assembly with a reusable inserter is described in US9883888B2 disclosing a sensor cartridge with a sterile capsule comprising a needle as well as a retracting mechanism.

[0005] The Patent US10945649B2 discloses a reusable insertion assembly, wherein the insertion assembly is configured to receive a needle hub and a sensor hub, which are transferred to the inserter with the help of a carrier. The carrier may also be used to remove the needle hub from the inserter after insertion of the sensor, but the carrier is neither keeping the needle in a sterile environment before transferring the needle to the inserter nor sealing it when used for removal of the needle.

[0006] A further insertion assembly with a reusable insertion gun is known from US6579690B1.

[0007] The US10737021B2 discloses inserter for inserting a part of a medical system, such as a cannula of an insulin pump, wherein the needle is capsuled in an inner housing before it is inserted into the inserter.

[0008] The reusable design of an insertion device does have the advantage of a reduced amount of waste per application. This advantage comes at the cost of a higher effort regarding production as well as during use as the user has first to prepare the inserter assembly before using.

[0009] The US20210052302A1 discloses a disposable biosensor inserter assembly with a carrier for the bio sensor, an insertion device and a retraction mechanism positioned inside a housing consisting. After insertion the retraction mechanism prevents reinsertion of the insertion device fixedly positioning the insertion device within the housing. The housing may be formed of recyclable or biodegradable or compostable material.

[0010] The advantage of the completely disposable design is the lower effort and more convenient handling for the user but the produced garbage and the effort of disposing the inserter device are typically higher.

SUMMARY

[0011] The disadvantages of the prior art are addressed by providing a mechanism to separate recyclable or biodegradable parts of an insertion device from encapsulated sharp and/or contaminated parts after use of the insertion device. The disadvantages are resolved by an apparatus, a kit and a method for inserting at least a part of a medical device into a subject with the features of the independent claims. Advantageous examples which might be realized in an isolated fashion or in any arbitrary combinations are listed in the dependent claims, in the list of examples and throughout the specification.

[0012] 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 all 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.

[0013] 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.

[0014] 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 present disclosure may, as the skilled person will recognize, be performed by using alternative features. Similarly, features introduced by "in an embodiment of the present disclosure" or “in an example of the present disclosure”, or similar expressions are intended to be optional features, without any restriction regarding alternative examples of the present disclosure, without any restrictions regarding the scope of the present disclosure and without any restriction regarding the possibility of combining the features introduced in such way with other optional or non-optional features of the present disclosure.

[0015] According to an aspect of the present disclosure, there is provided an insertion device for inserting at least a part of a medical device into a subject. The insertion device comprises a chamber for receiving the medical device, an insertion tool for inserting the medical device or an insertable portion of the medical device, an insertion mechanism for penetrating the insertion tool into the subject and therewith inserting

the medical device or the insertable portion of the medical device into the subject, a retraction mechanism for retracting the insertion tool from the subject into an end position after insertion, a retaining mechanism for retaining the insertion tool in the

end position after retraction, an inner housing comprising the retaining mechanism and the retracted insertion tool in the end position, and an inserter housing comprising the insertion mechanism as well as the inner housing. The inserter housing is formed of recyclable or biodegradable or compostable material. Furthermore, the insertion device comprises an ejection mechanism to remove the inner housing from the inserter housing when the insertion tool is retained within the inner housing by the retaining mechanism, and the ejection mechanism is activatable by the user.

[0016] The term “insertion device” refers to a device configured for inserting the medical device fully or partially into the body tissue. The insertion device may be configured for transcutaneously or subcutaneously inserting the medical device or a part of the medical device into the body tissue, such as by performing an incision or a puncture in a skin of the user and by transferring the medical device fully or partially into the body tissue.

[0017] The term “inserting” refers to an action or process of one or more of transcutaneously or subcutaneously implanting and/or positioning the medical device into the body tissue of the user. The medical device, such as the analyte sensor or a drug delivery device, may fully or partially be inserted into the body tissue. The insertion of the medical device may be performed by using the insertion device. After insertion, the medical device or at least a part of the medical device may remain in the body tissue of the user for a predetermined period of time, such as for several hours, or days or weeks.

[0018] The term “medical device” refers 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.

[0019] For example, the medical device may comprise at least one of: a device for delivery of at least one therapeutic fluid, for example insulin, into the body tissue of the user, specifically at least one infusion set comprising at least one infusion cannula; at least one analyte sensor for detecting at least one analyte, for example blood glucose or a pH value; specifically at least one analyte sensor for detecting at least one bodily analyte in the at least one bodily fluid, more specifically at least one electrochemical analyte sensor comprising at least one sensor electrode for detecting the at least one analyte.

[0020] "Chamber" for receiving the medical device refers to a void or cavity within the insertion device in which the medical device may be positioned before an insertion step. The chamber may, for example, be a void within the inner housing or a void within the inserter housing next to the inner housing. In some examples, the chamber comprises holding means holding or fixing the medical device within the chamber before the insertion, and releasing the medical device during or after the insertion step.

[0021] "Insertion tool" refers to a sharp or at least solid member suitable to enter the skin for inserting a medical device, such as needle or cannula with a hollow tube and a sharp tip. The insertion tool is considered as part of the insertion device. However, in particular during manufacturing of the insertion device, the insertion tool may also be considered as a part of the medical device. For example, the insertable part of the medical device such as a sensor and/or sensor electrodes may be positioned within the insertion tool, e.g. a needle with a longitudinal slit

[0022] "Insertion mechanism" refers to a mechanism and/or components for inserting the medical device fully or partially into the body tissue. In other words the insertion mechanism is arranged to move the medical device from a first position, a proximal position, to a second position, a distal position, wherein in the first position the medical device is completely located within the insertion device, e.g. at a proximal end of the insertion device, and in the second position at least a part of the medical device is located outside of the insertion device, e.g. protruding from a distal opening of the insertion device. The movement may be caused by a force exerted by the user and/or a spring or the like.

[0023] In some examples, the medical device comprises an on-body-unit and a sensor protruding from a lower surface of the on-body-unit wherein in the second position the on-body-unit is positioned at a distal end of the insertion device so that the lower surface of the on-body-unit is located within the distal opening of the insertion device and the sensor protrudes the insertion devices.

[0024] The inserter housing may be comprised of one or two or more parts. For example the inserter housing comprises an insertion cap and a contact sleeve wherein the insertion cap may be part of the insertion mechanism. For example, the insertion cap is movable relative to the contact sleeve moving or pushing the medical device from the proximal position within the contact sleeve to a distal position wherein the medical device at least partially protrudes a distal opening of the contact sleeve.

[0025] "Retraction mechanism" refers to a mechanism and/or one or more components for retracting the insertion tool from the body tissue of the user after the insertion of the medical device, i.e. a mechanism moving the insertion tool from the distal position at least partially protruding the insertion device to a proximal position inside the insertion device, the end position. The insertion tool may be retracted deeply into the needle housing of the insertion device to minimize the infection risk. The retraction of the insertion tool may be initiated by the user or automatically after an insertion movement of the insertion tool into the skin.

[0026] "End position" refers to a position the insertion tool reaches after retraction, in which the insertion tool is fully comprised within the inner housing.

[0027] "Retaining mechanism" refers to a mechanism and/or one or more components for retaining the insertion tool within the insertion device after the insertion tool has been retracted by the retraction mechanism. In some examples, the retaining mechanism comprises locking means to fix the insertion tool in the position reached after the insertion tool has been retracted by the retraction mechanism.

[0028] The "inner housing" refers to a housing that at least comprises the retaining mechanism as well as the insertion tool in the end position reached after retraction and that prevents any further contact with the insertion tool. The inner housing is encapsulating the insertion tool thus the sharp and contaminated parts guaranteeing a safe handling of the insertion tool when disassembling the insertion device.

[0029] "Recyclable or biodegradable or compostable material" refers to any materials that after use may be converted into new material, or may be biodegraded, thus broken down by microorganisms, such as bacteria and fungi, or may be composted.

[0030] "Ejection mechanism" refers to a mechanism, i.e. one or more components, configured to disassemble the insertion device, and in particular to separate the inner housing from the rest of the inserter medical device, in particular from the inserter housing. That way the insertion tool may be safely disposed and the rest of the insertion device, in particular the inserter housing, may be recycled or composted thereby significantly reducing the environmental burden of the overall system.

[0031] "Activatable" refers to being configured to activate and/or trigger a function, e.g. to trigger a mechanism such as the ejection mechanism to operate. With the ejection mechanism being activatable by the user, the user may determine the point in time the insertion device is disassembled.

[0032] An advantage of the inventive insertion device is the improved sustainability due to using recyclable material where possible. A further advantage is the safety and easy handling that is maintained due to the inventive concept of encapsulating any sharp and/or contaminated parts and providing a mechanism to easily and safely disassemble the different portions of the inventive insertion device. No extra tools are necessary and there is no risk of contacting the sharp.

[0033] The insertion device may also include where the ejection mechanism is configured to withdraw at least one fastener from a stop position.

[0034] “Fastener” refers to a device and/or a means for fixing a component in a defined position. A fastener such as a pin may be an easy way of securing the inner housing in a fixed position within the inserter housing during use. The ejection mechanism may then comprise at least one tool, part and/or mechanism to move the fastener from the first position, also referred to as stop position, securing the inner housing to a second position, wherein the inner housing may freely move relative to the inserter housing when the fastener is in the second position. The inner housing may then be unhinged from the inserter housing, e.g. by shear force.

[0035] The insertion device may also include where for activating the ejection mechanism the inserter housing includes at least one push button.

[0036] In another example, the ejection mechanism further comprises a securing device that has to be removed and/or activated to be able to push the push button to prevent unintentional activation of the ejection mechanism. In an alternative example, the ejection mechanism comprises two push buttons that have to be pushed simultaneously to activate the ejection mechanism. Other security measures may be comprised by the ejection mechanism to prevent unintentional activation of the ejection mechanism and/or to prevent an activation of the ejection mechanism before an insertion process has occurred, i.e. before the insertion tool has been inserted, retracted and retained in the end position by the corresponding mechanisms.

[0037] The insertion device may also include at least one opening to at least partially insert an activation tool into the inserter housing for activating the ejection mechanism. "Activation tool" refers to any part or component configured to trigger the ejection mechanism. For example, the activation tool may comprise a stick-like part that may be inserted through the opening to activate the ejection mechanism.

[0038] Therewith, the ejection mechanism may be fully retrieved within the housing, reducing or suspending the risk of inadvertent actuation.

[0039] The insertion device may also include where the insertion device includes a removable component forming the activation tool when removed from the insertion device.

[0040] For example, a part of the inserter housing may comprise an elongated part, such as a stick or finger or the like, which may be easily removed from the insertion device, i.e. Form the removable component, and function as activation tool.

[0041] The insertion device may also include where the removable component of the insertion device is a sealing cap or part of a sealing cap.

[0042] "Sealing cap" or safety cap refers to a cap that covers a distal opening of the insertion device as long as the insertion device is not used. The sealing cap may comprise an elongated part protruding from the sealing cap after it is removed from the insertion device, e.g. by pulling or rotating the cap relative to the rest of the insertion device.

[0043] The insertion device may also include where the at least one opening of the inserter housing is sealed by a removable or breakable cover.

[0044] For example, the opening may be sealed with an adhesive label which may be removed or pierced by the activation tool. The cover may help to improve the hygiene preventing any contamination to enter via the opening.

[0045] The insertion device may also include where the chamber for receiving the medical device is comprised by the inner housing.

[0046] Another alternative is to position the medical device within a chamber within the inserter housing that is not comprised by the inner housing.

[0047] There is disclosed a kit that includes the insertion device of any of the above aspect or examples of the present disclosure and a medical device.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0048] The above-mentioned aspects of exemplary embodiments will become more apparent and will be better understood by reference to the following description of the embodiments taken in conjunction with the accompanying drawings wherein:

[0049] FIG. 1 schematically illustrates an insertion device in accordance with a first embodiment.

[0050] FIG. 2 schematically illustrates an insertion device in accordance with a second embodiment.

CLAIMS

What is claimed is:

1. An insertion device (102, 202, 302, 502, 602) for inserting at least a part of a medical device (310, 606) into a subject comprising:

- a chamber (110, 206) for receiving the medical device (310, 606),
- an insertion tool (312, 608, 704, 804) for inserting the medical device (310, 606) or an insertable portion of the medical device (310, 606),
- an insertion mechanism for penetrating the insertion tool (312, 608, 704, 804) into the subject and therewith inserting the medical device (310, 606) or the insertable portion of the medical device (310, 606) into the subject,
- a retraction mechanism (316) for retracting the insertion tool (312, 608, 704, 804) from the subject into an end position after insertion,
- a retaining mechanism (722, 806) for retaining the insertion tool (312, 608, 704, 804) in the end position after retraction,
- an inner housing (104, 204, 308, 710, 802) comprising the retaining mechanism (722, 806) and the retracted insertion tool (312, 608, 704, 804) in the end position, and
- an inserter housing (106, 304, 506, 604, 712) comprising the insertion mechanism as well as the inner housing (104, 204, 308, 710, 802),

wherein

- the inserter housing (106, 304, 506, 604, 712) is formed of recyclable or biodegradable or compostable material,
- the insertion device (102, 202, 302, 502, 602) comprises an ejection mechanism (318) to remove the inner housing (104, 204, 308, 710, 802) from the inserter housing (106, 304, 506, 604, 712) when the insertion tool (312, 608, 704, 804) is retained within the inner housing (104, 204, 308, 710, 802) by the retaining mechanism (722, 806), and
- the ejection mechanism (318) is activatable by the user.

2. The insertion device of claim 1, wherein the ejection mechanism (318) is configured to withdraw at least one fastener (718) from a stop position.

3. The insertion device of claim 2, wherein for activating the ejection mechanism (318) the inserter housing (106, 304, 506, 604, 712) comprises at least one push button.

4. The insertion device of claim 2, at least one opening to at least partially insert an activation tool into the inserter housing (106, 304, 506, 604, 712) for activating the ejection mechanism (318).

5. The insertion device of claim 4, wherein the insertion device (102, 202, 302, 502, 602) comprises a removable component forming the activation tool when removed from the insertion device (102, 202, 302, 502, 602).

6. The insertion device of claim 5, wherein the removable component of the insertion device (102, 202, 302, 502, 602) is a sealing cap or part of a sealing cap (306, 402, 504).

7. The insertion device of any one of claims 4 to 6, wherein the at least one opening of the inserter housing (106, 304, 506, 604, 712) is sealed by a removable or breakable cover.

8. The insertion device of any one of claims 1 to 6, wherein the chamber for receiving the medical device (310, 606) is comprised by the inner housing (104, 204, 308, 710, 802).

9. A Kit comprising the insertion device of any of the preceding claims and a medical device (310, 606).