

PREFILLED SYRINGE**Description**

5 The invention relates to a prefilled syringe that has a syringe cylinder which is formed in an open manner on one axial side and is closed by a plunger and which has a Luer lock connection on the other axial side, said Luer lock connection being integrally formed on an end wall that terminates the syringe cylinder and being closed by a stopper.

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Prefilled syringes of this type are used increasingly in particular in medicine and are filled with a flowable medium, i.e. typically a liquid or pasty substance, for example a medicament or a contrast agent. This medium is discharged by means of the plunger which is pushed into the syringe cylinder, with the result that the medium
15 emerges through the opening in the Luer cone of the Luer lock connection. In order to ensure that the medium located in the syringe cylinder does not emerge from the Luer lock connection before it is used and that the syringe cylinder is hermetically sealed, in particular protected against the penetration of germs, provision is made of a stopper made of soft-elastic material which closes at least the Luer within the Luer
20 lock connection. In this case, care should be taken to ensure, in particular in the case of medical products, that it is immediately discernible from the outside if the stopper has already been removed once. To this end, provision is made of a tamper-evident closure which has a separating web that has to be destroyed in order to reach the stopper and in particular to remove the stopper from the Luer.

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For syringe cylinders that consist of glass, as are used almost exclusively for medical products, the prior art includes plugging a plastics tamper-evident closure, together with a Luer connection and a stopper closing the latter, on the discharging end of the syringe cylinder in the manner of a latching connection (EP 0 397 951 A1). A
30 problem with tamper-evident closures of this type is that on the one hand these have to be so elastic that they can be pushed in a latching manner over a bead at the discharging end of the syringe cylinder, but on the other hand the latching connection is configured such that the tamper-evident closure breaks at its predetermined

breaking point during opening and the latching connection is not released. This is demanding from a manufacturing point of view and requires a high degree of precision in production.

5 More favorable in this respect is the tamper-evident closure known from DE 102 47 965 A1, in which the syringe cylinder and Luer lock are formed in one piece from an injection-molded plastics part and the stopper and tamper-evident closure are connected to the syringe cylinder on the other hand via a cohesive connection. A disadvantage with the embodiments described therein is that first of all
10 the stopper has to be produced as a separate component and has to be introduced into the tamper-evident closure, likewise produced as a separate part, with the unit formed in this way then being welded or adhesively bonded to the syringe cylinder. On account of the predetermined breaking point provided in the tamper-evident closure, a part of this closure always remains on the syringe after the tamper-evident
15 closure has been opened, this being disadvantageous for a number of reasons. Firstly, the Luer is not freely accessible at its outer circumference, and secondly the destroyed separating web always harbors a certain risk of injury. Although provision is made therein, as an alternative, for the weld seam between the tamper-evident closure and the syringe cylinder to be formed itself as a separating web, it has been
20 found to be problematic to form the weld seam as a separating web, and a risk of injury also remains there when the separating web is destroyed.

Finally, the use of plastics material as the syringe cylinder for prefilled syringes in medical technology has not proved successful, and for this reason use is always made
25 of syringe cylinders made of special glass for high purity products.

Against this background, the present invention is based on the object of creating a prefilled syringe which largely avoids the abovementioned disadvantages, is cost-effective to produce and is reliable and safe to use.

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According to the invention, this object is achieved by a prefilled syringe having the features specified in claim 1. Advantageous developments of the syringe according to the invention can be gathered from the dependent claims, the following description

and the drawing. In this case, according to the invention, the features specified in the dependent claims and the description can each further develop the solution according to the invention according to claim 1 on their own or in any desired combination.

- 5 The prefilled syringe according to the invention has a syringe cylinder which is formed in an open manner on one axial side and is closed by a plunger, as is conventional in syringes of this type, but which has a Luer lock connection on the other axial side, said Luer lock connection being integrally formed on an end wall that terminates the syringe cylinder, i.e. being formed in one piece with the syringe
10 cylinder and the end wall as an injection-molded plastics part. The flowable medium which is located in the syringe and which can be pasty, liquid or optionally also gaseous, is enclosed circumferentially by the syringe cylinder, axially by the plunger on one side and by the end wall having the Luer lock connection and the soft-elastic stopper on the other side. In this case, the stopper closes off at least the Luer, i.e. the
15 actual discharging cone, in a sealed manner within the Luer lock connection. The stopper is surrounded toward the outside by a tamper-evident closure which has a predetermined breaking point. The tamper-evident closure is formed from a plastics material of the same type as or a similar type to the syringe cylinder and is welded to the end wall of the syringe cylinder, wherein, according to the invention, the welded
20 connection forms the predetermined breaking point and the stopper is incorporated into the tamper-evident closure. Since, according to the invention, the syringe cylinder is formed from a transparent plastics material, the contents of the syringe can be seen from the outside, specifically both through the syringe cylinder and through the end wall as far as the Luer lock connection. The tamper-evident closure
25 is preferably, but not necessarily, likewise formed from a transparent plastics material. In any case, it is formed from a plastics material of the same type or a similar type, such that the weldability between the tamper-evident closure and the end wall of the syringe cylinder is ensured.
- 30 Within the meaning of the invention, an end wall is understood to be the entire region between the Luer lock connection and the outer circumference of the syringe cylinder. The tamper-evident closure can thus optionally be aligned with the syringe cylinder or entirely or partially project radially beyond the latter. As a result of the

tamper-evident closure being welded to the end wall of the syringe cylinder, the welding operation is easy to carry out and monitor even in large-scale production.

Here, the essential advantage of the configuration according to the invention is that, unlike in the prior art, a separating web is not provided, but rather the welded connection itself forms the predetermined breaking point, this affording the major advantage, in particular in connection with the transparent configuration of the components, that once the tamper-evident closure has been detached from the syringe, i.e. after the welded connection has been removed or the welded connection has been overcome, a virtually projection-free surface remains on the end wall of the syringe cylinder, said surface not harboring the risk of injury or restricting the view into the interior of the syringe cylinder. Particularly the latter is of great importance in the field of medicine in order to exclude the possibility of gas bubbles accidentally having been drawn in or only in order to be able to visually check the controlled flow of the medium from the syringe cylinder into the Luer connection.

In particular when the tamper-evident closure is likewise formed in a transparent manner, as is advantageous, it is possible to ascertain the correct fit of the stopper and the integrity of the medium located within the syringe cylinder from the outside, even before said tamper-evident closure is opened. Thus, compared with the prior art, the solution according to the invention provides a much more cost-effective solution than the syringe cylinders that have hitherto consisted of glass, but at the same time also provides a much safer solution that is easier to handle than is known in the case of previous syringes consisting of plastics material.

It is particularly advantageous for the stopper and the tamper-evident closure to be produced in a two-component injection-molding process. As a result, it is possible to form the stopper from a suitable soft-elastic, thermoplastic material and the tamper-evident closure from a comparatively hard plastics material, similar to that of the syringe cylinder. Two-component injection-molding processes are technically easy to control and thus represent a cost-effective possibility of producing two mutually independent components as it were in one piece in an injection-molding process. Thus, the mounting of the stopper within the tamper-evident closure is dispensed

with, with the result that the manufacturing costs for the prefilled syringe can be reduced further.

According to an advantageous development of the invention, the tamper-evident
5 closure and the stopper are connected together in a form-fitting manner. Such a form-fitting connection ensures that the stopper is arranged in a form-fitting manner within the tamper-evident closure, i.e. is always handled together with the latter. Such a design of the components affords the advantage that the materials used for the stopper and tamper-evident closure in the two-component injection-molding process
10 can be selected with a greater degree of freedom, since these do not have to form either a cohesive or any other kind of adhesive connection, but in an extreme case can be connected together exclusively by the form fit. In this case, the form fit between the stopper and the tamper-evident closure is advantageously formed toward the outside and about the longitudinal center axis in the direction of rotation. This
15 arrangement ensures that, both in the event of rotation and in the event of tilting of the tamper-evident closure on the syringe, the stopper is always moved together therewith and thus when the predetermined breaking point, i.e. the welded connection between the tamper-evident closure and the end wall of the syringe cylinder, is destroyed, the stopper is also reliably moved together therewith and
20 finally removed. Since the tamper-evident closure circumferentially surrounds the stopper, given a corresponding form-fitting connection, a comparatively large manual force can be applied to the stopper via said tamper-evident closure, and so, even in the case of a firm fit of the stopper within the Luer connection or Luer lock connection, when the stopper also circumferentially surrounds the Luer connection,
25 easy releasing is nevertheless ensured by way of manual force.

Advantageously, the syringe cylinder with the integrally formed Luer lock connection and optionally also the tamper-evident closure consists of a polyolefin. Numerous compounds which meet the specific requirements placed on the material
30 for a prefilled syringe, i.e. in particular are formed in a transparent manner, ensure a high degree of dimensional accuracy during injection molding and afford a high barrier to the penetration of the medium stored in the syringe cylinder, are known from this group of plastics materials. A cost-effective plastics material for the syringe

cylinder and the integrally formed Luer lock connection and the tamper-evident closure is polypropylene. Alternatively, the syringe cylinder can advantageously also consist of a cyclic olefin copolymer or of other suitable thermoplastic materials.

- 5 Expediently, the syringe cylinder consists of a barrier plastics material, wherein the barrier properties are adapted to the filling medium.

Advantageously, the stopper consists of a thermoplastic polymer and, compared with the material of the syringe cylinder, is softer and more elastic. A particularly suitable
10 material for this purpose is a thermoplastic polyurethane which is easy to handle in injection molding, in particular two-component injection molding.

The invention is explained in more detail in the following text with reference to an exemplary embodiment illustrated in the drawing, in which:

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Figure 1 shows a highly simplified, schematic illustration in longitudinal section of the discharging end of a prefilled syringe with the tamper-evident closure in place and

- 20 Figure 2 shows a section along the section line A-A in figure 1.

Figure 1 illustrates only the discharging part of a prefilled syringe 1. This syringe has an elongate syringe cylinder 2 which is formed in an open manner at its axial end (not visible in figure 1) and is closed by a stopper (likewise not shown) that is guided
25 in a displaceable manner within the cylinder 2. On the other axial side, illustrated in figure 1, the syringe cylinder 2 is closed off by an end wall 3 on which a Luer lock connection 4 is integrally formed. The syringe cylinder 2, end wall 3 and Luer lock connection 4 are formed as a one-piece injection-molded plastics part and consist of one material, as is specified at the beginning by way of example and as an advantage.

30 The Luer lock connection 4 consists, in a manner known per se, of an inner Luer cone 5, which corresponds to a conventional Luer connection and which has an inner through-duct 6 to the syringe cylinder 2. The Luer connection 5 is surrounded by a cylindrical portion 7 which bears an internal thread on its inner side and forms the

Luer lock connection 4 in a manner known per se together with the Luer connection 5.

The medium 8 located in the syringe cylinder 2 is hermetically sealed off circumferentially by the syringe cylinder 2, at the open axial side (not visible in figure 1) by the stopper and at the other axial side, closed off by the end wall 3 and the Luer lock connection 4, by means of a stopper 9. The stopper 9 consists of a soft-elastic thermoplastic material and has a conical protrusion 10 that is directed into the through-duct 6 of the Luer connection 5 and closes the through-duct 6 off in a sealed manner toward the outside. The protrusion 10 is adjoined by an annular portion 11 at a radial spacing, which projects considerably beyond the protrusion 10 in its axial length in the direction of the syringe cylinder 2. This annular portion 11 circumferentially surrounds the Luer cone 5, and in this case an annular groove is formed between the protrusion 10 and the annular portion 11, the free end of the Luer cone 5 engaging in said groove. Sealing is produced on the one hand by the protrusion 11, which closes the free end of the through-duct 6 in a sealed manner, and on the other hand by the annular portion 11, which rests in a sealing manner against the outer circumference of the Luer cone 5. The protrusion 10 and the annular portion 11 merge into a substantially cylindrical portion 12 through which five radially extending webs 13 pass, said webs 13 leading into a central space 14.

In the region of the webs 13 and of the central space 14, a plastics component that forms a tamper-evident closure 15 passes through the stopper 9. This tamper-evident closure 15 has, in addition to the portions that project into the clearances 13 and 14, an annular portion 16 which surrounds the stopper 9 as far as close to the axial end of the protrusion 10. This annular portion 16 is connected via a region that is interrupted by annularly arranged recesses 17 to a radially widened, annular portion 18 which bears with little play by way of its cylindrical internal diameter against the outer circumference of the cylindrical portion 7 of the Luer lock connection 4 and reaches as far as the end wall 3, where it is sectionally welded to the latter. In this case, the annular portion 18 extends in a narrowing manner toward the end wall 3, and has axially parallel ribs 19 which increase the grip of this portion.

As is apparent from figure 1, the annular portion 18 is not welded to the end wall 3 around the entire circumference but only in sections, in a similar manner to the arrangement of the recesses 17 on the other axial side of the tamper-evident closure. Since the annular portion 18 is only welded sectionally to the end wall 3 of the
5 syringe cylinder 2, a predetermined breaking point which can be broken open by a simple manual force is formed between these two components. In this case, the welded connection is released, i.e. after the tamper-evident closure is opened, the end wall 3 remains virtually in its original form, i.e. it remains flat and smooth and substantially transparent such that it is possible to look into the interior of the syringe
10 1 and thus see the filling medium 8 through the transparent plastics material of the syringe cylinder. In particular the discharging region of the syringe 1 is thus visible after removal of the tamper-evident closure 15 and thus easy to check visually. The surface of the end wall 3 is also smooth and substantially free of remains of the tamper-evident closure 15.

15 The stopper 9, which is not formed in a transparent manner in the embodiment illustrated, is passed through by the tamper-evident closure 15, which likewise consists of a transparent thermoplastic, such that on the one hand once this component that consists of the stopper 9 and tamper-evident closure 15 and has been
20 produced in a two-component injection-molding process has been mounted, the correct fit of the stopper 9 is on the one hand always ensured and, on the other hand, when the welded connection is broken open, the possibility of moving and thus removing the stopper 9 is also ensured. It is clear that the materials that form the stopper 9 and the tamper-evident closure 15 do not have to form any cohesive
25 connection at all with one another, but rather that the form fit, caused by the design, between these components suffices to connect them firmly and nondetachably together.

As the sectional illustration according to figure 1 makes clear, the component formed
30 from the stopper 9 and tamper-evident closure 15 in a two-component injection-molding process is configured structurally such that when this component is placed on the syringe, the inner side of the annular portion 18 is guided on the outer side of the cylindrical portion 7 of the Luer lock connection 4. As a result of this cylindrical

guidance, first of all the annular portion 18 is placed on the Luer connection 5, wherein, in the final phase of the mounting operation, the protrusion 10 is incorporated in a sealing manner into the end of the through-duct 6. This guidance ensures that the stopper 9 always closes the Luer connection 5 as intended. As a
5 result of the arrangement of the annular portions 21, by way of which the tamper-evident closure 15 is welded to the end wall 3 of the syringe, these weld-seam portions can also be easily produced in large-scale production, since the regions are readily accessible. In addition, this production process can be monitored not only visually but also by other suitable test methods. Finally, it is immediately discernible
10 from this exposed point of the syringe if the tamper-evident closure 15 has been broken open, i.e. the welded connection has been released from the end wall 3. This is readily visible in particular in that welding does not take place around the entire circumference but only in the region of the end-side portions 21, such that when the tamper-evident closure 15 is removed and replaced again, rotation about the
15 longitudinal center axis 20 typically takes place, this being visible at the end wall 3, since the welded locations are then no longer aligned with the end-side portions 21.

List of reference signs

	1	Syringe
5	2	Syringe cylinder
	3	End wall
	4	Luer lock connection
	5	Luer cone, Luer connection
	6	Through-duct
10	7	Cylindrical portion
	8	Filling medium
	9	Stopper
	10	Protrusion
	11	Annular portion
15	12	Cylindrical portion
	13	Webs
	14	Central space
	15	Tamper-evident closure
	16	Annular portion
20	17	Recesses
	18	Annular portion
	19	Ribs
	20	Longitudinal center axis
	21	End-side portions

Claims

1. A prefilled syringe having a syringe cylinder (2) which is formed in an open manner on one axial side and is closed by a plunger that has a Luer lock connection (4) on the other axial side, said Luer lock connection (4) being
5 integrally formed on an end wall (3) that terminates the syringe cylinder (2), having a flowable medium (8) filled into the syringe cylinder (2), having a soft-elastic stopper (9) that closes at least the Luer (5) and having a tamper-evident closure (15) that surrounds the stopper (9) toward the outside and has
10 a predetermined breaking point, wherein the syringe cylinder (2), the end wall (3) and the Luer lock connection (4) are formed in one piece as a transparent injection-molded plastics part, the tamper-evident closure (15) consists of a plastics material of the same type as or a similar type to the syringe cylinder (2) and is welded to the end wall (3) of the syringe cylinder (2), wherein the
15 welded connection forms the predetermined breaking point and the stopper (9) is incorporated into the tamper-evident closure (15).
2. The prefilled syringe as claimed in claim 1, in which the stopper (9) and the tamper-evident closure (15) are produced in a two-component injection-
20 molding process.
3. The prefilled syringe as claimed in claim 1 or 2, in which the tamper-evident closure (15) and the stopper (9) are connected together in a form-fitting manner.
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4. The prefilled syringe as claimed in one of the preceding claims, characterized in that the tamper-evident closure (15) is formed in a transparent manner.
5. The prefilled syringe as claimed in one of the preceding claims, in which the
30 form fit between the stopper (9) and the tamper-evident closure (15) is formed toward the outside and about the longitudinal center axis (20) in the direction of rotation.

6. The prefilled syringe as claimed in one of the preceding claims, in which the syringe cylinder (2) consists of a polyolefin.
7. The prefilled syringe as claimed in claim 5, in which the syringe cylinder (2) consists of polypropylene.
8. The prefilled syringe as claimed in one of the preceding claims, in which the syringe cylinder (2) consists of a cyclic olefin copolymer.
9. The prefilled syringe as claimed in one of the preceding claims, in which the syringe cylinder (2) consists of a barrier plastics material, the barrier properties of which are adapted to the filling medium (8).
10. The prefilled syringe as claimed in one of the preceding claims, in which the stopper (9) consists of a thermoplastic polymer (TPE).
11. The prefilled syringe as claimed in one of the preceding claims, in which the stopper (9) consists of a thermoplastic polyurethane (TPU).