically a solid body, i.e. the rigid needle may not comprise a through hole or an orifice and may therefore not be a cannula.

In some embodiments, the rigid needle penetrates the septum in an essentially central position of the septum, when the insertion unit is attached to the cannula unit. A septum having two
25 coplanar surfaces is thus penetrated essentially along a central axis being perpendicular to both

coplanar surfaces. Such an arrangement facilitates establishing the connection between the cannula unit and the insertion unit.

In further embodiments the cavity is formed by inner walls of the cannula unit and the septum.

In some embodiments, the rigid cannula comprises a locking structure for fixedly connecting the
5 cannula to the cannula unit.

In certain embodiments the locking structure provides a positive lock and/or an adhesive bond between the rigid cannula and the cannula unit. For example, an adhesive such as a glue may be used to lock the cannula to the cannula unit.

In some embodiments the locking structure includes at least one protrusion, preferably a collar
10 which is preferably arranged at the most distal end of the rigid cannula. It is understood that the distal part of the cannula refers to the end area of the cannula that is facing away from the patient in an operative state. Alternatively, or additionally, the locking structure may comprise at least one hole, preferably a through bore or a blind hole. Such locking structures are preferred, in particular if the cannula unit is injection molded. During production, the material can enter
15 the hole or surround the protrusion, which provides a strong positive locking connection after cooling.

In further embodiments the insertion unit comprises connecting means for connecting the insertion unit to an inserter. The connecting means may comprise any suitable connecting mechanism, such as bayonet, snap fit, latches, hooks and the like. Typically, the connecting
20 means are configured for providing a releasable connection between the insertion unit and the inserter.

In some embodiments the insertion unit comprises a slit extending towards the rigid needle. The slit may comprise an adhesive such as a glue. The slit may for example be arranged transversal

to the rigid needle. The slit enables a secure connection of the needle within the insertion unit and further simplify the production process of the insertion unit.

In further embodiments the rigid needle is unmovably connected to the rest of the insertion unit.

In some embodiments the attachment structure comprises a releasable adhesive or a releasable
5 positive locking structure. The releasable adhesive may for example be an adhesive layer, whose connecting force may readily be overcome by a user. The positive locking structure may comprise any suitable form-lock mechanism, such as bayonet, snap fit, latches, hooks and the like.

In further embodiments a force required for releasing the cannula unit from the insertion unit is smaller than a force exerted by the connecting structure for reversibly or irreversibly connecting
10 the cannula unit to the cannula unit holder and/or smaller than a force required to separate the rigid cannula from the cannula unit. Thus, if a pulling force is exerted on the insertion unit away from the cannula unit, the attachment structure is released and the insertion unit is separated from the cannula unit, while the rigid cannula remains connected to the cannula unit and the cannula unit remains connected to a cannula unit holder.

15 According to a further aspect of the invention, the overall objective is achieved by an infusion system comprising a cannula system according to any of the embodiments as described herein.

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

Brief description of the figures

20 Figure 1 shows a schematic cross-sectional view of a cannula system according to an embodiment of the invention.

Exemplary embodiments

Figure 1 depicts a cannula system 1 with rigid steel cannula 2, cannula unit 3 and insertion unit 4. Rigid cannula 3 is connected to cannula unit 2 via locking structure 21, which in the particular embodiment shown, comprises an enlarged cross-section at the most distal end area of cannula 2, such as a collar. Cannula unit 3 comprises septum 31, which is mounted to mounting structure 32 of cannula unit 3. As can be seen, mounting structure 32 is formed by inner wall 35 of the cannula unit 3, which crimp the septum into cannula unit 3. Cannula unit 3 further comprises cavity 34, which is partially formed by septum 31 and partially by inner wall 35 of cannula unit 3. As can be readily seen from Figure 1, rigid cannula 2 is in fluidic communication with cavity 34, such that a liquid medicament can be delivered to cavity 34 and infused into the patient via cannula 2 in an operative state, i.e. in a state in which inserter 4 is removed and an infusion pump is in fluidic communication with cavity 34 via septum 31. Cannula unit 3 further comprises connecting structure 33 for connecting cannula unit 3 to an infusion pump cradle. As shown, connecting structure 33 comprises protrusions and recesses which may be part of a snap fit connection.

Insertion unit 4 comprises rigid needle 41, which maintains insertion unit 4 and cannula unit 3 axially aligned to each other. Rigid needle 41 penetrates septum 31 in an essentially central position and preferably extends up to the cavity 34. Rigid needle 41 preferably does not extend into rigid cannula 2, in particular, the tip of the rigid needle 41 does not extend into the lumen of the rigid cannula 2. Due to its rigidity, the rigid cannula 2 is able to penetrate and insert into the skin without help of a rigid insertion needle that envelopes or is enveloped by the rigid cannula 2. This is in contrast to hitherto known soft cannulas which require a rigid insertion needle that either envelopes the soft cannula or is enveloped by the soft cannula for stabilization of the soft cannula at least during insertion of the soft cannula into the skin. Insertion needle 41 may be fixedly connected to the insertion unit by an adhesive, which is provided within slit 44. As can be seen, slit 44 extends transversally towards needle 41, such that the adhesive can

fixedly connect insertion needle 41 and insertion unit 4. It should be noted that in contrast to rigid cannula 2, needle 41 aims to provide a fixed connection, thus needle 41 is typically a compact body, i.e. is not a hollow needle. Insertion unit 4 further comprises attachment structure 42 for releasably connecting insertion unit 4 and cannula unit 3. Via connecting means 43a and 5 43b, the insertion unit 4, respectively the cannula system 1 may be connected to an inserter as known in the prior art. In use, cannula system 1 is connected to an inserter, inserted into the patient, upon which cannula unit 1 is preferably connected to an infusion pump cradle via connecting structure 33 and then the insertion unit is released. Importantly, attachment structure 42 is in general configured such that a force required for releasing the cannula unit 3 from the 10 insertion unit 4 is smaller than a force exerted by the connecting structure 33 for reversibly or irreversibly connecting the cannula unit 3 to the cannula unit holder (5) (cannula holder not shown) and/or smaller than a force required to separate rigid cannula 2 from cannula unit 3.