

Container Having a Head Piece, Which Container Can Be or Is Filled with a Medium

The invention relates to a container having a head piece with the feature of the preamble of claim 1.

Plastic containers, which are produced with a blow molding, filling, and sealing method (BFS method), such as that described in EP 2 269 558 A1, for example, and which is also referred to as the bottelpack® system in technical parlance, are used for staple and luxury foods and also very effectively in the medicinal sector for packaging of pharmaceuticals, diagnostic products, enteral nutrition and medicinal products, e.g. rinsing solutions and dialysis solutions. A significant advantage of such containers intended for these kinds of applications is that the contents only come into contact with a polymer forming the container material, typically a plastic such as LDPE, HDPE or PP. With one-piece containers produced and filled using this BFS method it is possible to guarantee the low germ levels/sterility of the contents over longer periods of time. Containers which are intended for injections or infusions have a special formation of the head region (hereinafter referred to simply as "head piece") for obtaining access to the container contents. The integral formation of container and head piece makes it possible to ensure the sterility of the filling material while permitting particularly efficient realization of the production process. Caps with elastomer sealing elements (DIN ISO 15759) are mounted on the head piece by means of welding or injection molding. Such head pieces, as are known from DIN ISO 15759, for example, have a head surface in the form of a head membrane having a convex curvature, which can be penetrated by means of a spike or a cannula when the container is used. Containers with such head pieces have several disadvantages. The use of less sharp spikes is preferred because of the reduced risk of injury to the users. This creates the risk that the head membrane pushes inwards during the piercing operation resulting in a leakage. Leakages can also occur when the head piece is punctured multiple times, e.g. with a spike for a removal operation or with a cannula for the transfer of a separate drug component into the corresponding container, before the actual administration of the container contents.

DE 25 04 253 A1 discloses a container with the features of the preamble of claim 1, having a head piece, which container can be or is filled with a medium and is produced from plastic materials using a blow molding, filling, and sealing method, comprising a transition

region between the container and at least one first type of a head surface, which is arranged on the head piece at a front end and can be penetrated by means of a piercing or cutting part and extends with a specifiable curvature, wherein at least one second type of a head surface, which likewise has a specifiable curvature, which matches the curvature of the head surface of the first type, but preferably is different therefrom, is present on the head piece, wherein the head surfaces transition into each other in such a way that an overall surface is formed, which spans the free end of the transition region directed away from the container, wherein the head piece is an integral component of the container, and wherein the head surfaces are formed rotationally symmetrical and extend concentric to a longitudinal axis of the container.

Further containers are disclosed in EP 0 763 476 A1, EP 0 621 027 A1, US 2013/0134161 A1 and DE 195 00459 A1.

Based on this prior art, the problem addressed by the invention is to provide a container intended in particular for a medicinal use, which is characterized by improved functional characteristics and which ensures a particularly safe handling, for example, in the case of parenteral or enteral administration.

According to the invention, this problem is solved by means of a container having the features of Claim 1 in its entirety.

A significant special characteristic of the invention is , with two types of head surfaces, both have a convex curvature or the one head surface is convex and the other head surface is, relative thereto, concave.

In addition, it is provided that at least one second type of a head surface, which has a specifiable curvature, which is different from the curvature of the first type, is present on the head piece forming an integral component of the container, wherein the head surfaces transition into each other in such a way that an overall surface is formed, which spans the free end of the transition region directed away from the container. Because the invention, instead of having one uniform head membrane which spans the end of the head piece with a standard curvature, provides for the formation of different head surfaces, which preferably form different curves at the head piece end, the overall surface can have greater resistance to bending and puncturing, cutting or penetration can be more easily achieved. The deformation of the head membrane during the opening operation and the risk of leaks is thus minimal. This permits safe handling even when less sharp spikes, cutters or thick cannulas are used. The design of the different head surfaces and the provision of a

penetration surface additionally provides a simple, economical solution for optimally adapting caps to the head surfaces, which has significantly smaller elastomer sealing elements compared with DIN ISO 15759, which sealing elements, according to the invention, essentially abut only the penetration surfaces or parts thereof.

Different types of the head surfaces provided on the head piece can transition into each other directly or via a connection region. In particularly advantageous exemplary embodiments, another, third type of a head surface is provided, which in turn has a different curvature than the other two head surfaces.

The arrangement can also advantageously be such that head surfaces are formed rotationally symmetrical and extend concentric to a longitudinal axis of the container and/or of the transition region and have surface pieces which are arranged extending transverse to this longitudinal axis.

A particularly effective increase in resistance to bending of the head membrane can be achieved with exemplary embodiments in which the head surface of the first type forms a connecting bridge which spans the free end of the transition region, wherein the other head surface of a different type connects to the connecting bridge at the edge thereof.

Furthermore, the arrangement can advantageously be such that at least one annularly closed head surface of the second type or of another type is arranged on the head surface of the first type. The region of the head surface of the first type surrounded by the annular surface can be provided as a piercing region/cutting region, which is reinforced by the surrounding annularly closed head surface.

The arrangement can particularly advantageously also be such that at least one of the head surfaces forms a bar-type stiffening rib, which is mounted on one adjacent head surface or which connects surface parts arranged next to one another of at least one other head surface to one another.

Such exemplary embodiments can be particularly advantageously designed such that the projecting head surface and the corresponding cap form at least one connecting part with distinctive connection characteristics, to which a corresponding connecting part in the form of an adapter can be removably attached for a media removal and/or media feed from or into the container. These adapter systems are state of the art. Such adapters can also, as is disclosed in WO 2012/143921 A1 or

EP 0 565 103 B1, for example, be used for a measured addition of a separate fluid, semi-solid or solid drug component to the container. For the direct transfer of the additional component from a receptacle containing this additional component, such adapters have a spike which is sharp on both sides for establishing a direct connection, by means of which even solid substances, for instance in powder form, can be introduced into the container. The design of the head piece and of the puncturing surfaces envisaged according to the invention permits application-appropriate spacing of puncture points, e.g. in order to simultaneously apply spikes with wide drip chambers (DIN EN ISO 8536-4) and an infusion device with a dosing container (DIN EN ISO 8536-5).

The container according to the invention, for example, in the form of an infusion bottle, can also have at least two opposite or adjacent filling and/or removal openings, on at least one of which a head piece with head surfaces of a first type and head surfaces of a second type is provided as an integral component of the container.

The subject matter of the invention also comprises multiple-chamber containers (e.g. WO 0076745 A1), which have more than one adjacent and/or opposite filling or removal openings, on at least one of which a head piece with head surfaces of a first type and of a second type is provided as an integral component of the container.

The subject matter of the invention also comprises caps with elastomer sealing elements, which essentially abut only on the penetration surfaces of the respective head piece.

The invention is explained in detail below with reference to exemplary embodiments depicted in the drawings, in which:

- Fig. 1 shows, in a depiction which is slightly enlarged compared with a practical embodiment, a front view of a container in the form of an infusion bottle with two removal openings, the upper one of which in the figure is provided with a head piece according to the prior art of DIN ISO 15759;
- Fig. 2 shows, depicted on a smaller scale, a perspective oblique view of the bottle of Fig. 1;
- Fig. 3a shows, depicted at approximately twice the size compared with a practical embodiment, a perspective oblique view of an exemplary

	embodiment of a head piece of a container according to the invention;
Fig. 3b	shows a partial cross-section, which shows a modified cross-sectional shape for the bar-type rib of the head piece of the exemplary embodiment of Fig. 3a;
Fig. 4a	shows a front view of another exemplary embodiment of the container;
Figs. 4b and 4c	show a front view or a top view of the head piece of another exemplary embodiment of the container according to the invention;
Figs. 5a to 5c	show a front view or perspective oblique views of other exemplary embodiments;
Figs. 6a and 6b	show a front view and a perspective oblique view, respectively, of another exemplary embodiment of the container;
Fig. 7a	shows a front view of another exemplary embodiment of the container;
Figs. 7b, 7c, 7d	show perspective oblique views (7b, 7d) or a side view (7c) of a modified embodiment of the head piece of the exemplary embodiment of Fig. 7a;
Figs. 8a and 8b	show a front view and a perspective oblique view, respectively, of another exemplary embodiment;
Figs. 9a and 9b	show a front view and a perspective oblique view, respectively, of another exemplary embodiment;
Figs. 10a and 10b	show a front view and a perspective oblique view, respectively, of another exemplary embodiment;
Fig. 11	shows a perspective oblique view of a head piece of another exemplary embodiment;
Fig. 11a	shows a depiction corresponding to Fig. 11 with an additional reinforcing rib;
Figs. 12 and 13	show perspective oblique views of two other exemplary embodiments of a head piece;

- Fig 13a shows a modification of the exemplary embodiment of Fig. 13 with an additional reinforcing rib;
- Fig. 14 shows a perspective oblique view of a modified embodiment of the head piece of Figs. 10a and 10b;
- Fig. 15a shows a front view of another exemplary embodiment of the container with a sectional depiction of a cover cap of the head piece in the state prior to a welding operation;
- Fig. 15b shows a perspective oblique view of a cover cap for the head piece of the exemplary embodiment of Fig. 5a;
- Fig. 15c shows a sectional depiction of a head piece with a welded on cap according to Fig. 15b after the welding operation;
- Fig. 16a shows a perspective oblique view of a modified embodiment of a cover cap for a container according to the invention according to the exemplary embodiment of Fig. 11;
- Fig. 16b shows a sectional depiction of the cap according to Fig. 16a on a head piece according to the exemplary embodiment of Fig. 11;
- Fig. 17 shows a depiction, corresponding to Fig. 1, of an embodiment of an infusion bottle with two removal openings, one of which is provided with a screw connection;
- Fig. 18 shows a depiction, corresponding to Fig. 1, wherein a head piece according to Fig. 5a is provided on a removal opening, and
- Fig. 19 shows the infusion bottle of Fig. 18, wherein the head piece lying at the bottom is provided with an end cap according to Fig. 15b, prior to the welding operation.

Figs. 1 to 5c, 7a to 8b, 10a to 11a and 14 to 19 merely serve to explain the background of the invention. The embodiments shown therein are the subject matter of any claim.

Figs. 1 and 2 show a container produced using the mentioned BFS method in the form of an infusion bottle 1 with a top removal position 3 and a bottom removal position 5. The bottle 1 is produced from a plastic material such as LDPE, HDPE, PP or PET. In the case

of a multiple layer embodiment, polyolefins in combination with EVOH, PET, COC, COP, PA or the like, can be provided, for example. In Figs. 1 and 2, the bottle 1 lying at the top in the drawings has a head piece 7, which corresponds to the prior art according to DIN ISO 15759. In the case of containers with head pieces of this type, caps with an elastomer sealant (DIN ISO 15759) can be connected, e.g. by means of welding, injection molding or sealing, to the head piece of the filled and sealed bottle 1. On the front end of the head piece 7, a head surface 11 is provided for removal and/or feeding operations, which, in the form of a head membrane penetrable by means of a cannula or a spike, spans a transition region 13 at which the head piece 7 transitions into the neck part 9 of the bottle 1. The head surface 11 formed by this head membrane spans the transition region 13 with a uniformly convex curvature in the prior art.

Figs. 3 to 15a and 17 to 19 show, to some extent in separate depictions, i.e. without depicted bottle bodies 1, different exemplary embodiments of containers according to the invention with head pieces 7, which have different types of head surfaces. Fig. 3a thus shows an example in which, in addition to a head surface 11 of the first type, which spans the transition region 13 with a convex curvature like the head surface 11 of the prior art, a head surface of the second type in the form of a reinforcing rib 15 is provided, which forms a bar projecting significantly from the head surface 11 of the first type, which spans the head surface 11 and lies diametrically therein. This bar-type rib 15 increases the resistance to the bending of the curvature of the head surface 11 into the inside of the container and permits the secure abutment of the elastomer component of a cover cap (not depicted) and thus the secure sealing of the pierced spike. Fig. 3b shows a modified cross-sectional shape for the reinforcing rib 15 of Fig. 3a, wherein the top side of the rib 15 is not flat, but convex.

Figs. 4a to 4c provide a bridge body 17 as a reinforcing or stiffening element, which, in the form of a projecting head with an oval contour, spans the free end of the transition region 13 and which, at its front top end, forms a head surface 19 of the first type with only a slightly convex curvature. Another head surface 21 connects to the foot of the bridge body 17, which other head surface is once again convex, but with greater curvature than the head surface 19. As Fig. 4c shows, the largest width of the bridge body 17 is somewhat more than half of the diameter of the transition region 13, and the height of the bridge body 17, measured relative to the surrounding head surface 21, is somewhat less than half of the largest width of the bridge body 17 as the comparison of Figs. 4b and 4c shows. From the front head surface 19, the side wall 23 extends out from a rounding 25 surrounding the head surface 19, to the surrounding head surface 21.

Figs. 5a and 5b show an exemplary embodiment, in which two nipple-shaped knuckles 29 project from a head surface 27 which spans the transition region 13. The knuckles 29 lie at a distance from one another on a line extending diametrically on the head surface 27 and form, on their respective front end, a round, easily penetrable head surface 31. These head surfaces have only an extremely slight curvature, i.e. they extend almost parallel to the main plane of the head surface 27. A side wall 33 with concave curvature connects the front face surface 31 with the surrounding head surface 27. In another embodiment (not depicted), a bar-type rib, as in Figs. 3a and 3b, can extend between the knuckles 29. Fig. 5c shows a modification compared with Figs. 5a and 5b, wherein the head surface 31 is not provided at the top end of the knuckles 29, but is rather set back towards the inside.

Figs. 6a to 9b show other exemplary embodiments, in which all of the head surfaces are formed rotationally symmetrical and extend concentric to a longitudinal axis 35 of the transition region 13. In the example of Figs. 6a and 6b, a convex head surface 37 is formed torus-like on the front edge of the circular cylindrical transition region 13. This head surface 37 surrounds concentrically a circular head surface 39 in the form of a concave depression, from which in turn another head surface 41 rises in the form of a convex dome, concentric to the axis 35. The radial width of the edge-side, outer head surface 37 is approximately $1/6$ of the diameter of the transition region 13. The diameter of the dome forming the head surface 41 is approximately $1/3$ of the diameter of the transition region 13. The depth of the depression forming the head surface 39 is in turn approximately $1/16$ of the diameter of the transition region 13.

The head piece 7 of the exemplary embodiment of Figs. 7a to 7c has a convex head surface 43 connecting to the front edge of the circular cylindrical transition region 13, which head surface, as part of a torus, encircles the transition region 13. This head surface 43 surrounds a knuckle 45, concentric to the axis 35, which forms a convex head surface 47 at its top side. The radial width of the outer edge-side head surface 43 corresponds to the width of the edge-side head surface 37 of the example of Figs. 6a and 6b. The height of the knuckle 45 projecting above the edge-side head surface 43 is approximately $1/8$ of the diameter of the transition region 13. In the example shown in Figs. 7c and 7d, an additional reinforcing rib 48 is provided, which spans the head surface 47 diametrically.

The exemplary embodiment of Figs. 8a and 8b has a head surface 51 in the form of a convex annular surface connecting to the circumferential edge 52. A knuckle 53 rises from the central region of this annular surface concentric to the axis 35, which knuckle forms a

head surface 55, which is also convex, but with greater curvature than the head surface 51. The diameter of the cylindrical transition region 13 is approximately two and a half times the diameter of the knuckle 53. The height of the knuckle 53 relative to the surrounding head surface 51 is approximately $1/6$ of the diameter of the knuckle 53.

The exemplary embodiment of Figs. 9a and 9b has, like the exemplary embodiment of Figs. 6a and 6b, a head surface 59 with convex curvature surrounding the circumferential edge 57 of the cylindrical transition region 13, to which a depression-like recess is connected and the base of which forms a concave head surface 61. The difference compared with the example of Figs. 6a and 6b is only that no knuckle is located in the center of the head surface 61. The width of the convex head surface 39 at the edge 57 is, in the example of Figs. 9a and 9b, a little greater than the width of the edge-side head surface 37 in the example of Figs. 6a and 6b. The width of the head surface 61 formed by the central depression, or pocket, is a little more than half of the diameter of the transition region 13. The axial depth of the depression forming the head surface 61 is approximately $1/10$ of the diameter of the transition region 13.

The exemplary embodiment of Figs. 10a and 10b resembles the exemplary embodiment of Figs. 4a to 4c to the extent that a bridge region 63 is provided, which projects from a convex head surface 65, which connects to the edge 66 of the connecting region 13. By contrast with the oval bridge body 17 of Figs. 4a to 4c, the bridge region 63 of the present example has a contour in the shape of a horizontal figure eight, with side walls 67, which descend from a front head surface 69, relatively steeply relative to the surrounding head surface 65. As Fig. 10a more clearly shows, the head surface 69 has a convex curvature. The height of the bridge body 63 relative to the surrounding head surface 65 is approximately $1/4$ of the diameter of the circular cylindrical transition region 13. The largest width of the bridge region 63 at the arms of the figure eight forming the contour is somewhat less than half of the diameter of the transition region 13.

Fig. 11 shows an exemplary embodiment which, similarly to the head surface 11 in the exemplary embodiment of Fig. 3, has a convex head surface 74, which connects to the edge 70 of the transition region 13 over the entire circumference thereof. Arranged on this head surface 74 are two annular bodies 71 in the form of flat circular rings, which are arranged at a spacing from one another along a line extending diametrically over the head surface 74. The external diameter of these flat rings is approximately $1/6$ of the diameter of the transition region 13, wherein the annular bodies 71 are arranged such that the spacing between them is greater than the spacing of each annular body 71 from the

circumferential edge 70 of the transition region 13. At their top side, the annular bodies 71 each form a head surface 73 in the form of a slightly convex circular surface.

In addition, as is also the case in the exemplary embodiments of Figs. 3a and 3b, a bar-type reinforcing rib 15 can be provided, extending diametrically over the head surface 74, as depicted in Fig. 11a.

The exemplary embodiment of Fig. 12 resembles the exemplary embodiment of Figs. 9a and 9b, in other words, it has a depression 77 delimited by the edge-side, convex head surface 75, which forms a concave head surface 79. Mounted on the base of the depression 77, a diametrically extending stiffening rib 81 extends in the form of a straight bar with axially parallel side walls and a slightly convex top side, which abuts the edge-side head surface 75 as another head surface 83.

Fig. 13 shows an exemplary embodiment, in which a convex head surface 85 continuously spans the transition region 13 between its circumferential edge 86. In a symmetrical arrangement, chamfers 89 lying diametrically opposite one another connect at arc-like connecting lines, which chamfers each form another, slightly convex head surface 91. As Fig. 13a shows, in the example of Fig. 13 too, an additional bar-type reinforcing rib 15 can be provided, which spans the head surface 85.

The exemplary embodiment of Fig. 14 resembles the exemplary embodiment of Figs. 10a and 10b, wherein side penetration surfaces 101, defined by the contour shape of the bridge body 63, are formed, however. In this configuration, the penetration surfaces 101 have a maximum spacing from one another. This is advantageous when both locations are used for piercing and the corresponding spike or the drip chamber remains therein. A reinforcing rib 15 is additionally provided in the example of Fig. 14 to ensure a high level of bending resistance. This reinforcing rib can also have a rounded shape, as depicted in Fig. 3b.

Figs. 15a to 16b also show by way of an example cover caps 93, with the design shown in Figs. 15a and 15b being provided for head pieces according to the examples of Figs. 5a to 5c and the design of Figs. 16a to 16c being provided for a head piece 7 according to the exemplary embodiment of Fig. 11, for example. The cover cap 93 of Figs. 15a to 15c is a hollow body made of a plastic, for example, the same material from which the bottle is made. The cover cap 93 has a hollow cylindrical main part 92, which spans the transition region 13 of the head piece 7 and has, at the open end, an edge 95 forming a radial extension, in which a circumferential annular groove 96 is located. In the case of a cover

cap 93 fixed onto the head piece 7 by means of welding, injection molding, adhesion or sealing, the edge 95 can form a connecting part for an adapter. Fig. 15a shows a state prior to welding. As can be seen, a lug 106 is formed on the end edge of the main part 92, which lug forms an energy guide for welding processes, such as ultrasonic welding. This lug 106 is welded so that, once a welding operation has been carried out, the state depicted in Fig. 15c is obtained. Sleeve bodies 97 are molded onto the top side 94, which sleeve bodies are aligned in such a way that they are flush with the knuckles 29 on the head piece 7. In the initial state, which is depicted in the figures, the sleeve bodies 97 are closed by a disk 98 which can be torn off at predetermined breaking points, at which a tab 99 is installed which permits easy tearing off of the disks 98 so as to clear the way for access to the elastomer 103 bearing against the penetrable head surface 31 of the head piece 7.

The example of Figs. 16a and 16b differs to this in that, instead of the projecting sleeve bodies 97 on the top side 94, a dome-shaped hollow box construction 100 is provided, in which two openings 102 are arranged in such a way that they are flush with the region of the annular bodies 71, which are located on the head surface 74 of the head piece 7. For use operations, the part of the head surface 74 surrounded by the annular body 71 can therefore be penetrated via the openings 102. As depicted, an elastomer 103 is provided above the penetration surface delimited by the annular bodies 71, for the formation of a seal on the penetration surfaces.

Fig. 17 shows, in a depiction corresponding to Fig. 1, an embodiment of the bottle 1 which has two removal positions 3 and 5 lying opposite one another, wherein the access lying at the bottom in the figure is provided with an external thread 105 and wherein a head piece 7 according to the exemplary embodiment of Fig. 1 is located at the top removal position.

Fig. 18 shows a bottle 1 corresponding to Fig. 17 with a head piece 7 according to the example of Fig. 5b located at the bottom removal position 5.

Fig. 19 shows the bottle 1 of Fig. 18, wherein the head piece 7 at the bottom removal position 5 is provided with a cap 93 according to the example of Fig. 15b.

All solutions according to the invention described above have in common that the container 1, which is produced using the blow molding, filling, and sealing method, is formed in one piece with its special head piece 7 according to the invention, i.e., that, amongst other things, the container wall transitions continuously into the wall of the head piece 7.

Claims

1. A container having a head piece (7), which container can be or is filled with a medium and is produced from plastic materials using a blow molding, filling, and sealing method, comprising a transition region (13) between the container (1) and at least one first type of a head surface (11), which is arranged on the head piece (7) at a front end and can be penetrated by means of a piercing or cutting part and extends with a specifiable curvature, wherein at least one second type of a head surface (41, 75), which likewise has a specifiable curvature, which matches the curvature of the head surface (39, 79) of the first type, but is different therefrom, is present on the head piece (7), wherein the respective head surfaces transition into each other accompanied by the formation of an overall surface which spans the free end of the transition region (13) directed away from the container (1), and wherein the head piece (7) is an integral component of the container (1), wherein the head surfaces are formed rotationally symmetrical and extend concentric to a longitudinal axis (35) of the container (1), characterized in that, with two types of head surfaces, the one head surface is convex and the other head surface is, relative thereto, concave.
2. The container according to Claim 1, characterized in that the respective one type of a head surface transitions directly, or via a connecting region, into the respective other type of a head surface accompanied by the formation of the overall surface.
3. The container according to Claim 1 or Claim 2, characterized in that at least one of the head surfaces has surface pieces which are arranged extending transverse to this longitudinal axis (35).
4. The container according to one of the preceding claims, characterized in that at least one of the head surfaces (79) has at least one bar-type stiffening rib (81).
5. A cap with an elastomer sealing element (103), which can be connected to a head piece (7) of a container (1) according to one of the preceding claims, characterized in that the elastomer sealing element (103) is located substantially only opposite the penetration surface of the head piece (7), is pressed on or connected or abuts with a small spacing.

6. The cap according to Claim 5, characterized in that it has an energy guide (94), which makes possiblea welding of the cap (93) and the container (1) by means of ultrasonic welding, friction welding or vibration welding.
7. The cap according to Claim 5 or Claim 6, characterized in that the elastomer sealing element (103) has an opening for a spike and is preferably formed cylindrical or annular.