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Karlsson et al.

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(54) **CONNECTOR FOR A MEDICAL CONTAINER**

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A61J 1/10 (2006.01)
(Continued)

(52) **U.S. Cl.**
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(58) **Field of Classification Search**
CPC A61J 1/1475; A61J 1/10; A61J 1/18; A61J 1/1425; A61J 1/1406; A61J 1/2065; A61J 1/2027; A61M 39/20
See application file for complete search history.

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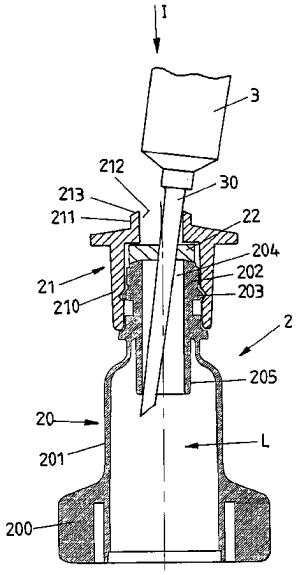
(57) **ABSTRACT**

A medical container and pharmaceutical product include a chamber containing a medical fluid and a connector secured to the chamber. The connector includes a connector element extending between a first end and a second end, and an inner lumen is defined between the first end and the second end. The connector element includes a fastening section, a pinch-off section extending from the fastening section, a head section extending from the pinch-off section, and a deflection element. The head section includes a locking rim and another rim that extends radially beyond the locking rim. The deflection element is directly connected to and extends from the another rim. The deflection element terminates at an end that extends into a portion of the inner lumen defined by the pinch-off section to protect the pinch-off section without hindering pinching of the pinch-off section.

24 Claims, 5 Drawing Sheets



Related U.S. Application Data

continuation of application No. 15/572,550, filed as application No. PCT/EP2016/059897 on May 3, 2016, now abandoned.

(51) **Int. Cl.**
A61J 1/18 (2023.01)
A61M 39/20 (2006.01)

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FIG 1

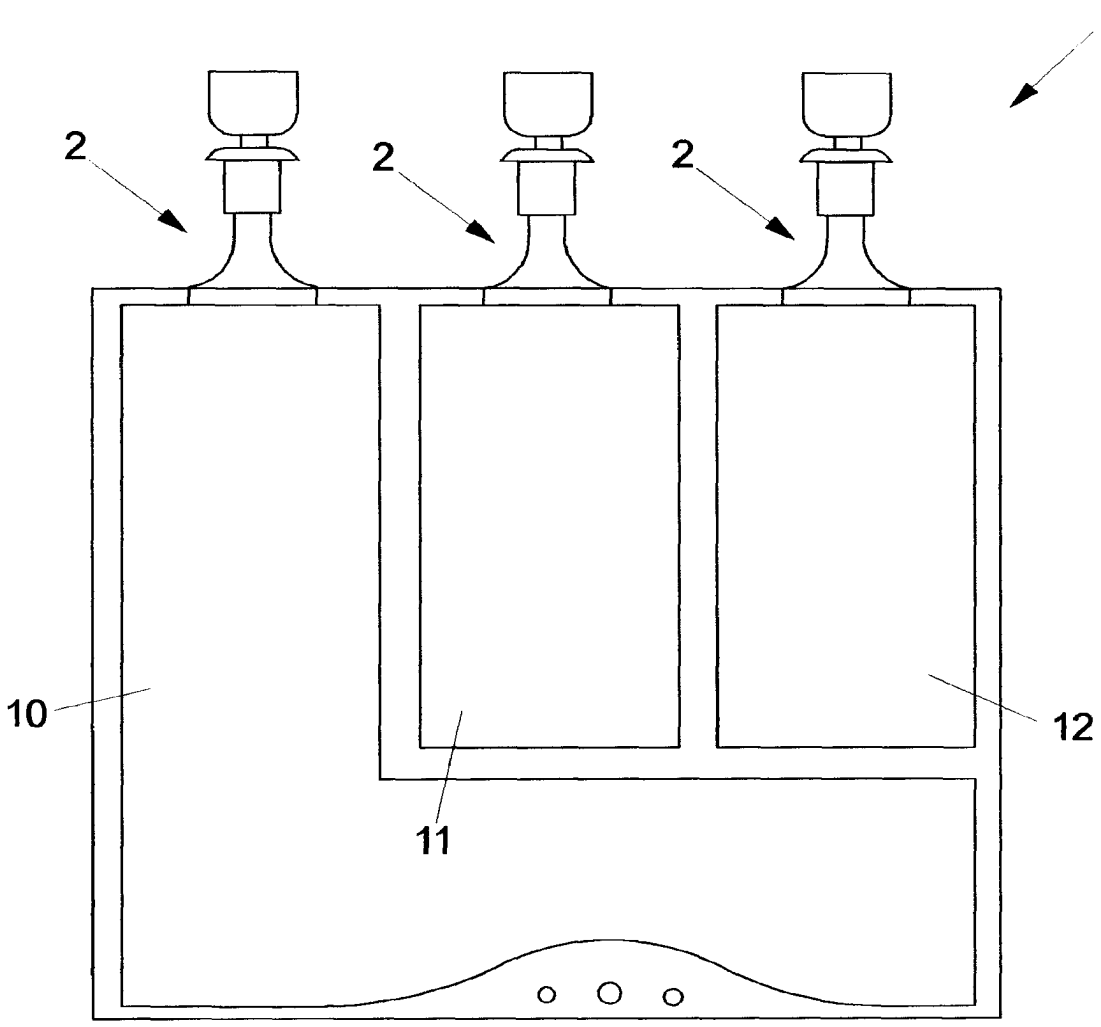


FIG 2A

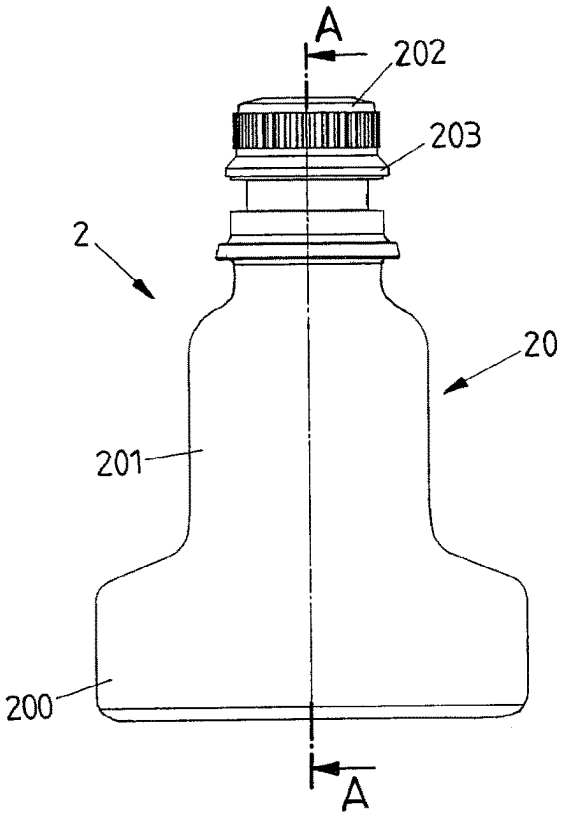


FIG 2B

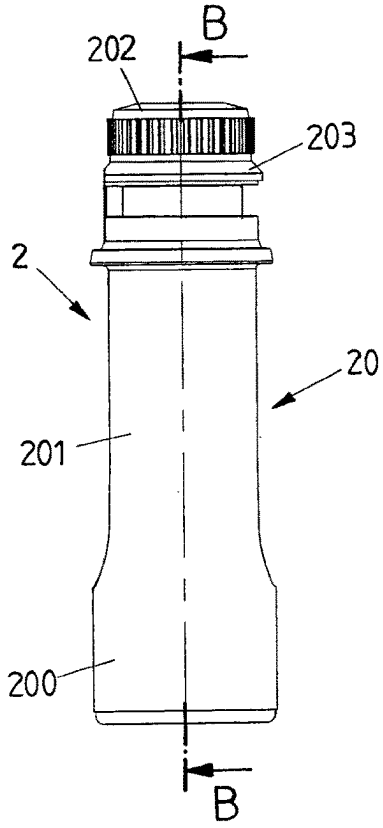


FIG 2C

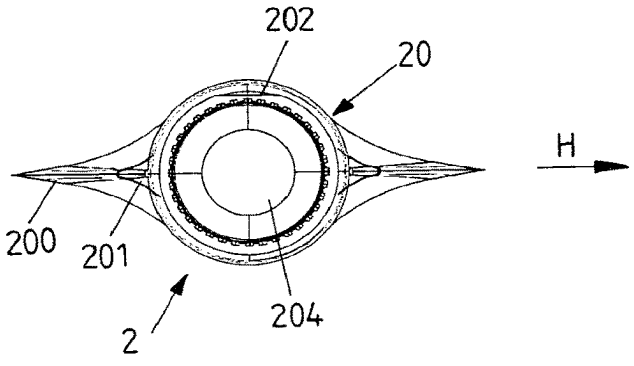


FIG 3A

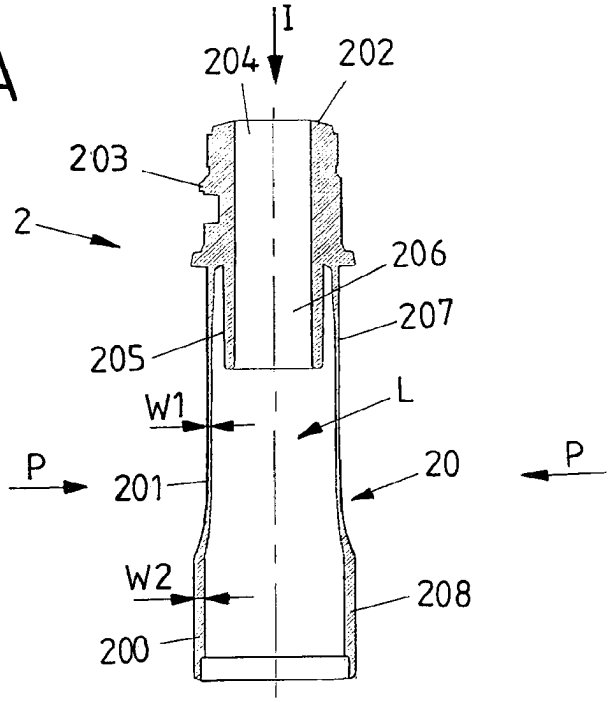

I
204
202
203
2
206
207
205
W1
L
P
201
20
P
W2
208
200

FIG 3B

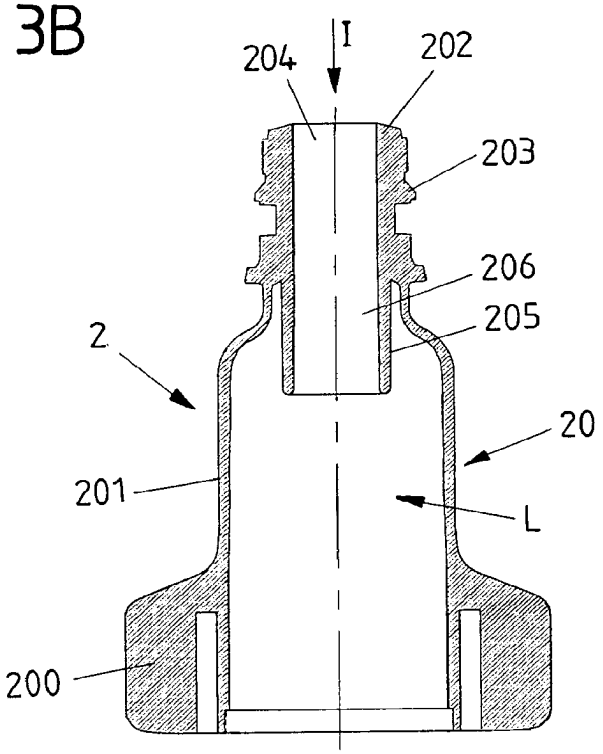

204
I
202
203
206
205
2
20
201
L
200

FIG 4A

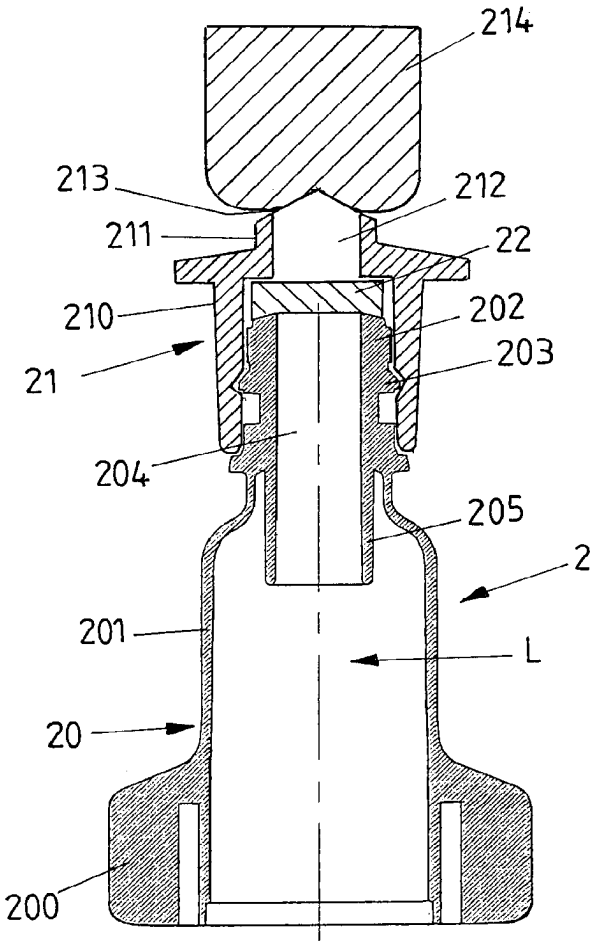
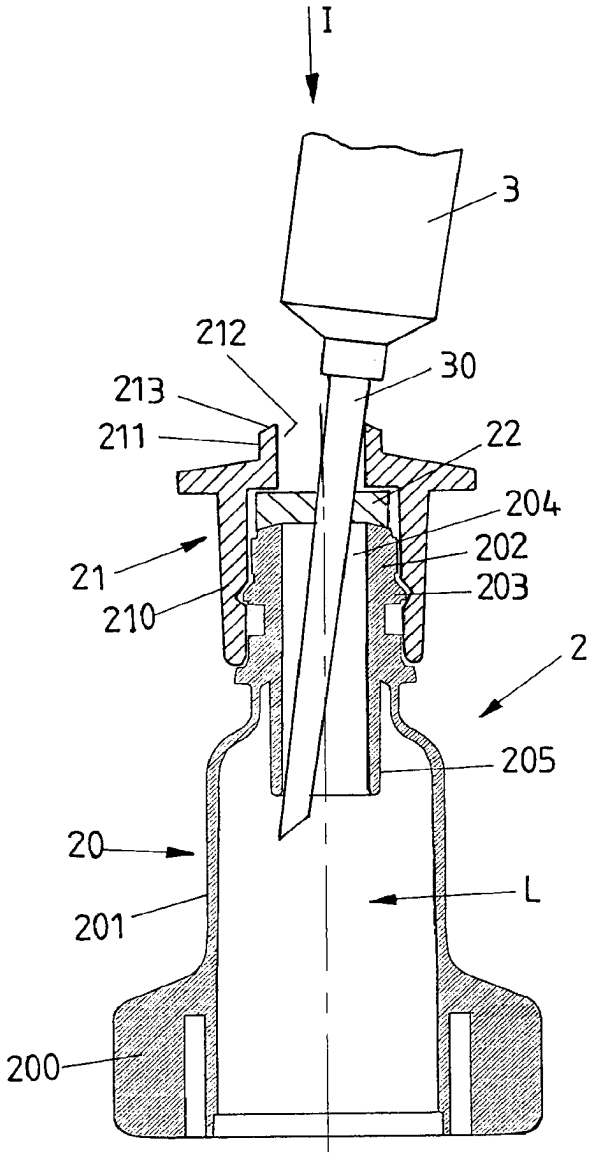


FIG 4B



CONNECTOR FOR A MEDICAL CONTAINER

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/217,804, filed Jul. 3, 2023, which is a continuation application of U.S. patent application Ser. No. 15/572,550, filed Nov. 8, 2017, now abandoned, which is a U.S. National Phase Application under 35 USC 371 of International Application No. PCT/EP2016/059897, filed May 3, 2016, which claims the benefit of the priority date of European Patent Application No. 15166901.7, filed May 8, 2015, the contents of the aforementioned applications are incorporated herein in their entirety.

BRIEF SUMMARY OF THE DISCLOSURE

The invention relates to a connector for a medical container according to the preamble of claim **1**.

A connector of this kind comprises a connector element to be attached to the medical container for providing a port to the medical container. The connector element comprises a head section and a pinch-off section adjoining the head section, wherein the head section comprises an opening and the pinch-off section encloses an inner lumen being in fluid connection with the opening of the head section for providing a fluid path through the connector element. The opening of the head section can be closed by a closure element which is attachable to the head section of the connector element such that, when the closure element is attached to the head section, the fluid path through the connector element is blocked. A membrane element can be placed in-between the closure element and the head section of the connector element. The membrane element can be pierced by a needle of a delivery device, for example a syringe, for injecting a medical fluid into the medical container or for extracting a medical fluid from the medical container.

The connector, when attached to a medical container, shall allow for filling the medical container with a medical fluid, for example a fluid for the parenteral feeding of a patient such as a glucose solution, a fat solution or an amino acid solution. The medical container herein may be filled for example by a medical supplier (which may be the container manufacturer) or in a pharmacy of a hospital and shall subsequently be prepared such that it can be stored and delivered for a later usage.

For filling the container, as it is described in WO 2004/084793 A1, a filling spike of a filling station may be inserted into the connector element prior to attaching the closure element to the connector element. After the filling is completed, the connector element is pinched-off at its pinch-off section such that the fluid path through the connector element is closed and fluid cannot exit from the medical container through the connector element. By attaching the closure element to the head section of the connector element, then, the connector element is sealed towards the outside such that the pinching of the pinch-off section can be released, and the medical container can be stored or delivered to a hospital or the like.

When using the medical container on a patient, the closure element may be opened, for example by breaking-off a break-off part. A user hence may access the connector element by piercing the membrane element placed in-between the head section of the connector element and the closure element using for example a needle of a syringe. In this way, fluid may be extracted from the medical container, or fluid may be added to the medical container in order to for example add further components such as vitamins or other nutritional components or the like to the fluid contained in the container.

When piercing the membrane element using a needle, it shall be avoided that the needle comes into contact with the pinch-off section of the connector element, e.g., because the pinch-off section could have a reduced wall thickness in order for it to be deformable for pinching off the connector element. If the needle were to come into contact with the pinch-off section, there may be a risk of damaging the pinch-off section, possibly rendering the medical container unsterile and hence useless. It is clear that the invention relates to any kind of pinch-off section being in the danger to be damaged by the needle. Reasons therefore may the thickness of the wall, selection of material of the wall or other. The invention will be described by a connector with thinner walls at the pinch-off section in way of example only.

It is an object of the invention to provide a connector for a medical container which in an easy and cost-efficient manner reduces the risk of damaging the pinch-off section of the connector element when piercing the membrane element by means of a needle.

This object is achieved by means of a connector comprising the features of the independent claims.

Accordingly, a deflection element is provided which extends from the head section towards the inner lumen of the pinch-off section for deflecting a needle of a delivery device when piercing the membrane element.

The deflection element serves to guide the needle towards the inner lumen of the pinch-off section when piercing the membrane element by means of the needle. The deflection element herein is shaped such that the risk for damaging the pinch-off section by means of the needle, when introducing it into the connector element, is reduced, in particular in that the needle is guided such that it would not come into contact with the walls of the pinch-off section.

In one embodiment, the deflection element reaches into the inner lumen of the pinch-off section. The deflection element hence extends from the head section and reaches into the inner lumen enclosed by the pinch-off section. Herein, the deflection element is formed as a comparatively rigid piece and in particular may be formed in one piece with the head section. When a needle is inserted into the opening of the head section, it is deflected by the deflection element or is stopped by the deflection element such that the needle cannot come into contact with the walls of the pinch-off section.

Although the deflection element may reach into the inner lumen of the pinch-off section, it extends into the inner lumen of the pinch-off section only that far that a pinching off of the pinch-off section is not hindered. In particular, the deflection element does not extend into a region of the pinch-off section in which (typically) a pinching off shall take place.

The deflection element may for example have the shape of a cylindrical pipe. The deflection element extends from the head section and provides a guide for the needle such that the needle cannot come into contact with walls of the pinch-off section when inserting it into the connector element.

In one embodiment, the deflection element, for example having the shape of a cylindrical pipe, comprises a guide opening through which the needle may be guided. The guide opening longitudinally extends along an insertion direction along which the needle of the delivery device can be inserted

into the connector element. Along the insertion direction, the guide opening beneficially is aligned with the opening of the head section of the connector element through which the needle of the delivery device is inserted into the connector element.

The deflection element, in one embodiment, is arranged at a radial distance to the walls of the pinch-off section. The deflection element, hence, is arranged radially inside the pinch-off section such that it provides a guide inside of the pinch-off section. Because the walls of the pinch-off section are arranged radially outside of the deflection element at a radial distance to the deflection element, a needle guided by the deflection element cannot come into contact with the walls of the pinch-off section such that the risk for damaging the walls of the pinch-off section when inserting the needle into the connector element is greatly reduced.

The connector element may for example have the shape of a ship-shaped conus. The connector element hence has a general ship shape and comprises for example a fastening section which can be inserted in-between foils of the medical container such that the connector element via its fastening section can be welded to the foils of the medical container (having the shape of for example a flexible bag). Herein, the fastening section has a rather rigid shape and has an increased wall thickness in comparison to walls of the pinch-off section. Because the walls of the pinch-off section have a reduced wall thickness (at least in particular regions), the pinch-off section is flexibly deformable for pinching-off the fluid path through the connector element after filling the medical container.

The closure element may for example comprise an attachment section attachable to the head section of the connector element and a break-off part connected to the attachment section along a break line along which the break-off part can be broken off the attachment section. The closure element may for example be attached to the connector element after filling of the medical container such that, with the closure element attached, the medical container can be stored or delivered for example to a hospital. When a user wants to access the medical container for example to inject a medical fluid into the medical container or to extract a medical fluid from the medical container, he breakes off the break-off part and hence opens the connector element such that the membrane element placed in-between the closure element and the connector element is accessible from the outside for piercing it by means of a needle of a suitable delivery device, for example a syringe or the like.

BRIEF DESCRIPTION OF THE DRAWINGS

The idea underlying the invention shall subsequently be described in more detail with reference to the embodiments shown in the figures. Herein,

FIG. **1** shows a schematic view of a medical container in the shape of a three-chamber flexible bag comprising three connectors;

FIG. **2**A shows a front view of a connector element of a connector;

FIG. **2**B shows a side view of the connector element;

FIG. **2**C shows a top view of the connector element;

FIG. **3**A shows a sectional view along line A-A according to FIG. **2**A;

FIG. **3**B shows a sectional view along line B-B according to FIG. **2**B;

FIG. **4**A shows a sectional view of the connector element with a closure element attached to a head section of the connector element; and

FIG. **4**B shows the view of FIG. **4**A, with a break-off part broken off the closure element and with a needle of a delivery device inserted into the connector element.

DETAILED DESCRIPTION OF THE DISCLOSURE

FIG. **1** shows in a schematic view a medical container **1** in the shape of a flexible bag made of thin, flexible foils welded to each other. The medical container **1**, in the shown embodiment, comprises three chambers **10-12** for receiving medical fluids, for example for the parenteral feeding of a patient. The chambers **10-12** herein may contain different medical fluids, for example a glucose solution, a fat solution and an amino acid solution, wherein the chambers **10-12** may be connected via tearable seams which may be torn open to bring the chambers **10-12** in fluid connection with each other for mixing the different solutions with each other prior to delivering them to a patient.

Each chamber **10-12** is associated with a connector **2**, as shown in FIG. **1**. The chambers **10-12** herein are filled via their respective connectors **2**, for example by a medical supplier or within a hospital pharmacy or the like. After the chambers **10-12** have been filled, the connectors **2** are closed such that the chambers **10-12** are sealed towards the outside and the medical container can be stored or delivered for use on a patient. The mixing of the different solutions contained in the chambers **10-12** then takes place immediately prior to injecting the medical fluid of the medical container **1** to a patient in that a user, for example a nurse, tears open the tearable seams in-between the chambers **10-12** such that the solutions contained in the chambers **10-12** can mix within the medical container **1**.

As shown in FIGS. **4**A and **4**B, each connector **2** comprises a connector element **20**, a closure element **21** and a membrane element **22** placed in-between the closure element **21** and the connector element **20**.

Detailed views of the connector element **20** are provided in FIGS. **2**A to **2**C and **3**A and **3**B. The connector element **20** comprises a fastening section **200** which can be inserted in-between foils of the medical container **1** for welding the connector element **20** to the medical container **1**. The fastening section **200** is adjoined by a pinch-off section **201**, which terminates in a head section **202**. To the head section **202** the closure element **21** is attached via an attachment section **210** in a form locking manner by engaging with a locking rim **203** of the head section **202**.

The closure element **21**, when it is attached to the head section **202** of the connector element **20**, closes off an opening **204** in the head section **202**. The closure element **21** comprises a head section **211** adjoining the attachment section **210** and being connected, in the state of FIG. **4**A, to a break-off part **214** along a circumferential break line **213**.

For manufacturing the medical container **1**, the connector elements **20** of the connectors **2** are placed in-between the foils of the medical container **1** and are welded to the foils when forming the chambers **10-12** of the medical container **1**. After completion of the manufacturing, the chambers **10-12** of the medical container **1** are filled for example by a medical supplier or in a pharmacy of a hospital by inserting a filling spike into the respective connector elements **20** and by filling the chambers **10-12** with medical solutions as desired.

Once a chamber **10-12** has been filled, the respective connector element **20** is pinched-off at its pinch-off section **201** by applying a suitable clamping device. For this, the connector element **20** is flexibly deformable at its pinch-off

section **201**, which comprises a reduced wall thickness W1 in comparison to other sections of the connector element **20**, for example in comparison to a wall thickness W2 of the walls **208** of the fastening section **201**, as depicted in FIG. **3**A.

By pinching off the connector element **20** at its pinch-off sections **201**, a fluid path through the connector element **20** is blocked in that an inner lumen L enclosed by the pinch-off section **201** is pinched-off. Subsequently, the closure element **21** can be attached to the head section **202** of the connector element **20** for closing the connector element **20**, and the pinching of the pinch-off section **201** can be released.

After all chambers **10-12** have been filled and respective closure elements **21** have been attached to the connector elements **20** of the connectors **2**, the medical container **1** can be stored or can be delivered to a place of usage, for example to a hospital.

Once the medical solution contained in the medical container **1** shall be administered to a patient, a user may break off one or multiple of the break-off parts **214** of the closure elements **21** of the connectors **2** and may insert a needle **30** of a suitable delivery device **3**, for example a syringe, into an opening **212** within the head section **211** of the closure element **21** and may pierce the membrane element **22** held in-between the closure element **21** and the connector element **20**. By piercing the membrane element **22** by means of the needle **30** and by inserting the needle **30** in an insertion direction I into the connector element **20** through the opening **204** of the head section **202** of the connector element **20**, a medical fluid may be added to the medical container **1** or a medical fluid may be extracted from the medical container **1**. For example, if the medical container **1** comprises different solutions for the parenteral feeding of a patient, further components such as vitamins or the like may be added via one of the connectors **2** prior to administering the (mixed) solutions to a patient.

The membrane element **22** is constituted as a self-sealing membrane which, after removing the needle **30** of the delivery device **3**, seals itself such that the connector element **20** is closed in a fluid-tight manner towards the outside.

When inserting the needle **30** of the delivery device **3** through the head section **202** of the connector element **20** towards the inner lumen L enclosed by the pinch-off section **201**, it shall be avoided that the needle **30** pierces the walls **207** of the pinch-off section **201** (having a reduced wall thickness W1 as shown in FIG. **3**A). For this, a deflection element **205** having the shape of a cylindrical pipe is provided which extends from the head section **202** towards the inner lumen L of the pinch-off section **201**, as shown in the sectional views of FIGS. **3**A and **3**B. The deflection element **205** comprises a longitudinal guide opening **206** which is aligned along the insertion direction I with the opening **204** of the head section **202** such that the needle **30** of a delivery device **3** is guided via the deflection element **205** towards the inner lumen L of the pinch-off section **201**, as shown in FIG. **4**B.

The deflection element **205** in the shape of a cylindrical pipe is formed in one piece with the connector element **20** and has a rigid shape such that a needle **30** pinching onto the inner circumferential face of the guide opening **206** is deflected and guided in the insertion direction I or is stopped such that it cannot come into contact with the outer walls **207** of the pinch-off section **201**. Hence, the risk that the walls **207** of the pinch-off section may be damaged by the needle **30** is reduced.

The deflection element **205** extends from the head section **202** in the insertion direction I and reaches into the inner lumen L of the pinch-off section **201**. It herein is placed inside the pinch-off section at a radial distance to the walls **207**.

Although the deflection element **205** reaches into the inner lumen L of the pinch-off section **201**, it does not extend through the pinch-off section **201** and in particular reaches into the inner lumen L only that far that a reliable pinching of the pinch-off section **201** is not hindered.

The connector element **20**, as visible from the top view of FIG. **2**C, has the general shape of a ship, with the fastening section **200** reducing in width towards both sides along a horizontal direction H such that the fastening section **200** may be reliably welded to the foils of the medical container **1** for providing a fluid-tight transition. The pinch-off section **201** likewise does not have a circular cross-section, but is formed such that it may be reliably pinched-off in a pinch-off direction P (see FIG. **3**A) for closing off the fluid path through the connector element **20**, as it is described for example in WO 2004/084793 A1.

The invention is not limited to the embodiments described above, but may be implemented in an entirely different fashion.

In particular, the invention is not limited to three-chamber medical bags, but may be applied to any sort of medical containers, having one, two or more chambers.

The medical container not necessarily is flexible, but may also have a rigid shape, such as the shape of a bottle or the like.

Each chamber of the medical container may be provided with one, two or more connector(s) according to the present invention. It is also understood that the medical container may provided with a mixture of both, inventive connector(s) and connector(s)/port(s) of the prior art, depending on the needs for the use of said container.

LIST OF REFERENCE NUMERALS

1 Medical container (bag)
10-12 Chamber
2 Connector
20 Connector element
200 Fastening section
201 Pinch-off section
202 Head
203 Locking rim
204 Opening
205 Deflection element
206 Guide opening
207, **208** Walls
21 Closure element
210 Attachment section
211 Head section
212 Opening
213 Break line
214 Break-off part
22 Membrane
3 Delivery device
30 Needle
H Horizontal direction
I Insertion direction
L Inner lumen
P Pinch-off direction
W1, W2 Wall thickness

The invention claimed is:

1. A medical container comprising:
a chamber containing a medical fluid; and
a connector secured to the chamber, the connector comprising:
a connector element extending between a first end and a second end, the connector element defining an inner lumen between the first end and the second end, the connector element comprising:
a fastening section at the first end of the connector element, the fastening section configured to be secured to the chamber;
a pinch-off section extending from the fastening section towards the second end of the connector element;
a head section extending from the pinch-off section towards the second end of the connector element, wherein the head section comprises:
a locking rim, and
another rim that extends radially beyond the locking rim, the another rim being closer to the first end of the connector element than the locking rim; and
a deflection element directly connected to and extending from the another rim towards the first end of the connector element,
wherein the deflection element terminates at an end that extends into a portion of the inner lumen defined by the pinch-off section to protect the pinch-off section without hindering pinching of the pinch-off section.

2. The medical container of claim 1, wherein the connector further comprises a closure element configured to lock to the locking rim of the head section and that axially terminates at the another rim of the head section when the closure element is locked to the connector element.

3. The medical container of claim 2, wherein:
the connector further comprises a membrane element between the connector element and the closure element, and
the membrane element is configured to seal the inner lumen.

4. The medical container of claim 1, wherein the deflection element is radially spaced from and within a wall of the pinch-off section.

5. The medical container of claim 1, wherein the deflection element does not axially overlap with the head section.

6. The medical container of claim 1, wherein:
the chamber is formed from a plurality of flexible foils, and
the fastening section is inserted in-between two of the plurality of flexible foils of the chamber.

7. The medical container of claim 1, wherein the fastening section is welded to the chamber.

8. The medical container of claim 1, wherein the medical fluid comprises a fluid for parenteral feeding of a patient.

9. A pharmaceutical product comprising:
a medical container comprising:
a chamber containing a medical fluid; and
a connector secured to the chamber, the connector comprising:
a connector element extending between a first end and a second end, the connector element defining an inner lumen between the first end and the second end, the connector element comprising:
a fastening section at the first end of the connector element, the fastening section configured to be secured to the chamber;
a pinch-off section extending from the fastening section towards the second end of the connector element;
a head section extending from the pinch-off section towards the second end of the connector element, wherein the head section comprises:
a locking rim, and
another rim that extends radially beyond the locking rim, the another rim being closer to the first end of the connector element than the locking rim; and
a deflection element directly connected to and extending from the another rim towards the first end of the connector element,
wherein the deflection element terminates at an end that extends into a portion of the inner lumen defined by the pinch-off section to protect the pinch-off section without hindering pinching of the pinch-off section.

10. The pharmaceutical product of claim 9, wherein the connector further comprises a closure element configured to lock to the locking rim of the head section and that axially terminates at the another rim of the head section when the closure element is locked to the connector element.

11. The pharmaceutical product of claim 10, wherein:
the connector further comprises a membrane element between the connector element and the closure element, and
the membrane element is configured to seal the inner lumen.

12. The pharmaceutical product of claim 9, wherein the deflection element is radially spaced from and within a wall of the pinch-off section.

13. The pharmaceutical product of claim 9, wherein the deflection element does not axially overlap with the head section.

14. The pharmaceutical product of claim 9, wherein:
the chamber is formed from a plurality of flexible foils, and
the fastening section is inserted in-between two of the plurality of flexible foils of the chamber.

15. The pharmaceutical product of claim 9, wherein the fastening section is welded to the chamber.

16. The pharmaceutical product of claim 9, wherein the medical fluid comprises a fluid for parenteral feeding of a patient.

17. The pharmaceutical product of claim 16, wherein the fluid for parenteral feeding of the patient comprises at least one of a glucose solution, a fat solution, or an amino acid solution.

18. The pharmaceutical product of claim 17, wherein the connector further comprises a closure element configured to lock to the locking rim of the head section and that axially terminates at the another rim of the head section when the closure element is locked to the connector element.

19. The pharmaceutical product of claim 18, wherein:
the connector further comprises a membrane element between the connector element and the closure element, and
the membrane element is configured to seal the inner lumen.

20. The pharmaceutical product of claim 17, wherein the deflection element is radially spaced from and within a wall of the pinch-off section.

21. The pharmaceutical product of claim 17, wherein the deflection element does not axially overlap with the head section.

22. A medical container comprising:

a first chamber containing a first medical fluid;

a first connector secured to the first chamber;

a second chamber containing a second medical fluid; and

a second connector secured to the second chamber,

wherein the first connector and the second connector each comprise:

a connector element extending between a first end and a second end, the connector element defining an inner lumen between the first end and the second end, the connector element comprising:

a fastening section at the first end of the connector element;

a pinch-off section extending from the fastening section towards the second end of the connector element;

a head section extending from the pinch-off section towards the second end of the connector element, wherein the head section comprises:

a locking rim, and

another rim that extends radially beyond the locking rim, the another rim being closer to the first end of the connector element than the locking rim; and

a deflection element directly connected to and extending from the another rim towards the first end of the connector element,

wherein the deflection element terminates at an end that extends into a portion of the inner lumen defined by the pinch-off section to protect the pinch-off section without hindering pinching of the pinch-off section.

23. The medical container of claim 22, wherein the first medical fluid is different from the second medical fluid.

24. The medical container of claim 22, wherein:

the first medical fluid comprises at least one of a glucose solution, a fat solution, or an amino acid solution, and

the second medical fluid comprises at least one of a glucose solution, a fat solution, or an amino acid solution.

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