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(71) Applicants: **FRESENIUS KABI DEUTSCHLAND GMBH** [DE/DE]; Else-Kröner-Straße 1, 61352 Bad Homburg (DE). **BREVETTI ANGELA S.R.L.** [IT/IT]; Via dell'Industria 99, I-36071 Arzignano (VI) (IT).

(72) Inventors: **SUND, Arild**; Eklundveien 35, N-1786 Halden (NO). **CONSOLARO, Roberto**; Via A. Diaz 34/1, I-36071 Arzignano (VI) (IT). **RAHIMY, Ismael**; Taunusstraße 14, 61169 Friedberg (DE). **KABBUR, Rajeev Virbhada**; Via Zin 6, I-35064 Montebello Vicentino (VI) (IT).

(74) Agents: **SUNDERMANN, Corinna** et al.; FRESENIUS KABI DEUTSCHLAND GMBH, Patent Department, Else-Kröner-Straße 1, 61352 Bad Homburg (DE).

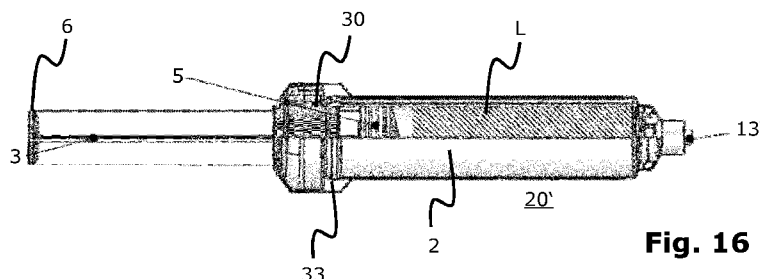
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(54) Title: PROCESS FOR PRODUCING AND ASSEMBLING A MEDICAL OPERATIONS SYRINGE

**Fig. 16**

(57) Abstract: A process for producing and assembling a medical operations syringe (20) comprising in the order the operations of extruding plastic material in order to obtain an intermediate tubular element (1) made of plastic material at least partially at molten state, performing on the intermediate tubular element (1) a blow moulding in order to obtain at least a hollow body (2), inserting firmly and at least partially a thrust piston (3) and a bush (30) into the hollow body (2) immediately after the blow moulding operation. The medical operation syringe (20, 20') comprises a hollow body (2) for containing a medical liquid (L) having an outlet for the medical liquid (L) and an inlet (4) for the medical liquid (4), a plunger (5) closing said inlet (4), a thrust piston (3) connected to said plunger (5) and extending partially outward said hollow body (2), a cap (21) packaging said outwardly extending part of said thrust piston (3) and being detachably connected to said hollow body (2) by means of a twist-off area (31) and a bush (30) for guiding said thrust piston (3) and for providing an abutting surface for said twist-off area (31).

**Process for producing and assembling a medical operations syringe**

Field of the invention:

The present invention concerns a process for producing and completely assembling a medical operations syringe, such as a syringe intended to contain a medical liquid to be injected or an organic liquid taken from organisms.

Background of the invention:

Notoriously, the syringes traditionally used to perform medical operations, such as injections or samples, include a usually cylindrical hollow body, made of preferably plastic material, and a thrust piston, partly contained into the hollow body within which is made sliding by actuating means, for example operator's hand, in order to perform medical interventions.

The thrust piston is provided at a first end with a handle head, accessible to the operator, and at a second end with a seal plunger, usually made of rubber, placed inside the hollow body and suit to come into contact with the liquid to be injected or taken during the medical operations.

In turn, the hollow body presents at a first end a main inlet, through which the thrust piston is inserted into the hollow body itself, and at a second end of a narrowing beak or neck at which a hollow needle is engaged through which the taken or injected liquid passes.

Currently, syringes for medical operations are mainly produced through a process of injection moulding, whereby the nominal essential components mentioned above, namely hollow body, thrust piston, seal plunger and needle, are obtained in operative steps separated each other and subsequently assembled by the operator.

This implies two main sets of drawbacks, without any doubt of not slight importance for the known technique of the field.

Firstly, in fact, the syringe assembly operations occur inevitably with some manipulation of the aforesaid components, with the obvious and consequent risks

of their even if minimal contamination, due to exposure or contact with external agents, although operations themselves are done with extreme care and caution in an environment with a high degree of microbiological cleanliness.

This problematic issue appears in all its evidence and critical state analyzing single-dose syringes pre-filled with medical liquid: in this case, the hollow body, thrust piston, seal plunger and needle with its needle-carrier are transferred and delivered to the producer of the drug who, after having filled the hollow body with the liquid, provides to assemble together the pieces just mentioned in a controlled atmosphere environment (so-called "white room") in order to avoid contaminating the liquid.

Although strict procedural protocols are provided, such an approach does not completely reduce the risk of contamination both of the components and the medical liquid: not by chance, however, it is usually required the application of an additional plastic envelope to package the syringe just assembled in order to assure the highest possible aseptic conditions and, therefore, of safety in the subsequent use thereof.

Secondly, the production technology and resulting assembling system of a syringe currently used require fairly long implementation times, which, combined also with the sophisticated equipment used to ensure the maximum aseptic conditions and, therefore, safe conditions of use, determine a certain economic expensive situation which reflects in market prices less competitive than expected.

An example for overcoming the mentioned drawbacks is proposed in the patent application WO 2011/001456 A2. The content of this patent application is completely incorporated by reference. There it is proposed a process for producing and assembling a medical operations syringe comprising the steps extruding plastic material in order to obtain an intermediate tubular element made of plastic material at least partially at molten state, performing on the intermediate tubular element a blow moulding in order to obtain at least a hollow body, filling the hollow body through its main inlet with a medical liquid, inserting a thrust piston into the respective hollow body via the main inlet, sealing the

portion of the thrust piston which protrudes from the hollow body, the main inlet and the outlet of the tubular element. In this manner it is provided a prefilled syringe. The inlet and piston sealing and the outlet sealing are provided by protection means. Each protection means comprise a kind of cap made of a plastic material which, at the hollow body, includes break means. The break means allow a detachment from the hollow body when the syringe will be used.

The process for producing and assembling the syringe for medical operations ensures to the syringe itself aseptic conditions better than those ones resulting from equivalent methods of known type. Risks and level of contamination of the components of the syringe and any medical liquid contained in it are reduced. The process is more rapid than other known processes. Production cost of the syringe itself compared to further prior art are reduced.

The present invention seeks to provide an improved prefilled syringe.

The inventive solution of the object is surprisingly achieved by each of the subject matter of the respective attached independent claims. Advantageous and/or preferred embodiments or refinements are the subject matter of the respective attached dependent claims.

Accordingly, the invention proposes a process for producing and assembling a medical operations syringe comprising in the order at least the following operations:

- extruding plastic material in order to obtain an intermediate tubular element of plastic material at least partially at molten state;
- performing on said intermediate tubular element a blow moulding in order to obtain at least a hollow body;
- inserting, preferably firmly and, at least partially a thrust piston carrying a bush, which at least partially surrounds the thrust piston, into said hollow body, preferably immediately, after said blow moulding operation, wherein said thrust piston carrying said bush is inserted into said hollow body through a main inlet present at a first end of said hollow body, positioning within said hollow body at

least a plunger of said thrust piston leaving protruding at least a handle head of said thrust piston, preferably positioning within said hollow body at least a lower side of said bush, and leaving protruding at least an upper side of said bush,

- sealing at least said handle head of said thrust piston and at least said upper side of said bush, performed after the operation of inserting said thrust piston carrying said bush into said hollow body for packaging said medical operations syringe, wherein the sealing is provided by forming a cap which is detachably connected to said hollow body by means of a twist-off region wherein the twist-off region is provided below said upper side of the bush. Preferably the thrust piston and the bush are inserted as an assembly.

The invention also proposes a medical operation syringe comprising a hollow body for containing a medical liquid having an outlet for the medical liquid and an inlet for the medical liquid, a plunger closing said inlet, a thrust piston connected to said plunger and extending partially outward said hollow body, a cap packaging said outwardly extending part of said thrust piston and being detachably connected to said hollow body by means of a twist-off area and a bush for guiding said thrust piston and/or for providing an abutting surface for said twist-off area region. In particular the medical operation syringe according to the invention is producible, preferably is produced, with the method according to the invention.

In one embodiment said operation of sealing at least said handle head of said thrust piston and said bush consists in the operation of closing at least two auxiliary half-shells belonging to a forming dye, whereby at least one section of a free portion of said intermediate tubular element made of plastic material is pressed against the outer surface of at least said handle head of said thrust piston and/or of said bush. The outer surface of the bush provides an end surface for the two auxiliary half-shells of the forming dye.

The included bush or ring provides an internal calibration and a support for twist off cut region in the molds. The bush or ring also adds the benefit of an easier starting force for the thrust piston in the syringe. Further the bush provides

stability to the plunger rod. Furthermore, the bush helps to guide and to align the thrust piston during the whole stroke.

In one embodiment an upper side of the bush is positioned above the twist-off area and a lower side of the bush is positioned below the twist-off area. In particular said bush extends partially into said hollow body and/or into said lid. A further embodiment of the medical operation syringe comprises a holder being located below an upper side of the bush and above a lower side of the bush.

In one further embodiment the formed twist-off region is provided as an annular leak tight groove. In this embodiment the medical operation syringe is essentially completely enclosed. Contamination of the thrust piston as well can be avoided.

In another embodiment an interior space of the cap for packaging said outwardly extending part of said thrust piston is in communication with the outside atmosphere by at least one ventilation opening. Collapsing of the cap during and/or after sterilization, for instance by autoclaving, can be at least reduced. In one version of this embodiment the twist-off region comprises at least one ventilation opening. Preferably the at least one ventilation opening is formed during sealing of said handle head.

In a further embodiment said outlet for the medical liquid is packaged by a capsule or cap detachably connected to said hollow body by means of a further twist-off region.

The connection between the syringe hollow body and the cap encapsulating the thrust piston and the connection between the syringe hollow body and the cap encapsulating the syringe outlet are named as twist-off region. The caps can be detached by breaking them off, for instance by means of twisting and/or bending.

In one design of the invention said thrust piston and said plunger are connected by means of a snap-fit connection. This provides an easier assembling. Said thrust piston or plunger rod can be provided with an essentially cruciform cross section. Material costs are reduced. Stability of the thrust piston is enhanced.

A further embodiment is characterized in that said bush comprises at least a first step at an outer surface of said bush for fixing said bush within the syringe and/or a second step at an inner surface of said bush for keeping said thrust piston in a, preferably initial, position and/or a third step at an outer surface of said bush for supporting the fixing of said bush within the syringe and/or a section at an inner surface of said bush to guide said thrust piston within said bush.

Preferably an axial length of said thrust piston and the dimensions of said handle head of said thrust piston are designed such that said handle head can dive essentially completely into said bush in an end position of said thrust piston within said hollow body. For instance a reflux into the syringe and/or a re-use of the syringe can be avoided.

Dependent on the application said outlet for the medical liquid can be provided by a needle or a luer-tip, preferably a luer-lock tip. In a preferred embodiment the syringe is prefilled. Advantageously, the process of the invention allows to fully arranging a syringe for medical operations, even in its minimal constructive composition, without any manipulation of the component organs of the syringe by the operator.

This allows making totally sterilized a syringe for medical operations and to ensure, therefore, a subsequent use thereof in optimal conditions of safety under the point of view of hygiene and health of the people involved, patients and operators.

Still advantageously, the process of producing and assembling of the invention allows getting a syringe for medical operations with a high degree of sterilization faster than processes of the known art.

Equally advantageously, this reflects in a significant reduction of the production cost of a syringe for medical operations compared to the current state of the art, of course the other factors involved being equal. In advantageous manner, moreover, the syringe for medical operations obtained with the process of producing and assembling of the invention presents features of functionality at

least equivalent to those ones of known syringes compared to which it keeps, however, the benefits just outlined.

Said purposes and advantages, as well as others that will emerge later, will appear to a greater extent by the following description relating to a preferred application of the process of the invention, given as an exemplifying and illustrative, but not limitative, title with reference to the attached drawings where:

figures 1-9 are schematic and simplified views of the sequential operations of the process of the invention;

- figure 10 is a block diagram of the process of figures 1-9;

- figure 11 is the exterior view of a needle syringe for medical injections obtained by the process of figures 1-9;

figure 12 is the longitudinal section of figure 11 ;

- figure 13 is the exploded view of figure 12;

figure 14 is the syringe of figure 13 immediately after use;

- figure 15 is the exterior view of a luer-lock type syringe for medical injections obtained by the process of figures 1-9;

figure 16 is the partially longitudinal section of figure 15 with removed protection means;

- figures 16 to 19 show a partial cross sectional view of the intermediate syringe part including bush, thrust piston and seal plunger in different positions.

The process for producing and assembling a syringe for medical operations, injections in the specific case, object of the invention, is shown schematically in figures 1-9, as well as in the block diagram of the subsequent figure 10.

In accordance with the invention, such a process includes in the order the following operations:

extruding plastic material at high temperature, for example 200°C, in order to obtain an intermediate tubular element 1 made of plastic material at least partially at molten state, known in jargon as "parison", according to what figure 1 illustrates;

- performing on the intermediate tubular element 1 a blow moulding in order to obtain a plurality of hollow bodies 2, according to what indicated in figure 4;
- inserting firmly and at least partially a thrust piston 3 within each of the hollow bodies 2 at a time immediately following the operation of blow moulding (operation shown in figures 7 and 8).

The operations of extrusion, blow moulding and insertion of the thrust piston 3 just cited take place continuously within the same industrial machinery in which ideal conditions of sterilization are kept.

In particular, the thrust piston 3 is inserted into the corresponding hollow body 2 through the main inlet 4 present at a first end 2a of the hollow body 2, positioning inside the latter at least the plunger 5 of the thrust piston 3 and leaving protruding at least the handle head 6 of the thrust piston 3 itself. Plunger 5 and thrust piston 3 are provided with a bush 30. Said bush 30 is for instance embodied as a ring. Said bush 30 is carried by said thrust piston 3. Said bush 30 at least surrounds the thrust piston 3 and extends along a part of the thrust piston 3. The thrust piston 3 is movably positioned inside the bush 30. Preferably the plunger 5, the thrust piston 3 and the bush 30 are provided and introduced in the hollow bodies 2 as an assembly. The bush 30 can stay above the obtained hollow body 2 as illustrated in figure 8. The bush partially can be introduced in the hollow body 2 as well (not shown in the figures). For further details related to the bush 30 it is referred to the description of figures 17 to 19.

Optionally, the process of the invention comprises the operation of calibrating the inner wall 2b of the hollow bodies 2, performed before the operation of inserting the thrust piston 3 into its hollow body 2 and, in practice, simultaneously to the extrusion operation, while the various hollow bodies 2 are still heated and at least partially at molten and/or malleable state.

It is clear that, in other applications of the process of invention, not represented, the operation of calibrating could affect only a longitudinal stretch of the inner wall of the hollow bodies.

More specifically, the operation of calibrating the inner wall 2b of the hollow bodies 2 consists in the operation of pressing the intermediate tubular element 1 onto a series of shaped tools 7 previously introduced within the intermediate tubular element 1 just obtained through the mentioned operation of extrusion of plastic material.

Accordingly, therefore, the operation of calibrating the inner wall 2b of the hollow bodies 2 is contextual with the operation of their blow moulding, distinguishing from the latter only for the initial phase of introduction of the shaped tools 7 into the intermediate tubular element 1.

Preferably, each of the shaped tools 7 includes a cylindrical element having a mostly longitudinal development, so that the inner wall 2b of the hollow bodies 2 presents a substantially linear profile.

According to the invention the process comprises the operation of inserting a bush 30 into the hollow body 2 or in each of the hollow bodies 2, performed together with or before the operation of inserting the thrust piston 3 into its hollow body 2.

Figures 1-9 highlight that the operation of extrusion and the operation of blow moulding occur inside a forming dye 8 of the type in itself known in the field under consideration. The operation is illustrated with a syringe 20 which finally includes a needle 13. Such a syringe 20 is shown in figures 11 to 14. Another syringe type 20' includes a male luer lock tip 13' as shown in figures 15 and 16.

The forming dye 8 presents in this case a plurality of cavities, not shown for ease of reference, each of which having the outer profile which approximates the predefined shape for the respective hollow body 2.

More in detail, the forming dye 8 includes first of all two main half-shells 9, 10 facing and opposed each other and two auxiliary half-shells 11, 12, operatively connected with the main half-shells 9, 10 in a position above them.

The forming dye 8 is open both during the operation of extrusion, keeping the main half-shells 9, 10 spaced apart from the intermediate tubular element 1, and during the operation of introducing the shaped tool 7 into the intermediate element 1, drawing up one to another the main half-shells 9, 10 and placing them close to the intermediate element 1. For illustration purposes the shaped tool 7 is shown with an included needle 13. As already mentioned above, instead of a needle 13 the shaped tool 7 can be equipped with a, preferably prefabricated, luer-lock tip 13'.

Therefore, the operation of pressing the intermediate tubular element 1 onto the shaped tools 7 consists in the operation of closing the lower part of the forming dye 8 which places the main half-shells 9, 10, one close to the other interposing the intermediate tubular element 1 and shaped tools 7 for at least a longitudinal section of the half-shells 9, 10 themselves. In a preferred but not binding way, the process of the invention includes the operation of coupling with the second end 2c, opposite to the first end 2a of each of the hollow bodies 2, an injections and sample needle 13 or luer-lock tip 13' communicating with the internal volume 14 of the respective hollow body 2, performed simultaneously with the operation of blow moulding and operation of calibrating the inner wall 2b of the hollow bodies 2.

More precisely, the needle 13 or luer-lock tip 13' is coupled with a narrowing beak, for the time being not shown, made in the second end 2c of each of the hollow bodies 2 through the forming dye 8.

In this respect, the process of the invention includes the preparatory operation, visible in figures 2 and 3, of inserting, by means of the shaped tools 7, the needle 13 or luer-lock tip 13' into the intermediate tubular element 1, performed before the proper operation of coupling the needle 13 or luer-lock tip 13' with the second end 2c of the corresponding hollow body 2 and simultaneously with the

operation of introducing the shaped tools 7 within the intermediate tubular element 1.

According to the preferred application here described of the invention, the process includes the operation, illustrated in figure 6, of filling the hollow bodies 2 with a medical liquid L in order to obtain pre-filled and single-dose syringes, one of which clearly visible apart in figures 11-14 where it is overall numbered with 20 and in figures 15 and 16 where it is overall numbered with 20'.

The operation of filling the hollow bodies 2 with the medical liquid L is performed after the operation of blow moulding the hollow bodies 2 and before the operation of inserting the thrust piston 3 into a respective hollow body 2.

The process also includes the operation of extracting progressively and partially the shaped tools 7 from the hollow bodies 2 for a prefixed length, performed during the operation of filling the hollow bodies 2 themselves, suitable to define the volume available for the medical liquid L inside the hollow bodies 2.

Before extracting or drawing back the shaped tools 7 from the hollow bodies 2, the process of the invention provides a partial opening of the forming dye 8, as shown in figure 5, in order to facilitate and make effective such an extraction operation: the opening of the forming dye 8 consists in removing one from the other the main half-shells 9, 10 of a predetermined distance, in the order of a few tenths of a millimeter.

Other applications of the process of invention, not illustrated in the attached drawings, may provide that the operation of extracting the shaped tool from the hollow body occurs by keeping the forming dye closed.

Advantageously, the process of the invention comprises the operation of retaining within the forming dye 8 the hollow bodies 2 just formed too, performed after the operation of blow moulding and during the operation of extracting the shaped tools 7 from the hollow bodies 2.

This operative trick prevents the shaped tools 7, during the backing movement from the hollow bodies 2, drag disadvantageously with them the hollow bodies 2 themselves, thus avoiding compromising the structural integrity of the latter.

Such an operation of retaining the hollow bodies 2 takes place preferably through an annular bar undercut 15 made in the inner surface of the end 8a of the forming dye 8.

It is understood that, in additional applications of the process of the invention, not represented here, the operation of retaining the hollow bodies may occur through only one bar undercut or through several undercuts separate and distinct each other.

Moreover, in other application solutions of the process of the invention, yet not illustrated in the drawings that follow, the operation of retaining the hollow bodies just formed by blow moulding can occur resorting to other operating tricks or alternative systems and apparatus.

In advantageous manner, the process of the invention includes, at purely preferential title, the operation of sealing the handle head 6 and a central portion, protruding from the respective hollow body 2, of the thrust piston 3, performed after the operation of inserting firmly and at least partially the thrust piston 3 into the hollow body 2.

This operation of sealing determines, in essence, the packaging of the syringe for medical operations 20 without interruption with respect to the other operations described above involving the production and complete assembly of the syringe 20 itself.

In this way, the invention obtains a further advantage over the equivalent known technique, in case of single-dose pre-filled syringes for injections. Indeed, the execution of the operation of sealing the portion of the thrust piston 3 protruding from the relative hollow body 2 directly in manufacturer's plant of the syringe 20 virtually eliminates the final packaging operation carried out today on the known syringes from the producer of the medical liquid.

Consequently, this aspect of the embodiment helps to reduce compared to the current state of the art handling of the syringe or its component organs by the operators, limiting the risks of contamination very much both of the same organs and the medical liquid introduced into the hollow body of the syringe, as well as to make operatively easier and quicker the works of complete setting up of the syringe.

The operation of sealing the handle head 6 and portion of the thrust piston 3 which protrudes from each of the hollow bodies 2 consists in the operation of closing the upper part, nominally the auxiliary half-shells 11, 12, of the forming dye 8: through such an operation, a section of the free portion 16 of the intermediate tubular element (parison) 1 made of plastic material is pressed against the outer surface of the handle head 6 and the protruding portion of the thrust piston 3. In this manner a lid 21 or 21' is formed to cover the handle head 6 and the protruding portion of the thrust piston 3 (see for instance figures 11 to 15). For activating the syringe 20 the lid 21 or 21' has to be detached. To enable a defined and reliable detachment of said lid 21 or 21', the above mentioned ring 30 is provided.

In addition, it is stated precisely that the entire process just described, consisting of the operations of extruding the intermediate element 1, blow moulding in order to obtain the hollow bodies 2, calibrating the inner wall 2b of each of these, coupling a needle 13 or luer-lock tip 13' with each of the hollow bodies 2, filling the hollow bodies 2, inserting a thrust piston 3 and the ring into each hollow body 2 and sealing at least its handle head 6, can occur in a total time not exceeding 20 seconds.

In particular it is mentioned that the operations of blow moulding, optionally calibrating the inner wall 2b of the hollow bodies 2, coupling the needle 13 or luer-lock tip 13' with each of the hollow bodies 2 and filling the hollow bodies 2 can be performed through the shaped tools 7.

In fact, each shaped tool 7 can be provided with a nozzle, not shown, which, besides being used to calibrate the inner wall 2b of the hollow body 2 with which it comes into contact, is also used to blow air and carried out, in practice, the

blow moulding of such a hollow body 2 and subsequently filling it with the medical liquid L.

Furthermore, as mentioned above, each shaped tool 7 is used to support the needle 13 or the luer-lock tip 13' while it is introduced into the intermediate tubular element 1. Beyond to calibrate the inner wall 2b of the hollow 2, the shaped tools 7 allow thus to get another advantage of not negligible relevance compared to the current state of the art.

Indeed, in optionally calibrating the inner wall 2a, the shaped tools 7 cool down the plastic material and, most importantly, the same inner wall 2b of the hollow bodies 2 which are forming.

In this way, the process of the invention produces more rapidly than the known art the ideal conditions of absence or at least maximum reduction of the risks of biological contamination for the medical liquid L which is housed in the various hollow bodies 2.

If it is considered that the hollow bodies of syringes are often filled with thermolabile chemical or biological products, so sensitive to heat up to the point of losing their own qualities, the advantage brought by the present invention is immediately apparent.

For these products, therefore, the invention reduces the waiting time for the introduction of the liquid product into the medical container, with the obvious advantages that this implies in terms of productive efficiency.

Alternative applications of the process of the invention, not shown, may provide that only one or some of the operations of blow moulding, calibrating the inner wall of the hollow bodies, coupling a needle or a luer-lock tip with each of the hollow bodies and filling the hollow bodies are performed through the shaped tool.

Subsequent figures 11-14 represent a syringe for medical operations 20, notably for injections, having a needle 13 and being directly produced by the process just described and, as such, itself subject of protection by the present invention.

Figure 11 to 14 essentially illustrate the use of the syringe 20. For details concerning the included ring it referred to the description of the subsequent figures 15 to 20.

As it can be noted, the syringe for injections 20 develops along a longitudinal axis of symmetry Y and includes the hollow body 2, the thrust piston 3 equipped with the plunger 5 and handle head 6 projecting from the hollow body 2.

The syringe 20 also includes the needle 13, coupled at the end 13a with the narrowing beak 17 of the hollow body 2 through junction means, consisting of the plastic material which, still at molten state, is pressed between the main half-shells 9, 10 of the forming dye 8 during the process of blow moulding.

The needle 13 is also completely covered with protection means, overall numbered with 18, applied externally to the needle 13 and made monolithic with the hollow body 2 during the aforesaid process of blow moulding, which produce in practice a sort of cap for the needle 13 in non-use conditions of the syringe 20.

More in particular, the protection means 18 comprise a laminar capsule made of plastic material which, at the hollow body 2, includes break means, not visible, so as to allow its practical, easy and quick detachment from the hollow body 2 when the syringe 20 must be used.

Figures 11-14 highlights, moreover, that, according to the preferred embodiment described herein of the invention, the syringe for injections 20 also comprises sealing means, as a whole indicated with 19, also made monolithic with the hollow body 2 due to the closure of the auxiliary half-shells 11, 12 of the forming dye 8 during the final part of the process of production and assembly of the invention.

The sealing means 19 cover or close the portion of the thrust piston 3 which, in non-use conditions of the syringe 20, protrudes from the hollow body 2.

As a matter of fact, therefore, the syringe 20 obtained by the process of invention is already packaged, according to the configuration shown in figures 11

and 12, and does not require additional operations, processes or treatments to be placed on the market, if not filling with the medical liquid in case it is produced and marketed empty.

The sealing means 19 includes a laminar lid 21 which, as figure 13 shows, the operator separates easily, turning it around the longitudinal axis  $Y_1$  from the hollow body 2 when he intends to arrange the syringe 20 in the conditions, shown in figure 14, of performing an injection on a patient.

Conveniently, if the syringe 20 is disposable, the laminar lid 21 is used to cover the needle 13 as soon as the injection has been completed and thus serve as an additional safety cap in order to prevent accidental and sometimes very dangerous contacts of people with the needle 13 already used.

In this regard, the inner wall 21a of the laminar lid 21 includes raised projections, not shown, which are snap forced inside respective grooves 22, shown in figure 14 and made in the needle-carrier insert 23 fixed to the hollow body 2, in order to match the laminate lid 21 to the needle 13.

Preferably but not necessarily, the syringe 20 includes retention means, as a whole indicated with 24, suitable to keep the thrust piston 3 firmly within the hollow body 2 when the medical operation is completed.

More in detail, the retention means 24 comprise an annular wing or a plurality of shaped wings 25 protruding from the outer wall 3a of the thrust piston 3, and an annular edge 26 positioned at the inlet 4, opposite to the narrowing beak 17 of the hollow body 2.

From the description just made, it is understood, therefore, that the process for producing and assembling a syringe for medical operations, object of the present invention, achieves the purposes and reaches the advantages mentioned above.

In execution phase, changes can be made to the process of the invention consisting, for example, in obtaining a single hollow body through the operation of blow moulding, for instance using a single cavity forming dye.

In such a case, the operative modes of the process of the invention described above will vary accordingly.

Furthermore, the thrust piston could be inserted into the respective hollow body of a stretch longer than that one previously described, so that only the handle head remains protruding from the hollow body to be handled by the operator.

Subsequent figures 15 and 16 present a syringe 20' for medical operations, notably for injections, having a luer-lock tip 13' instead of a needle 13 and being directly produced by the process just described and, as such, itself subject of protection by the present invention. The subsequent description focuses essentially on the included bush 30. For further details and to avoid repetitions it is referred to the above mentioned description of figures 11 to 14.

The syringe 20' includes a luer-lock tip 13', coupled at the end with the narrowing beak 17 of the hollow body 2 through junction means, consisting of the plastic material which, still at molten state, is pressed between the main half-shells 9, 10 of the forming dye 8 during the process of blow moulding.

Preferably the luer-lock tip 13' is provided by a separate component which is fixed in the hollow body 2. The luer-lock tip 13' is completely covered with protection means, overall numbered with 18, applied externally to the luer-lock tip 13' and made monolithic with the hollow body 2 during the aforesaid process of blow moulding, which produce in practice a sort of cap for the tip 13' in non-use conditions of the syringe 20'.

The protection means 18 comprise a preferably laminar capsule made of plastic material which, at the hollow body 2, includes break means 32 so as to allow its practical, easy and quick detachment from the hollow body 2 when the syringe 20' must be used. Preferably, the luer-lock tip 13' is provided with a sleeve. The outer surface of the sleeve provides a defined end or stop surface for the moulding tool during the formation of the hollow body 2 and of the protection means 18.

Figures 15 and 16 highlight that the syringe 20' for injections also comprises sealing means, as a whole indicated with 19, also made monolithic with the

hollow body 2 due to the closure of the auxiliary half-shells 11, 12 of the forming dye 8 during the final part of the process of production and assembly of the invention.

The sealing means 19 cover or close the portion of the thrust piston 3 which, in non-use conditions of the syringe 20, protrudes from the hollow body 2. As a matter of fact, therefore, the syringe 20 obtained by the process of invention is already packaged, according to the configuration shown in figures 15 and 16, and does not require additional operations, processes or treatments to be placed on the market, if not filling with the medical liquid in case it is produced and marketed empty. If medical regulations require a final sterilization step, of course the obtained syringe 20 finally can be sterilized.

The sealing means 19 include a laminar cap or lid 21 which, as figure 16 shows, the operator separates easily, turning it around the longitudinal axis from the hollow body 2 when it is intended to arrange the syringe 20' in use conditions.

On one hand the cap 21 should be fixed to the hollow body 2 in leak-proved manner to avoid a contamination in the syringe's interior. On the other hand the lid 21 should be released or twisted off manually in a reliable manner. Therefore, the twist-off region 31 or breaking ring 31 which provides the connection between the cap 21 and the hollow body 2 has to be produced in a defined manner. Since the interior space of the cap 21 is separated from the content stored in the hollow body 2, the interior space of the cap 21 can be provided in communication with the outside atmosphere by at least one ventilation opening. Such a ventilation opening at least reduces cap collapsing during sterilization. In one example the twist-off region 31) can comprise such a ventilation opening.

This is achieved by the included bush 30. The outer surface of the bush 30 provides a defined end or stop surface for the moulding tool during the formation of the cap 21. In detail, the end surface for the moulding tool is provided by an upper area of the outer surface of the bush 30.

The twist-off region 31 or breaking ring 31 is defined by reduced wall thickness, for instance in comparison to the hollow body 2 of the syringe 20'. The twist-off

region 31 is not cut so that the piston cover or cap 21 remains attached to the main syringe body. However, the reduced wall thickness enables a, preferably manual, detachment of the piston cover 21 when the piston cover 21 is turned or twisted. The piston cover 21 gets separated as these segments are weak enough.

The bush 30 is described in more details in figures 17 to 19. Figures 17 to 19 show a partial cross sectional view of the intermediate syringe part including bush 30, thrust piston 3 and seal plunger 5 in different positions. Figure 17 shows the thrust piston 3 and the seal plunger 5 in a first, preferably initial, position. Figure 18 shows the thrust piston 3 and the seal plunger 5 in a second position wherein the thrust piston 3 and the seal plunger 5 are moved downwardly, in particular to expel the medical liquid L contained in the syringe 20'. Figure 19 shows the thrust piston 3 and the seal plunger 5 in a third position wherein the thrust piston 3 and the seal plunger 5 are moved more downwardly in comparison to figure 18. Additionally, in figure 19 the bush 30 is shown in a different side view.

The bush 30 is embodied as a ring. Preferably the ring 30 extends completely around its circumference. The thrust piston 3 extends through the bush 30. The seal plunger 5 is positioned below the bush 30, preferably already in its initial position. The bush 30 comprises a plurality of sections 30-1 to 30-4, an upper side 30b and a lower side 30a. The bush 30 is positioned in the region of the holder 33. Preferably the bush 30 extends above and below the holder 33. Preferably the bush 30 is provided by a material being harder than the material of the hollow body 2 and/or the cap 21, in particular during the formation of the hollow body 2 and/or the cap 21. The material of the bush 30 has a higher softening temperature than the material of the hollow body 2 and/or of the cap 21. In this manner it is provided a defined end or stop position for the forming dies to produce the twist-off area. A possible material for the bush 30 is plastic material.

The twist-off region 31 is located below the upper side 30b of the bush 30 and preferably above a first step 30-1 included in the bush 30 (see below).

The bush 30 comprises a first step 30-1. The first step 30-1 is located at the outer surface of the bush 30. This first step 30-1 prevents an axial movement of the bush 30 and keeps the bush 30 in its intended position. The first step 30-1 is arranged below the twist-off region 31.

Further, the bush 30 includes a second step 30-2. The second step 30-2 is located at the inner surface of the bush 30. The second step 30-2 on the bush 30 keeps the thrust piston 3 (also named as piston rod) in its intended position so that thrust piston 3 does not move axially during normal handling and insertion. Preferably the second step 30-2 is embodied as a preferably annular recess at the inner surface of the bush 30. The thrust piston 3 comprises at least one projection 3-2, preferably an annular projection 3-2. The preferably annular projection 3-2 of the thrust piston 3 and the preferably annular recess 30-2 of the bush 30 are essentially complementary to each other. They provide a preferably ring-shaped snap joint, preferably for the initial position of the thrust piston 3 in the syringe 20'. In this position a starting force has to be applied to release the snap joint and to initiate the expelling of the medical liquid L. An unintentional expelling of medical can be avoided.

Furthermore, the bush 30 includes a third step 30-3. The third step 30-3 is provided in the outer surface of the bush 30. The third step 30-3 is located below the first step 30-1 and the second step 30-2. The third step 30-3 supports the fixing of the bush 30 in the syringe 20'. Preferably the third step 30-3 provides the area where the bush 30 is embedded in the syringe main body 2. The lower side 30a of the bush 30 is embedded in syringe main body or the hollow body 2.

Additionally, the bush 30 includes at its inner surface a section 30-4 to guide the thrust piston 3 within the bush 30. This guiding section 30-4 is essentially complementary to the shape of the thrust piston received therein. The included bush 30 enables a reduced starting force for the thrust piston 3. Since the thrust piston 3 does not get into direct contact with the inner surface of the cap 21, in particular during the formation of the cap 21. So an adhesion can be avoided.

Preferably the syringe 20 or 20' according to the invention is operated manually. Holder 33 is gripped between pointer finger and middle finger. Handle head 6 is

gripped or axially moved by the thumb. The syringe can have a volume of 5 ml to 500 ml, preferably 10 ml to 50 ml. Examples are 10 ml, 20 ml or 50 ml.

It is also stated precisely that the present invention, despite having been described with particular reference to a disposable pre-filled syringe for injections, also extends to empty syringes used both for injections and other medical operations, such as samples of blood or other liquid from the human or animal body.

It is clear that numerous other variations can be made to the process in question, without for this reason going out of the novelty principles inherent to the inventive idea here expressed, as it is clear that, in the practical implementation of the invention, materials, shapes and sizes of the illustrated details can be any, as needed, and replaced with others technically equivalent.

Where the constructive features and the techniques mentioned in the following claims are followed by reference numbers or signs, those reference signs have been introduced with the sole objective of increasing the intelligibility of the claims themselves and therefore they have no limiting effect on the interpretation of each element identified, by way of example only, by these reference signs.

It will be understood that the invention may be embodied in other specific forms without departing from the spirit or central characteristics thereof. The present examples and embodiments, therefore, are to be considered in all respects as illustrative and not restrictive, and the invention is not to be limited to the details given herein. Accordingly, features of the above described specific embodiments can be combined with one another. Further, features described in the summary of the invention can be combined with one another. Furthermore, features of the above described specific embodiments and features described in the summary of the invention can be combined with one another.

## CLAIMS

1. Process for producing and assembling a medical operations syringe (20) comprising in the order at least the following operations:

- extruding plastic material in order to obtain an intermediate tubular element (1) of plastic material at least partially at molten state;
- performing on said intermediate tubular element (1) a blow moulding in order to obtain at least a hollow body (2);
- inserting, preferably firmly and, at least partially a thrust piston (3) carrying a bush (30), which at least partially surrounds the thrust piston (3), into said hollow body (2), preferably immediately, after said blow moulding operation, wherein said thrust piston (3) carrying said bush (30) is inserted into said hollow body (2) through a main inlet (4) present at a first end (2a) of said hollow body (2), positioning within said hollow body (2) at least a plunger (5) of said thrust piston (3) leaving protruding at least a handle head (6) of said thrust piston (3), preferably positioning within said hollow body (2) at least a lower side (30a) of said bush (30), and leaving protruding at least an upper side (30b) of said bush (30),
- sealing at least said handle head (6) of said thrust piston (3) and at least said upper side (30b) of said bush (30), performed after the operation of inserting said thrust piston (3) carrying said bush (30) into said hollow body (2) for packaging said medical operations syringe (20), wherein the sealing is provided by forming a cap (21, 21') which is detachably connected to said hollow body (2) by means of a twist-off region (31) wherein the twist-off region (31) is provided below said upper side (30b) of the bush (30).

2. Process as claim 1 characterized in that said operation of sealing at least said handle head (6) of said thrust piston (3) and said bush (30) consists in the operation of closing at least two auxiliary half-shells (11, 12) belonging to a forming dye (8), whereby at least one section of a free portion (16) of said intermediate tubular element (1) made of plastic material is pressed against the

outer surface of at least said handle head (6) of said thrust piston (3) and/or of said bush (30).

3. Process as any of the previous claims characterized in that the outer surface of the bush (30) provides an end surface for the two auxiliary half-shells (11, 12) of the forming dye (8).

4. Process as any of the previous claims characterized in that the twist-off region (31) is provided as an annular leak tight groove or the twist-off region (31) is provided with at least one ventilation opening.

5. Process as any of the previous claims characterized in that the thrust piston (3) and the bush (30) are inserted as an assembly.

6. Process as any of the previous claims characterized in that

said operations of extrusion, blow moulding and insertion of said thrust piston (3) takes place continuously within the same industrial machinery in which ideal conditions of sterilization are kept and/or

it comprises the operation of calibrating at least a longitudinal stretch of the inner wall (2b) of said hollow body (2), performed before said operation of inserting said thrust piston (3) into said hollow body (2) and after said operation of blow moulding, while said hollow body (2) is still heated and at said at least partially molten and/or malleable state and/or

said operation of calibrating said inner wall (2b) of said hollow body (2) consists in the operation of pressing said intermediate tubular element (1) on at least one shaped tool (7) previously introduced within said intermediate tubular element (1) obtained through said operation of extruding plastic material and/or

said operation of extrusion and said operation of blow moulding occur within a forming dye (8) which presents one or more cavities each of which having the outer profile which approximates the predefined shaped for said hollow body (2), said dye (8) being composed of at least two main half-shells (9, 5 10) facing and opposed each other.

7. Process as any of the previous claims characterized in that

said forming dye (8) is open both during said extrusion operation, keeping said main half-shells (9, 10) spaced apart from said intermediate tubular element (1), and during the operation of introducing said shaped tool (7) into said intermediate tubular element (1), drawing up one to another said main half-shells (9, 10) and placing them close to said intermediate tubular element (1) and/or

said operation of pressing said intermediate tubular element (1) onto said shaped tool (7) consists in the operation of closing said forming dye (8) which places said main half-shells (9, 10) one close to the other interposing said intermediate tubular element (1) and said shaped tool (7) for at least a longitudinal section of said main half-shells (9, 10) and/or

it includes the operation of coupling with the second end (2c) of said hollow body (2), opposite to said first end (2a), an injections and/or samples needle (13) or a luer tip (30'), preferably a luer-lock tip, communicating with the internal volume (14) of said hollow body (2), performed simultaneously with said operation of blow moulding and said operation of calibrating said inner wall (2b) of said hollow body (2) and/or

it includes the operation of inserting said needle (13) or said luer tip (13') into said intermediate tubular element (1) by means of said shaped tool (7), performed before the operation of coupling said needle (13) or luer-tip (13') with said second end (2c) of said hollow body (2) and simultaneously with said operation of introducing said shaped tool (7) into said intermediate tubular element (1).

8. Process as any of the previous claims characterized in that

it comprises the operation of filling said hollow body (2) with a medical liquid (L), performed after the operation of blow moulding said hollow body (2) and before the operation of inserting said thrust piston (3) and/or said bush (30) into said hollow body (2) and/or

it includes the operation of extracting progressively and partially said shaped tool (7) from said hollow body (2) for a prefixed length, performed during said operation of filling said hollow body (2), suitable to define the volume available for said medical liquid (L) introduced into said hollow body (2) and/or

it comprises the operation of retaining within said forming dye (8) said hollow body (2) just formed, performed after said operation of blow moulding and during said operation of extracting said shaped tool (7) from said hollow body (2).

9. Process as any of the previous claims characterized in that

said operations of extruding, blow moulding, calibrating said inner wall (2b), coupling said needle (13) or luer tip (13'), filling said hollow body (2), inserting said thrust piston (3) and said bush (30) and sealing at least said handle head (6) occur in a total time not exceeding 20 seconds and/or

at least one of said operations of blow moulding, calibrating said inner wall (2b) of said hollow body (2), coupling said needle (13) or luer-tip (13') with said hollow body (2) and filling said hollow body (2) are performed through said shaped tool (7).

10. Medical operation syringe (20, 20') comprising a hollow body (2) for containing a medical liquid (L) having an outlet for the medical liquid (L) and an inlet (4) for the medical liquid (4), a plunger (5) closing said inlet (4), a thrust piston (3) connected to said plunger (5) and extending partially outward said hollow body (2), a cap (21) packaging said outwardly extending part of said thrust piston (3) and being detachably connected to said hollow body (2) by means of a twist-off area (31) and a bush (30) for guiding said thrust piston (3) and for providing an abutting surface for said twist-off area (31).

11. Medical operation syringe (20, 20') as claim 10 characterized in that said bush (30) extends partially into said hollow body (2) and/or into said lid (21).

12. Medical operation syringe (20, 20') as any of the claims from 10) to 11) characterized in that an upper side (30b) of the bush (30) is positioned above

the twist-off area (31) and a lower side (30b) of the bush (30) is positioned below the twist-off area (31).

13. Medical operation syringe (20, 20') as any of the claims from 10) to 12) characterized in that a holder (33) is located below an upper side (30b) of the bush (30) and above a lower side (30b) of the bush (30).

14. Medical operation syringe (20, 20') as any of the claims from 10) to 13) characterized in that the twist-off region (31) is an annular leak tight groove.

15. Medical operation syringe (20, 20') as any of the claims from 10) to 14) characterized in that an interior space of the cap (21) for packaging said outwardly extending part of said thrust piston (3) is in communication with the outside atmosphere by at least one ventilation opening.

16. Medical operation syringe (20, 20') as any of the claims from 10) to 15) characterized in that the twist-off region (31) comprises at least one ventilation opening.

17. Medical operation syringe (20, 20') as any of the claims from 10) to 16) characterized in that said outlet for the medical liquid (L) is packaged by a capsule (18) detachably connected to said hollow body (2) by means of a further twist-off region (32).

18. Medical operation syringe (20, 20') as any of the claims from 10) to 17) characterized in that

said thrust piston (3) and said plunger (5) are connected by means of a snap-fit connection and/or

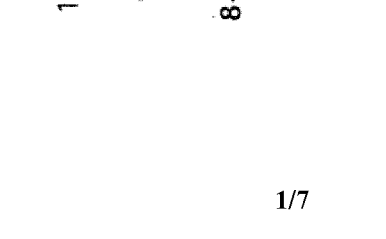
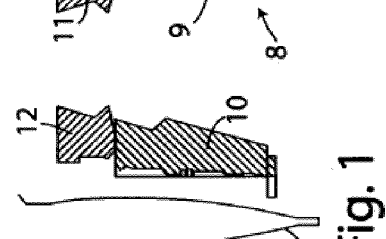
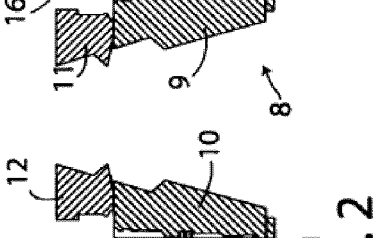
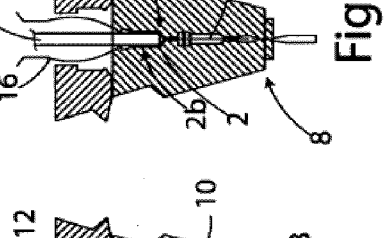
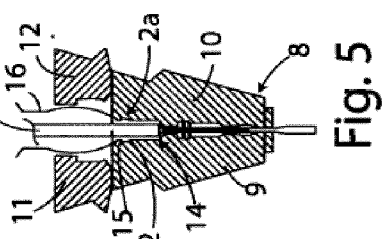
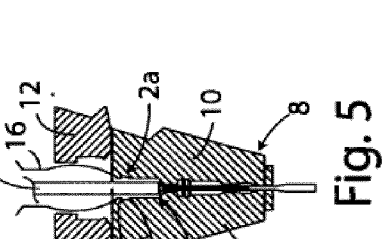
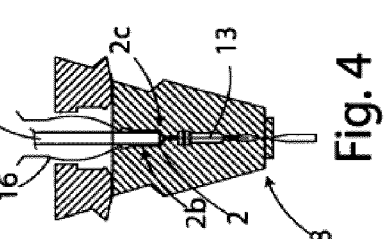
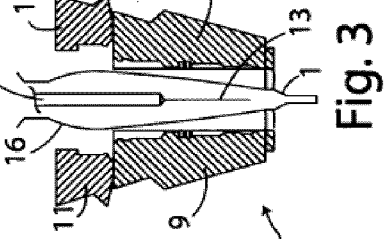
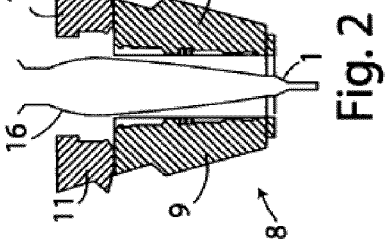
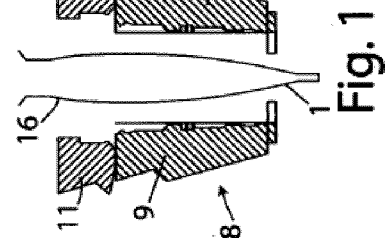
said thrust piston (3) is provided with an essentially cruciform cross section.

19. Medical operation syringe (20, 20') as any of the claims from 10) to 18) characterized in that said bush (30) comprises at least a first step (30-1) at an outer surface of said bush (30) for fixing said bush (30) within the syringe (20, 20') and/or a second step (30-2) at an inner surface of said bush (30) for keeping said thrust piston (3) in a, preferably initial, position and/or a third step

(30-3) at an outer surface of said bush (30) for supporting the fixing of said bush (30) within the syringe (20, 20') and/or a section (30-4) at an inner surface of said bush (30) to guide said thrust piston (3) within said bush (30).

20. Medical operation syringe (20, 20') as any of the claims from 10) to 19) characterized in that an axial length of said thrust piston (3) and dimensions of said handle head (6) of said thrust piston (3) are designed such that said handle head (6) can dive essentially completely into said bush (30) in an end position of said thrust piston (3) within said hollow body (2).

21. Medical operation syringe (20, 20') as any of the claims from 10) to 20) characterized in that said outlet for the medical liquid (L) is provided by a needle (13) or a luer-tip (13') and/or that the syringe (20, 20') is prefilled.



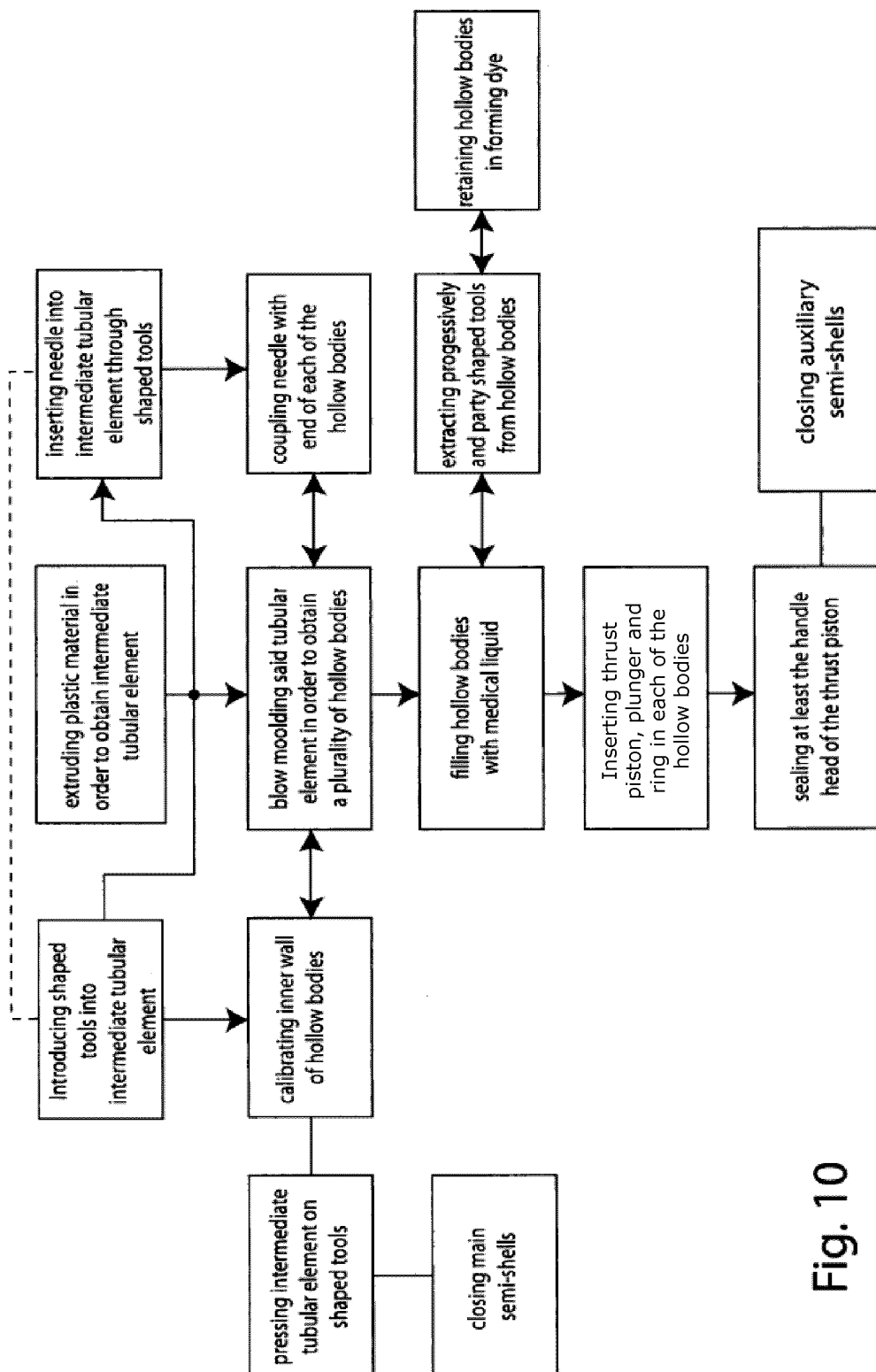
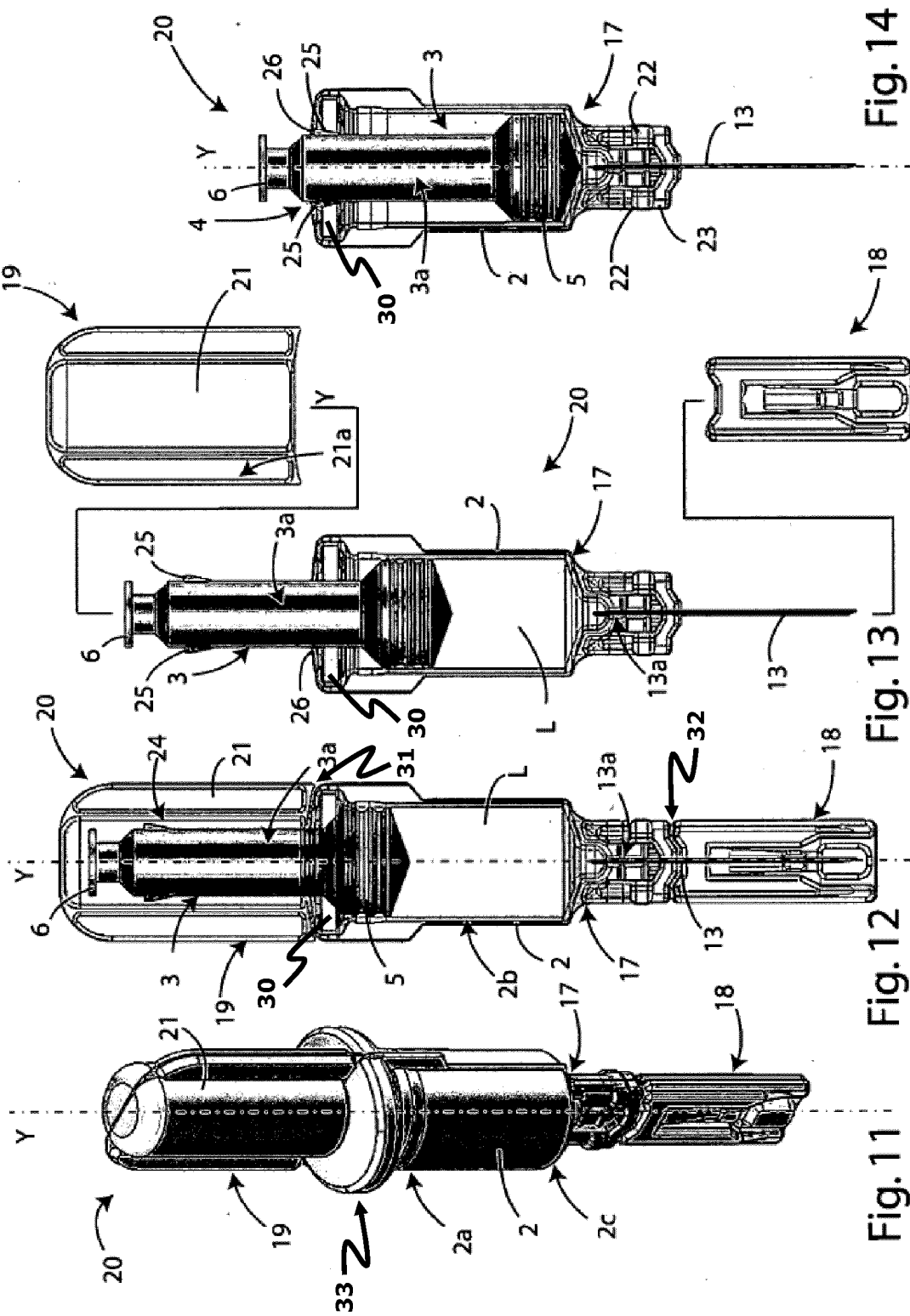


Fig. 10



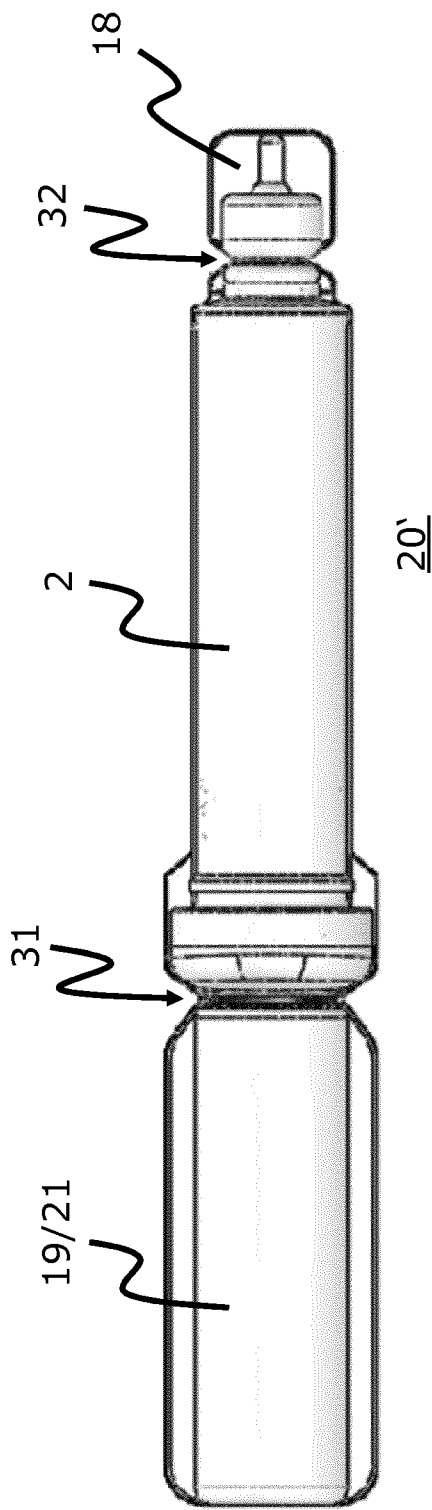


Fig. 15

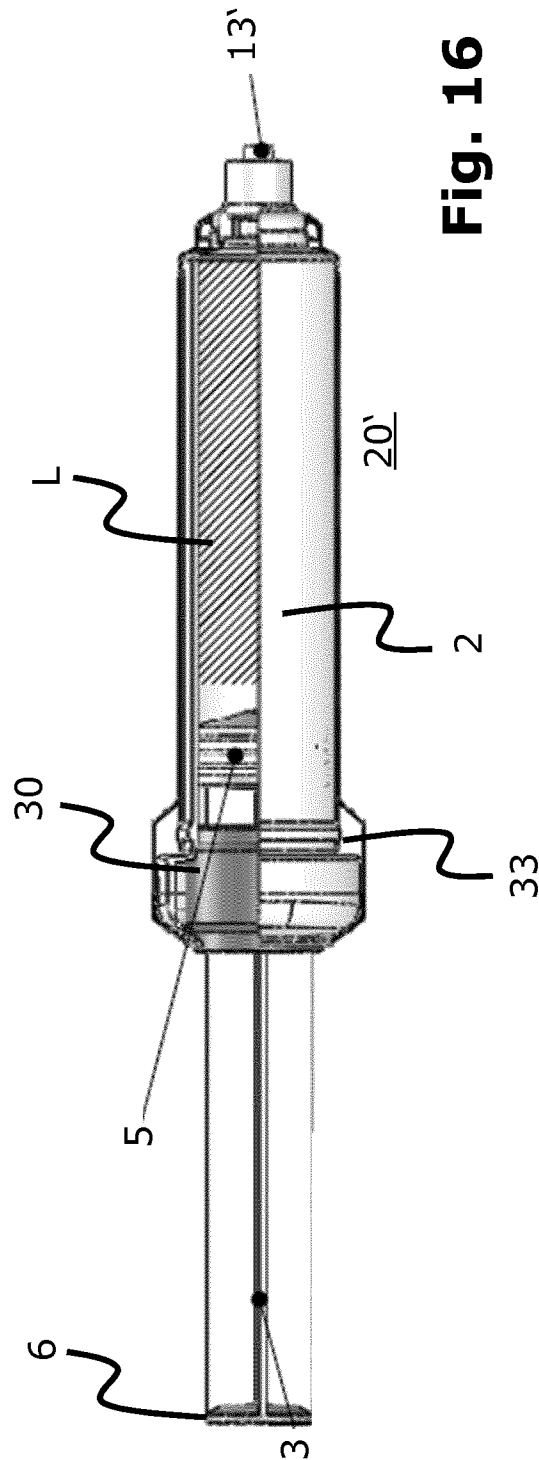


Fig. 16

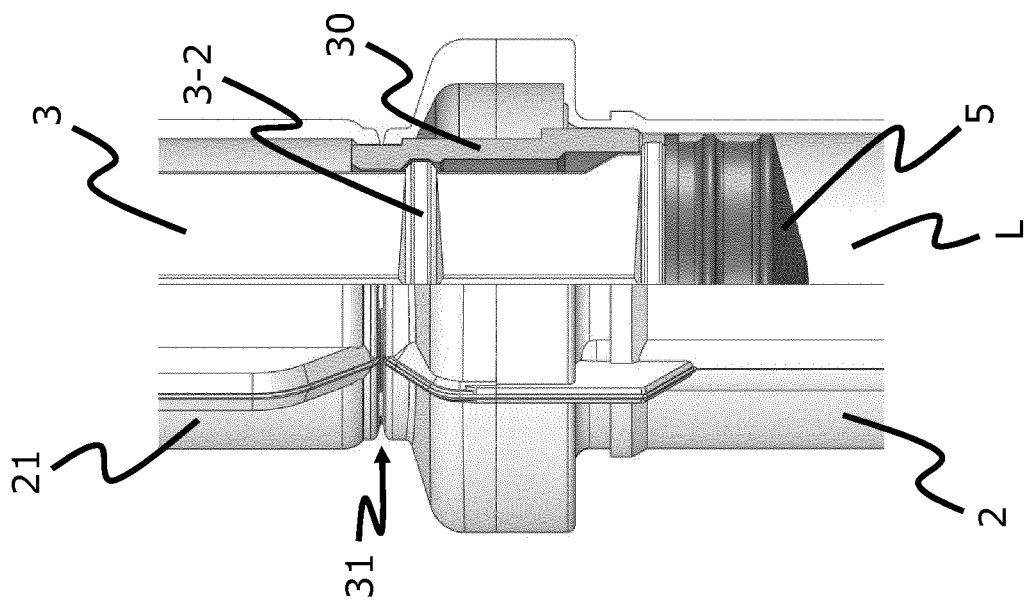


Fig. 17

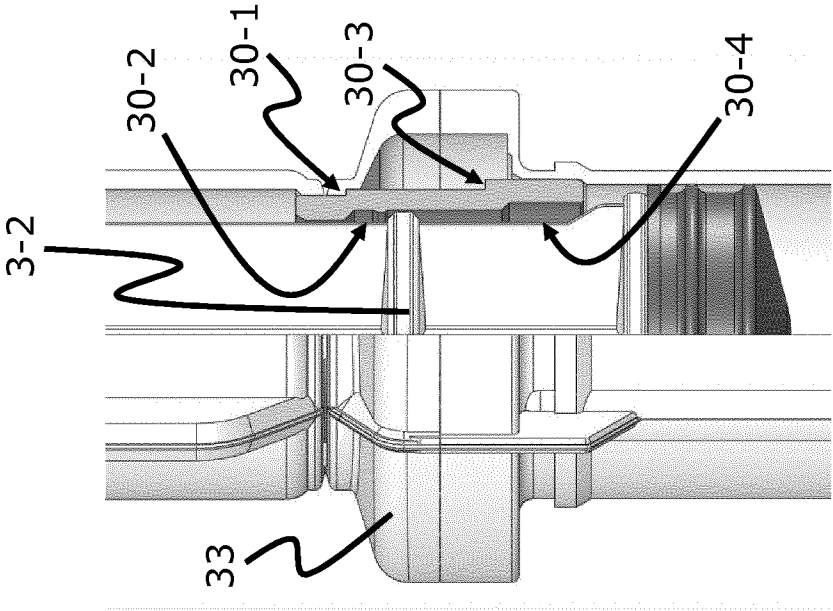


**Fig. 18**

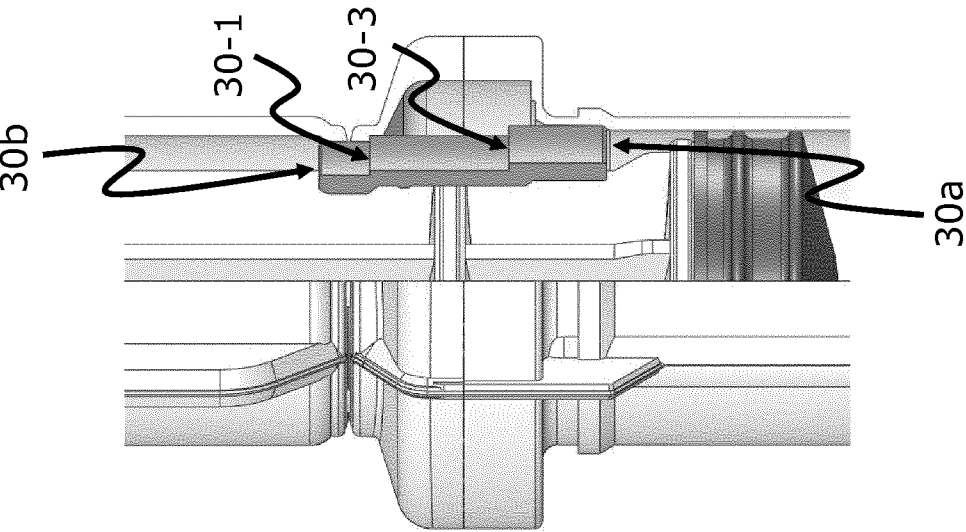


**Fig. 19**

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2013/076069

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                               |                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>INV.    A61M5/178            A61M5/31            B29C49/04            B29C49/20            B29C49/42<br>B29C49/48            B29C49/76            B29L31/00<br>ADD.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                       |
| According to International Patent Classification (IPC) or to both national classification and IPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                       |
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>B29C   A61M                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                               |                       |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                               |                       |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>EPO-Internal, WPI Data                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                               |                       |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                               |                       |
| Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Citation of document, with indication, where appropriate, of the relevant passages                                            | Relevant to claim No. |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | US 2012/167528 A1 (CONSOLARO ROBERTO [IT] ET AL) 5 July 2012 (2012-07-05)<br>abstract; figures 1-14<br>-----                  | 1-21                  |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | US 7 883 660 B2 (MATSUDA NAOTO [JP] ET AL) 8 February 2011 (2011-02-08)<br>abstract; figures 1-7<br>-----                     | 1-21                  |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | EP 1 910 058 B1 (BREV ANGELA S R L [IT]) 16 April 2008 (2008-04-16)<br>abstract; figures 1-12<br>-----                        | 1-21                  |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | EP 0 701 833 A1 (VITAL SIGNS INC [US]) 20 March 1996 (1996-03-20)<br>abstract; figures 1-8<br>-----                           | 1-21                  |
| <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="display: flex; align-items: center;"> <input type="checkbox"/> Further documents are listed in the continuation of Box C.         </div> <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> See patent family annex.         </div> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                               |                       |
| * Special categories of cited documents :                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                               |                       |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p> </div> </div> |                                                                                                                               |                       |
| Date of the actual completion of the international search<br><br><div style="text-align: center; font-size: 1.2em;">8 April 2014</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Date of mailing of the international search report<br><br><div style="text-align: center; font-size: 1.2em;">16/04/2014</div> |                       |
| Name and mailing address of the ISA/<br>European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Authorized officer<br><br><div style="text-align: center; font-size: 1.2em;">Muller, Gérard</div>                             |                       |

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