It is therefore desirable to provide an insertion system and a method for inserting a medical device into a body tissue of a user which at least partially address the above-mentioned technical challenges. Specifically, an insertion system is desirable which allows a safe and user-friendly handling of the insertion device while ensuring a reliable insertion of a medical device into a body tissue of a user.

Summary

This problem is addressed by an insertion system and a method for inserting a medical device into a body tissue of a user with the features of the independent claims. Advantageous embodiments which might be realized in an isolated fashion or in any arbitrary combinations are listed in the dependent claims as well as throughout the specification.

According to an aspect of the present invention, there is provided an insertion system, the insertion system comprising a medical device and an insertion device for inserting the medical device into a body tissue of a user, the insertion device comprising:

i) an insertion component configured for inserting the medical device into the body tissue;

ii) an insertion component retractor;

iii) a cap;

iv) a guide sleeve and an insertion sleeve guided therein;

v) a locking sleeve positioned in the insertion sleeve; and

vi) an elastic member positioned between the locking sleeve and the insertion component retractor;

wherein, for inserting the medical device, the cap, the insertion component retractor, the locking sleeve and the insertion sleeve are movable relative to the guide sleeve from a distal position to a proximal position, wherein the insertion device is separable from the medical device, wherein the insertion system is configured such that a separation of the insertion device from the medical device releases a movement of the locking sleeve from its proximal position to a further proximal position, and

wherein the movement of the locking sleeve from its proximal position to the further proximal position releases a movement of the insertion component retractor from its proximal position to a retracted position.

As used in the following, the terms “have”, “comprise” or “include” or any arbitrary grammatical variations thereof are used in a non-exclusive way. Thus, these terms may both refer to a situation in which, besides the feature introduced by these terms, no further features are present in the entity described in this context and to a situation in which one or

more further features are present. As an example, the expressions “A has B”, “A comprises B” and “A includes B” may both refer to a situation in which, besides B, no other element is present in A (i.e. a situation in which A solely and exclusively consists of B) and to a situation in which, besides B, one or more further elements are present in entity A, such as element C, elements C and D or even further elements.

Further, it shall be noted that the terms “at least one”, “one or more” or similar expressions indicating that a feature or element may be present once or more than once typically will be used only once when introducing the respective feature or element. In the following, in most cases, when referring to the respective feature or element, the expressions “at least one” or “one or more” will not be repeated, non-withstanding the fact that the respective feature or element may be present once or more than once.

Further, as used in the following, the terms "preferably", "more preferably", "particularly", "more particularly", "specifically", "more specifically" or similar terms are used in conjunction with optional features, without restricting alternative possibilities. Thus, features introduced by these terms are optional features and are not intended to restrict the scope of the claims in any way. The invention may, as the skilled person will recognize, be performed by using alternative features. Similarly, features introduced by "in an embodiment of the invention" or similar expressions are intended to be optional features, without any restriction regarding alternative embodiments of the invention, without any restrictions regarding the scope

of the invention and without any restriction regarding the possibility of combining the features introduced in such way with other optional or non-optional features of the invention.

In ~~a first aspect~~embodiments of the present invention, an insertion system is disclosed. The insertion system comprises a medical device and an insertion device for inserting the medical device into a body tissue of a user.

The term "system" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to a group of at least two elements which may interact with each other in order to fulfill at least one common function. The at least two components may be handled independently or may be coupled, connectable or integrable in order to form a common device. The term "insertion system" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to a group of at least two elements or components which are capable of interacting with each other in order to perform at least one transcutaneous or subcutaneous insertion of at least one of the two elements or components into a body tissue of a user, such as by performing an incision or a puncture in a skin of the user and by transferring the at least one of the two elements or components fully or partially into the body tissue.

The term "medical device" as used herein is a broad term and is to be given its ordinary and customary meaning to a person of ordinary skill in the art and is not to be limited to a special or customized meaning. The term specifically may refer, without limitation, to an arbitrary element or article being configured for use in the field of medical technology, specifically in the field of medical analytics or medical diagnostics. The medical device may be configured for performing at least one medical function and/or for being used in at least one medical process, such as one or more of a therapeutic process, a diagnostic process or another medical process.

The medical device may be configured to be mounted on a skin site of an extremity of the user. The extremity may be selected from the group consisting of: an arm, specifically an upper arm; a stomach; a shoulder; a back; hip; a leg. Specifically, the extremity may be the upper arm. However, also other applications may be feasible.

upper end against the insertion component retractor. The elastic member may specifically be the spring. The spring may be pre-tensioned, specifically before the insertion device is separated from the medical device. Further, the spring may be pre-tensioned before the medical device is inserted into the body tissue. The spring may specifically be trapped between the locking sleeve and the insertion component retractor as long as the medical device blocks the linear component of the helical movement of the locking sleeve, specifically relative to the insertion sleeve. The elastic member may be actuable by separating the insertion component from the medical device. Provided that the user applies the force to the cap, the elastic member may not be able to move the insertion component retractor from its proximal position to the retracted position. The elastic member may be configured for moving the insertion component retractor to its retracted position. Thereby the insertion component may be retracted into the insertion device.

As outlined above, the locking sleeve may comprise the at least one second locking sleeve slot. Further, as also outlined above, the insertion sleeve may comprise the at least one inward protrusion. The second locking sleeve slot may be configured for interacting with the inward protrusion. The rotational movement of the locking sleeve within the insertion sleeve may be blocked as long as the linear movement of the locking sleeve is blocked.

As outlined above, the insertion sleeve may comprise the holding elements. The housing may be held by the holding elements. The housing may be configured for blocking a movement of the locking sleeve in direction of the housing while the housing is held by the holding elements. Specifically, the movement of the locking sleeve in direction of the housing may be blocked if the medical device and the insertion device are connected. The housing may be configured for providing a pressure, specifically a counter-pressure on the locking sleeve. The insertion system may be configured for releasing the holding elements from the housing. The insertion device may be configured such that the separation of the insertion device from the medical device releases a movement of the locking sleeve in said direction. By separating the insertion device from the medical device, the pressure, specifically the counter pressure, on the locking sleeve may be lifted.

In ~~a further aspect~~embodiments of the present invention, a method for inserting a medical device using the insertion system as described above or as will further be described below in more detail is disclosed. Thus, for possible definitions and options, reference may be made to the disclosure of the insertion system according to the present invention.

The method comprises the following steps which specifically may be performed in the given order. The method may comprise further method steps which are not listed.

The method comprises:

a) applying the insertion device to a user's skin,

b) applying a force to the cap of the insertion device so that the cap moves from a distal position to a proximal position,

c) removing the insertion device from the user's skin, thereby separating the insertion device from the medical device, wherein the separation releases a movement of the locking sleeve from its proximal position to a further proximal position.

In step a), the guide sleeve, in particular the proximal end of the guide sleeve, may be set in contact with the user's skin, specifically at an insertion site. Thus, the guide sleeve may be applied to the skin site of the user.

In step b), the force to the cap may be applied by action of the user. By moving the cap from the distal position to the proximal position, the insertion sleeve, the locking sleeve, the insertion component retractor, the insertion component, the medical device and the elastic member may be moved relative to the guide sleeve from the distal position to the proximal position. During step b), the insertion component may be inserted into the body tissue of the user, thereby inserting the medical device into the body tissue of the user. The force may be applied by the user of the insertion device before and during the insertion of the insertion component into the body tissue.

During step c), the insertion component may be withdrawn from the body tissue of the user. By separating the insertion device from the medical device, a pressure of the medical device on the locking sleeve may be lifted. The locking sleeve moves from the proximal position to the further proximal position and releases the movement of the insertion component retractor from its proximal position to the retracted position.

In ~~a further aspect~~embodiments of the present invention, an insertion system is disclosed. The insertion system comprises a medical device and an insertion device for inserting the medical device into a body tissue of a user. The insertion device comprises:

i) an insertion component configured for inserting the medical device into the body tissue;

ii) an insertion component retractor;

iii) a cap;

Claims

1. An insertion system ~~(110)~~, the insertion system ~~(110)~~ comprising a medical device ~~(112)~~ and an insertion device ~~(113)~~ for inserting the medical device ~~(112)~~ into a body tissue of a user, the insertion device ~~(113)~~ comprising:
   i) an insertion component ~~(118)~~ configured for inserting the medical device ~~(112)~~ into the body tissue;
   ii) an insertion component retractor ~~(120)~~;
   iii) a cap ~~(122)~~;
   iv) a guide sleeve ~~(124)~~ and an insertion sleeve ~~(128)~~ guided therein;
   v) a locking sleeve ~~(126)~~ positioned in the insertion sleeve ~~(128)~~; and
   vi) an elastic member ~~(130)~~ positioned between the locking sleeve ~~(126)~~ and the insertion component retractor ~~(120)~~;

   wherein, for inserting the medical device ~~(112)~~, the cap ~~(122)~~, the insertion component retractor ~~(120)~~, the locking sleeve ~~(126)~~ and the insertion sleeve ~~(128)~~ are movable relative to the guide sleeve ~~(124)~~ from a distal position to a proximal position, wherein the insertion device ~~(113)~~ is separable from the medical device ~~(112)~~, wherein the insertion system ~~(110)~~ is configured such that a separation of the insertion device ~~(113)~~ from the medical device ~~(112)~~ releases a movement of the locking sleeve ~~(126)~~ from its proximal position to a further proximal position, and
   wherein the movement of the locking sleeve ~~(126)~~ from its proximal position to the further proximal position releases a movement of the insertion component retractor ~~(120)~~ from its proximal position to a retracted position.

2. The insertion system ~~(110)~~ according to claim 1, wherein the movement of the locking sleeve ~~(126)~~ from its proximal position to the further proximal position is a helical movement of the locking sleeve ~~(126)~~.

3. The insertion system ~~(110)~~ according to any one of claims 1 or 2, wherein the locking sleeve ~~(126)~~ comprises at least one first locking sleeve slot ~~(240)~~, wherein the insertion component retractor ~~(120)~~ comprises at least one wing ~~(136)~~ and wherein the insertion sleeve ~~(128)~~ comprises at least one insertion sleeve slot ~~(186)~~.

4. The insertion system ~~(110)~~ according to claim 3, wherein for inserting the medical device ~~(112)~~ the wing ~~(136)~~ is configured for protruding through the first locking

sleeve slot ~~(240)~~ and for engaging the insertion sleeve slot ~~(186)~~, thereby blocking a movement of the insertion component retractor ~~(120)~~.

5. The insertion system ~~(110)~~ according to any one of claims 3 or 4, wherein the first locking sleeve slot ~~(240)~~ is z-shaped.

6. The insertion system ~~(110)~~ according to any one of claims 3 to 5, wherein the first locking sleeve slot ~~(240)~~ has at least one inclined surface configured for blocking movement of the insertion component retractor ~~(120)~~.

7. The insertion system ~~(110)~~ according to any one of claims 3 to 6, wherein a rotational movement of the locking sleeve ~~(126)~~ within the insertion sleeve ~~(128)~~ causes at least partial alignment of the first locking sleeve slot ~~(240)~~ and the insertion sleeve slot ~~(186)~~ such that the wing ~~(136)~~ of the insertion component retractor ~~(120)~~ is movable, wherein the elastic member ~~(130)~~ is configured for moving the insertion component retractor ~~(120)~~ to its retracted position, thereby the insertion component ~~(118)~~ is retracted into the insertion device ~~(113)~~.

8. The insertion system ~~(110)~~ according to claim 7, wherein the locking sleeve ~~(126)~~ comprises at least one second locking sleeve slot ~~(242)~~, wherein the insertion sleeve ~~(128)~~ comprises at least one inward protrusion ~~(202)~~, wherein the second locking sleeve slot ~~(242)~~ is configured for interacting with the inward protrusion ~~(202)~~, wherein a rotational movement of the locking sleeve ~~(126)~~ within the insertion sleeve ~~(128)~~ is blocked as long as a linear movement of the locking sleeve ~~(126)~~ is blocked.

9. The insertion system ~~(110)~~ according to any one of claims 1 to 8, wherein the elastic member ~~(130)~~ comprises at least one spring ~~(252)~~.

10. The insertion system ~~(110)~~ according to claim 9, wherein the spring ~~(252)~~ is pre-tensioned.

11. The insertion system ~~(110)~~ according to any one of claims 1 to 10, wherein the medical device ~~(112)~~ comprises a housing ~~(232)~~ and the insertion sleeve ~~(128)~~ comprises holding elements ~~(228)~~, wherein the housing ~~(232)~~ is held by the holding elements ~~(228)~~, wherein the housing ~~(232)~~ is configured for blocking movement of the locking sleeve ~~(126)~~ in direction of the housing ~~(232)~~ while the housing ~~(232)~~ is held by the holding elements ~~(228)~~.

12. The insertion system ~~(110)~~ according to any one of claims 1 to 11, wherein the medical device ~~(112)~~ comprises at least one device selected from the group consisting of an analyte sensor ~~(114)~~ for detecting at least one analyte in a body fluid of a user and an infusion cannula.

~~13. A method for inserting a medical device (112) using the insertion system (110) according to any one of claims 1 to 12, the method comprising the steps:~~

~~a) applying the insertion device (113) to a user's skin,~~

~~b) applying a force to the cap (122) of the insertion device (113) so that the cap (122) moves from a distal position to a proximal position,~~

~~c) removing the insertion device (113) from the user's skin, thereby separating the insertion device (113) from the medical device (112), wherein the separation releases a movement of the locking sleeve (126) from its proximal position to a further proximal position.~~