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

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, 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.

~~It is therefore an overall objective~~ Embodiments of the present invention seek 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~~may be avoided or at least significantly reduced.

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~~ may be reduced.

According to a first aspect~~object~~ of the present invention, there is provided a method for manufacturing a cannula system with a body unit and a compressing unit, the method comprising the steps:

- Providing a body unit comprising a mounting structure, the body being mounted onto a molding core pin, wherein the body unit is optionally provided by injection molding onto the molding core pin;
- Threading a soft cannula on the mounting structure of the body unit;
- Injection molding of the compressing unit on the soft cannula and at least parts of the body unit, wherein the compressing unit circumferentially surrounds the mounting structure, at least parts of the soft cannula and at least parts of the body unit;
- Cooling of the compressing unit, thereby providing an internal material tension of the compressing unit;
- Removing the molding core pin.

~~overall objective is achieved by a method for manufacturing a cannula system with a body unit and a compressing unit. The method comprises 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 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 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 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

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 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 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.

According to a second aspect of the present invention, there is provided ~~overall objective is achieved by~~ a cannula system comprising a soft cannula and a cannula unit for holding the soft cannula, wherein~~. T~~ 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, wherein~~. T~~ the soft cannula is threaded on the mounting structure, ~~of the body unit. Furthermore,~~ wherein the compressing unit circumferentially surrounds the mounting structure and at least parts of the body unit~~.~~ and wherein ~~T~~the compressing unit contains~~also comprises~~ an internal material tension for exerting a compression force on the soft cannula and the mounting structure.

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 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 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~~ a third aspect of the invention, ~~the overall objective is achieved by~~ there is provided a ~~the~~ use of a cannula system ~~according to any of the embodiments described herein~~as defined in the second aspect in an infusion set.

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.

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

Claims

1. Method for manufacturing a cannula system with a body unit and a compressing unit, the method comprising the steps:

- Providing a body unit comprising a mounting structure, the body being mounted onto a molding core pin, wherein the body unit is optionally provided by injection molding onto the molding core pin;
- Threading a soft cannula on the mounting structure of the body unit;
- Injection molding of the compressing unit on the soft cannula and at least parts of the body unit, wherein the compressing unit circumferentially surrounds the mounting structure, at least parts of the soft cannula and at least parts of the body unit;
- Cooling of the compressing unit, thereby providing an internal material tension of the compressing unit;
- Removing the molding core pin.

2. The method according to claim 1, wherein only a distal end area of the soft cannula is threaded on the mounting structure of the body unit and wherein the compressing unit preferably circumferentially surrounds only the distal end area of the soft cannula.

3. The method according to claim 2, wherein the distal end area is provided with a locking structure for establishing a form lock and/or an adhesive bond between the soft cannula and the compressing unit.

4. The method according to claim 3, wherein prior to threading the soft cannula on the mounting structure of the body unit, a locking structure is generated at the distal end area of the soft cannula.

5. The method according to any of claims 3 or 4, wherein the locking structure includes at least one protrusion, preferably a collar arranged at the most distal part of the distal end area, protruding from the distal end area and/or at least one hole, preferably a through bore or a blind hole.

6. The method according to any of claims 2 to 5, wherein 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.

7. The method according to any of the previous claims, wherein the internal material tension of the compressing unit exerts a compression force which is directed radially inwards and/or wherein the internal material tension of the compressing unit compresses the soft cannula.

8. The method according to any of the previous claims, wherein the body unit and the compressing unit and/or wherein the compressing unit and the soft cannula form a bonded connection during injection molding of the compressing unit.

9. Cannula system ~~(1)~~ comprising a soft cannula ~~(10)~~ and a cannula unit for holding the soft cannula ~~(10)~~, wherein the cannula unit comprises a compressing unit ~~(20)~~ and a body unit ~~(30)~~, wherein the body unit ~~(30)~~ contains a mounting structure ~~(31)~~ and a cavity ~~(32)~~ for holding a septum, wherein the soft cannula ~~(10)~~ is threaded on the mounting structure ~~(31)~~, wherein the compressing unit ~~(20)~~ circumferentially surrounds the mounting structure ~~(31)~~ and at least parts of the body unit ~~(30)~~ and wherein the compressing unit ~~(20)~~ contains an internal material tension for exerting a compression force on the soft cannula ~~(10)~~ and the mounting structure ~~(31)~~.

10. Cannula system ~~(1)~~ according to claim 9, wherein only a distal end area ~~(11)~~ of the soft cannula ~~(10)~~ is threaded on the mounting structure ~~(31)~~ and wherein the compressing unit ~~(20)~~ circumferentially surrounds the distal end area ~~(11)~~ of the soft cannula ~~(10)~~.

11. Cannula system ~~(1)~~ according to claim 10, wherein the distal end area ~~(11)~~ of the soft cannula comprises a locking structure providing a form lock and/or an adhesive bond between the soft cannula ~~(10)~~ and the compressing unit ~~(20)~~.

12. Cannula system according to claim 10 or 11, wherein the locking structure includes at least one protrusion, preferably a collar ~~(12b)~~ arranged at the most distal part of the distal end area ~~(11)~~, protruding from the distal end area ~~(11)~~ and/or at least one hole ~~(12a)~~, preferably a through bore or a blind hole.

13. Cannula system ~~(1)~~ according to any of claims 10 to 12, wherein distal end area ~~(11)~~ of the soft cannula ~~(10)~~ has a larger diameter than the rest of the soft cannula ~~(10)~~.

14. Cannula system ~~(1)~~ according to any of claims 10 or 13, wherein the compressing unit ~~(20)~~ compresses at least the distal end area ~~(11)~~ of the soft cannula ~~(10)~~ and/or wherein the body unit ~~(30)~~ and the compressing unit ~~(20)~~ are connected by a bonded connection and/or wherein the soft cannula ~~(10)~~ and the compressing unit ~~(20)~~ are connected by a bonded connection.

15. Use of a cannula system according to any of claims 9 to 14 in an infusion set.