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(54) **Cap for container**

(57) A package (10) comprises a container (20), a closure member (40) removably inserted into the mouth of the container, and a cap (50). The cap has a cover member (52) which overlies the closure and has a region (66) which is removable to expose the upper surface of the closure to allow piercing thereof by a needle

or the like. The removable region is provided with a pull-ring (68) protected from accidental operation by a protective portion (60) projecting upwardly from the edge of the cover member (52). The protective portion is formed separately from the rest of the cap and is attached thereto.

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Description

[0001] The present invention relates to a cap for a container, and to a package comprising a container and a cap.

[0002] In the medical field, sterile fluids, such as medicaments, pharmaceuticals, sterile saline solution and so on are frequently required for the treatment of patients. Such sterile fluids are commonly supplied in bottles made of glass, which are chemically inert and highly unlikely to contaminate or otherwise adulterate the sterile fluid.

[0003] The bottles are normally closed by a rubber stopper or closure inserted into the mouth of the bottle. The stopper is designed so that it can be pierced by a needle of a hypodermic syringe, an infusion spike of an infusion set, a spike of an autoinjector, or the like, to allow the contents of the bottle to be withdrawn. The stopper can also be removed to allow the contents of the bottle to be poured out, or to be sucked up using a quill or straw of an autoinjector.

[0004] In order to hold the stopper in place, one approach has been to provide a cap made of aluminium or similar thin sheet metal which is crimped over the stopper and the upper part of the bottle. In order to gain access to the stopper, either to pierce it or remove it, the sheet metal cap is either partially or totally torn away.

[0005] However, packages incorporating aluminium caps have a number of disadvantages. For example, tearing the aluminium cap away can cause problems, as sharp edges are left where the cap is torn. These edges are sharp enough to puncture surgical gloves and human skin, which is obviously a hazard to the operator as well as a disadvantage in the medical field in particular, where the risk of infection must be kept to a minimum.

[0006] In addition, in many European countries, waste must be sorted by nature before disposal. Having a metal cap and a rubber stopper on a glass bottle means that the package contains three different sorts of material (glass, metal and plastics) which may need to be disposed of separately.

[0007] Alternative approaches to containers for sterile fluids have also been tried, with varying degrees of success. In one known product, plastic bottles with screw caps are used, the screw caps having stoppers attached thereto. When the screw cap is removed, the stopper is also removed from the bottle. However, the package is not compatible with infusion procedures, and cannot be used with hypodermic needles as the standard packages can.

[0008] In another proposal, described in DE 19500460, a plastic bottle is provided with an injection moulded cap which is covered by a plastic foil. In this proposal there is no stopper in the mouth of the bottle and the primary sealing of the bottle is by an integrally moulded closure wall which is pierceable by a cannula or spike but not otherwise openable. The cap fits over

the closure wall. When it is desired to access the contents of the bottle the foil is removed and both the cap and the closure wall must be pierced, requiring sufficient force to penetrate both these parts. There is thus an associated risk of the cannula or spike being plugged by the material of the closure wall, or coring of that material to create undesirable particles in the contents of the bottle.

[0009] Further types of closure, manufactured by Stelmi of France, are marketed under the name of "Monobloc" and "Duobloc". Corresponding patent publications are believed to be FR 2745793 and EP 0794129. The "Monobloc" comprises a plastic cap which fits over the neck and stopper of a traditional glass bottle. A removable portion may be torn away to allow access to the stopper, and the entire cap can be removed if necessary. The "Duobloc" is similar, but has a screw-threaded insert which snaps over the neck of the glass bottle, and the remainder of the cap is threadedly engaged with the insert.

[0010] In the case of such plastic caps, the removable portion is integrally moulded with the rest of the cap. A line of weakness is normally provided around the removable portion to allow the removable portion to be torn away to gain access to the stopper. The stopper can then be pierced by a needle or infusion spike or the like. An engageable member in the form of a pull-ring is integrally moulded with the removable portion and when it is desired to gain access to the top surface of the stopper a force is applied to the pull-ring to remove the removable portion.

[0011] There is however a disadvantage of such plastic caps provided with pull-rings. In order for the pull-rings provided on the caps to be accessible they generally project from the cap. However, during shipping and storage, there is a risk that the pull-rings will snag on something and accidentally be operated to cause the line of weakness to be torn. This may result in the complete removal of the removable portion and thus result in the scrapping of the package and its contents. Alternatively, the tear may only be very small and, although not sufficient to cause the removable portion to be removed, allow contamination of the stopper. Such accidental partial opening of the cap may only be detected upon close inspection of the cap. In certain cases adequate inspection of the integrity of the cap seal may not be performed before it is opened and, consequently, the package may be used when in fact the top surface of stopper has become contaminated. This is clearly undesirable.

[0012] A proposed solution to the problem of accidental opening of packages incorporating a cap with a removable portion has been to surround the pull-ring with a raised section in the form of an annular wall. In such a proposal, shown in Figure 7 of EP 0480196, a two piece injection moulded cap is provided, to be welded to a plastic bottle. In this proposal a first moulding defines the portion of the cap to be attached to the bottle

and a hole is formed in the upper surface thereof for receiving a cannula. The hole may be covered by a membrane. An annular wall is formed which extends about the periphery of the upper surface. A second moulding is made up of a ring, which fits inside the annular wall of the first moulding, and a pull-ring attached to a removable portion which in turn is attached to the ring by a circumferential weakened region. The two mouldings are formed separately and then ultrasonically welded to form a sealing bond between the upper surface of the first moulding and the ring of the second moulding. The cap is then permanently attached to the plastic bottle. When it is desired to gain access to the contents of the bottle the pull-ring is removed by tearing along the weakened region and a cannula may be introduced into the bottle through the hole formed in the first moulding.

[0013] However, with such a cap the sterility of the upper surface of the first moulding is dependent on the quality of the ultrasonic weld, so that any defect in the weld will create the potential for contamination of the upper surface.

[0014] Another proposal for a cap having a protective annular wall for a pull-ring for removing a removable portion is described in EP 0079676. This cap is for a plastic bottle and is made up of a plug member and three plastic injection mouldings. The first moulding consists of the pull-ring, the removable portion connected to the rest of the moulding by a frangible region, and an annular wall which extends around the pull-ring. The plug member is positioned in a cavity, formed by a portion of the annular wall projecting below the removable portion, and sealed in place by the second moulding which is formed around the lower part of the first moulding. The cap is completed by a third moulding which is formed around the external surfaces of the first and second mouldings. The cap is then heat-welded along its lower edge to the neck of a plastic bottle. In order to gain access to the contents of the bottle the removable portion is removed by pulling on the pull-ring, causing the weakened region to tear. A syringe, cannula or other such device may then be introduced through the plug member and a wall of the second moulding.

[0015] The arrangement of EP 0079676 avoids the problem mentioned above concerning EP 0480196, of relying on a single ultrasonic weld to maintain the sterility of a region to be pierced after tearing away the removable portion. It is however a relatively complicated arrangement in that it consists of four separate components: three mouldings and the plug member.

[0016] Moreover, there is no teaching in EP 0079676 of how the first moulding is actually made. It is however assumed, based on the shape of the moulding as seen in Figures 2 to 4 of the document, that the first moulding would be injection moulded using axially movable mould tools. The three tools would be:

(a) a lower tool employed to define the cavity for the plug member;

(b) a first upper tool of generally cylindrical shape to define the space inside the pull-ring;

(c) a second upper tool of generally tubular shape to define the space radially outwardly of the pull-ring and radially inwardly of the annular wall and also the space below the pull-ring.

[0017] The pull-ring has a chamfered radially outer surface, so that it is assumed that after injection moulding has taken place the first upper tool is withdrawn axially upwardly, followed by axial upward withdrawal of the second upper tool. During this latter withdrawal, the chamfered surface on the pull-ring should allow it to be pushed radially inwardly by a camming action of the second upper tool. This would enable the pull-ring to be moulded with an integral connection at one region around its circumference to the wall of the moulding below, but otherwise at an upward spacing from the wall.

[0018] Attempts to injection mould a plastic cap having a pull-ring, a removable portion, and an annular wall using the method described above have been made. The inventor of the present invention has discovered that it is extremely difficult to use the method without a high failure rate. The pull-ring tends to be pulled up with the second upper tool, leading to the pull-ring being torn apart and/or the frangible region being weakened, with a risk of compromising the sterility of the area below the frangible region. These problems are particularly acute when the material used is polypropylene, which is unfortunate, because polypropylene is a preferred material for forming injection mouldings and, in particular, plastic caps.

[0019] Viewed from a first aspect the present invention provides:

a cap [50] for a container [20] having a closure member [40], wherein said cap comprises:

(i) a moulding comprising a retaining portion for engaging the container and retaining the cap thereon, and a removable portion [66] which is frangibly removable to expose at least partly said closure member, and a user engageable member [68] operable by a user to remove said removable portion; and

(ii) a protective portion [60] for the user engageable member [68], provided annularly outwardly thereof, and attached to the moulding;

wherein the protective portion [60] is formed separately to the moulding.

[0020] The container [20] has a mouth or aperture, which is sealed with the closure member [40]. Suitable containers are known in the art, and include bottles, vials and infusion bags. In one preferred embodiment, the container is a bottle. The container may be made of any material suitable for storing sterile preparations. Preferred materials are glass, coated glass or plastic, most preferably plastic. A plastic material which is suitable for making disposable containers for the storage of biocom-

patible fluids is most especially preferred.

[0021] The "retaining portion" of the cap functions to secure the cap [50] on the container [20]. This is suitably achieved by engaging the container eg. by a snap fit on the container, complementary threading, a bayonet locking mechanism, or the cap may be weakly welded to the container, making it possible to remove the cap from the container. This permits the user the option of removing the cap to pour the contents out of the container. Preferably, the retaining portion of the cap is chosen so that the cap is reversibly attachable to the container. This has the advantage that, after any use involving removal of the cap, any unused contents in the container can be retained prior to disposal, by simply reattaching the cap. Most preferably, the retaining portion of the cap has threads which are complementary to those of a container having external threads around its' mouth. This permits the cap to be removably attached to the container [20] and provides a simple, versatile and effective way of securing the cap on the container.

[0022] It is preferred that the moulding portion of the cap further comprises a tamper-evident feature, to reduce the risk of fluid being inadvertently administered from a package which has already been opened and closed. Any such prior opening and closing of the container could result in the fluid losing its sterility, or imply potential adulteration or contamination of the fluid. One suitable form of tamper-evident feature is a tamper-evident member removably attached to the cap, which must be detached irreversibly from the cap before the cap can be removed. A preferred such tamper-evident member is frangibly removable from the moulding of the cap. The absence of the tamper-evident member is then a clear sign that the container package has previously been opened, and should not be used.

[0023] The engageable member [68] of the cap [50] suitably comprises a pull-ring, a tab or a lever. The engageable member preferably comprises a pull-ring upwardly spaced from the removable portion [66]. This allows the user to hook a finger beneath the engageable member, and thus makes it easier to operate. The cap moulding preferably further comprises at least one projection which acts as a pivot for the engageable member [68]. If a pivot is not used, then the force exerted on the engageable member by the user is simply transmitted to the removable portion [66]. However, if a pivot point is provided, then a leverage effect can allow the force exerted on the engageable member [68] to be amplified, thus making it easier to remove the removable portion [66].

[0024] The moulding and the protective portion [60] of the cap are 'formed separately', ie. are two separate parts produced in two different processes (eg. by separate injection moulding procedures). This has the advantage that the problems of damaging the engageable member [68] or the removable portion [66] when separating the moulding from its mould are minimised. Rather than using axially movable mould members as de-

scribed above, the absence of the protective portion [60] during moulding allows radially movable mould members to be used, because they are unobstructed by the protective portion. Such radially movable mould members, and associated injection moulding techniques, are known to persons skilled in the art.

[0025] The protective portion [60] may be attached to the moulding (ie. the rest of the cap) either removably or by bonding together, e.g. by heat or by ultrasonic welding. Preferably, the protective portion [60] is removably attached to the moulding, most preferably in a reversible removable manner. Removable attachment gives increased compatibility with existing medical equipment (eg. spikes and infusion injectors) due to easier access to the closure member [40], and hence the container contents. Reversible attachment has the advantage that the protective portion [60] can be replaced (eg. in the situation when only a portion of the container contents has been used). Reversible attachment can be achieved by an appropriate mechanical means, such as a threaded screw fit or via a screw fit or other mechanical means, such as a snap fit. The protective portion [60] is most preferably attached to the moulding by complementary threads. Typically, a snap fit may be achieved by the formation of complementary projections, or complementary projections and indentations, on the protective portion [60] and on the moulding. These will normally engage to prevent relative axial movement of the moulding and the protective portion. When the moulding and the protective portion are attached by bonding together it is generally unnecessary to form a hermetically sealed joint line between the protective portion and the moulding, because the joint line may advantageously be located such that any break or interruption therein does not provide a pathway to the covered closure member [40].

[0026] In the situation when both the retaining portion and protective portion [60] are attached *via* complementary threads, the threads for attaching the protective portion are preferably reversed relative to those used for attaching the retaining portion to the container. In this arrangement unscrewing of the protective portion [60] does not cause the cap to be unscrewed, and vice versa. This has the further benefit of allowing the protective portion to be used to aid the removal of the cap, for example by insertion of a lever or the like.

[0027] Preferably, the protective portion [60] of the cap comprises a wall which extends generally about the periphery of the engageable member [68] to protect it from accidental operation or entanglement, e.g. with other packages. As a result, the engageable member is "shrouded", and there is less chance that it can be accidentally operated. When the engageable member is a pull-ring, it is advantageous for it to be protected around its circumference.

[0028] It is further preferred that the wall of the protective portion has at least one opening [62] there-through. Most packages of sterile fluid for medical use

are sterilised by autoclaving in either a steam atmosphere or in a water cascade. In steam autoclaves the steam can condense into water on the package as the atmosphere in the autoclave cools. Similarly, for water cascade autoclaves water may collect on the package once the sterilisation process is complete. If the wall is unbroken, then it can form a cup in which the water used for sterilisation collects. It would then be necessary to invert the container to remove the water, or to rely on evaporation. Forming the protective portion [60] with openings [62] allows the water to simply drain out. In a preferred embodiment, the opening [62] is sufficiently large to allow radial access by a user's finger to the engageable member [68]. Thus, protection of the engageable member can be provided without unduly hindering deliberate removal of the removable portion [66] when desired. Preferably, the opening [62] allowing such radial access is located opposite to a portion (such as a leg or pair of legs) of the moulding which connects the engageable member and the removable portion. This can assist a user to access the part of the engageable member furthest from the connecting portion and therefore most readily able to be lifted away from the removable portion. This will be easily understood in the context of the engageable member [68] being a pull-ring.

[0029] In order to ensure that the protective portion [60] is positioned correctly relative to the moulding (eg. correctly positioning a radial opening relative to the engageable member [68]) during assembly of the cap [50], a mechanical interlock between the protective portion and the moulding may be appropriately designed. Such mechanical interlock may, for example, allow only one or two relative positions.

[0030] In a preferred embodiment, the protective portion [60] is in the form of a removable cover [61] over the engageable member [68]. Such a cover can prevent inadvertent operation of the engageable member, whilst being removable when it is desired to gain access to the engageable member.

[0031] The cap [50] and protective portion [60] are suitably of a plastic material, especially one which can be injection moulded and which can withstand autoclaving conditions. Preferred such plastic materials are polypropylene or polyethylene or other polyolefins. Polypropylene is an especially preferred plastic material. Although the cap and protective portion are generally formed from the same material they may alternatively each be formed from a different material.

[0032] Although the closure member [40] may be part of the cap, for example being in the form of a pierceable wall of the cap, the closure member preferably comprises a stopper provided in the mouth of the container. The closure member [40] is preferably formed from a thermoplastic polymer material, but may be formed from other synthetic polymer materials, or synthetic rubber (e.g. chlorobutyl rubber), or natural rubber.

[0033] The removable portion [66] may have an inclined surface to assist drainage thereof when the cap

is in an upright position. Drainage may then for example take place towards an opening [62] in the protective portion [60]. Preferably, the removable portion is upwardly convex. The drainage of water can be further assisted by forming the cover member [52] in such a manner that it is not planar, for example by having the central part of the member projecting above the peripheral region.

[0034] Preferably, the cap is provided with a sealing member which engages with the closure member [40] when the package is closed to protect a defined region of the closure member from contamination. The integrity of seal created by the sealing member is preferably achieved by the member resiliently deforming the part of the closure member against which it engages. The sealing member is advantageously an annular member which extends downwardly from the cap and engages with the upper surface of the closure member. The annular member then provides a physical barrier to contaminants and helps keep the defined region sterile.

[0035] A container [20] provided with a closure member [40] and cap [50] as defined herein can be opened in a number of ways. The removable portion [66] can be removed to gain access to the closure member [40], whilst leaving the closure member in place. The closure member can then be pierced by a hypodermic needle, or similar. If the protective portion [60] and the removable portion [66] are both removed, the container may normally be used in conjunction with a standard autoinjector. Alternatively, the entire cap can be removed (which may entail removal of a tamper-evident feature), which then allows access to the entire closure member. This may be useful if, for example, an infusion spike or quill or straw which is wider than the removable portion [66] is to be used. As a further alternative, the entire cap and the closure member can be removed, to enable pouring or the insertion of a quill or straw to load an autoinjector.

[0036] Upon removal of the protective portion [60] of the cap of the present invention, the container may advantageously be used in existing autoinjector and pump equipment without modifying the equipment. This thus avoids the disadvantage of known caps, formed with an integral annular wall, that the container cannot readily be used in standard autoinjector equipment as the integral annular wall tends to prevent the proper engagement of the cap with the autoinjector.

[0037] The invention thus provides a relatively simple cap construction with a removable portion for covering a closure member, with a high level of confidence that the closure member is protected from contamination by the removable portion up until the time when it is desired to remove the removable portion.

[0038] Viewed from a second aspect, the invention provides a package [10] comprising a container [20] having a closure member [40] removably inserted into the mouth of said container, and the above described cap [50] overlying said closure member.

[0039] The container of the package preferably con-

tains a sterile fluid suitable for human administration, such as a medicament or pharmaceutical, sterile saline solution, or a contrast medium for X-ray, ultrasound or MRI imaging, or a radiopharmaceutical preparation.

[0040] Preferred embodiments of the invention will now be described by accompanying drawings, in which:

Figure 1 is a side view, partially broken away, of a package [10] according to a first embodiment of the invention;

Figure 2 is a cross-sectional view, along line IV-IV of Figure 1, but showing the protective portion [60] only;

Figure 3 is a cross-sectional view, also along line IV-IV, but showing the moulding of the cap only;

Figure 4 is a cross-sectional view, also along line IV-IV, showing the protective portion [60] attached to the moulding;

Figure 5 is a perspective view of the cap of Figure 1 before the protective portion [60] is attached to the moulding;

Figure 6 is a perspective view of the cap of Figure 1 after the protective portion [60] has been attached;

Figure 7 is a cross-sectional view of a protective portion according to a second embodiment;

Figure 8 is a cross-sectional view of a moulding of the cap according to a second embodiment; and

Figure 9 is a cross-sectional view of the protective portion attached to the moulding according to the second embodiment.

[0041] Figure 1 shows one example of a package [10] according to a first embodiment of the invention. The package [10] comprises a container [20] (illustrated as a bottle), a closure member [40], and a closure cap [50].

[0042] The container [20] has a body [22], a shoulder portion [24], and a narrowed neck portion [26] extending from the shoulder portion. The outer surface of the neck has an external screw thread [28] formed thereon. A lip [30] projects radially outwardly from the neck [26] below the external screw thread [28].

[0043] The inner surface of the neck is substantially cylindrical. However, the inner surface also has a portion [32] of reduced diameter. The purpose of this portion is to prevent the closure member [40] from being pushed into the neck [26] when a force is applied to the closure member, for example by a hypodermic needle or the like. The portion [32] can have a diameter only slightly less than that of the remainder of the neck, as shown in Figure 1, or the diameter can be substantially less.

[0044] The closure member [40] has a generally cylindrical body [42], and the radius of the body is slightly greater than the radius of the inner surface of the neck of the container. This allows the body [42] of the closure member [40] to be an interference fit in the neck [26] of the container. The closure member thus seals the container. The lower end of the body [42] has a chamfer

[44], to aid insertion of the body [42] into the neck [26] of the container [20].

[0045] At the upper end of the body [42] is a flange [46]. The flange [46] rests on the top of the neck of the container when the closure member [40] is fully inserted thereinto.

[0046] In addition, the lower surface of the closure member [40] is formed with a hollow [48] therein. The hollow [48] extends upwardly from the lower surface towards the top of the closure member, and as a result the thickness of the central portion of the closure member [40] is considerably less than its' length. This makes it easier for the closure member to be pierced by a hypodermic needle, an infusion spike or the like.

[0047] The cap [50] for the closure member [40] is attached to the upper part of the neck [26] of the container. The cap [50] has a cover member [52] which overlies the closure member [40], and an annular skirt [54] extending downwardly from the edge of the cover member [52].

[0048] The skirt [54] has an internal screw thread [56] formed on its inner surface, and the internal screw thread [56] engages with the external screw thread [28] formed on the neck [26] of the container so that the cap retains the closure member in place. The diameter of the skirt [54] is reduced at its upper end to form an external shoulder [47]. A pair of radially inward indentations [53] are formed in the outer surface of the shoulder [47], as shown in Figure 3.

[0049] Detachably attached to the lower end of the skirt [54] is a ring [57]. The ring [57] engages beneath the lip [30] on the neck [26] of the bottle. The detachable ring [57] thus serves as a tamper-evident member. In order to remove the cap [50] from the container [20], it is first necessary to detach the ring [57] from the cap [50], and the detached ring makes it clear to the user that the package [10] has been opened.

[0050] The underside of the cover member [52] has an annular member [58] extending downwardly from it. The lower end of the annular member engages with the upper surface of the closure member [40] and helps to ensure the integrity of the package [10]. In addition, the annular member [58] surrounds a central region of the upper surface of the stopper, and helps to prevent contamination of it. The central region of the upper surface of the stopper is the part which is contacted by a needle or the like when the closure member [40] is punctured, and provision of the annular member [58] helps to safeguard the overall sterility of the package [10].

[0051] A protective portion [60] of the cap [50], as shown in Figures 2 and 5, is formed separately from the rest of the cap and is attached to the shoulder [47]. The protective portion [60] is formed as a single piece and comprises a continuous ring member [49] with a series of upwardly projecting castellations [59]; in the present embodiment there are four such castellations [59]. A pair of radially inward projections [51] are formed on the inner surface of the ring member [49] and correspond

with the radially inward indentations [53] formed in the shoulder [47]. When the protective portion [60] is positioned on the closure cap [50], by applying an axial force, the projections [51] engage in the indentations [53] to prevent axial and rotational motion between the cap [50] and the protective portion [60]. The combined protective portion and cap arrangement is most clearly shown in Figures 4 and 6. The upper surface of the ring member [49], at its internal edge, corresponds to the level of the upper surface of the cover member [52]. Similarly, the outer surface of the ring member [49], at its lower edge corresponds to the outer surface of the skirt [54].

[0052] The openings [62] provided between each of the castellations [59] allow any liquid on top of the cover member [52] to drain away.

[0053] The lower surface of the cover member [52] is formed with a line of weakness [64] around a removable portion [66]. The line of weakness facilitates the removal of the removable portion [66] in a frangible manner. Removal of this portion [66] exposes the upper surface of the closure member [40], which can then be punctured by a hypodermic needle or the like.

[0054] In order to allow the removable portion [66] to be removed, a pull-ring [68] is attached to it by two legs [70] which extend from the portion [66] of the cover member [52] bounded by the line of weakness [64] to one side of the pull-ring [68].

[0055] The castellations [59], projecting upwards from the ring member [49], extend above the upper surface of the cover member [52] to a height in line with, or above, the upper surface of the pull-ring [68] and the legs [70]. This affords protection for the pull-ring [68] against accidental operation. Preferably, an opening [62] is provided between the castellations [59] radially opposite the legs [70] to provide a user with additionally space with which to raise the pull-ring [68] in order to hook it with the user's finger.

[0056] When the removable portion [66] of the cover member [52] is removed, it leaves an opening in the cover member, exposing the closure member [40].

[0057] The package [10] can be opened in different ways. First, as described above, the pull-ring [68] can be used to remove the removable portion [66] of the cover member [52] bounded by the line of weakness [64], by lifting and pulling the ring [68]. This exposes a portion of the surface of the closure member [40], which can then be punctured by a hypodermic needle or an infusion spike or the like to gain access to the contents of the package [10]. Once sufficient of the contents have been removed, the entire package [10] (comprising the container [20], the closure member [40] and the remainder of the cap [50]) can then be discarded. As the entire package [10] is formed from plastic material, there is no need to sort the various component parts for recycling or waste disposal.

[0058] Second, the cap [50] itself can be removed, followed by removal of the closure member [40]. This requires the removal of the detachable ring [57] from the

bottom of the skirt [54] of the cap [50], which can then be unscrewed and discarded. The closure member or stopper is removed, allowing the contents of the bottle to be poured out, or a quill or straw of e.g. an autoinjector to be inserted. Again, once the contents of the package [10] have been removed, the package [10] can be discarded without sorting.

[0059] As the protective portion [60] is formed independently of the closure cap [50], there are a number of benefits of the present package [10] over previous packages. For example, because the interconnection between the protective portion [60] and the rest of the closure cap [50] plays no part in the sealing of the upper surface of the closure member [40], there is no risk of contamination caused by an imperfect seal between separate mouldings. Additionally, because the protective portion [60] is located on the rest of the cap moulding after its removal from the mould, there is a reduced likelihood of the weakened region [64] or the pull ring [68] being damaged during the removal of the moulding from the mould.

[0060] The protective portion [60] of this embodiment may alternatively be bonded to the cap [50] by an appropriate means, such as heat or ultrasonic welding. Such a bond would prevent rotational and axial relative motion of the cap [50] and the protective portion [60]. A benefit of bonding the protective portion [60] in place is that the openings [62] and castellations [59] provide additional means with which a user may grip the closure cap [50] to unscrew it from the container [20]. Additionally, if required, a user may insert a lever means into the openings [62] to increase the rotational force applied to open the cap [50].

[0061] Although the above description refers to pairs of projections [51] and indentations [53], these could equally both be continuous formations along the circumference of the ring member [49] and the shoulder [47]. Similarly, the location of the projections [51] and the indentations [53] on the ring member [49] and the shoulder [47] could be reversed. Alternatively, a screw thread [51] may be formed for removably attaching the protective portion [60] to the cap [50]. The thread [51] may be "handed" in the same orientation as the screw thread [56] on the cap [50], or the threads [51,56] could be reverse-handed. If the screw threads [51,56] are reverse-handed the protective portion may also be used to provide additional means with which a user may grip the closure cap [50] or alternatively to allow a lever to be used to increase the rotational force applied to open the closure cap [50].

[0062] A cap [50] and protective portion [60] according to a second embodiment of the invention are shown in Figures 7, 8 and 9. The cap is generally similar to that used in the first embodiment of the package, and corresponding features are indicated by corresponding reference numerals. In this embodiment, the interengagement between the protective portion [60] and the rest of the cap [50] is in the form of screw threads [51] and [53],

respectively. As discussed previously, the screw threads [51] retaining the protective portion [60] may be reverse handed relative to the screw threads [56] on the cap [50] for attaching the cap [50] to the container [20].

[0063] In contrast to the first embodiment, the protective portion [60] has a removable upper portion or cover [61] which covers the pull-ring [68]. Thus, when the protective portion [60] is in position, the pull-ring [68] is enclosed and the likelihood of possible entanglement is reduced yet further. The outer surface of the protective portion [60] may further be provided with a series of protrusions or indentations (not shown), which make it easier for a user to grip the protective portion [60] in order to remove it. The protective portion [60] may also have a series of holes formed in its sides to allow any water which collects on top of the cover member [52], through condensation or the like, to drain off of the cap. Similarly, the upper surface of the protective portion [60] may be convex in shape to prevent water and the like collecting on top of the package [10].

[0064] The package [10] is supplied with the protective portion [60] positioned on the closure cap [50]. In order to remove the removable portion [66] the user must first unscrew the protective portion [60]. The removable region [66] may then be removed using the pull-ring [68], as outlined for the previous embodiment.

[0065] The protective portion [60] of the second embodiment has the advantage of providing additional protection to the removable portion [66] of the closure cap [50] right up until the time when the closure cap [50] is to be opened. Additionally, once the protective portion [60] has been removed there is additional space around the pull-ring [68] to allow a user to access the pull-ring [68] more easily. Furthermore, once the removable portion [66] and the protective portion [60] have been removed the package [10] may be used in standard autoinjectors.

[0066] Although a screw thread is suggested for attaching the protective portion [60] to the closure cap [50] any other method of removably attaching the protective portion [60] to the cap [50] would be appropriate.

[0067] It will thus be seen that in both embodiments the protective portion is formed separately from the rest of the cap and is attached thereto. The rest of the cap is a one-piece moulding, preferably made by injection moulding.

Claims

1. A cap [50] for a container [20] having a closure member [40], wherein said cap comprises:

(i) a moulding comprising a retaining portion for engaging the container and retaining the cap thereon, and a removable portion [66] which is frangibly removable to expose at least partly said closure member, and a user engageable

member [68] operable by a user to remove said removable portion; and
(ii) a protective portion [60] for the user engageable member [68], provided annularly outwardly thereof, and attached to the moulding;

wherein the protective portion [60] is formed separately to the moulding.

2. A cap as claimed in claim 1, wherein the protective portion [60] is removably attached to the moulding.

3. The cap of claims 1 or 2, where the cap material comprises polypropylene or polyethylene.

4. The cap of claims 1 to 3, where the moulding further comprises a tamper-evident member that is removably attached to the moulding.

5. The cap of claim 4, where said tamper-evident member is a ring which engages beneath a lip of the container [20].

6. A cap as claimed in claims 1 to 5, wherein the protective portion [60] comprises a wall which extends generally about the periphery of the engageable member [68], said wall having at least one opening [62] therethrough.

7. A cap as claimed in claim 6, wherein the opening [62] is sufficiently large to allow radial access by a user's finger to the engageable member [68].

8. A cap as claimed in claim 7, wherein the opening [62] allowing such radial access is located opposite to a portion of the moulding which connects the engageable member [68] and the removable portion [66].

9. A cap as claimed in any preceding claim, wherein the removable portion [66] has an inclined surface to assist drainage therefrom when the cap is in an upright position.

10. A cap as claimed in any preceding claim, wherein the protective portion [60] comprises a removable cover [61] over the engageable member [68].

11. A package [10] comprising a container [20] having a closure member [40] removably inserted into the mouth of said container, and a cap [50] of claims 1 to 10 overlying said closure member.

12. The package of claim 11, where the container contains a sterile fluid suitable for human administration.

13. The package of claim 12, where the sterile fluid suit-

able for human administration is a contrast medium for X-ray, ultrasound or MRI imaging.

14. The package of claim 12, where the sterile fluid suitable for human administration is a medicament or pharmaceutical. 5

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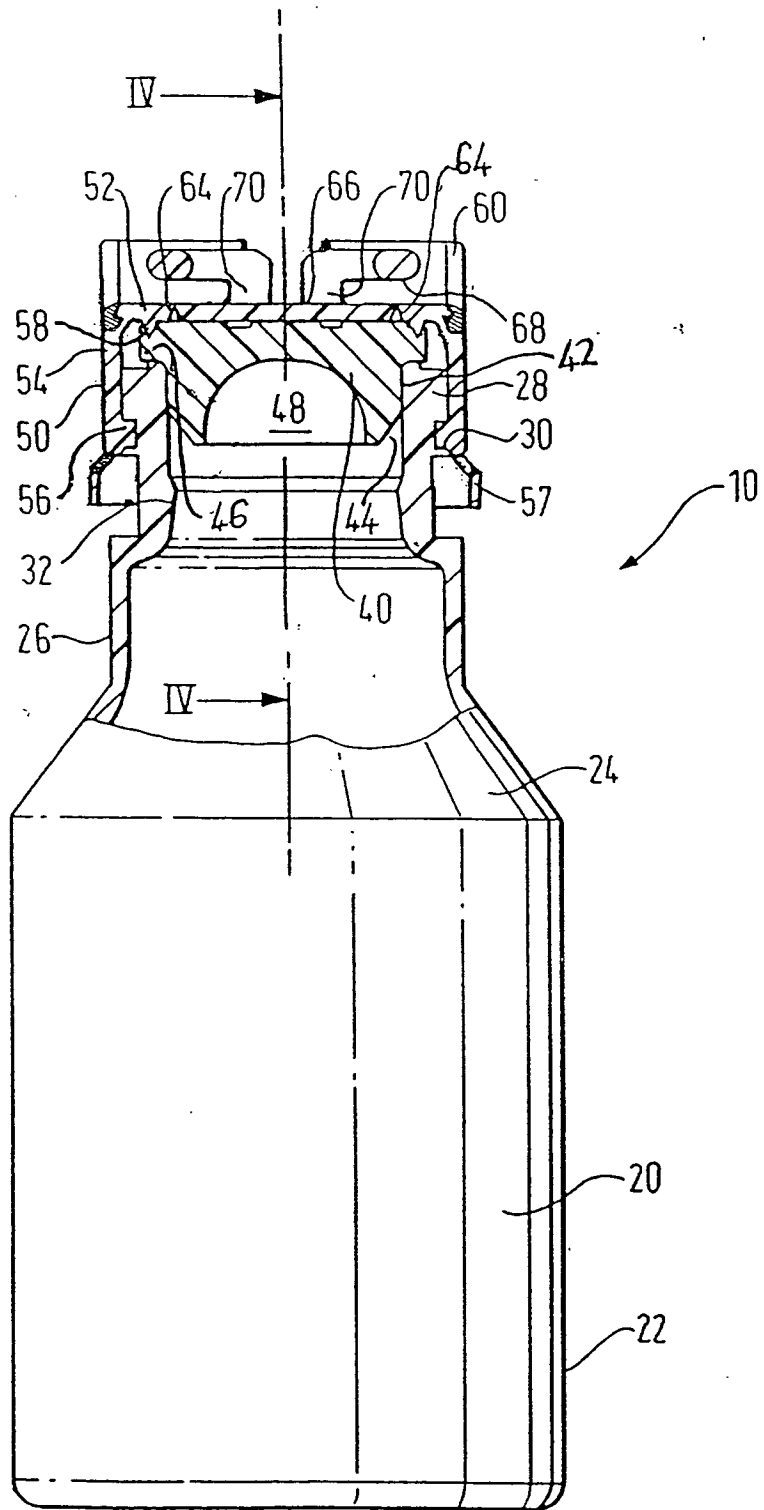


FIG. 1

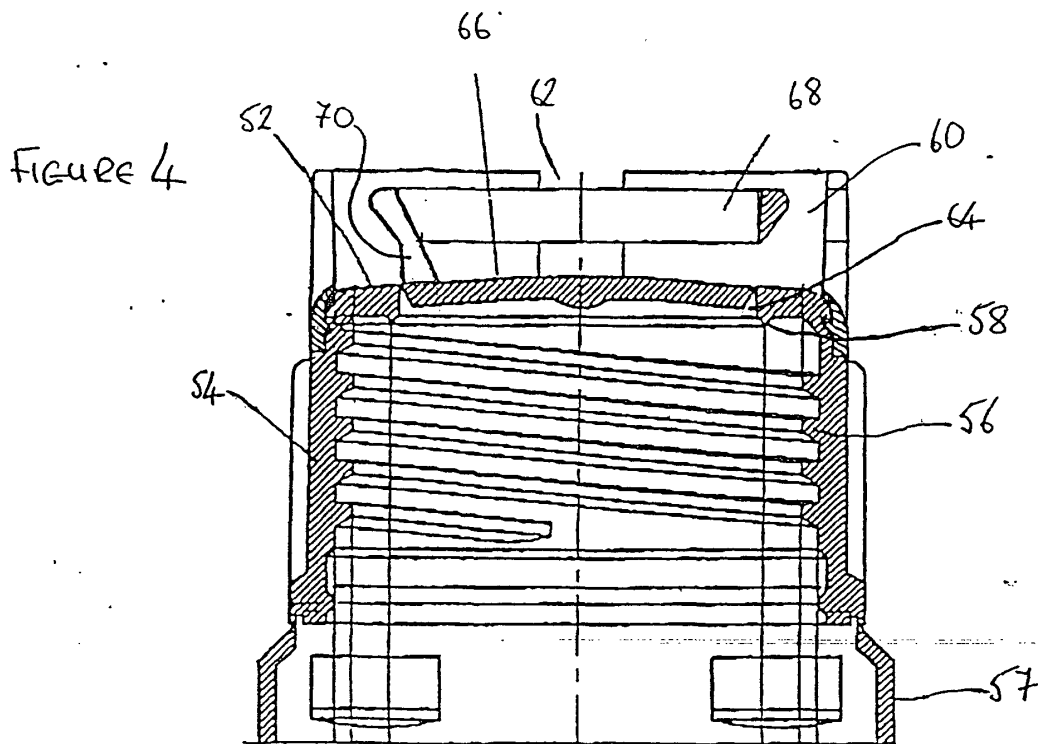
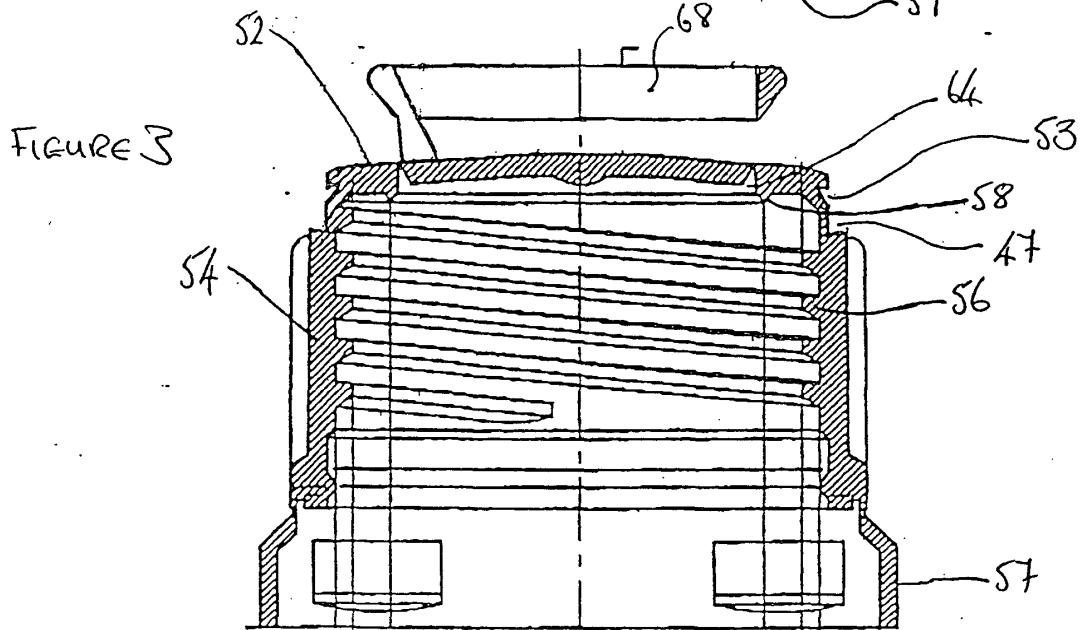
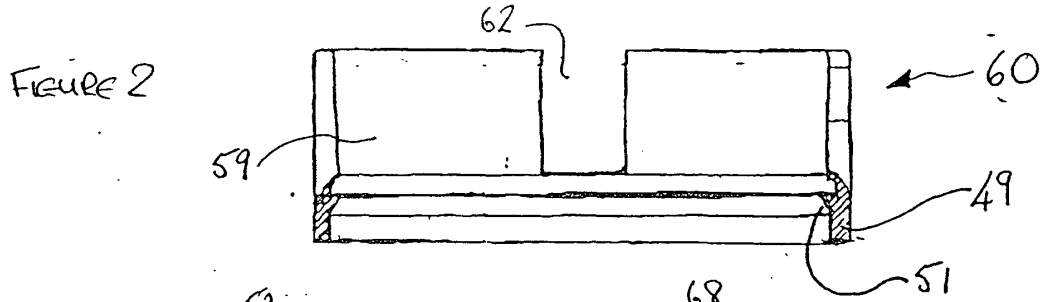


Fig.5.

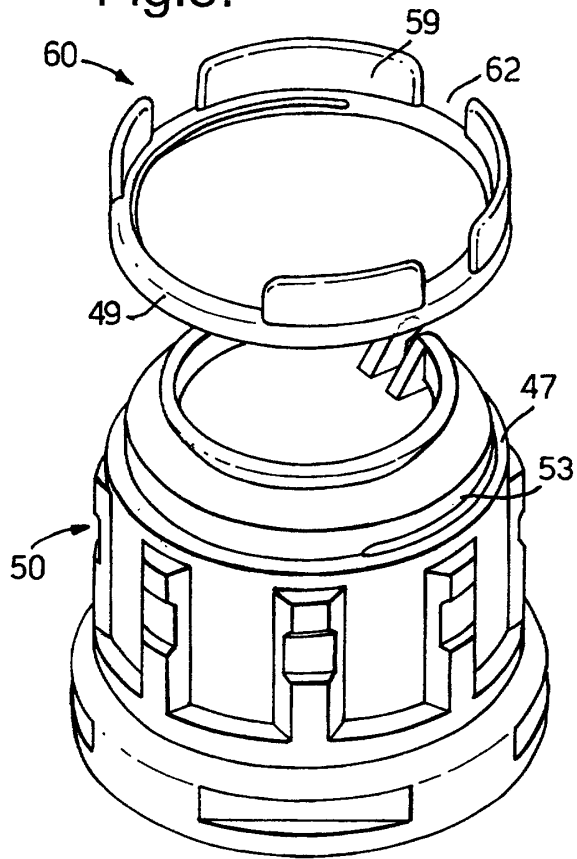


Fig.6.

