Single-use container with 3D printed functional element, printing method therefor and assembly

The invention relates to a single-use container, for example a single-use bioreactor, a method for producing this container and an assembly for producing items, particularly a single-use container and/or elements thereof. The invention is specifically related to the fields of biotechnology, bioprocessing, chemical and/or biological plant construction, food and beverage processing and/or chemical technology. The invention is particularly related to fluid management in biopharmaceutical industry.

In the production of items such as single-use containers, being comprised of single elements which are produced independently from each other, usually a production step of connecting single elements with each other is required, such as welding and/or gluing and/or mounting for example. Typically, elements comprise protruding portions and/or areas which extend from the main body of an element to provide a surface which may be an excess surface to which glue can be applied or at which a step of welding can be performed. In **Fig. 1a**, an example of a conventional production procedure is illustrated and discussed further below.

For example, EP1778828B1 discloses a bioreactor, comprising a reactor vessel embodied as a bag, wherein a receiving port is arranged at an upper side of the reactor bag and is provided with a flange piece tightly sealed to a vessel wall. A sensor piece is to be connected to the flange piece via a tubular connector piece in such a way that the sensor piece reaches into the reactant from above. Further, EP2707694A1 discloses a single-use bag having a flexible wall comprising a fixation flange for fixing a sensor head to the flexible wall of the single-use bag. The fixation flange may be set to the flexible wall by being adhesive-bonded, welded, screwed, clamped or latched thereto.

There is a need for increasing the degree of versatility of a single-use container, a method for producing this container and an assembly for

producing items, particularly in view of the number of materials which may be connected and the arrangement of functional elements on a single-use bag.

Summary

According to an aspect, the present disclosure refers to a single-use container, particularly a single-use bag such as a single-use bioreactor, comprising: a base material; and at least one functional element being at least partially, preferably permanently connected with the base material, wherein the functional element is obtained by a three dimensional printing technique from at least one printable material, wherein the printable material and/or the base material is heated during the three dimensional printing thereby at least partly connecting the printed functional element to the base material.

According to another aspect, the present disclosure refers to a method of producing a single-use container by producing a functional element and connecting the functional element with a base material of the container, comprising the steps of: providing the base material; three dimensional printing of the functional element from a printable material on a surface of the base material; and connecting at least a portion of the functional element with at least a portion of the base material by supplying heat to the printable material and/or the base material simultaneously to and/or prior to at least an interval of the step of three dimensional printing.

According to yet another aspect, the present disclosure refers to an assembly device for producing a functional element and connecting the functional element with a base material to produce a single-use container, comprising: a three dimensional printing device for printing a functional element on a surface of the base material; and at least one heating device for supplying heat to the printable material and/or the base material during the three dimensional printing and thereby at least partly connecting the printed functional element to the base material.

The problem is solved by the above aspects. Preferred examples are disclosed herein.

The aspects of the present disclosure provide a single-use container, a method for producing this container and an assembly for producing items, such as a single-use container allowing multiple materials to be combined and/or connected. Further, the structures of the functional elements, as well as the arrangement on a single-use bag may be improved.

According to one example, there is provided a single-use container, for example a single-use bioreactor, comprising

- a base material, particularly a wall element and/or a wall and/or skin of the single-use container, particularly of a single-use bioreactor which may be a single-use bag, such as a foil, a thin sheet and/or a stock sheet; and
- at least one functional element, for example a port, a sensor holder, a sensor part or the like, being at least partially, preferably permanently connected with or to the base material, wherein the functional element is obtained by a three dimensional (3D) printing technique from at least one printable material, wherein the printable material and/or the base material is/are heated during printing thereby (so as to) at least partly connecting the printed functional element to the base material.

In other words, a single-use container, which may be a single-use bag, comprises at least two parts: One part, i.e. a base material, such as for example a stock material and/or a pre-made item and/or a pre-made bag or a pre-made part thereof. The base material being connected to or with at least one second part. The at least one second part is a functional element which particularly is produced by being printed directly onto the base material. At least a portion or a part of the functional element may be in direct contact with the base material being directly connected to the base material such that a physical contact is established. The connection of the two parts, i.e. the base material and the at least one functional element, is established during at

provided more functional elements having a smaller distance to each other on a smaller area of the base material, as opposed to conventional containers being produced with conventional techniques.

In addition, it may be avoided to use and or implement adhesive materials such as glue, which may chemically harm the materials, for example the base material. Also, it can be avoided that degradation of a glued seam occurs, as the connection may be seamless, particularly being fused connection.

Moreover, the single-use container may be produced in an efficient, particularly cost efficient and easy way, as multiple steps may be automated, simplified and reduced or even avoided to connect parts or elements.

Optionally, several functional elements may be produced wherein a first functional element is connected to the base material and a second functional element is connected to the first functional element. For example, a reinforcement structure and/or a pad and/or a supporting layer, acting as a first functional element, may be printed onto a base material. A handle, acting as a second functional element, may be printed onto a surface of the reinforcement structure and/or a pad and/or a supporting layer. It is self-evident that any two of the disclosed functional elements and/or more than two of the disclosed functional elements may be connected in this or in a similar way.

According to another alternative example, there is provided a single-use container, for example a single-use bioreactor, comprising

- a base material, particularly a wall element and/or a wall and/or skin of the single-use container, particularly of a single-use bioreactor which may be a single-use bag, such as a foil, a thin sheet and/or a stock sheet; and
- at least one functional element, for example a port, a sensor holder, a sensor part or the like, being at least partially, preferably permanently connected with or to the base material, wherein the functional element is obtained by a three dimensional (3D) printing technique from at least one printable material,

and/or aerosol jetting an electronic component.

Particularly, the 3D printing technique may be based on a step of melting a metal powder and printing the same onto the base material. In this case, the metal powder may be considered the printable material. The connection between the base material and the functional element is established by the heating and the functional element may be an electronic component, for example. Alternatively and/or in addition, a metal powder may be implemented in a functional element by heating and melting the powder and printing the same onto the functional element, wherein, at the same time, a connection between the functional element and the melted powder may be established. As an example, a functional element may be composed of a thermoplastic and a layer of gold may be printed onto a surface of the thermoplastic material to provide an electronic connector.

Further, the 3D printing technique may - in addition to printing from a printable material and heating the same - also comprise the printing of electronic elements from metal compositions, such as for example a nanoparticle ink and/or spraying atomised metal and/or aerosol jetting, which may not necessarily require heat supply.

The above feature related to printing from a metal, may allow to easily implement electronic devices, such as electronic connectors, a conductive path, a chip, an RFID antenna or the like at least partially onto and/or into the functional element. This may allow to easily connect a sensor with other electronic elements and/or content or elements of the single-use container. Usually, an implementation of electronic elements may be complicated and may require high effort in production, as multiple steps are required to be performed during the assembly. Including and/or adding the step of printing an electronic device to the step of 3D printing a functional element, hence allows to simplify the production while achieving a high quality of the product. As a result the production costs and the number of production steps may be decreased essentially.

According to another example, there is provided a method of producing a single-use container, particularly a flexible or semi-flexible container, based on producing a

material may be a pre-made bag chamber onto which the functional element may be 3D printed. The pre-made bag chamber may either have a substantially 2D structure or a substantially 3D structure. The substantially 2D structure may be configured to be unfolded into a 3D structure and the 3D structure may be configured to be folded into a 2D structure. It is advantageous to print a functional element onto a folded, essentially 2D structure, however it may also be possible to print a functional element also on an unfolded, essentially 3D structure.

In a preferred example, the step of supplying heat comprises the step of pre-heating the base material, for example on a heated conveyor belt and/or by means of a heat source, such as a lamp and/or a hot air gun.

It is an advantage to heat the base material in view of a reliable polymerization and connection between the materials of the functional element and the base material. Particularly, the heat which is supplied to the base material is provided in addition to the heat provided to melt the printable material.

Preferably, the step of three dimensional printing of the functional element comprises a step of printing from a thermoplastic material and/or at least one of: acrylics (e.g. acrylic resins), EVA, ABS, PC, PE (like HDPE, LDPE, LLDPE), PMMA, PLA, PES, POM, PEEK, PEI, PP, PS, PTFE, TPE.

Other suitable polymer or material may be less preferable but still possible to be applied.

In other words, the printable material, from which the functional element is at least in parts formed, may be any one or more of the above mentioned materials. The said materials may be mixed and/or blended for example as a granulated material before being heated and fused and/or blended and before the 3D printing is performed. Alternatively or additionally, the 3D printing may be performed using different materials at a time such that distinct portions, particularly layers may be composed of different materials.

According to another example, there is further provided an assembly device for producing a functional element and connecting the functional element with a base material, comprising

- a three dimensional (3D) printing device for printing a functional element, such as a flange, a handle, a port, a holder, a marker, a fiducial or the like on a surface of the base material, such as the outer surface of the wall and/or skin of a SU bag; and
- a heating device and/or a heater for supplying heat to the functional element prior to and/or during at least an interval of the three dimensional printing and thereby at least partly connecting the printed functional element to the base material, i.e. establishing a connection at least between parts of the functional element and the base material; and optionally
- a heating device for pre-heating the base material.

In other words, an assembly device for producing a single-use container or a part thereof, particularly a SU bag and/or at least a part thereof, comprises a base material holder, i.e. means for holding a base material, such as a conveyor belt; a 3D printer for printing a functional element from a printable material onto a surface of a base material, such as an outer surface of a wall of a SU bag; and a heater for at least temporarily heating either the base material and/or the functional element and/or the printable material from which the functional element is printed.

The described assembly device has the advantage of producing a single-use container of materials which are usually challenging to be connected. Further, the assembly device can produce a single-use container with a high surface density of functional elements. The assembly device may be also efficient. A functional element or multiple functional elements may be printed in one single step onto a surface of a base material without the need for cumbersome steps such as gluing, welding, assembling, arranging, or the like. Further, the 3D printer may receive input data defining the design of the item, i.e. the single-use container, particularly the bioreactor and/or the functional elements. A user merely may be required to digitally design the final product, i.e. the single-use container, particularly the bioreactor,

Optionally, the recycling system may comprise a system which re-feeds the 3D printer with the recycled and/or collected removed excess material. Optionally, the recycling system may comprise a system, such as an extruder which can produce a new base material from the removed excess material. The single elements of the assembly device may not be dependent from each other and may all be optionally implemented in the assembly device.

The recycling system for recycling the excess material which is removed from either the functional element and/or the base material, being considered the primary base material, may comprise means for heating which is configured to heat the removed excess material. Further, the means for recycling, i.e. the system for recycling the removed excess material, may also comprise the system, for example an extruder, which manufactures the base material at least in parts from the excess material which is removed from either the functional element and/or the primary base material. In an alternative embodiment, the means for recycling the excess material does not comprise a system which manufactures the base material.

In other words, removed sheet bag material and/or removed material of the 3D printed functional element may be recycled into filament stock and fed back into the 3D printer for example as a filament. This may be very efficient and in particular cost-efficient and eco-friendly, as waste can be avoided and less material is needed.

According to the examples, it is possible to achieve a reliable and/or an intimate bonding between plastic components and/or between a metal and a plastic component using a 3D printing processes, e.g. Fused Filament Fabrication and/or material jetting. The drop-by-drop or layer-by-layer deposit of the plastic and/or metal above its melting point can heat up the base material, e.g. a plastic bag film and/or other plastic surfaces, sufficiently to melt its very contact surface, without degrading the base material, e.g. a film and to achieve a reliable adhesion.

The described embodiments may particularly benefit in reinforcing bags, providing marks on bags comprising instructions, to corporate a branding or even include warnings in braille. Mounting and location features may be added to hold the bag in place when completed. Inbuilt features or jig points to aid assembly may be printed

on to the structure of the bag. Features may be added to aid packaging. Increased material thickness in certain locations may be provided to improve a welding. Sensors or sensor parts may be printed directly (or indirectly) onto bags. The invention may also support reducing the number of parts for fabricating a single-use container as well as reducing effort, particularly the overall time of the fabrication process supporting an efficient process of assembly.

According to another example, there is provided a multiple-use container, for example a multiple-use bioreactor, comprising

- a base material, particularly a wall element and/or a wall and/or skin of the multiple -use container, particularly of a multiple-use bioreactor; and
- at least one functional element, for example a port, a sensor holder, a sensor part or the like, being at least partially connected with or to the base material, wherein the functional element is obtained by a three dimensional (3D) printing technique from at least one printable material, wherein the printable material is heated during printing thereby (so as to) at least partly connecting the printed functional element to the base material.

It is self-explanatory that all optional examples which have been described for a single-use container may be combined - if not contradictory - with a multiple-use container according to the above aspects.

In the following, example embodiments are described in detail. Single features being described in a particular embodiment may be arbitrarily combined, given that they are not excluding each other. In addition, different features which are provided together in the example embodiments are not to be considered restrictive to the invention.

Fig. 1a is a schematic view illustrating conventional technique connecting of a functional element with a base material using welding;
Fig. 1b is a schematic view illustrating a 3D printed functional element connected with a base material according to an example embodiment;

Claims

1. Single-use container, particularly a single-use bag such as a single-use bioreactor, comprising:

- a base material; and
- at least one functional element being at least partially, preferably permanently connected with the base material, wherein the functional element is obtained by a three dimensional printing technique from at least one printable material, wherein the printable material and/or the base material is heated during the three dimensional printing thereby at least partly connecting the printed functional element to the base material.

2. Single-use container according to claim 1, wherein the base material is at least one out of:

a two dimensional film;
a stock sheet;
a pre-cut bag;
a pre-made bag, particularly a single-use bag; and
a wall element of a bag or container.

3. Single-use container according to any one of the preceding claims, wherein the functional element comprises at least one out of the following: a flange, a port, an inlet and/or outlet point, a sensor holder, a sensor or a part of a sensor, a window or a window frame, a connector, a label and/or label information, a substantially three-dimensional text, a reference marker or fiducial, a three dimensional structure and/or a three dimensional pattern, particularly a stabilizing and/or stiffening and/or reinforcement element, a tube holder, a handle, a metallic element, particularly an

electronic component.

4. Single-use container according to any one of the preceding claims, wherein the base material and/or the functional element and/or the printable material comprises at least one of: PE, EVA, , ABS, PC, PMMA, PLA, PES, PSU, POM, PEEK, PEI, PPO, PP, PET, PS, PA , PTFE, PU, TPE, silicone, fluoropolymers, copolyesters, acrylic.

5. Single-use container according to any one of the preceding claims, wherein the three dimensional printing technique comprises a fused filament fabrication, a drop-by-drop application of the printable material and/or a layer-by-layer application of the printable material.

6. Single-use container according to any one of the preceding claims, wherein the three dimensional printing technique further comprises printing from a nanoparticle ink and/or spraying atomised metal and/or melting a metal powder and/or aerosol jetting an electronic component.

7. Method of producing a single-use container by producing a functional element and connecting the functional element with a base material of the container, comprising the steps of:

- providing the base material;
- three dimensional printing of the functional element from a printable material on a surface of the base material; and
- connecting at least a portion of the functional element with at least a portion of the base material by supplying heat to the printable material and/or the base material simultaneously to and/or prior to at least an interval of the step of three dimensional printing.

8. Method according to claim 7, wherein the step of supplying heat comprises the step of pre-heating the base material.

9. Method according to claim 7 or 8, wherein the step of three dimensional printing of the functional element comprises a step of printing from printable material, at least one of: acrylics, EVA, ABS, PC, PE, PMMA, PLA, PES, POM, PEEK, PEI, PP, PS, PTFE.

10. Method according to any one of claims 7 to 9, wherein the step of three dimensional printing comprises the step of printing from a nanoparticle ink and/or spraying atomised metal and/or melting a metal powder and/or aerosol jetting an electronic component.

11. Method according to any one of claims 7 to 10, further comprising the step of removing a portion of the base material and/or removing an excess portion of the functional element.

12. Method according to any one of claims 7 to 11, wherein the three dimensional printing of the functional element comprises a fused filament fabrication, a drop-by-drop application of the printable material and/or a layer-by-layer application of the printable material.

13. Method according to any one of claims 7 to 12, further comprising

- removing, particularly for cutting away excess material from either the functional element and/or the base material; and
- at least partly recycling the excess material being removed by particularly reusing it in the three dimensional printing step and/or in a step of manufacturing the base material.

14. Assembly device for producing a functional element and connecting the functional element with a base material to produce a single-use container, comprising:

- a three dimensional printing device for printing a functional element on a surface of the base material; and
- at least one heating device for supplying heat to the printable material

and/or the base material during the three dimensional printing and thereby at least partly connecting the printed functional element to the base material.

15. Assembly device according to claim 14, further comprising means for providing and positioning the base material, preferably a conveyor belt, and optionally the assembly device is configured to provide the base material from a roll.

16. Assembly device according to any one of claims 14 or 15, further comprising

- means for removing, particularly for cutting away excess material from either the functional element and/or the base material; and
- means for at least partly recycling the excess material being removed, particularly comprising means for heating and providing the excess material, being removed, to the three dimensional printing device and/or to a system which manufactures the base material.