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(54) **LEAKTIGHT ASSEMBLY AND METHOD FOR MANUFACTURING THE SAME**

(57) The invention relates to a Leaktight assembly comprising:
- A bag (1) comprising a wall (8) of flexible film,
- a connection system (9) comprising a connector (21) adapted to be mechanically connected to a complementary connector of a sterile enclosure (11) for sterile communication between the bag (1) and the enclosure (11), the connector (21) comprising a portion for attachment to the bag (210), the connection system (9) further comprising an overmolding (40) overmolded on the attachment portion (210), the wall of the bag (1) being welded to the overmolding (40) in a continuous closed manner along a predetermined portion of the wall of the bag (1), and
- a protective envelope (15) of the connection system (9), comprising a wall of flexible film, the wall of the protective envelope (15) being welded on said connection system (9) in a continuous closed manner along a predetermined portion of the wall of the protective envelope (15).

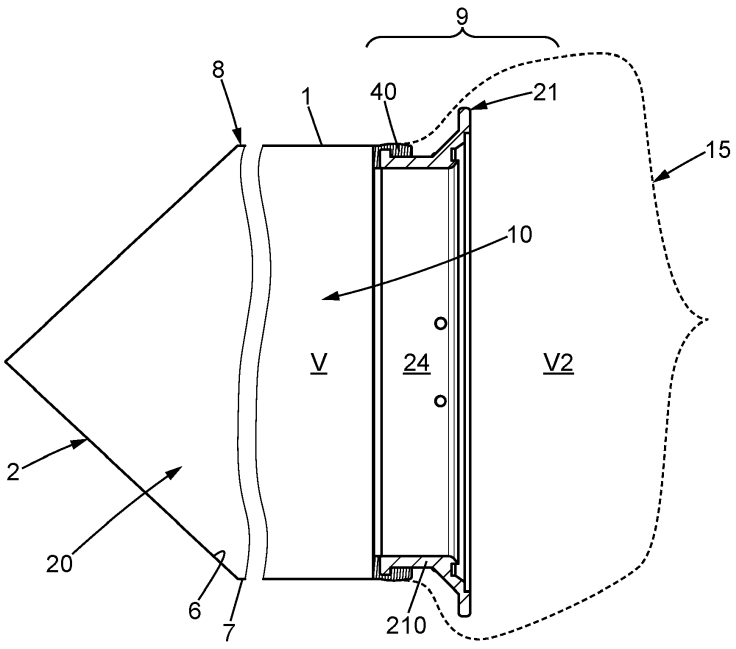

FIG. 1a

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Description

[0001] The present invention relates to sealed containers in the pharmaceutical or biotechnological field.

[0002] More particularly, the invention relates to leaktight containers used in leaktight assemblies between a sterile chamber such as an isolator and one or more of these containers. In this field, it is known to use a sterile chamber comprising several doors, and to connect, to these doors, containers themselves provided with doors. The doors are opened after the sterile chamber and the external container have been connected, to allow the objects contained in the container to be transferred to the sterile chamber, or even in the opposite direction if appropriate.

[0003] Already commonly known are methods for manufacturing leaktight containers for biopharmaceutical applications, such as the container disclosed in FR2721289. This involves mounting a leaktight assembly by assembling a bag comprising a wall and an opening for accessing a connector provided with a door, the other access opening of the bag being intended to be closed. A known mode of manufacturing such an assembly for such a container is by inserting the thickness of the bag wall at its access opening between the connector and a complementary part which then clamps the preceding assembly. However, this type of container is intended for exposure to high stresses, and the risk still exists of leakage at the assembly or of weakening the material of the bag which can ultimately lead to bursting. There was therefore a desire to reduce such risks for the increasingly demanding applications of the biopharmaceutical field.

[0004] Thus, also known is the method disclosed where a bag comprising a wall of flexible film is used, the wall of the bag defining an internal volume of the bag, where the wall of the bag is welded, at an access opening, to an overmolding of a connection system is provided, the connection system comprising a connector adapted for mechanical connection to a complementary connector of a sterile chamber in order to establish a sterile communication between the bag and the chamber, the connector comprising a portion for attachment to the bag, the connection system further comprising an overmolding molded over the attachment portion. However, this second type of container can also be exposed to high levels of stress, particularly in terms of pressure and negative pressure. More particularly, once filled, this second type of container may be subjected to stresses during transport, particularly in terms of pressure variation (for example variation in external pressure with respect to the internal pressure when the container is filled). These stresses can, in some situations, cause the container to lose some pressure. Such pressure loss can cause difficulties, for example during visual inspections of the container and its contents, more specifically when the container is inserted into an overpack, in which vacuum has been done. More specifically, a problem may also arise when the container is over-wrapped with an extra bag and a vacuum is created between the two bags. If the bag swells, sterility is lost (hence the overwrapping used in some cases). Such stresses can also potentially cause problems with the connector, leading to excess pressure in the connector itself at some points.

[0005] An alternative solution to these leaktight assemblies and methods for manufacturing leaktight assemblies is therefore sought.

[0006] For this purpose, is the leaktight assembly according to the invention which comprises:

- A bag comprising a wall of flexible film,
- a connection system comprising a connector adapted to be mechanically connected to a complementary connector of a sterile enclosure for sterile communication between the bag and the enclosure, the connector comprising a portion for attachment to the bag, the connection system further comprising an overmolding overmolded on the attachment portion, the wall of the bag being welded to the overmolding in a continuous closed manner along a predetermined portion of the wall of the bag, and
- a protective envelope of the connection system, comprising a wall of flexible film, the wall of the protective envelope being welded on said connection system in a continuous closed manner along a predetermined portion of the wall of the protective envelope.

[0007] In various embodiments of the leaktight assembly according to the invention, one or more of the following arrangements may possibly also be employed:

According to a feature, the bag and the protective envelope are welded one on top of the other to the overmolding.

According to a feature, the bag and the protective envelope are welded side by side to the overmolding.

According to a feature, the protective envelope is formed at least in part from an extension of the wall of the bag extending beyond the overmolding.

According to a feature, the protective envelope and the bag are made of a single piece of material having a predetermined shape which comprises a bottleneck the wall of which being welded to the overmolding.

According to a feature, the attachment portion has an annular shape and wherein the overmolding forms a ring around the attachment portion.

According to a feature, the wall of flexible film of the bag defines an internal volume of said bag and said bag having two opposite ends, a first access opening adapted for placing the internal volume of the bag in communication with the outside of the bag at the first end, a second access opening adapted for placing the internal volume of the bag in communication with the outside of the bag at the second end, and wherein

the predetermined portion of the wall of the bag welded on the overmolding is constituted by the first access opening.

According to a feature, the flexible film wall of the protective envelope defines an internal volume, the protective envelope having a two opposite ends, a connector opening adapted to be able to communicate the internal volume of the protective envelope with the outside of the protective envelope at the first end, a sealing opening adapted to be able to communicate the internal volume of the protective envelope with the outside of the protective envelope at the second end, the protective envelope wall, and wherein the predetermined portion of the wall of the protective envelope welded on In various embodiments of the leaktight container according to the invention, one or more the following arrangements may further be employed: the overmolding is constituted by the connector opening, so that the connection system is located inside the second internal volume; the connector comprises a door adapted to equip the access opening of the bag, the door comprising a flange-shaped frame, the attachment portion being at least a portion of the flange; the attachment portion of the connector comprises a body and a projecting member, the projecting member extending radially from said body, said projecting member being encapsulated in the overmolding.

[0008] In addition, the invention relates to a leaktight container comprising a leaktight assembly, the second access opening being closed in a leaktight manner. In addition, the invention relates to a leaktight assembly comprising a container wherein the connector is a first connector, the leaktight assembly further comprising a rigid chamber comprising a second connector complementary to the first connector, the connector of the leaktight container being connected in a leaktight manner to the second connector of said rigid chamber after at least part of the protective envelope is removed.

[0009] In addition, is the method for manufacturing a leaktight assembly according to the invention in which:

- a bag comprising a wall of flexible film is provided,
- a connection system is provided, the connection system comprising a connector adapted for mechanical connection to a complementary connector of a sterile chamber in order to establish a sterile communication between the bag and the chamber, the connector comprising a portion for attachment to the bag, the connection system further comprising an overmolding molded over the attachment portion,
- a protective envelope of the connection system comprising a wall of flexible film is provided,

the manufacturing method further comprising the steps of:

- positioning the wall of the bag facing the overmolding at a predetermined portion of the wall of the bag,
- positioning the wall of the protective envelope facing the overmolding at a predetermined portion of the protective envelope,
- welding the wall of the bag and the wall of the protective envelope to the overmolding in a closed continuous manner all along the predetermined portions.

[0010] In such a manufacturing method, the overmolding, selected in a suitable material, allows welding the wall of the bag and the wall of the protective envelope to said overmolding in order to create a good seal for the container so produced. In addition, the connector of the leaktight assembly is protected during use. In addition, the leaktight container so produced can be sterilized with steam or gamma irradiation. In various embodiments of the method for manufacturing a leaktight assembly according to the invention, one or more of the following arrangements may possibly be used:

According to a feature, welding the wall of the bag and the wall of the protective envelope to the overmolding in a closed continuous manner all along the predetermined portion comprises:

- welding the wall of the bag to the overmolding at a first predetermined location of the overmolding;
- welding the wall of the protective envelope to the overmolding at a second predetermined location of the overmolding.

According to a feature, the protective envelope and the bag are made of a single piece of material having a predetermined shape which comprises a bottleneck the wall of which being welded to the overmolding during the welding step.

According to a feature, the wall of the bag is of plastic film which comprises a layer of polyethylene.

According to a feature, a layer of plastic film which faces the overmolding is a layer of polyethylene.

According to a feature, the method further comprises a step of closing the assembly in a leaktight manner at the connector, a step of closing the protective envelope at its sealing opening, a step of filling the bag by the second access opening, and a step of closing the second access opening of the bag so as to close the bag in a leaktight manner at its second access opening.

According to a feature, the closing step consists of welding the wall of the bag to itself at its second access opening.

[0011] In addition, the invention relates to a method for manufacturing a leaktight container further comprising a step of closing the protective envelope, at its sealing

opening, after a door has been positioned at the connection system.

[0012] In addition, the invention relates to a method for manufacturing a leaktight container further comprising a step of filling the bag by the second access opening, and a step of closing the second access opening of the bag so as to close the bag in a leaktight manner at its second access opening after closing the assembly in a leaktight manner at the connector and filling the bag.

[0013] In various embodiments of the method for manufacturing a leaktight container according to the invention, one or more of the following arrangements may also possibly be used:

the closing step consists of assembling a closing surface to the wall of the bag (respectively the wall of the protective envelope), the closing surface being adapted for attachment to the wall of the bag (respectively the wall of the protective envelope) at its second access opening (respectively at its sealing opening).

the closing step consists of welding the wall of the bag (respectively the wall of the protective envelope) to itself at its second access opening (respectively at its sealing opening).

[0014] In various embodiments of the method for manufacturing a leaktight container according to the invention, one or more the following arrangements may further be employed:

the sealing opening of the protective envelope is closed in a leaktight manner.

the sealing opening is closed by a closing surface, the closing surface being adapted for attachment to the wall of the protective envelope at its sealing opening.

the sealing opening is closed by welding the wall of the protective envelope to itself at its sealing opening.

the second access opening is closed in a leaktight manner.

the second access opening is closed by a closing surface, the closing surface being adapted for attachment to the wall of the bag at its second access opening.

the second access opening is closed by welding the wall of the bag to itself at its second access opening.

[0015] Other features and advantages of the invention will be apparent from the following description of one of its embodiments, given by way of non-limiting example and with reference to the accompanying drawings.

[0016] In the drawings:

- FIGS. 1 a and 1b illustrate the leaktight container in the case where the bag is welded and, in the case, where a closing surface is mounted,
- FIGS. 2a and 2b illustrate the bag and the protective envelope in two different embodiments,
- FIG. 3 illustrates an embodiment of the assembly of the bag and the envelope to the overmolding;
- FIG. 4 illustrates the case of a projecting member at the attachment portion,
- FIG. 5a and 5b illustrate the manufacture of a leaktight assembly in two different embodiments,
- FIG. 6 shows the assembly between the container and a chamber by coupling intermediate doors. In the different figures, the same references designate identical or similar elements.

[0017] The present invention relates to leaktight containers and to their manufacturing for pharmaceutical or biotechnological applications requiring limited or no contamination, including by particles from the external environment. This typically involves a bag whose contents are to be isolated from the external environment, assembled to another chamber such as an isolator, for a sterile transfer between the bag and the chamber. A typical application would be to use such a container for the sterile transfer of packaging material or syringe stoppers from a bag within which they are initially contained and sterilized, to an isolator.

[0018] FIG. 1 shows a leaktight container. Said container comprises a leaktight assembly of which the second access opening 20 is closed in a leaktight manner. More specifically, the leaktight assembly comprises a bag 1 comprising a wall 8 of flexible film, the wall 8 of said bag defining an internal volume V of said bag, said bag 1 having two opposite ends, a first access opening 10 adapted for placing the internal volume of the bag in communication with the outside of the bag at the first end, a second access opening 20 adapted for placing the internal volume of the bag in communication with the outside of the bag at the second end. In addition, the bag 1 comprises an inner surface 6 facing towards the internal volume V. In addition, the bag 1 comprises an outer surface 7 opposite to the inner surface 6. The container also comprises a connection system 9 which includes a connector 21 comprising an attachment portion 210 and an overmolding 40 molded on the attachment portion 210. The wall of the bag is positioned facing the overmolding at the first access opening 10, the wall of the bag being welded to the overmolding 40. The second access opening 20 of said bag 1 is closed in a leaktight manner.

[0019] In addition, the connector 21 is protected by a protective envelope 15. The protective envelope 15 may be flexible. The protective envelope 15 may be welded on the overmolding 40, on top of the bag 1 (on the external, layer of the film of the bag 1 which is welded on the overmolding 40), or under the bag 1 (i.e. internal layer of the film of the bag 1 on the external layer of the protective envelope which is itself welded on the overmolding 40), or side-by-side of the bag 1 (both films are welded on the overmolding 40 at different locations), depending on the configuration. The protective envelope

15 is sealed on the overmolding 40 for example during the manufacturing process of the leaktight container, as exposed herein after. The protective envelope 15 is closed in a leaktight manner at its end. The protective envelope 15 may also be closed during use i.e., after the internal volume of the bag is filled, for example for ensuring an equality of the internal pressures of the bag and of the protective envelope. The connector 21 is thus protected against soiling / dirtiness, contamination and against various sources and effects of constraints that may be applied to the connector 21, this protection is active immediately at manufacturing.

[0020] Said assembly may be closed in a leaktight manner at the connector 21.

[0021] Said assembly may in particular be connected to a complementary connector of a sterile chamber, such an assembly between the connectors enabling a sterile communication between the contents of the bag 1 and the chamber 11. This connection to the complementary connector can be done after a dedicated portion of the sealed (closed) protective envelope 15 is removed, either by cutting or pealing the protective envelope. The attachment portion 210 is located at the access opening of the bag 1 and surrounds a space for passage 24 between the bag 1 and the chamber 11 at the access opening 10. The assembly thus formed may for example be removable and transportable, for example for one-time use, the assembly being small and the bag being flexible, which reduces the space requirements for transport and delivery of these containers.

[0022] The second access opening 20 is then closed in a leaktight manner, thereby forming a bag, in particular after introducing products into the bag 1. According to a first variant, the second access opening 20 is closed by a closing surface 2, the closing surface 2 being adapted to attach to the wall of the bag 1 at its second access opening 20 (FIG. 1b). Essentially all points on the circumference of the sealing surface 2 are welded together at ideally one point.

[0023] During use, the internal volume V of said bag 1 is filled with material to be introduced into the chamber 11, for example items such as syringe stoppers. The contents of the container thus formed are then sterilized with gamma irradiation for example.

[0024] Sterilization may for example take place through the wall 8 of the bag. Sterilization may also take place through the wall of the protective envelope 15. A portion of the wall of the bag 1 (respectively protective envelope 15) may for example be of Tyvec® which is a vapor-permeable material. The bag is for example then enclosed in over-packaging to guarantee sterility until use.

[0025] According to an embodiment, the protective envelope 15 is a part of the bag 1 itself. More specifically, the protective envelope 15 is an extension of the bag 1 that elongates from the overmolding 40 to the opposite end of the protective envelope. In such an embodiment, a predetermined portion of the bag 1 is welded on the overmolding 40 and the first end of the bag extends beyond the connector 21. This first end of the bag thus constitutes the protective envelope 15 which surrounds the connector. The first end of the bag is sealed during the manufacturing process or after, as explained herein before.

[0026] Figure 2A illustrates a top view of a flattened bag 1. As can be seen, this bag 1 comprises a bottleneck 16 which materialises the predetermined location at which the bag 1 is welded to the connector 21 (the bottleneck is thus the location at which the connecter 21 is welded on the overmolding 40). The width of this bottleneck 16 is greater or equal to the width of the connector 21 and more particularly is greater or equal to the width formed by the overmolding 40, so that the wall of the bag, can be welded at its bottleneck 16, to the overmolding 40, in a closed and continuous manner along the entire length of the bottleneck 16. The process for manufacturing the leaktight container using this first embodiment of the bag is illustrated below.

[0027] According to a second embodiment, the protective envelope 15 is an additional part which is added and is not part of the bag 1. Figure 2B illustrates this embodiment. In this embodiment, the protective envelope 15 may be made of a different material to that of the bag 1. The process for manufacturing the leaktight container according to this embodiment is illustrated below. The protective envelope 15 comprise a connector opening 151, sensibly of the length of the overmolding 40, so that the wall of the protective envelope 15, can be welded at its connector opening 151, to the overmolding 40, in a closed and continuous manner along the entire length of the connector opening 151. The protective envelope 15 also comprises a sealing opening 152, that can also be closed in a leaktight manner, thereby forming a protection around the connection system 9.

[0028] Whatever embodiment or variant is, at least on part of the protective envelope 15 may be removed, for example for allowing the connector 21 to be connected to a complementary connector. To this end, a part of the protective envelope 15 is pealable for example at a predetermined location. In another variant, the protective envelope 15 may be cut by an operator.

[0029] In an embodiment illustrated in FIG. 3, the connector 21 comprises a radially outer surface 22 facing radially outward of the connector 21, and the overmolding 40 comprises a radially inner surface 41 and a radially outer surface 42 opposite to the radially inner surface 41 of the overmolding 40. As a function of the configurations, the radially outer surface 42 may be divided in two sections: one for the welding of the bag and one for the welding of the protective envelope. In addition, the bag 1 comprises an inner surface 6 facing towards the internal volume V. In the container thus formed, the radially outer surface 22 of the connector 21 is facing the radially inner surface 41 of the overmolding 40, such that during the step of positioning the overmolding 40 to face the wall of the bag 1, the radially outer surface 42 of the overmolding

40 is also positioned facing the inner surface 6 of the bag 1. Thus, at the first access opening 10 of the bag 1 (or at the bottleneck 16 of the bag 1), the passage between the bag 1 and the outside is composed of the superposition, from inside to outside, of the thickness of the connector 21 at its attachment portion, the thickness of the overmolding, and the thickness of the wall of the bag 1.

[0030] In addition, in the case it constitutes a separated element from the bag 1, the protective envelope 15 also comprises, in an embodiment, an inner surface facing towards the internal volume V2. In the protection volume thus formed, the radially outer surface 22 of the connector 21 is facing the radially inner surface 41 of the overmolding 40, such that during the step of positioning the overmolding 40 to face the wall of the protective envelope 15, the radially outer surface 42 of the overmolding 40 is also positioned facing the inner surface of the protective envelope 15. Thus, at the connector opening of the protective envelope 15, the passage between the protective envelope 15 and the outside is composed of the superposition, from inside to outside, of the thickness of the connector 21 at its attachment portion, the thickness of the overmolding, and the thickness of the wall of the protective envelope 15. The protective envelope 15 end extends longitudinally beyond the connector 21, as illustrated by the doted lines 221 and 222. In particular, the wall 8 of the bag is of flexible film and is welded to the overmolding 40 in a closed continuous manner all along the first access opening 10. In particular, the wall of the protective envelope 15 is of flexible film and is welded to the overmolding 40 in a closed continuous manner all along the first connector opening 151.

[0031] In particular, as illustrated in FIG. 4, the attachment portion 210 of the connector 21 may comprise a body 70 with a projecting member 202 which extends radially from said main body 70. Said projecting member 202 is adapted to be encapsulated in the overmolding 40. The thickness of the body at the projecting member 202 is typically two to three times greater than that of the body where there is no projecting member.

[0032] A first method for manufacturing the assembly, for the first embodiment of the bag 1 (fig 2a), is shown in FIG. 5a and comprises the following steps:

- rolling up the bag 1, over the bottleneck 16, so that the widest part of the portion acting as a protective envelope 15 is turned over onto the rest of the bag 1. At the end of this step, an opening of the width of the bottleneck 16 is created.
- positioning the wall of the bag 1, at this opening to face the overmolding 40 at the bottleneck 16, the overmolding 40, carried by the connector 21, being for example inserted into the bag 1 by its access opening 10, in proximity to the access opening 10 of the bag 1,
- welding the wall of the bag 1, at its first access opening, to the overmolding 40, in a closed continuous manner all along the bottleneck 16.
- return the widest part of the portion acting as a protective envelope 15 to its initial position, so that the portion acting as a protective envelope 15 surrounds the connector 21.
- sealing the portion acting as a protective envelope 15, at its sealing opening 152, so as to isolate the connector 21.

[0033] A second method for manufacturing the assembly, for the second embodiment of the bag 1 (fig 2b), is shown in FIG. 5b and comprises the following steps:

- positioning the wall of the bag 1 to face the overmolding 40 at the first access opening 10, the overmolding 40, carried by the connector 21, being for example inserted into the bag 1 by its access opening 10, in proximity to the access opening 10 of the bag 1,
- welding the wall of the bag 1, at its first access opening 10, to the overmolding 40, in a closed continuous manner all along the first access opening.
- positioning the wall of the protective envelope 15 opposite the overmolding 40 at the connector opening 151, the overmolding 40, carried by the connector 21, being for example inserted into the protective envelope 15 through its connector opening 151, close to the access opening 10 of the bag 1,
- welding the wall of the protective envelope 15, at its connector opening 151, to the overmolding 40, in a closed and continuous manner along the entire length of the connector opening 151 or the portion intended to be welded (16, 10).
- sealing the wall of the protective envelope 15 at its second sealing opening 152.

[0034] According to a preferred variant of the second method the steps of welding the wall of the bag 1, at its first access opening 10, and the step of welding the wall of the protective envelope 15, at its connector opening 151 to the overmolding 40 are carried out together. For example, the protective envelope 15 takes place over the bag 1, and a single welding step is carried out. The method thus comprises:

- positioning the wall of the bag 1 to face the overmolding 40 at the first access opening 10, the overmolding 40, carried by the connector 21, being for example inserted into the bag 1 by its access opening 10, in proximity to the access opening 10 of the bag 1,
- positioning the wall of the protective envelope 15 to face the external layer of the bag 1 over the overmolding 40 at the connector opening 151, the overmolding 40 and the surrounded bag 1, carried by the connector 21, being for example inserted into the protective envelope 15 through its connector opening 151, over the access opening 10 of the bag 1,
- welding the wall of the bag 1 and the wall of the

protective envelope 15 to the overmolding 40, in a closed continuous manner all along the first access opening 10 and the connector opening 151.

- sealing the wall of the protective envelope 15 at its second sealing opening 152.

[0035] According to a variant, a portion of the overmolding 40 is set to weld the wall of the bag 1, at its first access opening 10 and a complementary portion of the overmolding 40 is set to weld the wall of the protective envelope 15. For example, the outer surface of the overmolding 40 is divided in two parts, and each of these two parts are used to weld the wall of the bag 1 for the first part and the protective envelope 15 for the second part.

[0036] According to a variant, the closure of the protective envelope 15, at the sealing opening 152, can be carried out upstream, i.e., before the protective envelope is welded to the overmolding 40. In this way, it is possible to independently manufacture protective envelopes which are welded to the overmolding 40 after a first series of stages in the manufacture of the bag assembly has been carried out (i.e., after the bag has been positioned and after the bag 1 has been welded to the over overmolding 40).

[0037] According to a variant, the closure of the protective envelope 15, at the sealing opening 152, is carried out after the sealing of the protective envelope on the overmolding 40.

[0038] In the case where the attachment portion 210 of the connector is annular for example, the overmolding 40 is annular. The weld is then a circular weld. Such method will be used in particular for assembling a bag made of plastic film to a connector 21 made of polycarbonate (PC) or acrylonitrile butadiene styrene (ABS) or polyvinylidene fluoride (PVDF) or polybutylene terephthalate (PBT). Such materials for the connector 21 will be rigid so as to withstand the locking forces from the second connector and will be resistant to the various treatments associated with sterilization by steam (at temperatures below 125° C.), gamma irradiation, or ethylene oxide. The plastic film may in particular be polyethylene (PE), high density polyethylene (HDPE), or low-density polyethylene (LDPE). The overmolding 40 will be made of polyethylene (PE), high density polyethylene (HDPE), or in the form of thermoplastic elastomer (TPE), or may be of thermoplastic elastomer or polypropylene or polyvinylidene fluoride (PVDF). The overmolding 40 made of such materials provides poor resistance during sterilization (<125° C.) and will also tend to deform at welding working temperatures above 120° C., its mechanical strength being inadequate at these temperatures, but it will not melt during the temperature increase when it is mounted on the connector which will then "contain" its deformation. However, it has been demonstrated by tests that the welding of the plastic film on the overmolding has good resistance to gamma irradiation sterilization or steam sterilization.

[0039] To carry out the welding, the film and the overmolding begin to melt almost at the same time, therefore within similar temperature ranges of about 120° C. (far from the welding temperatures of the materials selected for the connector 21 which instead are about 200° C.).

[0040] One will advantageously consider the case where:

- the connector 21 is of polyvinylidene fluoride (PVDF) and the overmolding 40 is of high-density polyethylene (HDPE) or thermoplastic elastomer (TPE);
- the connector 21 is of polycarbonate (PC) and the overmolding 40 is of high-density polyethylene (HDPE) or thermoplastic elastomer (TPE);
- the connector 21 is of acrylonitrile butadiene styrene (ABS) and the overmolding 40 is of high-density polyethylene (HDPE) or thermoplastic elastomer (TPE);
- the connector 21 is of polybutylene terephthalate (PBT) and the overmolding 40 is of high-density polyethylene (HDPE) or polyvinylidene fluoride (PVDF).

[0041] In one embodiment illustrated in FIG. 6, the connector 21 comprises for example a first door 14 adapted for equipping the access opening 10 of the bag 1. The first door 14 comprises a flange-shaped frame 200, the attachment portion 210 forming at least a portion of the flange 200. Thus, the first door 14 can be used to close the container in a leaktight manner. The protective envelope is then sealed at its sealing opening 152, as exposed herein before.

[0042] During use, one can then form a leaktight assembly by assembling the leaktight container described above to a chamber 11. This is done by first pealing or cutting the protective envelope 15 (the rest of which being illustrated by references 221 and 222 on figure 6) and then connecting the connector to a complementary connector at the chamber. Such a temporary assembly may enable for example a clean transfer of biopharmaceutical content between the bag thus formed and the chamber 11.

[0043] The chamber 11 also comprises for example a second door 12, comprising a flange-shaped frame 201, said second door 12 being adapted for equipping an access opening 13 of said chamber 11 and being complementary to the first door 14.

[0044] Specifically, each door may be circular, the diametrical dimension of the second door 12 being greater than the dimension of the opening formed in the flange 200 for the first door. Each door is provided with sealing means with its flange, such as a compressible O-ring carried by the flange and engaging with a seat of said door. Each door is also associated with means for locking in the closed position on its flange. For positioning the flange 200 of the first door with respect to the flange 201 of the second door, the flange 201 of the second door is integral with a plurality of longitudinal fingers projecting outwards and able to engage with circular notches

formed in the periphery of the flange 200 of the first door. In the absence of any transfer, each of the doors is locked to its flange. To transfer the contents of the bag to the chamber 11, the flange of the first door 200 is brought against that of the second door 201 where it is initially positioned by the fingers and then conclusively by engagement of a central boss of the second door in a recess of the first door. The two flanges are then locked together in the so-called coupled position, then the two doors are unlocked to allow communication between the bag and the chamber 11. As an example, one of the chambers consists for example of an isolator and the bag contains one or more objects or a load to be transferred when in the coupled position, through the passage thus formed between the two chambers, for example to supply the clean room with items or products required for the fabrication or production underway in the clean room, or conversely to eliminate trash or products from said clean room. The bag may contain sterile objects, plugs, tubes, syringe plungers.

[0045] In another embodiment, the overmolding is assembled to one side of the plastic film by adjusting the diameter of the hole to the elasticity of the film used, enabling an assembly of the connector referred to as flat assembly.

Claims

1. A Leaktight assembly comprising:

- A bag (1) comprising a wall (8) of flexible film,
- a connection system (9) comprising a connector (21) adapted to be mechanically connected to a complementary connector of a sterile enclosure (11) for sterile communication between the bag (1) and the enclosure (11), the connector (21) comprising a portion for attachment to the bag (210), the connection system (9) further comprising an overmolding (40) overmolded on the attachment portion (210), the wall of the bag (1) being welded to the overmolding (40) in a continuous closed manner along a predetermined portion of the wall of the bag (1), and
- a protective envelope (15) of the connection system (9), comprising a wall of flexible film, the wall of the protective envelope (15) being welded on said connection system (9) in a continuous closed manner along a predetermined portion of the wall of the protective envelope (15).

2. The Leaktight assembly according to claim 1, in which the bag (1) and the protective envelope (15) are welded one on top of the other to the overmolding (40).

3. The Leaktight assembly according to claim 1, in which the bag (1) and the protective envelope (15) are welded side by side to the overmolding (40).

4. The Leaktight assembly according to claim 1, in which the protective envelope (15) is formed at least in part from an extension of the wall (8) of the bag (1) extending beyond the overmolding (40).

5. The Leaktight assembly according to claims 1 and 4, in which the protective envelope (15) and the bag (1) are made of a single piece of material having a predetermined shape which comprises a bottleneck (16) the wall of which being welded to the overmolding (40).

6. The Leaktight assembly according to the preceding claims, wherein the attachment portion has an annular shape and wherein the overmolding (40) forms a ring around the attachment portion.

7. The Leaktight assembly according to the preceding claims wherein the wall (8) of flexible film of the bag (1) defines an internal volume (V) of said bag and said bag having two opposite ends, a first access opening (10) adapted for placing the internal volume of the bag in communication with the outside of the bag at the first end, a second access opening (20) adapted for placing the internal volume (V) of the bag (1) in communication with the outside of the bag at the second end, and wherein the predetermined portion of the wall of the bag (1) welded on the overmolding (40) is constituted by the first access opening (10).

8. The Leaktight assembly according to the preceding claims wherein the flexible film wall of the protective envelope (15) defines an internal volume (V2), the protective envelope (15) having a two opposite ends, a connector opening (151) adapted to be able to communicate the internal volume of the protective envelope with the outside of the protective envelope at the first end, a sealing opening (152) adapted to be able to communicate the internal volume of the protective envelope with the outside of the protective envelope at the second end, the protective envelope wall (15), and wherein the predetermined portion of the wall of the protective envelope (15) welded on the overmolding (40) is constituted by the connector opening (151), so that the connection system (9) is located inside the second internal volume (V2).

9. Method for manufacturing a leaktight assembly wherein:

- a bag (1) comprising a wall (8) of flexible film is provided,
- a connection system (9) is provided, the con-

nection system (9) comprising a connector (21) adapted for mechanical connection to a complementary connector (11) of a sterile chamber in order to establish a sterile communication between the bag and the chamber, the connector comprising a portion for attachment to the bag (210), the connection system further comprising an overmolding (40) molded over the attachment portion,
- a protective envelope (15) of the connection system (9) comprising a wall of flexible film is provided,

the manufacturing method further comprising the steps of:

- positioning the wall of the bag (1) facing the overmolding at a predetermined portion of the wall of the bag (1),
- positioning the wall of the protective envelope (15) facing the overmolding at a predetermined portion of the protective envelope (15),
- welding the wall of the bag (1) and the wall of the protective envelope (15) to the overmolding in a closed continuous manner all along the predetermined portions.

10. The method according to claim 9, wherein welding the wall of the bag and the wall of the protective envelope (15) to the overmolding in a closed continuous manner all along the predetermined portion comprises:

- welding the wall of the bag to the overmolding at a first predetermined location of the overmolding;
- welding the wall of the protective envelope (15) to the overmolding at a second predetermined location of the overmolding.

11. The method according to claim 9 wherein the protective envelope (15) and the bag (1) are made of a single piece of material having a predetermined shape which comprises a bottleneck (16) the wall of which being welded to the overmolding (40) during the welding step.

12. Method for manufacturing a leaktight assembly according to claim 9, wherein the wall of the bag is of plastic film which comprises a layer of polyethylene.

13. Method for manufacturing a leaktight assembly according to claim 12, wherein a layer of plastic film which faces the overmolding is a layer of polyethylene.

14. Method for manufacturing a leaktight container, comprising the method for manufacturing a leaktight assembly according to claim 9, and further comprising: a step of closing the assembly in a leaktight manner at the connector, a step of closing the protective envelope (15) at its sealing opening (152), a step of filling the bag by the second access opening, and a step of closing the second access opening of the bag so as to close the bag in a leaktight manner at its second access opening.

15. Method for manufacturing a leaktight container according to claim 14 wherein the closing step consists of welding the wall of the bag to itself at its second access opening.

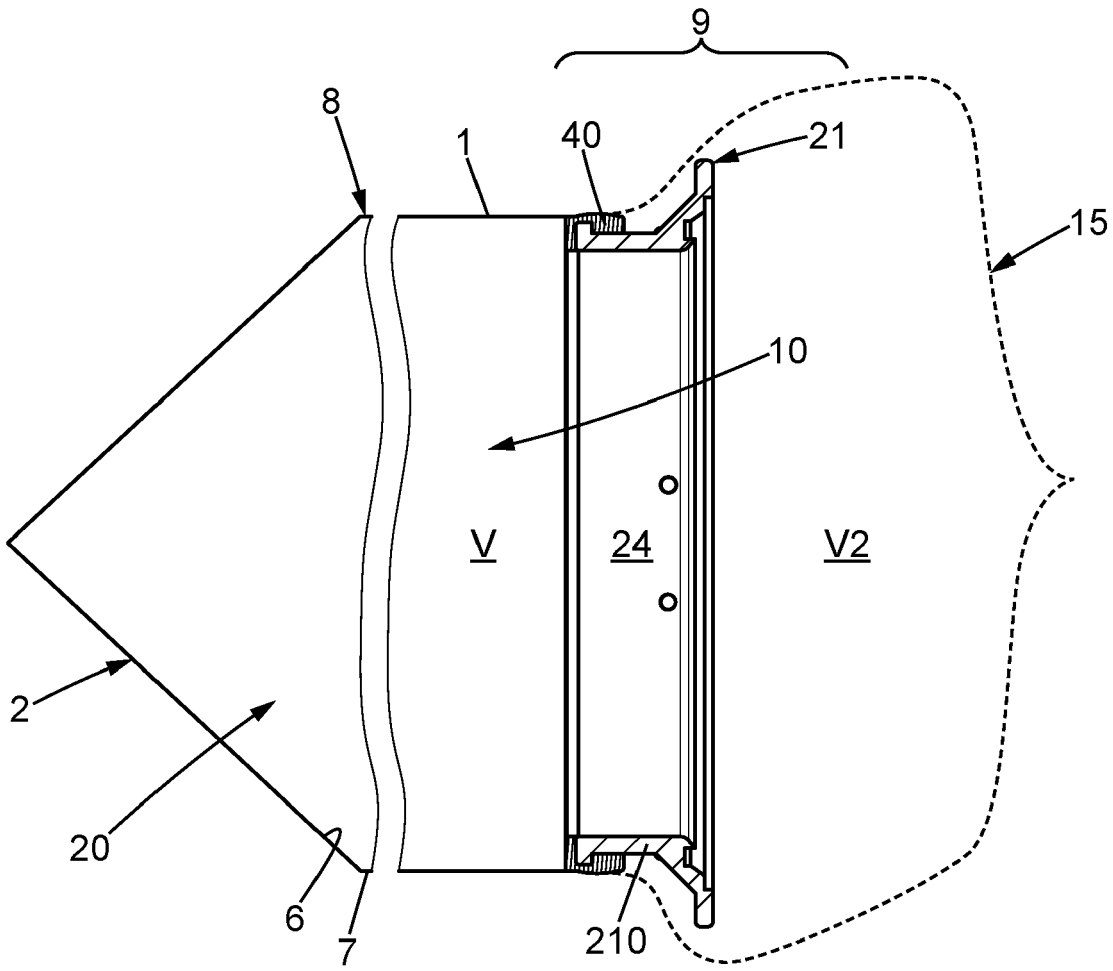

FIG. 1a

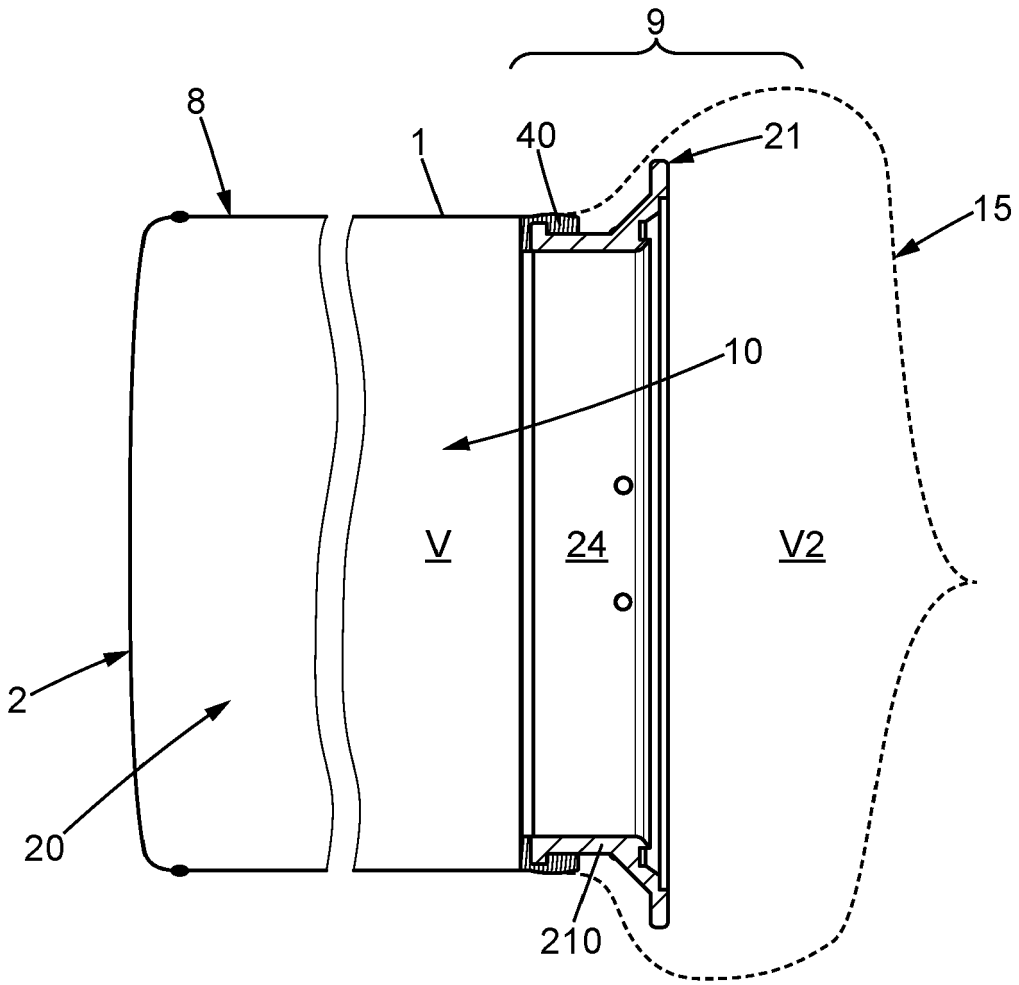

FIG. 1b

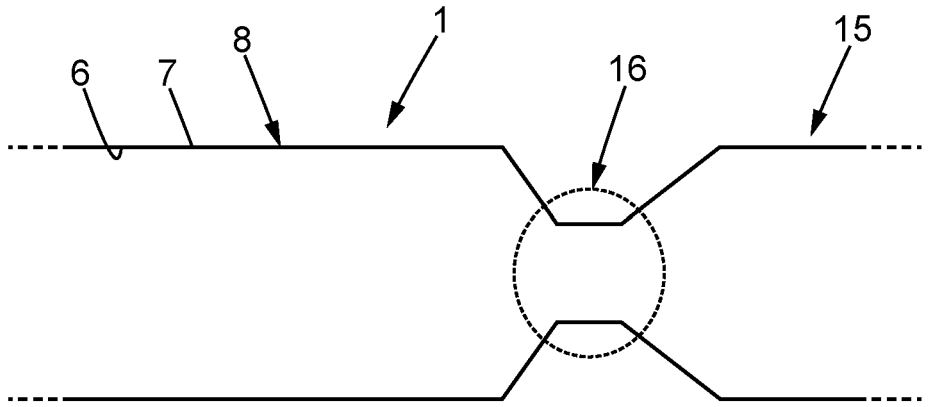

FIG. 2a

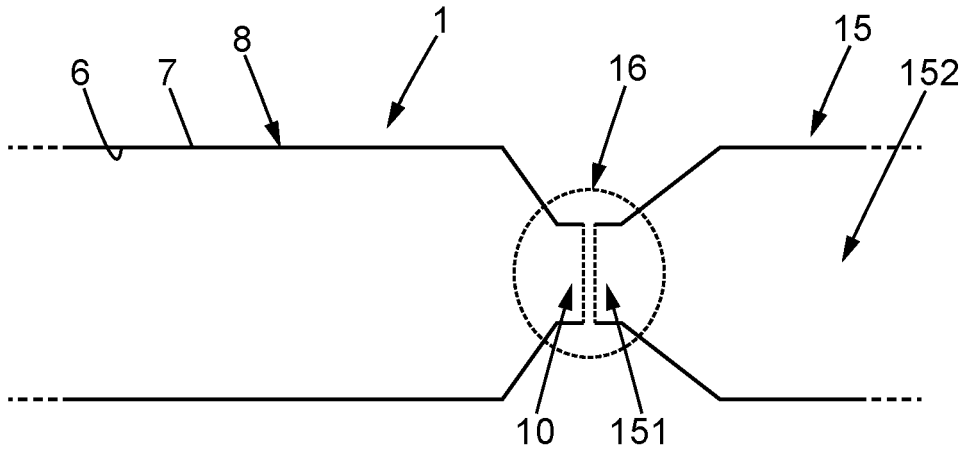

FIG. 2b

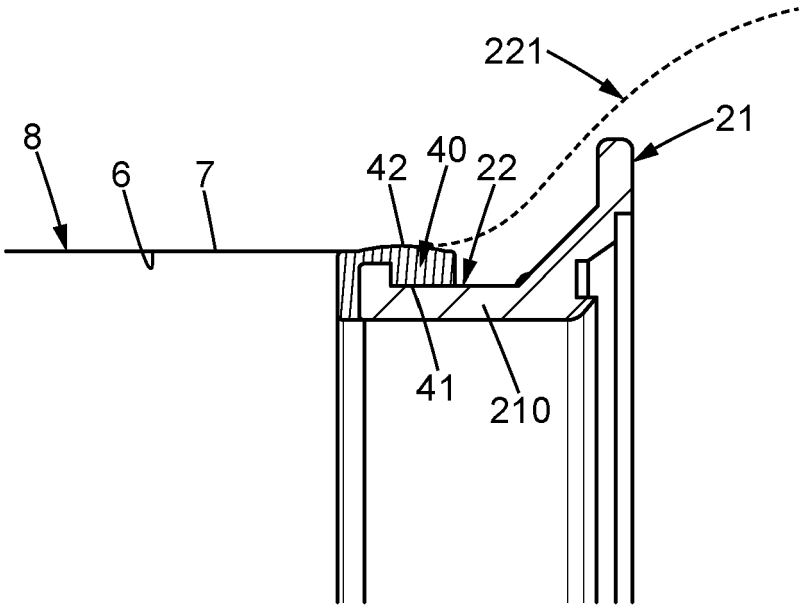

FIG. 3

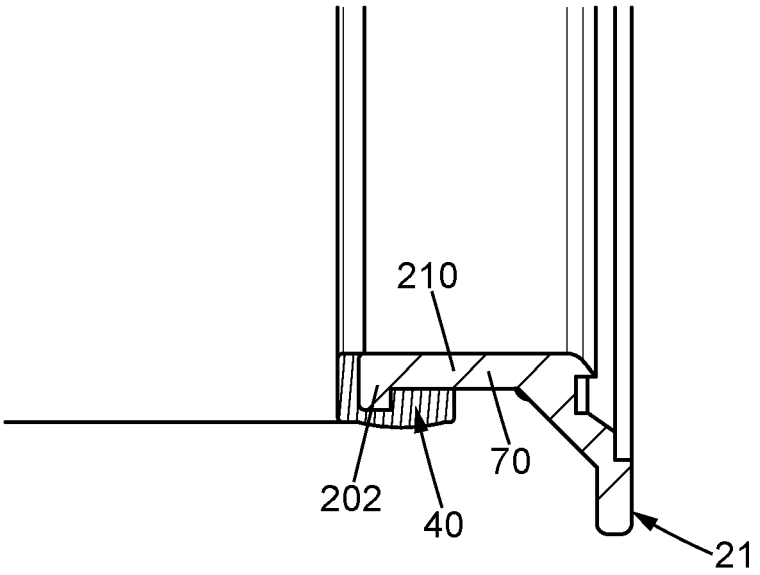

FIG. 4

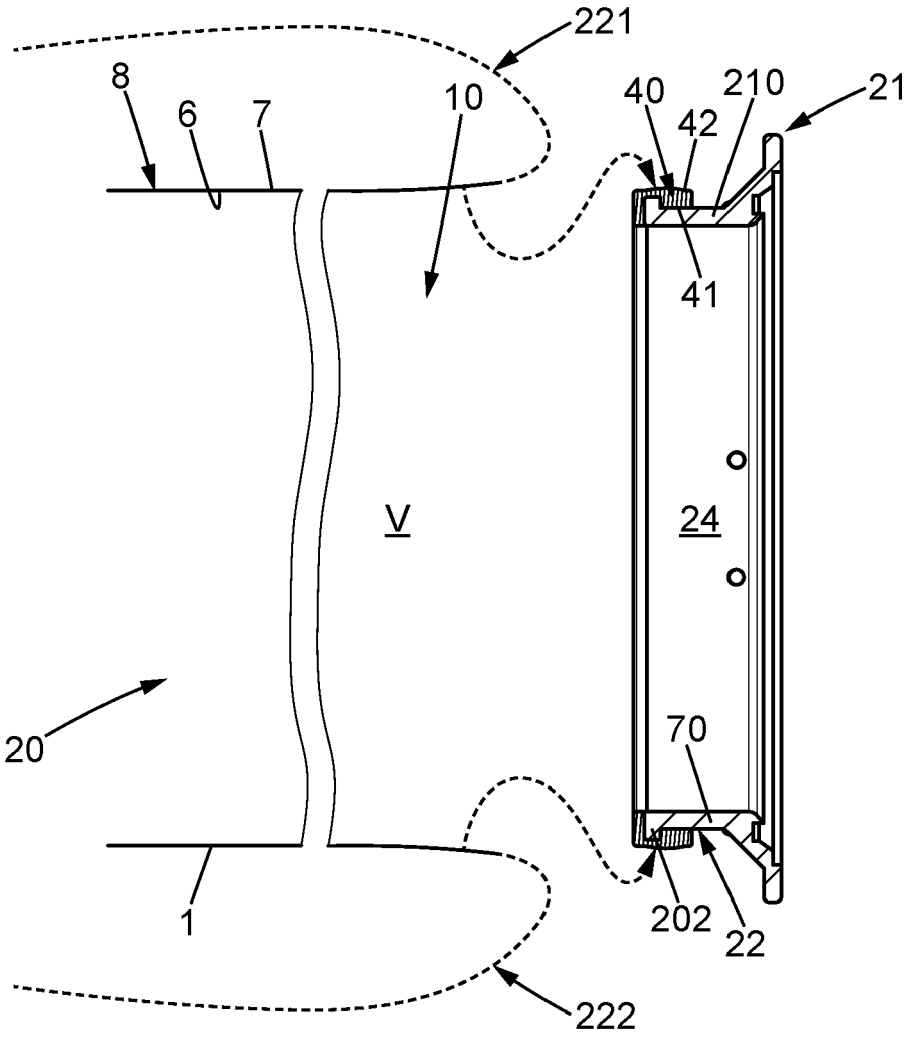

FIG. 5a

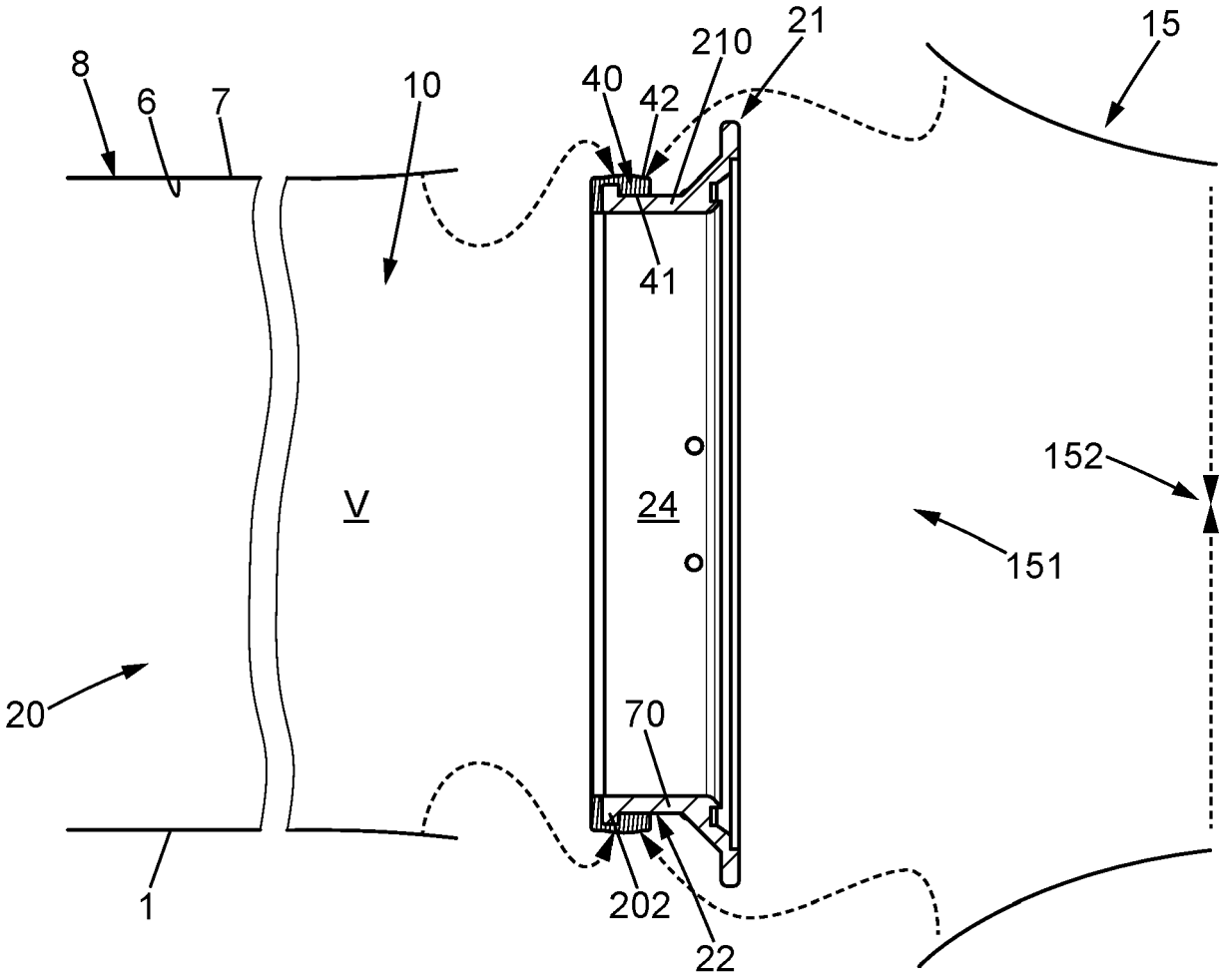

FIG. 5b

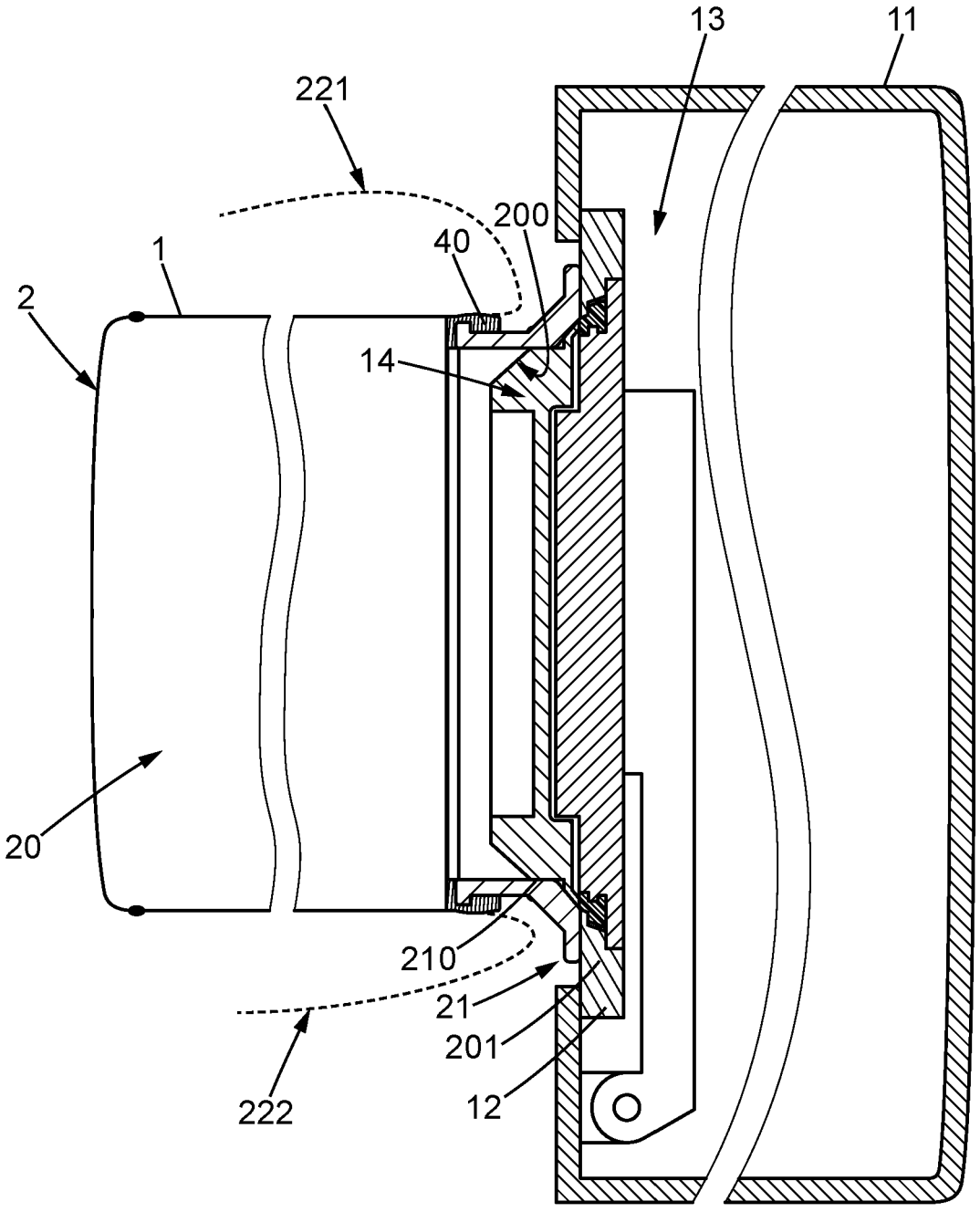

FIG. 6

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EUROPEAN SEARCH REPORT

Application Number
EP 23 30 6865

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	11 March 2024	Ueberfeld, Jörn

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