Sealing Arrangement and Container Associated with Same

The invention relates to a sealing arrangement comprising at least one container and/or at least one container part, such as a closure cap that is placed on the container, wherein the inside of the container is used to accommodate a medium, in particular in the form of a fluid that is bottled in a sterile manner, which can be removed from the container by means of a removal device such as a syringe needle, to which end said removal device penetrates at least one sealing material, which sealing material is connected to the container and/or parts thereof. The invention also relates to a container to which such a sealing arrangement is allocated.

Containers that, in particular, contain a fluid that has been bottled in a sterile manner, which can be removed from said container by means of a cannula, for example a syringe needle or a mandrel, are widely used, particularly for medical applications, for example in the form of ampules or infusion bottles. In the case of medical applications, such containers, which are made out of plastic using the blow-fill-seal method or the known bottelpack® method, are especially suitable because the product is only in contact with a polymer. These containers therefore offer a high degree of protection against microbial contamination,

even during long periods of storage under unfavorable environmental conditions. Plastic products of this kind have been disclosed, for example in US 5,897,008 A or EP 2 269 558 A1. When the product is to be removed by means of an insertable cannula or an insertable mandrel, such containers are only suitable for a single use, since it is not possible to reseal said containers after an initial opening thereof, because the polyolefins used in such BFS containers are not nearly elastic enough to reliably seal the puncture site. In order to remedy this, it is known that insertion parts or stoppers made out of rubber can be used in BFS containers that are intended for medical purposes. As a result, on the one hand, the manufacturing process is made substantially more costly and is slowed by this insertion. In addition, it is necessary to sterilize the rubber parts before inserting them in order to maintain low bacterial levels in the product. There is a serious disadvantage in the fact that the product is in contact with the insertion part, even during the storage period. Document US 5,467,878 A, EP O 721 897 A1, DE 2 844 206 C2 and DE 2 327 553 A1 disclose containers having caps, which have a rubber insert, and which are pressed onto the container head and are fixedly connected to the neck of the bottle by means of a mechanical fixation. Since the rubber insert is pressed onto the flexible, thin container wall only by mechanical means, a gap always remains as a result of the design. Unwanted microbiological contamination, bacterial growth, fungus, etc. may easily arise in this space. This contamination can easily find its way into the container when the container head is pierced. In addition, fluid can be easily drawn in a suction process as a result of capillary action, and thus, may find its way into the space between the insert and the container head.

In order to avoid the problems associated with rubber inserts, a container of the above-mentioned generic type is already known from EPO 364 783 A 1, in which, rather than a rubber material, a sealing material made out of a thermoplastic elastomer (TPE) is fixedly applied to a cap, which, in turn, can be applied to the container head in such a way that the sealing material of the cap fits snuggly along the wall region of the container, which sealing material is provided as a puncture site. It is therefore not possible to reliably avoid a cavity or gap between the container head and the sealing material, and fluid may possibly be drawn in a suction process as a result of a capillary action created by a thin gap. In order to ensure the sterility of the contact surface of the container head and sealing material, an autoclave process is also necessary, to which the contents of the container are also subjected. As a result, such container systems are only suitable for thermally stable products that can withstand the high temperatures (ca. 115° C to 132° C) of an autoclave process.

Starting from this prior art, the object of the invention is to provide a sealing arrangement, which offers increased protection, as compared to the prior art, against microbial loads that could affect sterility.

This object is achieved according to the invention by a sealing arrangement having the features of Claim 1 in its entirety.

As a result of the welded or bonded connection to the outside of the container or of a container part, such as a cap, it is possible to avoid the risk that a gap will form on the contact surface of the sealing material, as is the case in the corresponding solution in the prior art, in which the sealing material is pressed snuggly against the assigned contact surface by a contact pressure. It is thereby

possible to avoid contamination as a result of bacterial migration due to capillary action along a gap.

The respective sealing material is preferably fixedly welded to the outer wall of the container without filler material and preferably free of adhesives.

In particular, the configuration may be advantageously such, that the respective sealing material rests directly on the outer wall, to which it can be assigned, with no spacing, and with the entire contact surface of said sealing material that faces the container or container part resting against the outer wall, to which it can be assigned.

In an especially advantageous manner, elastomers or plastics that can be bonded or welded may be used, wherein a thermoplastic elastomer (TPE) is preferably used as a sealing material.

In the case of containers that are produced by means of a blow, fill and seal method, the sealing material is preferably applied to the container after the production of said container has been completed.

The subject matter of the invention according to Claim 6 is also a container made out of plastic, to which the sealing assembly according to one of the Claims 1 to 5 is assigned, and in which the respective sealing material is disposed on the outside of the container or on a part thereof facing the environment, wherein the respective sealing material is fixedly connected to the outside of the container and/or to parts thereof facing the environment by means of a welded and/or adhesively bonded connection.

In a particularly advantageous manner in the case of the invention, a sealing material in the form of a disk-like body is connected to the outside of the

container wall in a materially integrated bond, the inside of which is adjacent to a sealed container in order to receive the respective product that is to be bottled in a sterile manner. In the case of a plastic container and a thermoplastic sealing material, it is of particular advantage that such a connection in a materially integrated bond can be created by means of a thermal joining process, in which the two joining elements are welded at temperatures, which are adjusted according to the softening behavior of said materials, for example at temperatures in the range of 200° C, wherein both parts are preferably heated and then briefly pressed against one another. It is also possible to use corresponding friction-welded joints in order to connect the sealing material to the container or to parts thereof. In so doing, it is of particular advantage that the surfaces of the contact surface made out of thermoplastic sealing material and the container head both be simultaneously sterilized.

In particularly advantageous, exemplary embodiments, the container has a container head, which is connected to a main part of the container by means of a neck part, said container head having a wall section, which can be pierced for a removal procedure, wherein the sealing material is provided on the container head.

In a particularly advantageous manner, the configuration may be such that a protective film may be provided such that it rests detachably on the outside of the sealing arrangement. The protective film, which is to be removed prior to the first penetration, may serve as a seal of quality.

When the wall section of the container head that is connected to the body of the sealing material has a curvature that extends from the interior of the container

directed outward, the outside of the body of the sealing material preferably has a similar curvature, so that the body of the sealing material is a continuation of the outer contour of the container head.

Alternatively, the outside of the body of the sealing material may have at least one recess, for example in the form of an annular space, which extends concentrically to a central, non-recessed region. Other contouring of the outside of the body of the laminate material may be provided, for example a trough-like depression in the actual area to be punctured.

In particularly advantageous exemplary embodiments, a plastic ring that laterally encloses the body of the sealing material may be provided, which ring is connected to the container head and/or to the main part of the container. A plastic ring of this kind can be cast or molded onto the container head and body of the sealing material. A plastic ring of this kind may also have a mechanically fixed connection to the container head, for example by means of a catch mechanism, welded joint or riveting.

The plastic ring may engage behind a radially projecting edge region on the container head as a catch mechanism.

In the case of exemplary embodiments, in which a shoulder is formed at the transition between the main part of the container and the container head, the plastic ring can overlap over the container head in the manner of a cap and can be connected to the shoulder.

In particularly advantageous exemplary embodiments, the configuration is such that the cap-like plastic ring forms an enclosure for the body of the sealing material in the form of a cylinder, which projects axially outward beyond the

body. The cylinder wall of a cylinder of this kind may form a connection region for a removal adapter such as are known from EP 1 847 242 A1, for example, and which provide a mechanism for piercing or opening the container.

In a particularly advantageous manner, the outer end of a cylinder of this kind may also have a cover formed thereon, thereby forming at least one predetermined breaking point, on which cover, in turn, a tab is formed as an integral part, which makes it possible to separate the cover at the respective predetermined breaking point.

According to Claim 17, the subject matter of the invention is also a sealing material for a sealing arrangement according to one of the Claims 1 to 5, which comprises elastomers or plastics that can be bonded or welded, wherein, in particular, a thermoplastic elastomer (TPE) is provided, and wherein the sealing material may be formed by a block-shaped or disk-shaped body. A block-shaped sealing material of this kind may also be produced separately from the container and be made available for when the container is used, for example in a form such that a corresponding block is included when packaging the finished and filled container, so that a user can apply the block of sealing material, for example through the use of an adhesive bond with a plastic material. If the block of sealing material can be used by means of a releasable, adhesively bonded connection to the respective container, it would also be possible to combine a pack of ampules, for example having six container-shaped ampules, in a putty, having only one block of sealing material, which may then be placed on the respective ampule over the detachable, adhesively bonded connection for a removal procedure, and then after the use of this ampule container, said block

of sealing material may again be placed on the subsequent ampule for another removal procedure after having been removed from the preceding container.

According to Claim 20, the subject matter of the invention is also a method for producing a container according to one of the Claims 6 to 16.

In the case of the method according to the invention, when a sealing material is used, which contains an antimicrobial additive, the outer surface of the sealing material may also be kept in a low-germ state over an extended period. This provides the additional advantage that the puncture site of the sealing material need not be disinfected prior to the insertion of the mandrel or cannula.

The invention is described in greater detail below on the basis of exemplary embodiments depicted in the Figures. Shown are:

Fig. 1 a longitudinal section, drawn in a larger scale as compared to a practical embodiment, depicting only the region adjacent to the container head of an exemplary embodiment of the container according to the invention;

Fig. 2 an oblique top view, in perspective, in a smaller scale, of the region shown in Fig. 1;

Figs. 3 and 4 depictions corresponding to Figs. 1 and 2 of a second exemplary embodiment;

Figs. 5 and 6 depictions corresponding to Figs. 1 and 2 of a third exemplary embodiment;

Fig. 7 a longitudinal section of only the region adjacent to the container head of a fourth exemplary embodiment;

Fig. 8 a top view of a fourth exemplary embodiment;

Figs. 9 and 10 depictions corresponding to Figs. 1 and 2 of a fifth exemplary embodiment;

Figs. 11 and 12 depictions corresponding to Figs. 1 and 2 of a sixth exemplary embodiment;

Figs. 13 and 14 depictions corresponding to Figs. 1 and 2 of a seventh exemplary embodiment;

Figs. 15 and 16 depictions corresponding to Figs. 1 and 2 of an eighth exemplary embodiment;

Fig. 17 a side view with a partial cut-away in the region of the container head of a ninth exemplary embodiment;

Fig. 18 a depiction similar to that of Fig. 17 of a tenth exemplary embodiment;

Fig. 19 a sectional view of only the head region of the ninth exemplary embodiment shown in Fig. 12, depicted in a larger scale,

and

Fig. 20 a depiction similar to that of Fig. 10 of the head region of the tenth exemplary embodiment from Fig. 18.

The invention is explained below on the basis of exemplary embodiments of containers, such as those which can be used as infusion bottles or, having

smaller dimensions, as ampules, for example, for the removal of the product by directly inserting an injection cannula. When using an infusion bottle, an insertion mandrel may be provided in order to remove the product. The containers are produced out of a plastic material, which is suitable for the known blow-fill-seal method, for example in accordance with the known bottelpack® system, thus made out of a polyolefin such as a polyethylene having a lower or higher density, or polypropylene.

Figs. 1 and 2 show a first exemplary embodiment, in which the main part of the container, of which only the upper end section is shown, is designated as 1. A narrowed, circular-cylindrical neck part 3 is connected to the main part of the container, which has an oval contour, which neck part, in turn, transitions into a container head 5, which forms the upper terminal end of the container head 5. The upper side of said container head has a wall region 7 that is curved slightly outward, which region is provided as an area to be punctured for the piercing of the container wall during a removal procedure. A sealing material made out of a thermoplastic elastomer (TPE) in the form of a disk-shaped body 9 is non-detachably affixed to the wall region 7. This body 9 is made out of a polymer, which has increased elasticity as compared to the container material, so that a puncture site is resealed in the same way as occurs in the case of a sealing element made out of rubber. In the case of the material of the body 9, this may be a polyethylene having a lower or higher density, for example Santoprene® 181-55MED, Laprene ® SEBS, Thermolast® TM 3RST, or the like. In order to form the non-detachable connection of the body 9 to the wall region 7, this wall region and the contact surface of the body 9 are heated to a softening temperature, approximately in the range of 200° C, and are pressed against one

another so that an inseparable connection in a materially integrated bond is created. A protective film 11 made out of plastic is detachably applied to the upper surface of the body 9, which can be removed for the initial use of the container by means of a projecting tab 13. The upper surface of the protective film 11 may be provided with markings, which represent an original seal, for example. As can be seen in Fig. 1, the upper surface of the body 9, which is covered by the protective film 11, is curved in a corresponding manner, like the wall region 7 at the container head 5. In the examples of Figs. 1 and 2, the disk-shaped body 9 covers almost the entire wall region 7 up to the vicinity of a lateral convexity 15, as a result of which, the diameter of the container head 5 is enlarged as compared to the diameter of the neck part 3.

The second exemplary embodiment from Figs. 3 and 4 differs from the first exemplary embodiment in that the neck part 3 transitions into the container head 5 without a convexity and having the same diameter. Again, this forms an outer curved wall region 7 for the non-detachable connection with the body 9 of the sealing material (TPE). A further difference as compared to the first example is that the body 9 of the sealing material has a depression 19, which is concentric to the principal axis 17, which depression has the form of trough having oblique side walls, which diverge outward. This depression 19 forms an area to be punctured in the body 9, which has a reduced wall strength, while the remaining part of the body 9 extends with no depression to the outer edge of the wall region 7 at the container head 5.

The third exemplary embodiment from Figs. 5 and 6 differs from the preceding examples in that, starting from the convexity 15, which is connected to the neck part 3, the container head 5 is lengthened by a cylinder part 21 upward to the

wall section 7. The body 9 of the sealing material corresponds to the example in Figs. 3 and 4 in its configuration and contour, with the exception that the depression 19 is designed in the form of an annular space, which is concentric to the axis 17.

The fourth exemplary embodiment according to Figs. 7 and 8 corresponds to the exemplary embodiment from Figs. 3 and 4 in terms of the design of the neck part 3 and of the container head 5. The difference as compared thereto is that the body 9 of the sealing material has a smaller diameter than the associated wall region 7 at the container head 5, without a depression being formed therein. The body 9 is encompassed by a plastic ring 23 in the region between the outside of the body 9 and the outer edge of the wall region 7. The enclosure of the body 9 facilitates handling during the manufacturing process. The plastic ring 23 may be bonded or welded to the body 9. In producing a connection of the body 9 to the wall region 7 at the container head 5 in a materially integrated bond, the plastic ring 23 may, in turn, form a welded connection at the container head 5.

Figs. 9 and 10 show a fifth exemplary embodiment, in which the design of the neck part 3, convexity 15 and container head 5 corresponds to the example in Figs. 5 and 6. As in the example in Figs. 7 and 8, however, the body 9 of the sealing material is encompassed by a plastic ring 23, as is the case with the example in Figs. 7 and 8. A depression 19 is formed on the upper surface of the body 9 in a form that is similar to the depression 19 from Fig. 3, wherein, in Fig. 9, the recess is open, up to the vicinity of the outer edge of the body 9.

Figs. 11 and 12 show a sixth exemplary embodiment, in which the design of the neck part 3 and of the container head 5 corresponds to the example in Figs. 3

and 4, wherein the body 9 of the sealing material has a diameter, which, however, is reduced as compared to the wall region 7 at the container head 5. Accordingly, the inner diameter of the plastic ring 23, which is provided as an enclosure, is reduced accordingly, whereas the outer diameter of the plastic ring 23 is enlarged in such a way that said ring extends over the edge of the wall region 7 and projects beyond the container head 5. In this way, an additional, lateral anchoring of the plastic ring 23 is implemented.

In the case of the seventh exemplary embodiment shown in Figs. 13 and 14, the neck part 3 is again extended to the convexity 15, to which the container head 5 is directly connected. As in the example in Figs. 11 and 12, the body 9 of the sealing material has a reduced diameter as compared to the diameter of the container head 5. The encompassing plastic ring 23 is enlarged as compared to Figs. 11 and 12 in order to form a kind of cap, the outer edge 25 of which projects over the convexity 15 at the end of the neck part 3 in such a way that a snapping or locking connection is formed for the plastic ring 23.

In the case of the exemplary embodiment from Figs. 15 and 16, the shape of the neck part 3, the convexity 15 and the container head 5 corresponds to the example in Figs. 13 and 14. However the encompassing plastic ring 23 is lengthened using an outer cylinder 27 in order to form a cap-like cover such that the cylinder end rests against a shoulder 29, which is formed at the transition between the main part of the container 1 and the neck part 3. The cylinder end may be affixed to the shoulder 29, for example by adhesive bonding or welding.

Figs. 17 and 19 show a ninth exemplary embodiment. Like the preceding example in Figs. 15 and 16, the plastic ring 23 is enlarged in a cap-like manner,

having an outer cylinder 27, which extends to a shoulder 29 on the main part of the container 1. The neck part 3, convexity 15 and container part 5 correspond to the example in Figs. 15 and 16. Unlike what is shown there, however, the plastic ring 23 forms an enclosure for the body 9 of the sealing material in the form of a cylinder 31, which projects axially upward beyond the body 9, and having projections 33, see Fig. 19, which project partially over the protective film 11. The projecting wall of the cylinder 31 having the projections 33 may form a receptacle for affixing a known removal adapter.

The tenth exemplary embodiment from Figs. 18 and 20 differs from the example in Figs. 17 and 19 in that, instead of the protective film 11 on the upper end of the cylinder 31, a protective cover 35 is formed as an integral part, wherein predetermined breaking points 37 (Fig. 20) are formed, which make it possible to tear off the cover 35 for a removal procedure. In order to make it easier to tear off said cover, a ring 39, which serves as a handle, is formed above a connection tab 41 on the cover 35.

In order to obtain a low-germ surface, an antimicrobial additive may be added to the sealing material of the body 9 during production, for example With Stand® from Poly One or HP 7A 4000 AM from Gabriel Chemie. This has the advantage that the puncture site on the body 9 no longer needs to be disinfected prior to piercing said site by means of a mandrel or cannula.

Claims

1. A sealing arrangement comprising at least one container (1) and/or at least one container part, such as a closure cap that is placed on the container (1), wherein the inside of the container (1) is used to accommodate a medium, in particular in the form of a fluid that is bottled in a sterile manner, which can be removed from the container (1) by means of a removal device such as a syringe needle, to which end said removal device penetrates at least one sealing material (9), which sealing material is connected to the container (1) and/or parts thereof, characterized in that the respective sealing material (9) is disposed on the outside (7) of the container (1) and/or on container parts thereof facing the environment, and in that the respective sealing material (9) is fixedly connected to the outside (7) of the container (1) and/or to parts thereof facing the environment by means of a welded and/or adhesively bonded connection.

2. The sealing arrangement according to Claim 1, characterized in that the respective sealing material (9) is welded to the outer wall (7) of the container (1) and or the container parts thereof without filler material and preferably free of adhesives.

3. The sealing arrangement according to Claim 1 or 2, characterized in that the respective sealing material (9) rests directly on the outer wall (7), to which it can be assigned, with no spacing, and with the entire contact

surface of said sealing material that faces the container (1) or container part resting against the outer wall (7), to which it can be assigned.

4. The sealing arrangement according to one of the preceding Claims, characterized in that elastomers or plastics that can be bonded or welded are used as a sealing material (9), and in that a thermoplastic elastomer (TPE) is preferably used as a sealing material (9).

5. The sealing arrangement according to one of the preceding Claims, characterized in that the container (1) is produced by means of a blow, fill and seal process, and in that the sealing material (9) is preferably applied to the container (1) after the production of said container is complete.

6. A container (1) associated with a sealing arrangement according to one of the Claims 1 to 5, said container being made out of plastic, and being produced, filled and sealed in a sterile manner in a blow molding process, and it being possible to pierce the container wall (7) of said container by means of a cannula or a mandrel in order to remove product, wherein the sealing arrangement has a sealing material (9) in order to seal a puncture site that is formed in the container wall (7) during a removal process, characterized in that the sealing material (9) is disposed on the outside (7) of the container (1) or on a part thereof facing the environment, and in that the respective sealing material (9) is fixedly connected to the outside (7) of the container (1) and/or to parts thereof facing the environment by means of a welded and/or adhesively bonded connection.

7. The container according to Claim 6, characterized in that the sealing material, in the form of a disk-like body (9), is connected to the container wall (7) in a materially integrated bond.

8. The container according to Claim 6 or 7, characterized in that said container is provided with a container head (5), which is connected to a main part of a container (1) by means of a neck part (3), said container head having a wall section (7) which can be pierced for a removal procedure, and in that the sealing material (9) is provided on the container head (5).

9. The container according to one of the Claims 6 to 8, characterized in that a removable protective film (11) is provided on the outside of the sealing arrangement, said protective film resting detachably on the body (9) of the sealing material.

10. The container according to one of the Claims 6 to 9, characterized in that the wall section (7) of the container head (5), which is connected to the body (9) of the sealing material, has a curvature that extends from the interior of the container directed outward, and in that the outside of the body (9) of the sealing material has a similar curvature.

11. The container according to one of the Claims 6 to 10, characterized in that the outside of the body (9) of the sealing material has at least one recess (19).

12. The container according to one of the Claims 6 to 11, characterized in that the recess of the body (9) has the form of an annular space (19), which extends concentrically to a central, non-recessed region.

13. The container according to one of the Claims 6 to 12, characterized in that a plastic ring (23) that laterally encloses the body (9) of the sealing material is provided, which ring is connected to the container head (5) and/or to the main part of the container (1).

14. The container according to one of the Claims 6 to 13, characterized in that the plastic ring (23) engages behind a radially projecting edge region (15) on the container head (5).

15. The container according to one of the Claims 6 to 14, characterized in that said container forms a shoulder (29) at the transition between the main part of the container (1) and the container head (5), and in that the plastic ring (23) overlaps over the container head (5) in the manner of a cap, and is connected to the shoulder (29).

16. The container according to one of the Claims 6 to 15, characterized in that the cap-like plastic ring (23) forms an enclosure for the body (9) of the sealing material in the form of a cylinder (27), which projects axially outward beyond the body (9).

17. A sealing material for a sealing arrangement according to one of the Claims 1 to 5, characterized in that it is made out of an elastomer or plastic that can be bonded or welded.

18. The sealing material according to Claim 17, characterized in that said material is composed of a thermoplastic elastomer (TPE).

19. The sealing material according to Claim 17 or 18, characterized in that said material is formed by a block-shaped or disk-shaped body (9).

20. A method for producing a container according to one of the Claims 6 to 16, in which a non-detachable, form-fitting connection between a region (7) of the container wall, which has been provided as a puncture site for a removal procedure, and a sealing material (9) made out of a plastic that can be welded, preferably a thermoplastic elastomer (TPE), is formed by a joining process, in which the contact surface on at least one of the joining elements (7, 9) is heated at least to the sterilization temperature before the joining elements (7, 9) are pressed against one another to form a welded joint.

21. The method according to Claim 20, characterized in that a sealing material (9) is used which contains an antimicrobial additive.

Sealing Arrangement and Container Associated with Same

The invention relates to a sealing arrangement comprising at least one container, such as a closure cap that is placed on the container, wherein the inside of the container is used to accommodate a medium, in particular in the form of a fluid that is bottled in a sterile manner, which can be removed from the container by means of a removal device such as a syringe needle, to which end said removal device penetrates at least one sealing material, which sealing material is connected to the container, wherein the respective sealing material is disposed on the outside of the container thereof facing the environment. The invention also relates to a container to which such a sealing arrangement is allocated.

Containers that, in particular, contain a fluid that has been bottled in a sterile manner, which can be removed from said container by means of a cannula, for example a syringe needle or a mandrel, are widely used, particularly for medical applications, for example in the form of ampules or infusion bottles. In the case of medical applications, such containers, which are made out of plastic using the blow-fill-seal method or the known bottelpack® method, are especially suitable because the product is only in contact with a polymer. These containers therefore offer a high degree of protection against microbial contamination, even during long periods of storage under unfavorable environmental conditions. Plastic products of this kind have been disclosed, for example in US 5,897,008 A or EP 2 269 558 A1. When the product is to be removed by means of an insertable cannula or an insertable mandrel, such containers are only suitable for a single use, since it is not possible to reseal said containers after an initial opening thereof, because the polyolefins used in such BFS containers are not nearly elastic enough to reliably seal the puncture site. In order to remedy this, it is known that insertion parts or stoppers made out of rubber can be used in BFS containers that are intended for medical purposes. As a result, on the one hand, the manufacturing process is made substantially more costly and is slowed by this insertion. In addition,

it is necessary to sterilize the rubber parts before inserting them in order to maintain low bacterial levels in the product. There is a serious disadvantage in the fact that the product is in contact with the insertion part, even during the storage period. Document US 5,467,878 A, EP 0 721 897 A1, DE 2 844 206 C2 and DE 2 327 553 A1 disclose containers having caps, which have a rubber insert, and which are pressed onto the container head and are fixedly connected to the neck of the bottle by means of a mechanical fixation. Since the rubber insert is pressed onto the flexible, thin container wall only by mechanical means, a gap always remains as a result of the design. Unwanted microbiological contamination, bacterial growth, fungus, etc. may easily arise in this space. This contamination can easily find its way into the container when the container head is pierced. In addition, fluid can be easily drawn in a suction process as a result of capillary action, and thus, may find its way into the space between the insert and the container head.

In order to avoid the problems associated with rubber inserts, a container of the above mentioned generic type is already known from EP 0 364 783 A1, in which, rather than a rubber material, a sealing material made out of a thermoplastic elastomer (TPE) is fixedly applied to a cap, which, in turn, can be applied to the container head in such a way that the sealing material of the cap fits snuggly along the wall region of the container, which sealing material is provided as a puncture site. It is therefore not possible to reliably avoid a cavity or gap between the container head and the sealing material, and fluid may possibly be drawn in a suction process as a result of a capillary action created by a thin gap. In order to ensure the sterility of the contact surface of the container head and sealing material, an autoclave process is also necessary, to which the contents of the container are also subjected. As a result, such container systems are only suitable for thermally stable products that can withstand the high temperatures (ca. 115 °C to 132 °C) of an autoclave process.

In EP 0 364 783 A1—as well as EP 0 763 476 A1, EP 0518 191 A2 and DE 93 17 644 U1—the sealing material is only pressed against the outside of the container by a cap.

Starting from this prior art, the object of the invention is to provide a sealing arrangement, which offers increased protection, as compared to the prior art, against microbial loads that could affect sterility.

This object is achieved according to the invention by a sealing arrangement having the features of Claim 1 in its entirety.

According to the characterizing portion of claim 1, the respective sealing material is produced separately from the container and is fixedly connected to the outside of the container facing the environment by means of a welded and/or adhesively bonded connection.

As a result of the welded or bonded connection to the outside of the container, such as a cap, it is possible to avoid the risk that a gap will form on the contact surface of the sealing material, as is the case in the corresponding solution in the prior art, in which the sealing material is pressed snuggly against the assigned contact surface by a contact pressure. It is thereby possible to avoid contamination as a result of bacterial migration due to capillary action along the gap.

The respective sealing material is preferably fixedly welded to the outer wall of the container without filler material and preferably free of adhesives.

In particular, the configuration may be advantageously such, that the respective sealing material rests directly on the outer wall, to which it can be assigned, with no spacing, and with the entire contact surface of said sealing material that faces the container resting against the outer wall, to which it can be assigned.

In an especially advantageous manner, elastomers or plastics that can be bonded or welded may be used, wherein a thermoplastic elastomer (TPE) is preferably used as a sealing material.

In the case of containers that are produced by means of a blow, fill and seal method, the sealing material is preferably applied to the container after the production of said container has been completed.

The subject matter of the invention according to Claim 6 is also a container made out of plastic, to which the sealing assembly according to one of the Claims 1 to 5 is assigned, and in which the respective sealing material is produced separately from the container and is disposed on the outside of the container facing the environment, wherein the respective sealing material is fixedly connected to the outside of the container facing the environment by means of a welded and/or adhesively bonded connection.

In a particularly advantageous manner in the case of the invention, a sealing material in the form of a disk-like body is connected to the outside of the container wall in a materially integrated bond, the inside of which is adjacent to a sealed container in order to receive the respective product that is to be bottled in a sterile manner. In the case of a plastic container and a thermoplastic sealing material, it is of particular advantage that such a connection in a materially integrated bond can be created by means of a thermal joining process, in which the two joining elements are welded at temperatures, which are adjusted according to the softening behavior of said materials, for example at temperatures in the range of 200 °C, wherein both parts are preferably heated and then briefly pressed against one another. It is also possible to use corresponding friction-welded joints in order to connect the sealing material to the container. In so doing, it is of particular advantage that the surfaces of the contact surface made out of thermoplastic sealing material and the container head both be simultaneously sterilized.

In particularly advantageous, exemplary embodiments, the container has a container head, which is connected to a main part of the container by means of a neck part, said container head having a wall section, which can be pierced for a removal procedure, wherein the sealing material is provided on the container head.

In a particularly advantageous manner, the configuration may be such that a protective film may be provided such that it rests detachably on the outside of the sealing arrangement. The protective film, which is to be removed prior to the first penetration, may serve as a seal of quality.

When the wall section of the container head that is connected to the body of the sealing material has a curvature that extends from the interior of the container directed outward, the outside of the body of the sealing material preferably has a similar curvature, so that the body of the sealing material is a continuation of the outer contour of the container head.

Alternatively, the outside of the body of the sealing material may have at least one recess, for example in the form of an annular space, which extends concentrically to a central, non-recessed region. Other contouring of the outside of the body of the laminate material may be provided, for example a trough-like depression in the actual area to be punctured.

In particularly advantageous exemplary embodiments, a plastic ring that laterally encloses the body of the sealing material may be provided, which ring is connected to the container head and/or to the main part of the container. A plastic ring of this kind can be cast or molded onto the container head and body of the sealing material. A plastic ring of this kind may also have a mechanically fixed connection to the container head, for example by means of a catch mechanism, welded joint or riveting.

The plastic ring may engage behind a radially projecting edge region on the container head as a catch mechanism.

In the case of exemplary embodiments, in which a shoulder is formed at the transition between the main part of the container and the container head, the plastic ring can overlap over the container head in the manner of a cap and can be connected to the shoulder.

In particularly advantageous exemplary embodiments, the configuration is such that the cap-like plastic ring forms an enclosure for the body of the sealing material in the form of a cylinder, which projects axially outward beyond the body. The cylinder wall of a cylinder of this kind may form a connection region for a removal adapter such as are known from EP 1 847 242 A1, for example, and which provide a mechanism for piercing or opening the container.

In a particularly advantageous manner, the outer end of a cylinder of this kind may also have a cover formed thereon, thereby forming at least one predetermined breaking point, on which cover, in turn, a tab is formed as an integral part, which makes it possible to separate the cover at the respective predetermined breaking point.

According to Claim 17, the subject matter of the invention is also a sealing material for a sealing arrangement according to one of the Claims 1 to 5, which comprises elastomers or plastics that can be bonded or welded, wherein, in particular, a thermoplastic elastomer (TPE) is provided, and wherein the sealing material may be formed by a block-shaped or disk-shaped body. A block-shaped sealing material of this kind may also be produced separately from the container and be made available for when the container is used, for example in a form such that a corresponding block is included when packaging the finished and filled container, so that a user can apply the block of sealing material, for example through the use of an adhesive bond with a

plastic material. If the block of sealing material can be used by means of a releasable, adhesively bonded connection to the respective container, it would also be possible to combine a pack of ampules, for example having six container-shaped ampules, in a putty, having only one block of sealing material, which may then be placed on the respective ampule over the detachable, adhesively bonded connection for a removal procedure, and then after the use of this ampule container, said block of sealing material may again be placed on the subsequent ampule for another removal procedure after having been removed from the preceding container.

According to Claim 20, the subject matter of the invention is also a method for producing a container according to one of the Claims 6 to 16.

In the case of the method according to the invention, when a sealing material is used, which contains an antimicrobial additive, the outer surface of the sealing material may also be kept in a low-germ state over an extended period. This provides the additional advantage that the puncture site of the sealing material need not be disinfected prior to the insertion of the mandrel or cannula.

The invention is described in greater detail below on the basis of exemplary embodiments depicted in the Figures. Shown are:

Fig. 1 a longitudinal section, drawn in a larger scale as compared to a practical embodiment, depicting only the region adjacent to the container head of an exemplary embodiment of the container according to the invention;

Fig. 2 an oblique top view, in perspective, in a smaller scale, of the region shown in Fig. 1;

Figs. 3 and 4 depictions corresponding to Figs. 1 and 2 of a second exemplary embodiment;

Figs. 5 and 6 depictions corresponding to Figs. 1 and 2 of a third exemplary embodiment;

Fig. 7 a longitudinal section of only the region adjacent to the container head of a fourth exemplary embodiment;

Fig. 8 a top view of a fourth exemplary embodiment;

Figs. 9 and 10 depictions corresponding to Figs. 1 and 2 of a fifth exemplary embodiment;

Figs. 11 and 12 depictions corresponding to Figs. 1 and 2 of a sixth exemplary embodiment;

Figs. 13 and 14 depictions corresponding to Figs. 1 and 2 of a seventh exemplary embodiment;

Figs. 15 and 16 depictions corresponding to Figs. 1 and 2 of an eighth exemplary embodiment;

Fig. 17 a side view with a partial cut-away in the region of the container head of a ninth exemplary embodiment;

Fig. 18 a depiction similar to that of Fig. 17 of a tenth exemplary embodiment;

Fig. 19 a sectional view of only the head region of the ninth exemplary embodiment shown in Fig. 12, depicted in a larger scale; and

Fig. 20 a depiction similar to that of Fig. 10 of the head region of the tenth exemplary embodiment from Fig. 18.

The invention is explained below on the basis of exemplary embodiments of containers, such as those which can be used as infusion bottles or, having smaller dimensions, as ampules, for example, for the removal of the product by directly inserting an injection cannula. When using an infusion bottle, an insertion mandrel may be provided in order to remove the product. The containers are produced out of a plastic material, which is suitable for the known blow-fill-seal method, for example in accordance with the known bottelpack® system, thus made out of a polyolefin such as a polyethylene having a lower or higher density, or polypropylene.

Figs. 1 and 2 show a first exemplary embodiment, in which the main part of the container, of which only the upper end section is shown, is designated as 1. A narrowed, circular-cylindrical neck part 3 is connected to the main part of the container, which has an oval contour, which neck part, in turn, transitions into a container head 5, which forms the upper terminal end of the container head 5. The upper side of said container head has a wall region 7 that is curved slightly outward, which region is provided as an area to be punctured for the piercing of the container wall during a removal procedure. A sealing material made out of a thermoplastic elastomer (TPE) in the form of a disk-shaped body 9 is non-detachably affixed to the wall region 7. This body 9 is made out of a polymer, which has increased elasticity as compared to the container material, so that a puncture site is resealed in the same way as occurs in the case of a sealing element made out of rubber. In the case of the material of the body 9, this may be a polyethylene having a lower or higher density, for example Santoprene® 181-55MED, Laprene ® SEBS, Thermolast® TM 3RST, or the like. In order to form the non-detachable connection of the body 9 to the wall region 7, this wall region and the contact surface of the body 9 are heated to a softening temperature, approximately in the range of 200 °C, and are pressed against one another so that an inseparable

connection in a materially integrated bond is created. A protective film 11 made out of plastic is detachably applied to the upper surface of the body 9, which can be removed for the initial use of the container by means of a projecting tab 13. The upper surface of the protective film 11 may be provided with markings, which represent an original seal, for example. As can be seen in Fig. 1, the upper surface of the body 9, which is covered by the protective film 11, is curved in a corresponding manner, like the wall region 7 at the container head 5. In the examples of Figs. 1 and 2, the disk-shaped body 9 covers almost the entire wall region 7 up to the vicinity of a lateral convexity 15, as a result of which, the diameter of the container head 5 is enlarged as compared to the diameter of the neck part 3.

The second exemplary embodiment from Figs. 3 and 4 differs from the first exemplary embodiment in that the neck part 3 transitions into the container head 5 without a convexity and having the same diameter. Again, this forms an outer curved wall region 7 for the non-detachable connection with the body 9 of the sealing material (TPE). A further difference as compared to the first example is that the body 9 of the sealing material has a depression 19, which is concentric to the principal axis 17, which depression has the form of trough having oblique side walls, which diverge outward. This depression 19 forms an area to be punctured in the body 9, which has a reduced wall strength, while the remaining part of the body 9 extends with no depression to the outer edge of the wall region 7 at the container head 5.

The third exemplary embodiment from Figs. 5 and 6 differs from the preceding examples in that, starting from the convexity 15, which is connected to the neck part 3, the container head 5 is lengthened by a cylinder part 21 upward to the wall section 7. The body 9 of the sealing material corresponds to the example in Figs. 3 and 4 in its configuration and contour, with the exception that the depression 19 is designed in the form of an annular space, which is concentric to the axis 17.

The fourth exemplary embodiment according to Figs. 7 and 8 corresponds to the exemplary embodiment from Figs. 3 and 4 in terms of the design of the neck part 3 and of the container head 5. The difference as compared thereto is that the body 9 of the sealing material has a smaller diameter than the associated wall region 7 at the container head 5, without a depression being formed therein. The body 9 is encompassed by a plastic ring 23 in the region between the outside of the body 9 and the outer edge of the wall region 7. The enclosure of the body 9 facilitates handling during the manufacturing process. The plastic ring 23 may be bonded or welded to the body 9. In producing a connection of the body 9 to the wall region 7 at the container head 5 in a materially integrated bond, the plastic ring 23 may, in turn, form a welded connection at the container head 5.

Figs. 9 and 10 show a fifth exemplary embodiment, in which the design of the neck part 3, convexity 15 and container head 5 corresponds to the example in Figs. 5 and 6. As in the example in Figs. 7 and 8, however, the body 9 of the sealing material is encompassed by a plastic ring 23, as is the case with the example in Figs. 7 and 8. A depression 19 is formed on the upper surface of the body 9 in a form that is similar to the depression 19 from Fig. 3, wherein, in Fig. 9, the recess is open, up to the vicinity of the outer edge of the body 9.

Figs. 11 and 12 show a sixth exemplary embodiment, in which the design of the neck part 3 and of the container head 5 corresponds to the example in Figs. 3 and 4, wherein the body 9 of the sealing material has a diameter, which, however, is reduced as compared to the wall region 7 at the container head 5. Accordingly, the inner diameter of the plastic ring 23, which is provided as an enclosure, is reduced accordingly, whereas the outer diameter of the plastic ring 23 is enlarged in such a way that said ring extends over the edge of the wall region 7 and projects beyond the container head 5. In this way, an additional, lateral anchoring of the plastic ring 23 is implemented.

In the case of the seventh exemplary embodiment shown in Figs. 13 and 14, the neck part 3 is again extended to the convexity 15, to which the container head 5 is directly connected. As in the example in Figs. 11 and 12, the body 9 of the sealing material has a reduced diameter as compared to the diameter of the container head 5. The encompassing plastic ring 23 is enlarged as compared to Figs. 11 and 12 in order to form a kind of cap, the outer edge 25 of which projects over the convexity 15 at the end of the neck part 3 in such a way that a snapping or locking connection is formed for the plastic ring 23.

In the case of the exemplary embodiment from Figs. 15 and 16, the shape of the neck part 3, the convexity 15 and the container head 5 corresponds to the example in Figs. 13 and 14. However the encompassing plastic ring 23 is lengthened using an outer cylinder 27 in order to form a cap-like cover such that the cylinder end rests against a shoulder 29, which is formed at the transition between the main part of the container 1 and the neck part 3. The cylinder end may be affixed to the shoulder 29, for example by adhesive bonding or welding.

Figs. 17 and 19 show a ninth exemplary embodiment. Like the preceding example in Figs. 15 and 16, the plastic ring 23 is enlarged in a cap-like manner, having an outer cylinder 27, which extends to a shoulder 29 on the main part of the container 1. The neck part 3, convexity 15 and container part 5 correspond to the example in Figs. 15 and 16. Unlike what is shown there, however, the plastic ring 23 forms an enclosure for the body 9 of the sealing material in the form of a cylinder 31, which projects axially upward beyond the body 9, and having projections 33, see Fig. 19, which project partially over the protective film 11. The projecting wall of the cylinder 31 having the projections 33 may form a receptacle for affixing a known removal adapter.

The tenth exemplary embodiment from Figs. 18 and 20 differs from the example in Figs. 17 and 19 in that, instead of the protective film 11 on the upper end of the cylinder 31, a protective cover 35 is formed as an integral

part, wherein predetermined breaking points 37 (Fig. 20) are formed, which make it possible to tear off the cover 35 for a removal procedure. In order to make it easier to tear off said cover, a ring 39, which serves as a handle, is formed above a connection tab 41 on the cover 35.

In order to obtain a low-germ surface, an antimicrobial additive may be added to the sealing material of the body 9 during production, for example With Stand® from Poly One or HP 7A 4000 AM from Gabriel Chemie. This has the advantage that the puncture site on the body 9 no longer needs to be disinfected prior to piercing said site by means of a mandrel or cannula.

Claims

1. A sealing arrangement comprising at least one container (1), such as a closure cap that is placed on the container (1), wherein the inside of the container (1) is used to accommodate a medium, in particular in the form of a fluid that is bottled in a sterile manner, which can be removed from the container (1) by means of a removal device such as a syringe needle, to which end said removal device penetrates at least one sealing material (9), which sealing material is connected to the container (1), wherein the respective sealing material (9) is disposed on the outside (7) of the container (1) thereof facing the environment, **characterized in that** the respective sealing material (9) is produced separately from the container and is fixedly connected to the outside (7) of the container (1) facing the environment by means of a welded and/or adhesively bonded connection.

2. The sealing arrangement according to Claim 1, characterized in that the respective sealing material (9) is welded to the outer wall (7) of the container (1) without filler material and preferably free of adhesives.

3. The sealing arrangement according to Claim 1 or 2, characterized in that the respective sealing material (9) rests directly on the outer wall (7), to which it can be assigned, with no spacing, and with the entire contact surface of said sealing material that faces the container (1) resting against the outer wall (7), to which it can be assigned.

4. The sealing arrangement according to one of the preceding Claims, characterized in that elastomers or plastics that can be bonded or welded are used as a sealing material (9), and in that a thermoplastic elastomer (TPE) is preferably used as a sealing material (9).

5. The sealing arrangement according to one of the preceding Claims, characterized in that the container (1) is produced by means of a blow, fill and seal process, and in that the sealing material (9) is preferably applied to the container (1) after the production of said container is complete.

6. A container (1) associated with a sealing arrangement according to one of the Claims 1 to 5, said container being made out of plastic, and being produced, filled and sealed in a sterile manner in a blow molding process, and it being possible to pierce the container wall (7) of said container by means of a cannula or a mandrel in order to remove product, wherein the sealing arrangement has a sealing material (9) in order to seal a puncture site that is formed in the container wall (7) during a removal process, characterized in that the sealing material (9) is produced separately from the container and is disposed on the outside (7) of the container (1) facing the environment, and in that the respective sealing material (9) is fixedly connected to the outside (7) of the container (1) facing the environment by means of a welded and/or adhesively bonded connection.

7. The container according to Claim 6, characterized in that the sealing material, in the form of a disk-like body (9), is connected to the container wall (7) in a materially integrated bond.

8. The container according to Claim 6 or 7, characterized in that said container is provided with a container head (5), which is connected to a main part of a container (1) by means of a neck part (3), said container head having a wall section (7) which can be pierced for a removal procedure, and in that the sealing material (9) is provided on the container head (5).

9. The container according to one of the Claims 6 to 8, characterized in that a removable protective film (11) is provided on the outside of the sealing arrangement, said protective film resting detachably on the body (9) of the sealing material.

10. The container according to one of the Claims 6 to 9, characterized in that the wall section (7) of the container head (5), which is connected to the body (9) of the sealing material, has a curvature that extends from the interior of the container directed outward, and in that the outside of the body (9) of the sealing material has a similar curvature.

11. The container according to one of the Claims 6 to 10, characterized in that the outside of the body (9) of the sealing material has at least one recess (19).

12. The container according to one of the Claims 6 to 11, characterized in that the recess of the body (9) has the form of an annular space (19), which extends concentrically to a central, non-recessed region.

13. The container according to one of the Claims 6 to 12, characterized in that a plastic ring (23) that laterally encloses the body (9) of the sealing material is provided, which ring is connected to the container head (5) and/or to the main part of the container (1).

14. The container according to one of the Claims 6 to 13, characterized in that the plastic ring (23) engages behind a radially projecting edge region (15) on the container head (5).

15. The container according to one of the Claims 6 to 14, characterized in that said container forms a shoulder (29) at the transition between the main part of the container (1) and the container head (5), and in that the

plastic ring (23) overlaps over the container head (5) in the manner of a cap, and is connected to the shoulder (29).

16. The container according to one of the Claims 6 to 15, characterized in that the cap-like plastic ring (23) forms an enclosure for the body (9) of the sealing material in the form of a cylinder (27), which projects axially outward beyond the body (9).

17. A sealing material for a sealing arrangement according to one of the Claims 1 to 5, characterized in that it is made out of an elastomer or plastic that can be bonded or welded.

18. The sealing material according to Claim 17, characterized in that said material is composed of a thermoplastic elastomer (TPE).

19. The sealing material according to Claim 17 or 18, characterized in that said material is formed by a block-shaped or disk-shaped body (9).

20. A method for producing a container according to one of the Claims 6 to 16, in which a non-detachable, form-fitting connection between a region (7) of the container wall, which has been provided as a puncture site for a removal procedure, and a sealing material (9) made out of a plastic that can be welded, preferably a thermoplastic elastomer (TPE), is formed by a joining process, in which the contact surface on at least one of the joining elements (7, 9) is heated at least to the sterilization temperature before the joining elements (7, 9) are pressed against one another to form a welded joint.

21. The method according to Claim 20, characterized in that a sealing material (9) is used which contains an antimicrobial additive.