"Device for mixing medical fluids and related assembling method"

This application claims priority from Italian Application No. TO2010A000919 filed on 19 November 2010, the contents of which are to be taken as incorporated herein by this reference.

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Field of the invention

The present invention relates in general to medical devices and more in particular to a device for mixing medical fluids including two distinct and coaxial tubular bodies of which a first body, made of a first material, has a hollow spike, which can be inserted into a container for a medical fluid, and a second body, made of a second material more elastic than the first material, has an outlet set on the side opposite to the spike. The first body moreover has a lateral access for introduction of a second medical fluid that can be mixed with the first.

The two bodies have respective open ends of mutual joining, of which the end of the second body is inserted axially and blocked within the end of the first body.

Mixing devices of the above sort are typically used for extraction of a toxic drug contained within the container, in which the hollow spike is inserted for mixing of said drub with a secondary fluid and then for drawing in the mixture thus obtained through the outlet.

Prior art

In the above known mixing devices there is the problem of providing a secure permanent connection between the two tubular bodies, which, as has been said, are made of two different materials, traditionally plastic materials: the first body may be made of a thermoplastic polymeric material (for example, polypropylene, polycarbonate, ABS, and the like), and the second body may be made of an elastomeric polymeric material or thermoplastic rubber. The irreversible connection between such materials, which is necessary for preventing in use any risk of accidental leakage of medical fluids, cannot be obtained in a sufficiently safe and reliable way via glues or adhesives.

In an attempt to solve said problem, it has been proposed in the patent No. EP-1492590 B1, filed in the name of Carmel Pharma AB, to make the connection between the two bodies of the mixing device by means of insertion by friction of the open end of the second body within the open end of the first body and via a snap-action connection: the open end of the second body is formed with one or more radial projections designed to engage one or more respective openings formed in the wall of the end of the first body.

This arrangement, albeit suitable for rendering irreversible the connection between the two bodies, hence preventing any risk of accidental separation, does not exclude the risk of leakage of medical fluid through the areas of mutual snap-action coupling between the ends of the two bodies, which constitutes a serious drawback.

A reference herein to a patent document or other matter which is given as prior art is not to be taken as an admission or a suggestion that the document or matter was known or that the information it contains was part of the common general knowledge as at the priority date of any of the claims.

Summary of the invention

~~The object of the present invention is~~It would be desirable to overcome or at least ameliorate the aforesaid drawback and hence to provide a device for mixing medical fluids and a method for its assembly in which the irreversible connection between the two bodies of the device is substantially free from by any risk of accidental leakage of medical fluid outside.

According to embodiments of the invention, ~~the above object~~ an advantage is achieved thanks to the fact that the connection between the aforesaid open ends of the first and second bodies of the device is obtained via radial projections engaged against the end of the second body and obtained by plastic deformation of the wall of said end of the first body following upon axial insertion by friction of the end of the second body into the end of the first body.

Thanks to this arrangement, which eliminates the aforesaid known formations for mutual snap-action engagement between the two bodies of the device, any risk of leakage of medical fluids during use is eliminated.

The radial projections of the wall of the end of the first body, obtained via a purposely provided apparatus for plastic deformation by means of an apparatus with mobile punches that act radially, conveniently have substantially spherical surfaces.

Viewed from one aspect, the present invention provides a medical device, particularly for mixing medical fluids, the medical device comprising two distinct and coaxial tubular bodies, of which a first body is made of a first plastic material and is formed with a hollow spike that can be inserted in a container for medical fluid, and a second body is made of a second plastic material more elastic than the first material and has an outlet set on the side opposite to said spike, wherein said two bodies have respective open ends to be joined together, of which the end of the second body is inserted axially by friction within the end of the first body and blocked via a substantially irreversible connection, wherein said substantially irreversible connection consists of radial projections of the end of the first body engaged against said end of the second body, said radial projections being obtained by applying localized radial compression on the lateral wall of the first body so as to generate on its outer surface concave impressions corresponding on its inner surface to convex projections engaging against the lateral wall of the second body following upon insertion of said end of the second body within said end of the first body.

Viewed from another aspect, the present invention provides a method for assembly of a medical device, particularly for mixing medical fluids, the medical device comprising two hollow bodies, of which a first body is made of a first plastic material and is formed with a hollow spike that can be inserted in a container for fluid, and a second body is made of a second plastic material more elastic than the first material and has an outlet set on the side opposite to said spike, and wherein said two bodies have respective open ends to be joined together, said method comprising the steps of axial insertion by friction of said end of said second body into said end of said first body and of mutual blocking of said ends via a substantially irreversible connection, wherein said blocking step is performed, following upon complete insertion of the end of the second body within the end of said first body, by means of a localized plastic

deformation of said end of the first body that provides radial projections that engage against said end of said second body, said radial projections being obtained by applying localized radial compression on the lateral wall of the first body so as to generate on its outer surface concave impressions corresponding on its inner surface to convex projections engaging against the lateral wall of the second body.

Where the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification (including the claims) they are to be interpreted as specifying the presence of the stated features, integers, steps or components, but not precluding the presence of one or more other features, integers, steps or components, or group thereto.

Brief description of the drawings

The invention will now be described in detail with reference to the annexed drawings, which are provided purely by way of non-limiting example and in which:

Figure 1 is an exploded perspective view of a device for mixing medical fluids according to the invention represented prior to its assembly;

Figure 2 is an axial cross-sectional view of the mixing device represented following upon a first assembly step;

Figure 3 is an axial cross-sectional view similar to that of Figure 2 but rotated through 90°;

Figure 4 shows a detail of Figure 2 at a larger scale;

Figure 5 is a perspective view that shows the mixing device in its final configuration, following upon a second assembly step;

Figure 6 is an axial cross-sectional view of the assembled device;

Figure 7 is an axial cross-sectional view similar to that of Figure 6 but rotated through 90°; and

Figure 8 shows a detail of Figure 6 at a larger scale.

Detailed description of the invention

With initial reference to Figure 1, a device for mixing medical fluids according to the invention comprises a first hollow body 1 and a second hollow body 2 obtained as distinct elements by means of moulding of two different plastic materials, of which the material of the second body 2 is more elastic than the material of the first body 1. By way of example, the first body 1 can be made of a thermoplastic polymeric material such as polypropylene,

CLAIMS

The claims defining the invention are as follows:

1. A medical device, particularly for mixing medical fluids, the medical device comprising two distinct and coaxial tubular bodies ~~(1, 2)~~, of which a first body ~~(1)~~ is made of a first plastic material and is formed with a hollow spike ~~(3)~~ that can be inserted in a container for medical fluid, and a second body ~~(2)~~ is made of a second plastic material more elastic than the first material and has an outlet ~~(12)~~ set on the side opposite to said spike ~~(3)~~, wherein said two bodies ~~(1, 2)~~ have respective open ends ~~(7, 11)~~ to be joined together, of which the end ~~(11)~~ of the second body ~~(2)~~ is inserted axially by friction within the end ~~(7)~~ of the first body ~~(1)~~ and blocked via a substantially irreversible connection, wherein ~~said device being characterized in that~~ said substantially irreversible connection consists of radial projections ~~(15)~~ of the end of the first body engaged against said end ~~(11)~~ of the second body ~~(2)~~, said radial projections being obtained by applying localized radial compression on the lateral wall of the first body so as to generate on its outer surface concave impressions corresponding on its inner surface to convex projections engaging against the lateral wall of the second body ~~plastic deformation of the wall of the end (7) of the first body (1)~~ following upon insertion of said end ~~(11)~~ of the second body ~~(2)~~ within said end ~~(7)~~ of the first body ~~(1)~~.

2. The device according to Claim 1, ~~characterized in that~~ wherein said radial projections ~~(15)~~ are arranged in a ring.

3. The device according to Claim 1 or Claim 2, ~~characterized in that~~ wherein said radial projections ~~(15)~~ have substantially spherical surfaces.

4. The device according to any one of Claims 1 to 3, ~~characterized in that~~ wherein said end ~~(11)~~ of the second body ~~(2)~~ is inserted axially between said end ~~(7)~~ of the first body ~~(1)~~ and a coaxial tubular appendage ~~(8)~~ defining with said end ~~(7)~~ of the first body ~~(1)~~ an annular gap ~~(9)~~.

5. The device according to any one of the preceding claims, ~~characterized in that~~ wherein said hollow spike ~~(3)~~ has a first axial inlet passage ~~(4)~~ for said medical fluid and a second axial passage ~~(5)~~ connected to a lateral access ~~(6)~~

for introduction of a second medical fluid.

6. The device according to any one ~~or more~~ of the preceding claims, ~~characterized in that~~ wherein said end ~~(11)~~ of the second body ~~(2)~~ has an annular groove ~~(14)~~ axially corresponding to said at least one radial projection ~~(15)~~ of the end ~~(7)~~ of the first body ~~(1)~~.

7. A method for assembly of a medical device, particularly for mixing medical fluids, the medical device comprising two hollow bodies ~~(1, 2)~~, of which a first body ~~(1)~~ is made of a first plastic material and is formed with a hollow spike ~~(3)~~ that can be inserted in a container for fluid, and a second body ~~(2)~~ is made of a second plastic material more elastic than the first material and has an outlet ~~(12)~~ set on the side opposite to said spike ~~(3)~~, and wherein said two bodies ~~(1, 2)~~ have respective open ends ~~(7, 11)~~ to be joined together, said method comprising the steps of axial insertion by friction of said end ~~(11)~~ of said second body ~~(2)~~ into said end ~~(7)~~ of said first body ~~(1)~~ and of mutual blocking of said ends ~~(11, 7)~~ via a substantially irreversible connection, wherein ~~said method being characterized in that~~ said blocking step is performed, following upon complete insertion of the end ~~(11)~~ of the second body ~~(2)~~ within the end ~~(7)~~ of said first body ~~(1)~~, by means of a localized plastic deformation of said end ~~(7)~~ of the first body ~~(1)~~ that provides ~~at least one~~ radial projections ~~(15)~~ that engage~~s~~ against said end ~~(11)~~ of said second body ~~(2)~~, said radial projections being obtained by applying localized radial compression on the lateral wall of the first body so as to generate on its outer surface concave impressions corresponding on its inner surface to convex projections engaging against the lateral wall of the second body.

8. The method according to Claim 7, ~~characterized in that~~ wherein said plastic deformation provides a plurality of radial projections ~~(15)~~ arranged in a ring.

9. The method according to Claim 8, ~~characterized in that~~wherein said radial projections ~~(15)~~ are formed with substantially spherical surfaces.