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(54) **METHOD FOR REALIZING AN ASEPTIC CONNECTION BETWEEN A VALVE UNIT AND A TANK CONTAINER**

(57) The invention relates to a method for realizing an aseptic connection between a valve unit and a tank container comprising an inliner, wherein a disinfection unit comprising the valve unit is positioned around the spout of the tank container. The valve unit is then disinfected by exposing it to a disinfection fluid and/or to electromagnetic radiation while the valve of the valve unit is in an open position. After having closed the valve, an end portion of the valve unit is pressed against a closure element that blocks the spout of the inliner, to thereby effect that the inner environment of the inliner and the interior of the valve unit are in fluid communication. The disinfection unit is then removed and the valve unit is fastened to the tank container to ensure an aseptic connection between the valve unit and the tank container.

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Dit octrooi is verleend ongeacht het bijgevoegde resultaat van het onderzoek naar de stand van de techniek en schriftelijke opinie. Het octrooischrift komt overeen met de oorspronkelijk ingediende stukken.

METHOD FOR REALIZING AN ASEPTIC CONNECTION BETWEEN A VALVE UNIT AND A TANK CONTAINER

The invention relates to a method for realizing an aseptic connection between a valve unit and a tank container comprising an inliner with the aid of a disinfection unit, to an assembly of a valve unit and a disinfection unit and to a tank container comprising such assembly.

For the transportation and preservation/storage of liquid products, it is common practice to use tank containers wherein such liquids temporarily reside, and which have dimensions that allow them to be transported over common (rail) roads and on (container)ships. They usually have a volume in the range of 5.000 dm^3 to 50.000 dm^3 and are shaped in a more or less cylindrical form. Such tank containers are usually filled and emptied via a spout that is present at or near their bottom.

To avoid contact of the charged liquid with the inside of the tank container, the liquid may be completely contained in a so-called inliner. After discharge of the liquid, the inliner is removed from the tank container. Since no traces of liquid are then left in the interior of the container, the container does not have to be cleaned – a laborious and expensive process that is not environmentally friendly. Another important function of such inliner is to protect the liquid in the container against contamination, decay and spoilage. Moreover, since a new inliner is aseptic and void of contaminants by nature, and since for each new charge of the container a new inliner may be used, a higher degree of cleanliness can be achieved when an inliner is used.

During the filling and discharging of a tank container, there is a risk of introducing contaminants and/or micro-organisms into the liquid. This may especially occur when a hose for the supply or discharge has to be connected to the spout. Although the presence of an inliner in the container does in principle not affect the risk on contamination, the effect of contamination is more pronounced in an inliner than in an unprotected container, because an inliner has a much higher cleanliness from itself and an inliner-less container has a higher background of contaminations. In other words, the relative impact of a contamination is higher when an inliner is used in a tank container.

Therefore, with the higher standards of cleanliness that can be imposed due to the use of inliners, there is an increased need for creating aseptic conditions during the filling and discharging of a tank container. However, proper means for disinfection are not yet available. In particular, there is no equipment that ensures that all parts where the liquid charge passes remain aseptic, and that the inliner's interior is closed off from the outside environment at all times.

It is therefore an objective of the invention to provide a method and equipment that solves one more of the above problems.

Therefore, the present invention relates to a method for realizing an aseptic connection between a valve unit and a tank container that comprises an inliner, the method comprising providing

1) a tank container and an inliner which is present in an interior of the tank container, wherein
   - the tank container as well as the inliner comprises a spout for the supply and discharge of a liquid;
   - the spout of the inliner is placed in the spout of the tank container;
   - the spout of the inliner is closed by a closure element separating an inner environment of the inliner from an outer environment, which closure element is capable of being punctured and/or displaced from the spout so as to allow supply and discharge of liquid through the spout;
2) a valve unit comprising a tube having
   - a first end portion comprising a valve that is configured to open and close the tube at the first end portion;
   - a second end portion that is capable of displacing the closure element from the spout and/or of or puncturing the closure element;
   - an interior that extends from the valve to the second end portion;

   wherein the valve unit is equipped with fastening means for fastening the valve unit to the spout of the tank container (or to the tank container itself) to ensure an aseptic connection between the valve unit and the tank container, in particular between the tube of the valve unit and the spout of the inliner;
3) a disinfection unit comprising a wall defining an interior space, wherein

- the wall comprises an opening for receiving into the interior space the valve unit that is to be disinfected, which opening is adapted to abut and/or enclose the spout of the tank container;
- the disinfection unit comprises means for exposing the interior of the tube of the valve unit to a disinfection fluid and/or to electromagnetic radiation;
- the disinfection unit is provided with means for changing the position of the valve unit in the disinfection unit and for pressing the second end portion of the tube of the valve unit against the closure element of the inliner when 1) the valve unit is contained in the interior space of the disinfection unit; and 2) the opening of the disinfection unit is placed against and/or around the spout of the tank container;

and thereafter performing the steps of

a) placing the valve unit into the interior space of the disinfection unit and placing the opening of the disinfection unit against or around the spout of the tank container; thereafter

b) disinfecting the valve unit by exposing the interior of the tube of the valve unit to a disinfection fluid and/or to electromagnetic radiation while the valve is in an open position; thereafter

c) closing the valve of the valve unit; thereafter

d) pressing the second end portion of the tube of the valve unit against the closure element that is present in the spout of the inliner so that the closure element becomes displaced or punctured and a fluid connection is generated between the second end portion of the tube and the spout, providing the inner environment of the inliner and the interior of the tube in fluid communication; thereafter

e) removing the disinfection unit from the valve unit and fastening the valve unit to the spout of the tank container to ensure an aseptic connection between the valve unit and the tank container, in particular between the tube of the valve unit and the spout of the inliner; thereafter

f) optionally covering the first end portion of the tube with a cap.

The invention further relates to an assembly suitable for use in this method.

Figure 1 displays a cross-sectional view of a disinfection unit (10) in the method of the invention.

Figure 2 displays a cross-sectional view of a valve unit (20) in the method of the invention.

Figure 3 displays a cross-sectional view of an assembly (30) of a valve unit and a disinfection unit of the invention.

Figure 4 displays a cross-sectional view of a tank container (40) in the method of invention.

Figure 5 displays a cross-sectional view of a tank container (40) comprising an assembly (30) of the invention.

Figure 6 is a representation of the different steps of the method of the invention.

Elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help improve understanding of various exemplary embodiments of the present invention. Furthermore, the terms "first", "second", and the like herein, if any, are generally used for distinguishing between similar elements and not necessarily for describing a sequential or chronological order.

In the context of the invention, by the term "aseptic" is meant "free or freed from germs and any other unwanted micro-organism". By an aseptic connection is meant a connection that is gas-tight and liquid-tight, and so does not allow that any germs and any other unwanted micro-organism can pass, *e.g.* from an outer environment to an inner environment. As a result, an aseptic connection does neither allow the passage of other pollutions such as sand, dust, liquids and gases, in particular gases such as oxygen.

The tank container in the method and the assembly of the invention may in principle be any type of tank container, as long as it has an interior in which an inliner may be placed, and in such manner that the spout of the inliner fits into the spout of the tank container. Typically, both spouts are designed such that, when combined, the outer circumference of the spout of the inliner is adjacent to the inner circumference of the spout of the tank container, preferably in a tight fit.

The tank container is preferably of a cylindrical or cylindrical-like shape, since inliners experience less stress forces in such containers than in containers with *e.g.* flat walls and corners.

A tank container typically comprises a manhole, which is an opening in the wall of the container that can be shut off with a lid. Such opening is usually circular with a diameter in the range of 25–50 cm and can be used to introduce an inliner in the tank container. Preferably, it is located close to the spout, *e.g.* at a distance thereof that is 0.5–3 times its diameter. Usually, the tank container also comprises a venting hole for the release of air during the filling of the container.

The tank container in the method and the assembly of the invention has an interior in which an inliner is present. The inliner is configured as a bag and defines an interior space for storing a liquid. It comprises an opening for the supply and discharge of a liquid charge, which opening merges into a spout. The tank container also comprises an opening with a spout to allow for the supply and discharge of a liquid charge. This spout is typically a tube-like structure that extends, at a particular angle, from the container. Both spouts are designed such that the spout of the inliner can be inserted into the spout of the container. When a method of the invention is carried out, the spout of the inliner is present in the spout of the container. When, thereafter, the inliner is actually being filled or emptied with liquid, the spout of the inliner is still present in the spout of the container. Accordingly, also for a tank container comprising an assembly of the invention, the spout of the inliner is present in the spout of the container,

In a method of the invention, the inliner has an inner environment that is initially closed-off from an outer environment by a closure element. This closure element is typically placed in or at the spout, so that it blocks the spout and separates the interior of the inliner from an environment outside the inliner. It is capable of becoming displaced from its position (*e.g.* by pushing it into the interior of the inliner) or of becoming disrupted/punctured, so that supply and discharge of liquid through the spout of the inliner becomes possible. Displacement or puncture of the closure element in a method of the invention occurs when it is pressed against by the second end portion of the tube of the valve unit.

In a preferred method, the closure element of the spout is a stopper with a shape that is complementary to the shape of the spout, which stopper is

initially present in the spout and so blocks the spout. It is held by the circumferential wall of the spout due to the tight fit it has in the spout, and is kept in position by the friction with the inner wall of the spout. When pressed against by the second end portion of the tube of the valve unit, the closure element is displaced, releases from the spout and ends up somewhere in the inliner.

In an alternative method, the closure element of the spout of the inliner is a membrane that separates the interior of the inliner from an environment outside the inliner, which membrane is capable of being disrupted and/or punctured when pressed against by the second end portion of the tube.

Figure 4 displays a cross-sectional view of a tank container (40) comprising a spout (41). In the interior of the container (40) is present an inliner (42). The inliner (42) comprises a spout (43) and a closure element (44).

The valve unit in a method and assembly of the invention provides the container with means to open and close the spout of the tank container so that there is control over the flow of liquid through the spout. It may shut off the spout so that no liquid can enter or exit the tank container, or it may be open and so allow the passage of liquid so that the tank container can be filled or emptied.

A permanent connection between a valve (or a unit comprising a valve) and a tank container is not preferred since this would go at the expense of tank volume, since the dimensions of a tank container have to be within certain standard dimensions, often legally prescribed, for tank containers. Moreover, for a proper and aseptic installation of the inliner in the tank container, it is inconvenient when the spout of the container is always capped with a valve. Therefore, it is preferred that a valve is only temporarily connected to the tank container when a tank container needs to be charged or emptied. Such temporary and aseptic connection is provided for by a method of the invention.

A valve for the opening and closure of the spout is part of the valve unit. Such unit comprises a tube that is equipped with a valve on one end portion (*i.e.* the first end portion), wherein the valve is designed to open or close the interior of that tube at the first end portion. The other end portion (*i.e.* the second end portion) is permanently open and serves as a means to displace the closure element from the spout of the inliner. When the valve unit is being placed in position, it presses against the closure element and so displaces it. This is also

meant to include puncturing or rupturing of the closure element, in the event that the closure element is a membrane that is to be destructed by pressure of a protruding object such as the first end portion. After displacement or destruction of the closure element, the second end portion is further pressed into the spout until both components are coupled and have a leak-tight fit. Then, a fluid connection is generated between both components, so that the inner environment of the inliner and the interior of the tube are in fluid communication. By a fluid connection is meant an arrangement (such as a coupling) of two components which allows a fluid to pass from one component to the other. Spaces within each component are then in fluid communication. In the present invention, one such component is the tube of the valve unit and the other is the spout of the inliner.

When the valve unit is in place, it needs to be fastened to the spout of the tank container (or to the tank container itself), to ensure that there is a sustainable and aseptic connection between (the tube of) the valve unit and the spout of the tank container, *e.g.* a connection that can withstand the pressures that are common during filling and emptying the tank container, when the liquid passes through the connection. Therefore, the valve unit is equipped with fastening means for fastening the valve unit to the spout of the tank container (or to the tank container itself).

For an improved air- and/or liquid-tightness of the connection, the spout of the inliner and the second end portion of the tube of the valve unit are preferably of a corresponding conical shape.

Figure 2 displays a cross-sectional view of a valve unit (20). It comprises a tube (23) having a first end portion (21) and a second end portion (22). A valve (24) is present at the second end portion (22), wherein the valve (24) is shown in an open position.

To keep the inner environment of the inliner aseptic, the displacement of the closure element should not occur under a normal atmosphere, because then pollution, germs or other unwanted micro-organisms gain access to the inner environment of the inliner. Therefore, the valve unit is temporarily shielded by a disinfection unit. In the interior of this unit, an aseptic environment is created by a disinfection process that is applied prior to the displacement of the closure element. During this process, the valve of the valve unit has to be open, so that

the entire interior of the tube, from the first end portion to the second end portion, also becomes disinfected. The disinfection also includes that side of the closure element that faces the environment outside the inliner.

Thus, the disinfection unit comprises a wall that defines an interior space, which wall comprises an opening for bringing the valve unit into the interior space. The opening is further adapted to abut and/or enclose the spout of the tank container. It is not necessary that the disinfection unit is tightly connected to the tank container and/or its spout (liquid-tight and/or gas-tight). For example, the disinfection unit is loosely slided over the spout, *e.g.* as a sort of slip case. The disinfection unit may also surround the spout without being in contact with it. Since during (and possibly also after) disinfection an overpressure is usually generated in the interior space of the disinfection unit by the release of gas and/or liquid into the interior of the tube and/or the disinfection unit, unwanted pollutions and germs of the external environment do not have a chance to enter the interior space of the disinfection unit through accidental chinks or gaps. A connection that is not liquid-tight or gas-tight then does not disturb the asepticity of the interior of the tube.

It is, on the other hand, also possible that the disinfection unit is indeed firmly connected to the tank container and/or its spout, for example in a manner that is liquid-tight and/or gas-tight. A pressure relief valve may then be present in the disinfection unit to accommodate for a pressure build-up during disinfection. A (firm) connection may also be designed such that it allows the passage of liquid or gas, so that any disinfection fluid or purge gas may escape "naturally" from the interior space of the disinfection unit.

Optionally, the disinfection unit is provided with fastening means for fastening the disinfection unit to the tank container. In the method, the actual connection of the disinfection unit to the tank container is then made before step d), but it may also be performed before step c) or before step b), in particular in step a). This is to ensure that the disinfection unit does not drop off from the valve unit and the tank container during the disinfection, the closing of the valve or the displacing/puncturing of the closure element. The latter is especially important when the pressing against the closure element is driven from within the disinfection unit (*e.g.* electrically, mechanically, hydraulically or pneumatically

driven), because the connection of the disinfection unit to the tank container provides the required back force that prevents that the disinfection unit itself is pushed away from the spout.

The opening of the disinfection unit is adapted to abut and/or enclose the spout of a tank container. For example, the opening has a circular, elliptic, square or other polygonal shape, wherein the shape is of such dimension that it is capable of receiving the spout of a tank container and the valve unit. For example, the opening has a cross-section of which the longest dimension is 40 cm or less, 35 cm or less, 25 cm or less, 20 cm or less, or 15 cm or less. In particular, the opening has a cross-section of a circular shape with a diameter of 30 cm or less, 20 cm or less or 15 cm or less.

The disinfection unit is provided with means for changing the position of the valve unit in the disinfection unit. Such means then also have the function of pressing the second end portion of the tube of the valve unit against the closure element of the inliner. Such means are necessary since the process of the invention relies on the containment of the valve unit in the interior space of the disinfection unit. Also, during the process of the invention, the opening of the disinfection unit is placed against and/or around the spout of the tank container. As a result, the valve unit is shielded and cannot be accessed and operated directly.

For example, the valve unit in a method of the invention has a handle for handling of the valve unit and the disinfection unit has a design that allows that the handle can be held by an operator (*e.g.* by a slit through which the handle moves and penetrates). In this manner, an operator can move the valve unit towards the closure element of the inliner.

Alternatively, the disinfection unit or the valve unit may be equipped with an electric motor. In this way, the movement of the valve unit towards the closure element of the inliner can be electrically driven. This does not require an opening (such as a slit) in the wall of the disinfection unit as would be the case when the valve unit comprises a handle (in particular a handle that is allowed to have translational motion through a slit).

In another alternative, a pneumatic or hydraulic force is used to move the valve unit.

In yet another alternative, the movement can be initiated mechanically, *e.g.* by a rotating shaft that penetrates through the wall of the disinfection unit wherein an optional packing seal prevents the passage of any pollutions or germs along the shaft through the wall. The disinfection unit then typically comprises a mechanical element that converts the rotational motion of the shaft into translational motion of the valve unit.

Figure 1 displays a cross-sectional view of a disinfection unit (10). It comprises a wall (11) defining an interior space (12). The wall (11) comprises an opening (13) for receiving a valve unit (20). The disinfection unit (10) comprises means (14) for introducing a disinfection fluid into the interior space (12).

The disinfection unit and the valve unit are both designed such that the valve unit fits into the interior space of the disinfection unit. When put together in this manner, they form an assembly of the invention. Such assembly is suitable for use in a method according the invention.

Figure 3 displays a cross-sectional view of an assembly (30) of a disinfection unit (10) and a valve unit (20), wherein the valve unit (20) is present in the interior space (12) of the disinfection unit (10).

In the method of the invention, the valve unit is placed into the interior space of the disinfection unit, followed by placing the opening of the disinfection unit against or around the spout of the tank container, so that it abuts and/or encloses the spout of the tank container. The second end portion of the tube of the valve unit is then in the vicinity of the closure element, but it has not yet punctured or displaced it.

Before, during or after the placement of the disinfection unit, the valve of the valve unit is opened. When the valve is open, the disinfection of the valve unit is performed. The disinfection is primarily directed at freeing the tube of the valve unit and nearby surfaces (*e.g.* that of the closure element and that of the valve itself) from germs and any other unwanted micro-organism. Depending on the disinfection method, it is also possible to remove other pollutions such as sand, dust, liquids and gases, in particular gases such as oxygen.

The disinfection typically comprises the release of a disinfection fluid in the tube, which fluid is typically fed from a source outside the disinfection unit through an inlet in the disinfection unit. The release of such disinfection fluid

creates a small overpressure in the interior space and can escape through *e.g.* a discontinuity in the wall of the disinfection unit (a hole, a slit, a vent hole) or an opening at an interface of the tank container with the disinfection unit.

The disinfection fluid may be selected from the group of water, steam, ethanol, ozone, carbon dioxide gas and nitrogen gas. Application of the fluid may occur at ambient conditions but also at elevated temperatures, *e.g.* at a temperature of at least 80 °C, least 100 °C, or least 120 °C. It may *e.g.* be in the range of 95–115 °C. The choice of fluid and temperature is subject to the nature of the materials that are exposed during disinfection, in particular to the nature of the material of the inliner and the closure element, since these are typically made of plastic, such as polyethylene. Other components such as the valve unit and the disinfection unit are often made of stainless steel.

Alternatively, the disinfection is performed by exposure of the tube to electromagnetic radiation, for example ultraviolet radiation. In such case, the disinfection unit is provided with a source of electromagnetic radiation.

Optionally, after the disinfection in step b), a flow of a gas is released into the interior space, preferably a dry and inert gas, which flow has the function of preventing unwanted pollutions and germs of the external environment to enter the interior space of the disinfection unit. In addition, it may evaporate eventual liquid components of the disinfection fluid that remain in the interior of the tube after the disinfection (*e.g.* water and/or ethanol). Such gas flow creates a small overpressure in the interior space and can escape through *e.g.* a discontinuity in the wall of the disinfection unit (a hole, a slit, a vent hole) or an opening at an interface of the tank container with the disinfection unit. In this way, the interior space of the disinfection fluid and/or of the tube is continuously purged with such gas. Such purging is terminated before closing the valve in step c).

After the treatment with the disinfection fluid or the electromagnetic radiation, the valve is closed. In case the fluid has left behind some traces of a liquid (*e.g.* when ethanol or water/steam has been used), then a dry gas such as dry nitrogen may be purged through the tube to allow evaporation and removal of the liquid, which is then followed by closing the valve. It is in principle also possible that the valve of the valve unit is already closed during the disinfection of the valve unit, *i.e.* during the treatment with the disinfection fluid.

After closing of the valve, the second end portion of the tube of the valve unit is pressed against the closure element of the spout so that the closure element becomes displaced or punctured and a fluid connection is generated between the tube and the spout. The inner environment of the inliner and the interior of the tube are then in fluid communication. The second end portion of the tube is usually designed in such manner that its shape is complementary to that of the spout of the inliner, so that the valve unit nicely fits in the spout after the pressing. This has the effect that the valve unit is more or less connected to the tank container after the pressing.

This situation is visualized in Figure 5, displaying a cross-sectional view of a tank container (40) comprising an assembly (30) of the invention. The second end portion (22) of the tube (23) of the valve unit (20) has been penetrated though the spout (41) of the tank container (40) and through the spout (43) of the inliner (42). The closure element (44) has been dislocated from the spout (43) by the second end portion (22) and resides in the interior of the tank container (40). The disinfection unit (10) still surrounds the valve unit (20), but is to be removed in a next step of the method.

Since the valve unit itself is shielded by the disinfection unit and the spout of the tank container, moving of the valve unit towards the closure element and displacing/puncturing it is usually performed in an indirect manner. For example, the valve unit comprises a handle for pressing the second end portion of the tube of the valve unit against the closure element, which handle can be operated from the outside, *i.e.* when the valve unit is enclosed by the disinfection unit. In this way, an operator can press the second end portion of the tube of the valve unit against the closure element of the inliner. Alternatively, the disinfection unit may comprise a handle, which is then operably connected to the valve unit. In either case, the handle can move the valve unit in the desired direction (*i.e.* usually towards the closure element). Usually, such handle requires a discontinuity of the wall of the disinfection unit (*e.g.* a slit for translational movement of the handle), because the handle has to be accessible to an operator. One way of maintaining the aseptical interior of the tube of the valve unit is to use an overpressure of the disinfection fluid – the fluid may then escape through the discontinuity designed for the handle (and eventual other discontinuities) and so prevent undesired inflow of

gas (outside atmosphere) into the interior space of the disinfection unit. To further reduce the inflow, the disinfection unit may be equipped with flexible parts (*e.g.* rubber flaps) that are pushed backwards locally when the handle is operated.

The disinfection unit may also comprise an electrically, hydraulically or pneumatically driven mechanism that is designed to move the valve unit in the desired direction, in particular to press the second end portion of the tube of the valve unit against the closure element of the inliner. For example, an electric actuator, a pneumatic actuator or an hydraulic actuator is present. It is also possible that an electrical motor is present which is capable of moving the valve unit in the interior space of the disinfection unit.

After the puncturing or displacement of the closure element, the disinfection unit is removed from the spout of the tank container, and simultaneously also from the valve unit.

During or shortly after the removal, the valve unit is fastened to the spout of the tank container (or to the container itself) to ensure a leak-tight (*i.e.* aseptic) connection between the valve unit and the tank container. The fastening may be performed before or after removal of the disinfection unit. When the fastening is performed after the removal, it is preferred that the second end portion of the tube is completely enclosed by the spout so that the interior of the tube remains aseptic.

At this stage (*i.e.* after the fastening), the tank container is ready for being charged with a liquid. This is typically performed by connecting the first end portion of the tube to a hose or pipe that is connected to a storage or processing facility of the liquid (*e.g.* in a factory, brewery, bottling facility or a place where consumption of the liquid occurs). Such connection is also made under aseptic conditions; the required procedures for this are known in the art. When the valve of the valve unit is opened, then the liquid contents of the storage facility may flow into or out of the aseptic tank container.

The method of the invention as described above is illustrated in Figure 6. In step a) two actions are performed. This concerns 1) placing a valve unit (20) into a disinfection unit (10) yielding assembly (30); and 2) placing the opening of the disinfection unit around the spout of the tank container (40). Then, in step b) of the method, the interior of the valve unit (20) is disinfected with

disinfection fluid (15), visualized by a shading in the interior space of the disinfection unit (10) and in the interior of the tube of the valve unit (20). During the disinfection, the valve is in an open position so that the interior of the tube as well as the valve become disinfected (*i.e.* aseptic). This is then followed by closure of the valve (24) of the valve unit (20) in step c). The second end portion (22) of the tube (23) of the valve unit (20) is then pressed against the closure element (44) in step d), generating a fluid connection between the second end portion (22) of the tube (23) and the spout (43). Finally, in step e) the disinfection unit (10) is removed from the valve unit (20). The valve unit (20) is then fastened to the spout of the tank container (40) (fastening is not shown for reasons of clarity). Optionally, a cap (16) is placed on the first end portion (21) of the valve unit (20).

The invention further relates to an assembly (Figure 3) of a valve unit and a disinfection unit, for use in a method as described above, wherein

- the disinfection unit comprises
  - a wall defining an interior space, the wall comprising an opening for receiving into the interior space the valve unit, which opening is adapted to abut and/or enclose the spout of a tank container;
  - means for exposing the interior of the tube of the valve unit to a disinfection fluid and/or to electromagnetic radiation;
- the valve unit
  - is present in the interior space of the disinfection unit;
  - comprises a tube having
    - a first end portion comprising a valve that is configured to open and close the tube at the first end portion;
    - a second end portion;
    - an interior that extends from the valve to the second end portion;
  - is equipped with fastening means for fastening the valve unit to the spout of a tank container to ensure an aseptic connection between the valve unit and the tank container;
- the disinfection unit and/or the valve unit is/are provided with means to change the position of the valve unit in the disinfection unit, in particular with means for pressing the second end portion of the tube of the valve unit against a closure element when the assembly is used in a method as described above (*i.e.* a

method for realizing an aseptic connection between a valve unit and a tank container that comprises an inliner with such closure element).

To be able to maneuver the valve unit inside the disinfection unit, the valve unit preferably comprises a handle that goes through the wall defining an interior space. The means to change the position of the valve unit in the disinfection unit may therefore comprise such handle. The handle may be operated by a person who performs the method of the invention. Alternatively, the means to change the position comprise an electric actuator, a pneumatic actuator or an hydraulic actuator. In particular, the valve unit or the disinfection unit may be equipped with an electric motor with which the valve unit can be guided towards the closure element and displace or puncture it.

The invention further relates to a tank container comprising the assembly as described above (Figure 5), wherein the tank container comprises

- a spout for the supply and discharge of a liquid;
- an inliner in an interior of the tank container, wherein the inliner comprises an inner environment and a spout for the supply and discharge of a liquid, which spout is present in the spout of the tank container;

wherein

- the second end portion of the tube is present in the spout of the inliner (and thus also in the spout of the tank container) so that there is a fluid connection between the second end portion of the tube and the spout, providing the inner environment of the inliner and the interior of the tube in fluid communication;
- the valve unit is fastened to the spout of the tank container to ensure an aseptic connection between valve unit and the tank container, in particular between the tube of the valve unit and the spout of the inliner.

As mentioned above, the disinfection unit may be connected to the tank container or to the spout of the tank container. This is however not a necessity, since it is present around the valve unit only for a relatively short period of time, during which an operator can hold it in place. It may for example also be slided over the spout so that it is supported without being fixated. In this way, it does not fall off but stays in place during this short period.

When the method of the invention is carried out, the inliner is empty. It will therefore not contain the same volume it would have when the container (and thus the inliner) is charged with a liquid. Typically, the inliner is folded and/or rolled up prior to charging it, resulting in only a small interior volume. Most of this volume is typically present at and near the spout of the inliner. For example, the available volume in the interior of the inliner is less than 0.01%, in particular less than 0.005%, of the volume of the interior of the tank container.

It is an advantage of the method of the invention that the use of the disinfection unit provides a simple and reliable means for creating a leak-tight and aseptic connection between the inliner in the tank container and an external unit that provides or receives the liquid charge of the tank container. The method ensures that all parts where the liquid charge passes remain aseptic, and that the inner environment of the inliner is closed off from the outside environment at all times.

After charging and discharging of the fluid in and from the tank container, the inliner has fulfilled its function and is usually disposed. The valve unit can be reused, however. It is easily removable from the tank container and can be cleaned as such. This allows its reuse for a subsequent charge in the tank container. Also the disinfection unit can be reused.

Conclusies

1. Werkwijze voor het tot stand brengen van een aseptische verbinding tussen een kraanstuk (20) en een tank container (40) die een inliner (42) omvat, omvattende het verschaffen van
   1) een tank container (40) en een inliner (42) welke aanwezig is in een binnenruimte van de tank container (40), waarbij
      - zowel de tank container (40) als de inliner (42) een tuit (41, 43) omvatten voor de toevoer en afvoer van een vloeistof;
      - de tuit (43) van de inliner (42) in de tuit (41) van de tank container (40) geplaatst is;
      - de tuit (43) van de inliner (42) afgesloten is middels een sluitstuk (44) dat een binnenomgeving van de inliner (42) scheidt van een buitenomgeving, welk sluitstuk (44) in staat is om doorgeprikt te worden en/of verdreven te worden uit de tuit (43) om daarmee de toevoer en afvoer van vloeistof door de tuit (43) mogelijk te maken;
   2) een kraanstuk (20) omvattende een buis (23) met
      - een eerste eindstuk (21) omvattende een kraan (24) die geconfigureerd is om de buis (23) bij het eerste eindstuk (21) te openen en af te sluiten;
      - een tweede eindstuk (22) dat in staat is om het sluitstuk (44) te verdrijven uit de tuit (43) en/of om het sluitstuk (44) door te prikken;
      - een binnenruimte die zich uitstrekt van de kraan (24) naar het tweede eindstuk (22);

      waarbij het kraanstuk (20) is uitgerust met bevestigingsmiddelen voor het bevestigen van het kraanstuk (20) aan de tuit (41) van de tank container (40) om een aseptische verbinding tussen het kraanstuk (20) en de tank container (40) te zeker te stellen;
   3) een desinfectie-eenheid (10) omvattende een wand (11) die een binnenruimte (12) definieert, waarbij
      - de wand (11) een opening (13) omvat voor het opnemen van het kraanstuk (20) in de binnenruimte (12), welke opening (13) is

aangepast om aan te sluiten op de tuit (41) van de tank container (40) en/of om deze te omsluiten;

- de desinfectie-eenheid (10) middelen omvat om de binnenruimte van de buis (23) van het kraanstuk (20) bloot te stellen aan een ontsmettingsvloeistof (15) en/of aan elektromagnetische straling;
- de desinfectie-eenheid (10) is voorzien van middelen om de positie van het kraanstuk (20) in de desinfectie-eenheid (10) te veranderen en het tweede eindstuk (22) van de buis (23) van het kraanstuk (20) tegen het sluitstuk (44) van de inliner (42) aan te duwen, wanneer
  - het kraanstuk (20) is vervat in de binnenruimte (12) van de desinfectie-eenheid (10);
  - de opening (13) van de desinfectie-eenheid (10) tegen of rondom de tuit (41) van de tank container (40) is geplaatst;

en het daarna uitvoeren van de stappen van

a) het plaatsen van het kraanstuk (20) in de binnenruimte (12) van de desinfectie-eenheid (10) en het plaatsen van de opening (13) van de desinfectie-eenheid (10) tegen of rondom de tuit (41) van de tank container (40); daarna

b) het desinfecteren van het kraanstuk (20) door de binnenruimte van de buis (23) van het kraanstuk (20) bloot te stellen aan een ontsmettingsvloeistof (15) en/of aan elektromagnetische straling terwijl de kraan (24) in een open stand staat; daarna

c) het sluiten van de kraan (24) van het kraanstuk (20); daarna

d) het duwen van het tweede eindstuk (22) van de buis (23) van het kraanstuk (20) tegen het sluitstuk (44) dat aanwezig is in de tuit (43) van de van de inliner (42) zodat het sluitstuk (44) verplaatst of doorgeprikt wordt en een fluïde verbinding gegenereerd wordt tussen het tweede eindstuk (22) van de buis (23) en de tuit (43), daarmee realiserend dat de binnenomgeving van de inliner (42) en de binnenruimte van de buis (23) in fluïde communicatie zijn; daarna

e) het verwijderen van de desinfectie-eenheid (10) van het kraanstuk (20) en het bevestigen van het kraanstuk (20) aan de tuit (41) van de tank

container (40) om een aseptische verbinding tussen het kraanstuk (20) en de tank container (40) te zeker te stellen; daarna

f) het optioneel afdekken van het eerste eindstuk (21) van de buis (23) met een dop (16).

2. Werkwijze volgens conclusie 1, waarbij het sluitstuk (44) van de tuit (43) van de inliner (42) een stop is met een vorm die complementair is met de vorm van de tuit (43), welke stop
   - initieel aanwezig is in de tuit (43) en daardoor de tuit (43) afsluit;
   - na de desinfectie vrijkomt van de tuit (43) wanneer er tegenaan wordt geduwd door het tweede eindstuk (22) van de buis (23).

3. Werkwijze volgens conclusie 1, waarbij het sluitstuk (44) van de tuit (43) van de inliner (42) een membraan is dat in staat is om verscheurd en/of doorgeprikt te worden wanneer er tegenaan wordt geduwd door het tweede eindstuk (22) van de buis (23).

4. Werkwijze volgens een der conclusies 1–3, waarbij het kraanstuk (20) en/of de desinfectie-eenheid (10) een handvat omvat om het tweede eindstuk (22) van de buis (23) van het kraanstuk (20) tegen het sluitstuk (44) aan te duwen, welk handvat bediend kan worden wanneer het kraanstuk (20) is omsloten door de desinfectie-eenheid (10).

5. Werkwijze volgens een der conclusies 1–3, waarbij het duwen van het tweede eindstuk (22) tegen het sluitstuk (44) van de inliner (42) wordt uitgevoerd met behulp van een elektrisch, mechanisch, hydraulisch of pneumatisch aangedreven inrichting.

6. Werkwijze volgens een der conclusies 1–5, waarbij de tuit (43) van de inliner (42) en het tweede eindstuk (22) van een overeenkomstige conische vorm zijn.

7. Werkwijze volgens een der conclusies 1–6, waarbij de desinfectie-eenheid (10) is voorzien van bevestigingsmiddelen voor het bevestigen van de

desinfectie-eenheid (10) aan de tank container (40), en waarbij de desinfectie-eenheid (10) is bevestigd aan de tank container (40) voor stap d).

8. Werkwijze volgens een der conclusies 1–7, waarbij de ontsmettingsvloeistof (15) is geselecteerd uit de groep van water, stoom, ethanol, ozon, koolstofdioxidegas and stikstofgas.

9. Werkwijze volgens een der conclusies 1–8, waarbij, na de desinfectie in stap b), de binnenruimte (12) van de desinfectie-eenheid (10) en/of de binnenruimte van de buis (23) doorgespoeld worden met een gas.

10. Samenstel (30) van een kraanstuk (20) en een desinfectie-eenheid (10), voor gebruik in een werkwijze volgens een der conclusies 1–9, waarbij
    - de desinfectie-eenheid (10) omvat
        - een wand (11) die een binnenruimte (12) definieert, de wand (11) omvattende een opening (13) voor het opnemen van het kraanstuk (20) in de binnenruimte (12), welke opening (13) is aangepast om aan te sluiten op de tuit (41) van een tank container (40) en/of om deze te omsluiten;
        - middelen om de binnenruimte van de buis (23) van het kraanstuk (20) bloot te stellen aan een ontsmettingsvloeistof (15) en/of aan elektromagnetische straling;
    - het kraanstuk (20)
        - aanwezig is in de binnenruimte (12) van de desinfectie-eenheid (10);
        - een buis (23) omvat met
            - een eerste eindstuk (21) omvattende een kraan (24) die geconfigureerd is om de buis (23) bij het eerste eindstuk (21) te openen en af te sluiten;
            - een tweede eindstuk (22);
            - een binnenruimte die zich uitstrekt van de kraan (24) naar het tweede eindstuk (22);
        - is uitgerust met bevestigingsmiddelen voor het bevestigen van het kraanstuk (20) aan de tuit (41) van een tank container (40) om een

aseptische verbinding tussen het kraanstuk (20) en de tank container (40) te zeker te stellen;

- de desinfectie-eenheid (10) en/of het kraanstuk (20) voorzien is/zijn met middelen om de positie van het kraanstuk (20) in de desinfectie-eenheid (10) te veranderen.

11. Samenstel (30) volgens conclusie 10, waarbij het kraanstuk (20) een handvat omvat dat de wand (11) penetreert die een binnenruimte (12) definieert.

12. Samenstel (30) volgens conclusie 10, waarbij de middelen om de positie te veranderen omvatten een elektrische aandrijver, een pneumatische aandrijver of een hydraulische aandrijver.

13. Tank container (40) omvattende een samenstel (30) volgens een der conclusies 10–12, waarbij de tank container (40) omvat

- een tuit (41) voor de toevoer en afvoer van een vloeistof;
- een inliner (42) in een binnenruimte van de tank container (40), waarbij de inliner (42) een binnenomgeving omvat en een tuit (43) voor de toevoer en afvoer van een vloeistof, welke tuit (43) aanwezig is in de tuit (41) van de tank container (40);

waarbij

- het tweede eindstuk (22) van de buis (23) aanwezig is in de tuit (43) van de inliner (42) zodat er een fluïde verbinding is tussen het tweede eindstuk (22) van de buis (23) en de tuit (43);
- het kraanstuk (20) is bevestigd aan de tuit (41) van de tank container (40) om een aseptische verbinding tussen het kraanstuk (20) en de tank container (40) te zeker te stellen.

14. Tank container (40) volgens conclusie 13, waarbij de desinfectie-eenheid (10) is verbonden met de tank container (40) of met de tuit (41) van de tank container (40).

15. Tank container (40) volgens conclusie 13 of 14, waarbij de inliner (42) is gevouwen en/of opgerold, zodat het beschikbare volume in de binnenruimte

van de inliner (43) minder dan 0.01% van het volume van de binnenruimte van de tank container (40) is.

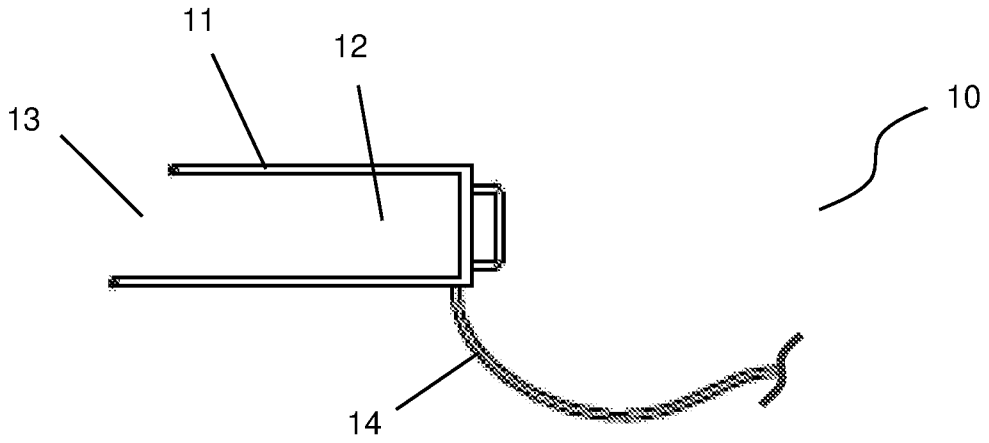

Figure 1

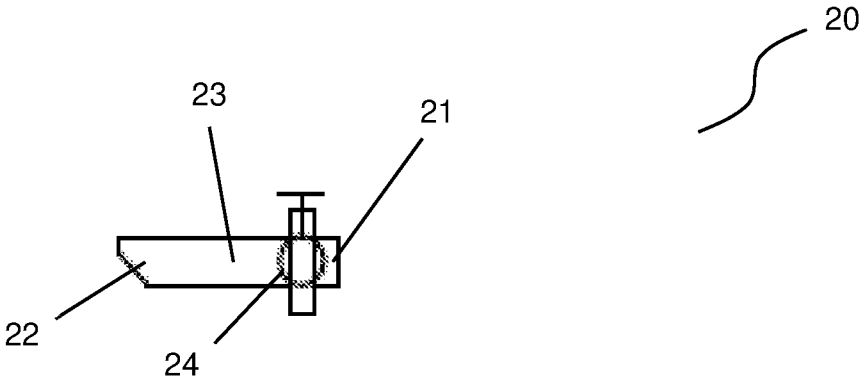

Figure 2

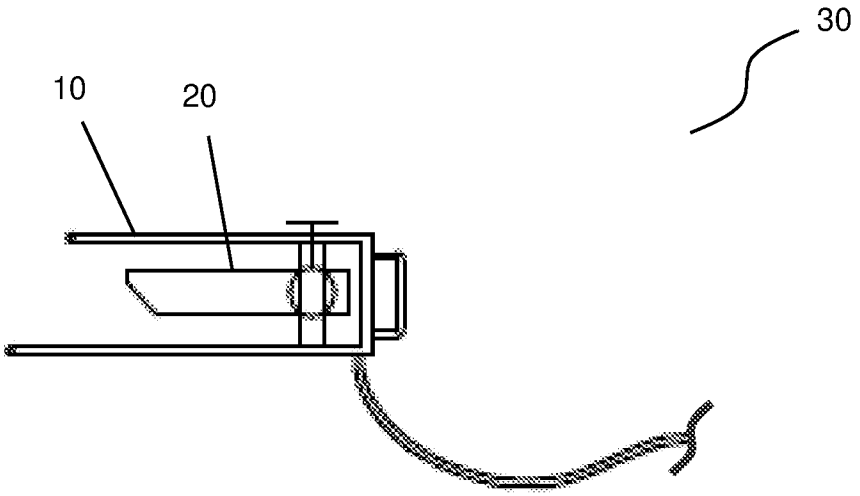

Figure 3

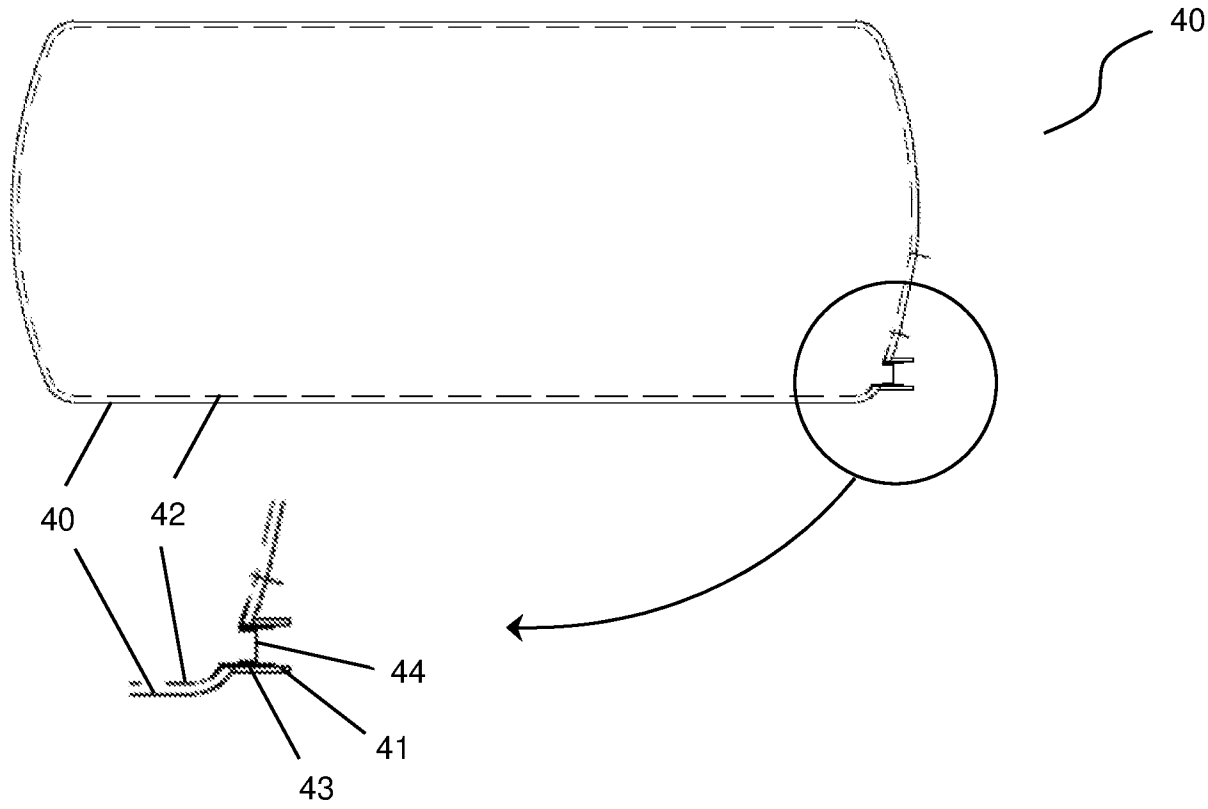

Figure 4

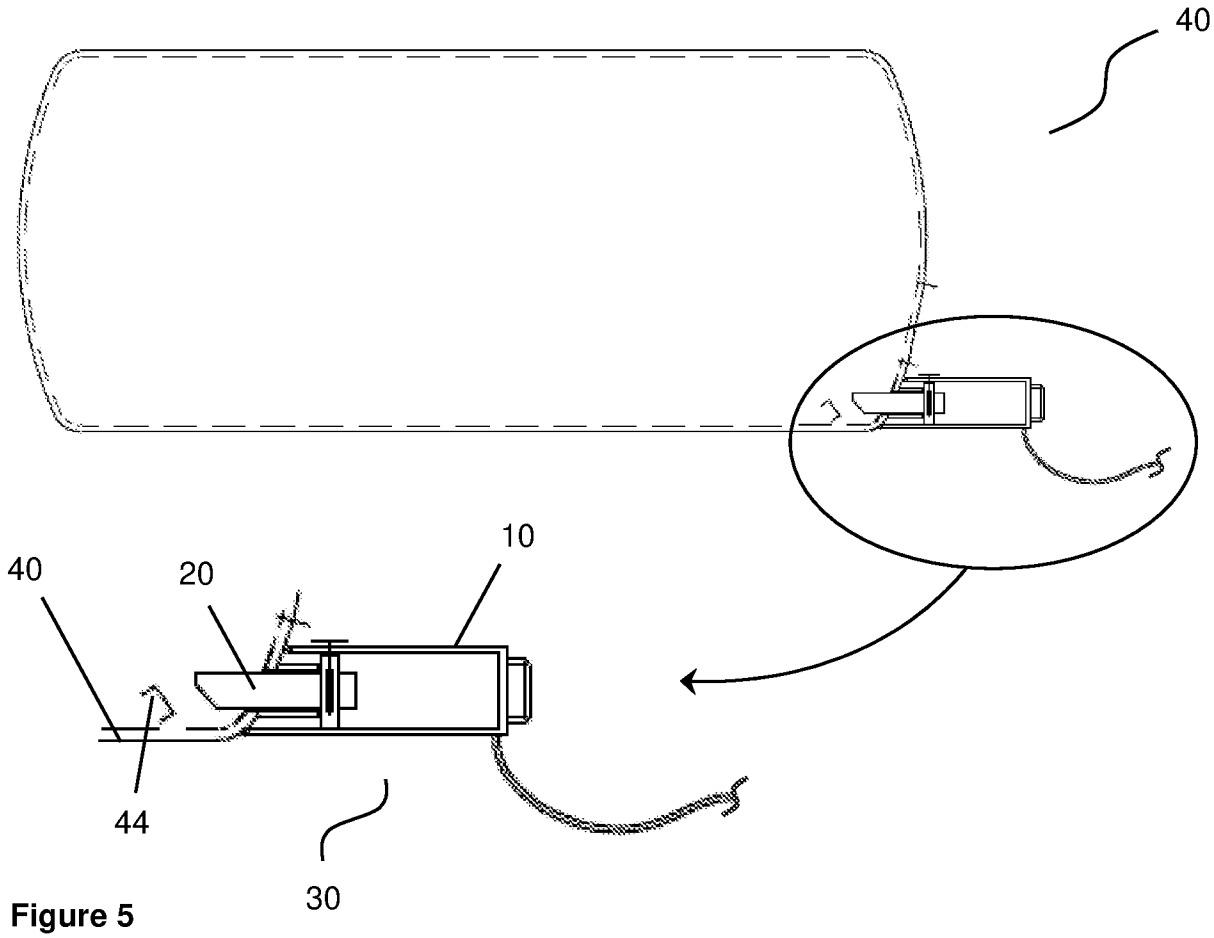

Figure 5

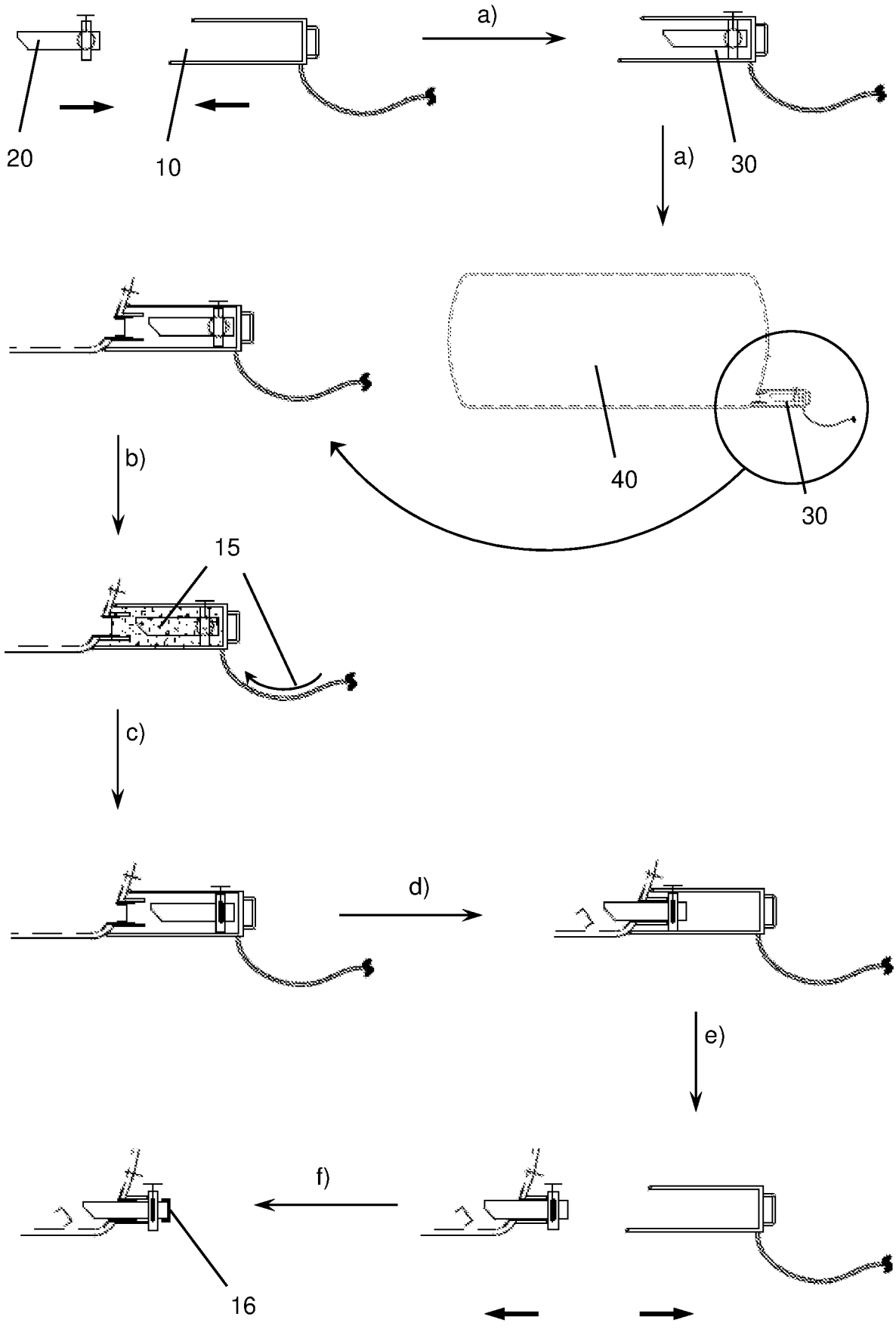

Figure 6

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	031.002.NLPD
Nederlands aanvraag nr. **2024686**	Indieningsdatum **16-01-2020**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **Mega-Inliner International Group BV**	
Datum van het verzoek voor een onderzoek van internationaal type **28-03-2020**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN75818**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

Zie onderzoeksrapport

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC	**Zie onderzoeksrapport**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III. ☐ **GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES** (opmerkingen op aanvullingsblad)

IV. ☐ **GEBREK AAN EENHEID VAN UITVINDING** (opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2024686

A. CLASSIFICATIE VAN HET ONDERWERP
INV. B67D1/08 B08B9/032
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
B67D B08B A61L B65D

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	EP 1 719 714 A1 (WILD GMBH & CO KG RUDOLF [DE]) 8 november 2006 (2006-11-08) * alineas [0044], [0045], [0060], [0069], [0076], [0084], [0087]; figuren *	1,10
A	WO 99/47432 A1 (SOUTHCORP AUSTRALIA PTY LTD [AU]; ANDERSON IAN [AU]) 23 september 1999 (1999-09-23) * bladzijde 4, regels 17-32; conclusies 1,15; figuren *	1,10
A	WO 03/033376 A1 (BAG IN A BOX LTD [GB]; DAVIDSON PAUL ANTHONY [GB]) 24 april 2003 (2003-04-24) * bladzijde 2, regels 4-30; figuren *	1,10

☐ Verdere documenten worden vermeld in het vervolg van vak C.

☒ Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
27 mei 2020	

Naam en adres van de instantie	De bevoegde ambtenaar
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Müller, Claus

Formulier PCT/ISA/201 (tweede blad) (Januari 2004)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2024686

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
EP 1719714 A1	08-11-2006	BR PI0603270 A	26-12-2006
		CA 2543309 A1	06-11-2006
		CN 1857970 A	08-11-2006
		EP 1719714 A1	08-11-2006
		EP 1724207 A2	22-11-2006
		JP 2006312493 A	16-11-2006
		KR 20060115590 A	09-11-2006
		KR 20080056122 A	20-06-2008
		KR 20080056123 A	20-06-2008
		RU 2351518 C2	10-04-2009
		TW 200642930 A	16-12-2006
		US 2008006636 A1	10-01-2008
		ZA 200603592 B	31-01-2007
WO 9947432 A1	23-09-1999	AT 333422 T	15-08-2006
		DE 69932438 T2	31-05-2007
		EP 1087895 A1	04-04-2001
		ES 2273476 T3	01-05-2007
		JP 4284457 B2	24-06-2009
		JP 2002506779 A	05-03-2002
		US 6427872 B1	06-08-2002
		US 2002170922 A1	21-11-2002
		US 2004016770 A1	29-01-2004
		US 2005072795 A1	07-04-2005
		WO 9947432 A1	23-09-1999
WO 03033376 A1	24-04-2003	GEEN	

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN75818	16.01.2020		NL2024686

International Patent Classification (IPC)
INV. B67D1/08 B08B9/032

Applicant
Mega-Inliner International Group BV

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the application
- ☐ Box No. VIII Certain observations on the application

	Examiner
	Müller, Claus

Application number

WRITTEN OPINION

NL2024686

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	1-15
	No:	Claims	
Inventive step	Yes:	Claims	1-15
	No:	Claims	
Industrial applicability	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Box No. VII Certain defects in the application

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents

D1	EP 1 719 714 A1 (WILD GMBH & CO KG RUDOLF [DE]) 8 november 2006 (2006-11-08)
D2	US 2011/286883 A1 (HECHT THOMAS R [US] ET AL) 24 november 2011 (2011-11-24)

1 The present application meets the requirements of patentability because the subject-matter of claim 1 involves an inventive step.

1.1 Document D1 is considered to be the prior art closest to the subject-matter of claim 1 and discloses:

Werkwijze voor het tot stand brengen van een aseptische verbinding tussen een kraanstuk en een tank container die een inliner omvat, omvattende het verschaffen van

a. een tank container (3) en een inliner (31) welke aanwezig is in een binnenruimte van de tank container, waarbij
    1. zowel de tank container als de inliner een tuit (15, 33) omvatten voor de toevoer en afvoer van een vloeistof;
    2. de tuit van de inliner in de tuit van de tank container geplaatst is;
    3. de tuit van de inliner afgesloten is middels een sluitstuk (35) dat een binnenomgeving van de inliner scheidt van een buitenomgeving, welk sluitstuk in staat is om doorgeprikt te worden en/of verdreven te worden uit de tuit om daarmee de toevoer en afvoer van vloeistof door de tuit mogelijk te maken;
b. een kraanstuk (17) omvattende een buis (55) met
    1. een eerste eindstuk omvattende een kraan (53) die geconfigureerd is om de buis bij het eerste eindstuk te openen en af te sluiten;

waarbij het kraanstuk is uitgerust met bevestigingsmiddelen voor het bevestigen van het kraanstuk aan de tuit van de tank container om een aseptische verbinding tussen het kraanstuk en de tank container te zeker te stellen.

1.2 The subject-matter of claim 1 therefore differs from this known state of the art in that the method further comprises:

a. *een kraanstuk omvattende*

1. een tweede eindstuk dat in staat is om het sluitstuk te verdrijven uit de tuit en/of om het sluitstuk door te prikken;
2. een binnenruimte die zich uitstrekt van de kraan naar het tweede eindstuk;

b. een desinfectie-eenheid omvattende een wand die een binnenruimte definieert, waarbij

1. de wand een opening omvat voor het opnemen van het kraanstuk in de binnenruimte, welke opening is aangepast om aan te sluiten op de tuit van de tank container en/of om deze te omsluiten;
2. de desinfectie-eenheid middelen omvat om de binnenruimte van de buis van het kraanstuk bloot te stellen aan een ontsmettingsvloeistof en/of aan elektromagnetische straling;
3. de desinfectie-eenheid is voorzien van middelen om de positie van het kraanstuk in de desinfectie-eenheid te veranderen en het tweede eindstuk van de buis van het kraanstuk tegen het sluitstuk van de inliner aan te duwen, wanneer
    a. het kraanstuk is vervat in de binnenruimte van de desinfectie-eenheid;
    b. de opening van de desinfectie-eenheid tegen of rondom de tuit van de tank container is geplaatst;

en het daarna uitvoeren van de stappen van

a. het plaatsen van het kraanstuk in de binnenruimte van de desinfectie-eenheid en
b. het plaatsen van de opening van de desinfectie-eenheid tegen of rondom de tuit van de tank container; daarna
c. het desinfecteren van het kraanstuk door de binnenruimte van de buis van het kraanstuk bloot te stellen aan een ontsmettingsvloeistof en/of aan elektromagnetische straling terwijl de kraan in een open stand staat; daarna
d. het sluiten van de kraan van het kraanstuk; daarna

e. het duwen van het tweede eindstuk van de buis van het kraanstuk tegen het sluitstuk dat aanwezig is in de tuit van de van de inliner zodat het sluitstuk verplaatst of doorgeprikt wordt en een fluïde verbinding gegenereerd wordt tussen het tweede eindstuk van de buis en de tuit, daarmee realiserend dat de binnenomgeving van de inliner en de binnenruimte van de buis in fluïde communicatie zijn; daarna

f. het verwijderen van de desinfectie-eenheid van het kraanstuk en het bevestigen van het kraanstuk aan de tuit van de tank container om een aseptische verbinding tussen het kraanstuk en de tank container te zeker te stellen; daarna

g. het optioneel afdekken van het eerste eindstuk van de buis met een dop.

1.3 This difference provides for the technical effect of sterilising in place of the dispensing unit.

1.4 Thus, the objective problem to be solved to provide method for assuring that for tanks being foreseen with an exchangeable liner, the tapping is aseptic such that the content of the liner can be dispensed under aseptic conditions.

1.5 The solution proposed in claim 1 of the present application is to be considered to involve an inventive step. Document D2 discloses an opening mechanism similar to that of the application. However, the devices as disclosed in D1 and D2 are not compatible with each other unless adaptations are made which hardly can be carried out without the exercise of inventive skill. Even if the teachings of D1 were combinable with those of D2, these teachings would lack the claimed "desinfectie-eenheid" and the steps that have to be carried out for disinfecting the tap.

2 For the same reason, i.e the lack of the "desinfectie-eenheid" the subject-matter of apparatus claim 10 is also new and involves an inventive step.

3 Claims 2-9 and 11-15 are dependent on claims 1 and 10, respectively, and as such also meet the requirements of inventive step.

4

Re Item VII

Certain observations on the application

5 However, the application does not meet the formal requirements.

5.1 The independent claims are not in the two-part form which, in the present case, would be appropriate, with those features known in combination from the prior art being placed in the preamble and the remaining features being included in the characterising part. Reasons should be given if the applicant is of the opinion that the one-part-form is more appropriate.

5.2 The prior art should be acknowledged in the description. This is of particular importance if the independent claim remains in the one-part form such that the reader of the application cannot deduce which features of the claim contribute over the prior art.