[0011] This problem is addressed by an insertion tool of the independent claim. Advantageous examples 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.

[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 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.

[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 disclosure may, as the skilled person will recognize, be performed by using alternative features. Similarly, features introduced by "in an example of the disclosure" or similar expressions are intended to be optional features, without any restriction regarding alternative examples of the disclosure, without any restrictions regarding the scope of the 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 disclosure.

[0014A] In accordance with an aspect of the disclosure, there is provided an insertion tool for inserting at least a part of a medical device into a subject. The insertion tool includes a penetrating portion including a composite material, the composite material including a first material and a second material. The first material is an amorphous material or amorphous composite. The second material is a fibrillary material or fibrillary composite or a crystalline material or crystalline composite. A fluid absorption of the first material of the composite material is higher than a fluid absorption of the second material of the composite material. The insertion device is adapted to soften when in contact with a body fluid at least due to the fluid absorption of the amorphous material or amorphous composite.

[0015] In an example of the disclosure, an insertion tool for inserting at least a part of a medical device into a subject is disclosed, wherein at least a penetrating portion of the insertion tool softens when in contact with a body fluid at least due to fluid absorption.

[0016] "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.

[0017] 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.

[0018] "Insertion tool" refers to member suitable to enter a subject's skin for being inserted. “Insertion tool” may, for example, refer to a needle-like or tube-like structure having a sharp or solid tip or the like when being inserted. The insertion tool or at least a part of the insertion tool may be part of the medical device, e.g., the insertion tool may be a cannula or a distal part of a cannula for drug administration. In another example the insertion

tool may form a substrate or bases for the medical device or a part of the medical device or the insertion tool may receive the medical device or a part of the medical device for insertion of the medical device. The insertion tool may insert the whole medical device or a portion or part of the medical device. Inserting a portion of the medical device may comprise positioning a non-insertable part of the medical device onto the skin of the subject.

[0019] "Penetrating portion" refers to a tip portion of the insertion tool, i.e., the distal part of the insertion tool adapted to enter a subject's skin during an insertion process.

[0020] The insertion tool may be inserted manually or using an insertion device, wherein "Insertion device" refers to a device configured for inserting the insertion tool and therewith the medical device fully or partially into the body tissue, i.e., comprising an insertion

mechanism to insert the insertion tool. The insertion device may be configured for transcutaneously or subcutaneously insertion of the insertion tool, such as by pushing the penetrating portion of the insertion tool into the body tissue of the user by performing an incision or a puncture in the skin.

[0021] "Fluid absorption" refers to a physical and/or chemical or reactive phenomenon or process in which a fluid, i.e., the fluids molecules, atoms and ions, is taken up or retained by another material, i.e., enters the bulk phase of the other material, e.g. a solid material.

[0022] In another example of the disclosure, the penetrating portion comprises a composite material that includes at least one first material and at least one second material, wherein the first material is an amorphous material or amorphous composite, the second material is a fibrillary material or fibrillary composite or a crystalline material or crystalline composite, and wherein a fluid absorption of the first material of the composite material is higher than a fluid absorption of the second material of the composite material. In other words, the composite material comprises a first portion consisting of one or more amorphous material or amorphous composites and a second portion consisting of one or more fibrillary material or fibrillary composites and/or crystalline material or crystalline composites. By combining the fibrillary or crystalline material or crystalline composite or a group of fibrillary and/or crystalline material or crystalline composites with an amorphous material or amorphous composite or a group of amorphous material or amorphous composites a composite is created that shows a high rigidity in ambient, i.e. dry, conditions due to its portion of fibrillary and/or crystalline material(s) and softens when exposed to a fluid due to fluid absorption which is enhanced due to its portion of amorphous material or amorphous composite(s) or materials.

[0023] "Composite material" or “composition material” or “composite” refers to a material which comprises at least a first material and a second material as constituent materials, wherein the two or more constituent materials have notably dissimilar chemical or physical properties and are merged to form a finished structure in which they remain separate and distinct. In other words, the starting materials are connected to each other but a solution of the individual starting materials with one another does not take place or only takes place superficially. For Example, particles or fibers of a first component are embedded in another

[0028] While the crystalline or fibrillary material or fibrillary composite portion is characterized by a certain hardness giving the insertion tool stability, the amorphous material or amorphous composite portion allows the absorption of a greater amount liquid or fluid, in particular of a body fluid, and thus the softening of the insertion tool. Thus, in normal ambient conditions, i.e. average humidity, temperature, pressure etc., the penetrating portion of the insertion tool is in a rigid or stiff state and therewith adapted to puncture or prick a subject's skin for insertion of the medical device. After being inserted, the penetrating portion softens due to the absorption of the surrounding body fluid. Therewith, the insertion tool may remain within the subject's skin for the whole time the medical device is left on and/or in the subject's skin without causing any discomfort or pain. A retraction of the insertion tool while dissembling from the medical device and leaving the medical device inserted is not necessary, thus, significantly simplifying the insertion process and the requirements to an insertion device, if used.

[0029] The fluid absorption of a material, i.e., the ability to absorb a certain amount of fluid depends for example on the inner structure of the material. For example, the water absorption of a material and thus its softening properties may depend primarily on an amount of cross-linking monomeric components within the material, such as disulfides, also called disulfide bridges or ss-bonds and does not depend on a degradation of the respective material. Furthermore, the softening properties due to fluid absorption are reversible upon drying, e.g., after retraction of the insertion tool.

[0030] In an example, a fluid absorption of the first material of the composite material is at least 70% of its weight in a dry state and the fluid absorption of the second material of the composite material is at most 35% of its weight in the dry state.

[0031] "Dry state" refers a first state of the first and second material when it is surrounded by air or another gas with an at least non-condensing relative humidity and/or a humidity falling below a threshold. For example, the dry state may be reached for ambient dry conditions, i.e., for air with an average humidity, temperature, pressure, etc. and not directly in contact with a fluid or tissue or the like. In another example, the dry state may be reached for air with a lower humidity, e.g., with a humidity reduced and or controlled by desiccants or the like that are added to a packaging of the insertion tool. The dry state of the

first and second material, respectively, may be defined by an overall water content of the material such as for example 10wt% water overall, i.e., in the dry state a mass fraction of 10% of the overall or total mass of the material is water.

[0032] In the example the amorphous material or amorphous composite portion is adapted to absorb, i.e., to take up, at least an amount of water corresponding to 70% of its weight in the dry state, i.e., of the amorphous material or amorphous composite portion's weight in the dry state. Correspondingly the crystalline or fibrillary material or fibrillary composite portion is adapted to absorb at most an amount of water corresponding to 35% of its weight in the dry state, i.e., of the crystalline or fibrillary material or fibrillary composite portion's weight in the dry state.

[0033] In another example, the fluid absorption of the first material of the composite material is at least 60% or at least 65% or at least 75% or at least 80% of its weight in a dry state. The fluid absorption of the amorphous material or amorphous composite portion of the composite material allows for the softening of the penetrating portion.

[0034] In a further example the fluid absorption of the second material of the composite material is at most 40% or at most 30% or at most 25% of its weight in the dry state. The second material portion of the composite material allows for the penetrating portion's rigidity in ambient conditions to enable the penetration of a subject's skin. A low ability to

[0035] In an example, a weight percent (wt%) of first material and second material with regard to the composite material in a dry state are equal or 20/80 or 80/20, i.e., the portion of the weight of the composite material in the dry state of the first material is at least 20% and at most 80%, while the portion of the weight of the composite material in the dry state of the second material is at most 80% and at least 20%.

[0036] In another example, the first material and the second material are homogeneously distributed within the composite material or are at least in parts structured.

[0037] In an example, a distribution of the second material within the composite material of the insertion tool is oriented along a longitudinal axis of the insertion tool.

[0038] The longitudinal axis typically points in the direction of insertion. With the second crystalline or fibrillary material or fibrillary composite proceeding along the longitudinal

axis, i.e., the direction of insertion, the penetrating portion's stability in the direction of insertion may be increased.

[0039] In another example, the first material and/or the second material is a biopolymer. "Biopolymer" refers to natural polymers produced by the cells of living organisms. For example, fibrin or keratin. A biopolymer may help to increase the biocompatibility of the composite material, i.e., of the penetrating portion, wherein here biocompatibility refers to the ability of a material to perform with an appropriate host response, e.g., to reduce an immune response in the subject when implanted. In other words, the biocompatibility refers to the quality of not having toxic or injurious effects on biological systems.

[0040] In a further example, the first material and/or second material is keratin. Keratin is an example of a biopolymer and has the properties of biocompatibility, biodegradability, bioactivity and it possesses a hydrophilic surface, which is absent in many synthetic polymers and enhances its capacity to absorb a fluid. Keratin is a fibrous protein that for example is a key structural material of hair, nails, horns, claws, and hooves.

[0041] In another example, the first material is keratin and the first material in a dry state contains at least 10 wt% cysteine. "Cysteine" refers to a sulfur-containing proteinogenic amino acid with the formula HOOC-CH(-NH_2)-CH_2-SH and is typically present in keratin in large amounts forming so called disulfide bridges and therewith conferring additional strength and rigidity by permanent, thermally stable crosslinking. "Disulfide bridge" refers to a covalent link between the Sulphur atoms of two cysteine amino acids and their formation stabilizes the tertiary and higher order structure of proteins. Disulfides in proteins are formed between the thiol groups of cysteine residues by the process of oxidative folding. The prototype of a protein disulfide bond is the two-amino-acid peptide cystine, which is composed of two cysteine amino acids joined by a disulfide bond. The structure of a disulfide bond can be described by its χ_{ss} dihedral angle between the $C^{\beta}–S^{\gamma}–S^{\gamma}–C^{\beta}$ atoms, which is usually close to ±90°. In another example the first material contains in the dry state at least 15 wt% cysteine or at least 20 wt% cysteine.

[0042] In a further example, the first material contains a first amount of a first cross-linking monomeric component or of different types of cross-linking monomeric

components, and the second material comprises a second amount of a second cross-linking monomeric

component or of different types of cross-linking monomeric components, wherein the first amount is smaller than the second amount. Each amount may be between to 0wt% or 100wt% with regard to dry state. The first and second cross-linking monomeric component may be identical, e.g., disulfide bridges. Via the amount of cross-linking monomeric components the water absorption capacity and therewith the softening properties may be controlled, e.g., chosen beforehand when manufacturing the penetrating portion of the medical device.

[0043] In an example, the first cross-linking monomeric component and/or the second cross-linking monomeric component is cysteine.

[0044] In another example, the first material comprises a first amount of disulfide, the second material comprises a second amount of disulfide, wherein the first amount is smaller than the second amount. The amount of disulfide bridges my for example be controlled by the amount of a cross-linking monomeric component, e.g., cysteine, as the cross-linking monomeric components, like cysteine, are required to form the disulfide bridges.

[0045] In an example, the penetrating portion is adapted to have a rigid state and a soft state, in the rigid state an overall fluid content of the composite material of the penetrating portion is at most 10wt% or at most 20wt% and in the soft state an overall fluid content of the composite material of the penetrating portion is at least 50wt% or at least 60wt%.

[0046] In another example, an insertion device comprising an insertion tool as descried above, and an insertion mechanism for penetrating the insertion tool into the subject and therewith inserting the medical device or the portion of the medical device into the subject.

[0047] "Insertion device" refers to a device configured for inserting the insertion tool and therewith the medical device fully or partially into the body tissue, i.e., comprising an insertion mechanism to insert the insertion tool. The insertion device may be configured for transcutaneously or subcutaneously insertion of the insertion tool, such as by pushing the penetrating portion of the insertion tool into the body tissue of the user by performing an incision or a puncture in the skin.

[0048] In another example, a medical device comprises an insertion tool as described above.

[0049] In a further example, a method for manufacturing an insertion tool as described above, comprises the steps of preparing the first material with a first amount of one or more cross-

CLAIMS

What is claimed is:

1. An insertion tool for inserting at least a part of a medical device into a subject, wherein

- the insertion tool comprises a penetrating portion comprising a composite material, the composite material comprising a first material and a second material, wherein

- the first material is an amorphous material or amorphous composite,

- the second material is a fibrillary material or fibrillary composite or a crystalline material or crystalline composite,

- a fluid absorption of the first material of the composite material is higher than a fluid absorption of the second material of the composite material, and

- the insertion device is adapted to soften when in contact with a body fluid at least due to the fluid absorption of the amorphous material or amorphous composite.

2. The insertion tool of claim 1, wherein a fluid absorption of the first material of the composite material is at least 70% of its weight in a dry state and the fluid absorption of the second material of the composite material is at most 35% of its weight in the dry state.

3. The insertion tool of claim 1 or 2, wherein a weight percent (wt%) of first material and second material with regard to the composite material in a dry state are equal or 20/80 or 80/20.

4. The insertion tool of any one of claims 1 to 3, wherein the first material and the second material are homogeneously distributed within the composite material or are at least in parts structured.

5. The insertion tool of any one of claims 1 to 4, wherein a distribution of the second material within the composite material of the insertion tool is oriented along a longitudinal axis of the insertion tool.

6. The insertion tool of any one of claims 1 to 5, wherein the first material and/or the second material is a biopolymer.

7. The insertion tool of any one of claims 1 to 6, wherein the first material and/or second material is keratin.

8. The insertion tool of any one of claims 1 to 7, the first material is keratin and the first material in a dry state contains at least 10 wt% cysteine.

9. The insertion tool of any one of claims 1 to 8, wherein the first material contains a first amount of a first cross-linking monomeric component or of different types of cross-linking monomeric components, and the second material comprises a second amount of a second cross-linking monomeric component or of different types of cross-linking monomeric components, wherein the first amount is smaller than the second amount.

10. The insertion tool of claim 9, wherein the first cross-linking monomeric component and/or the second cross-linking monomeric component is cysteine.

11. The insertion tool of any one of claims 1 to 10, wherein the first material comprises a first amount of disulfide, the second material comprises a second amount of disulfide and the first amount is smaller than the second amount.

12. The insertion tool of any one of claims 1 to 11, wherein the penetrating portion is adapted to have a rigid state and a soft state, wherein in the rigid state an overall fluid content of the composite material of the penetrating portion is at most 10wt% or at most 20wt% and in the soft state an overall fluid content of the composite material of the penetrating portion is at least 50wt% or at least 60wt%.

13. An insertion device comprising:

- the insertion tool of any one of the previous claims,
- an insertion mechanism for penetrating the insertion tool into the subject and therewith inserting the medical device or the portion of the medical device into the subject.

14. A medical device comprising the insertion tool of any one of claims 1 to 12.

15. A method for manufacturing the insertion tool of any one of claims 1 to 12, wherein the first material is prepared with a first amount of one or more cross-linking monomeric

components and the second material is prepared with a second amount of one or more cross-linking monomeric components.