

[54] **METHOD AND DEVICE FOR ASSEMBLING A STOPPER TO A SYRINGE BARREL**

[75] **Inventor:** Theodore H. Stawski, Union, N.J.

[73] **Assignee:** Becton, Dickinson and Company, East Rutherford, N.J.

[22] **Filed:** Oct. 20, 1970

[21] **Appl. No.:** 82,409

[52] **U.S. Cl.** 29/407, 29/434, 29/451, 29/235, 53/22, 53/43, 53/320

[51] **Int. Cl.** B23q 17/00

[58] **Field of Search** 29/451, 235, 407, 29/434; 53/7, 12, 22, 37, 43 X, 264, 319, 320 X; 220/24.5

[56]

References Cited

UNITED STATES PATENTS

204,913	6/1878	Pratt	29/235 UX
291,458	1/1884	Warden et al.	53/320
2,095,931	10/1937	Kraft	29/235 UX
3,270,483	9/1966	Smoyer et al.	29/434 X

2,903,832	9/1959	Graff et al.	53/320
3,358,869	12/1967	Palmer et al.	220/24.5

FOREIGN PATENTS OR APPLICATIONS

495,345	8/1953	Canada	53/43
329,382	2/1903	France	53/320

Primary Examiner—Charlie T. Moon

Attorney—Kane, Dalsimer, Kane, Sullivan & Kurucz

[57]

ABSTRACT

A device and method for assembling a stopper to a syringe barrel which includes a stopper holding means to hold the stopper as it is being inserted into the open end of the syringe barrel. Simultaneously air escape means on the device permits air within the barrel to escape from the open end of the barrel and when the stopper has been extended within the barrel to the desired depth, the stopper holding means will release from the stopper and may be removed from engagement with the stopper and the syringe barrel without disturbing the location of the stopper within the barrel.

7 Claims, 5 Drawing Figures

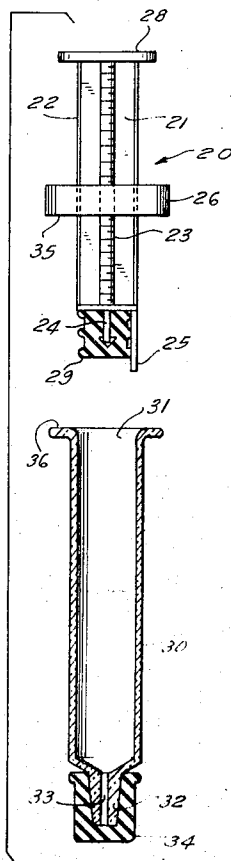


FIG. 1

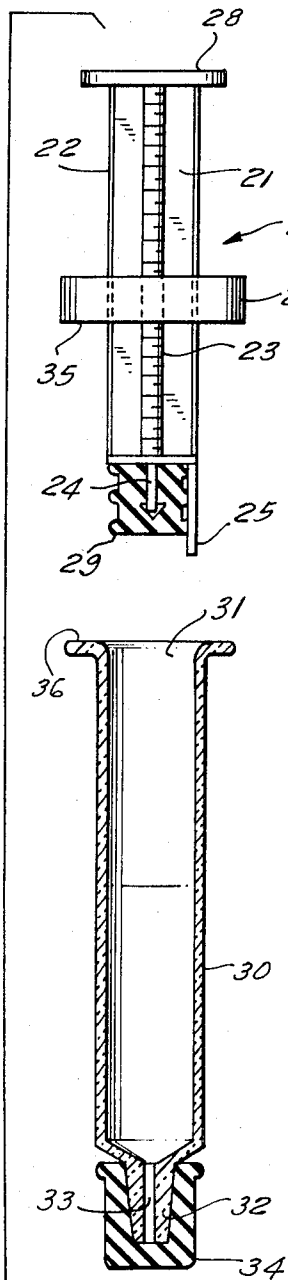


FIG. 4

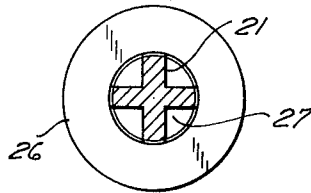


FIG. 5

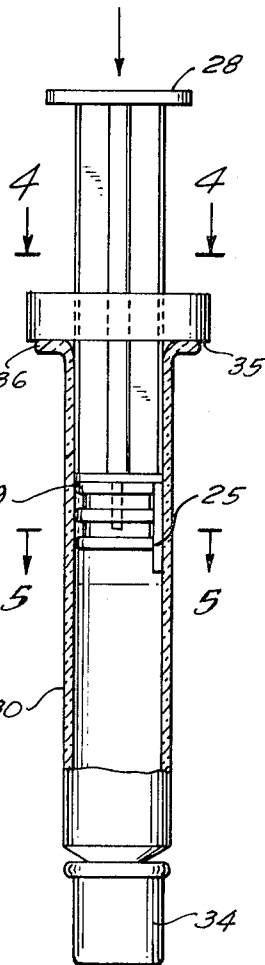
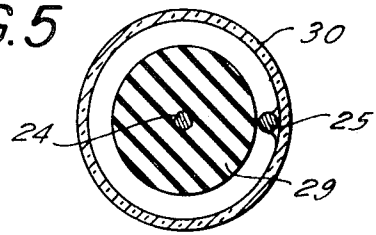


FIG. 2

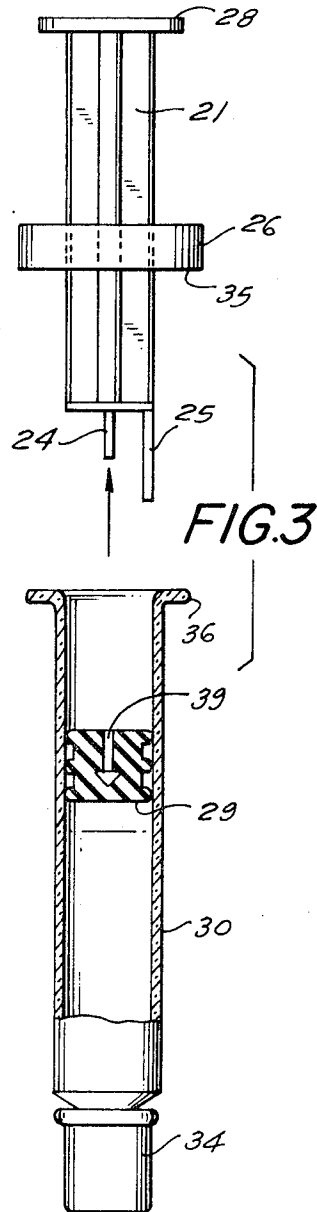


FIG. 3

INVENTOR
THEODORE H. STAWSKI

BY

For, (Palmer, N. S. Sullivan & P. Curry)
ATTORNEY 5

METHOD AND DEVICE FOR ASSEMBLING A STOPPER TO A SYRINGE BARREL

BACKGROUND OF THE INVENTION

In present day medical practice a very useful and effective device has been the prefilled syringe. The syringe is generally in the form of a syringe barrel having a capped tip end and a stoppered rear end with a predetermined dose of medicine contained therebetween. In use, a plunger need only be attached to the rear end of the stopper and the cap removed from the forward end and a needle and hub assembly attached thereto. The predetermined dose may be then administered by depressing the plunger. This whole assembly is generally economically constructed so that it may be disposed of after single use thereby permitting the use of a new prefilled syringe assembly for each additional dose to be administered.

Since it is desirable for this particular type of assembly to be disposable for economical reasons, it is particularly advantageous if the parts of the assembly can be manufactured economically and the predetermined dose located and sealed within the syringe barrel in the most efficient and economic manner.

The general practice in use today is to leave the forward tip of the syringe barrel uncapped and then place a stopper within the barrel until it is seated at the lower end thereof. The tip of the syringe barrel is then placed within a fluid container from which the specific unit dose is to be taken and then the stopper is drawn rearwardly within the syringe barrel creating a vacuum between the tip of the barrel and the forward surface of the stopper. Fluid then flows from the container into the evacuated portion of the syringe barrel and this process continues as the stopper is slowly withdrawn until the particular required dose is contained within the syringe. The forward tip of the barrel is then capped and the prefilled syringe is then ready for use. In this manner, there is hopefully no air contained within the portion of the syringe where the medicament to be injected is located. The aforesaid method is one of the major commercial processes by which a prefilled syringe is assembled. However, it can be readily seen that this technique of assembly is time-consuming. In addition, particular care must be taken so that no air is allowed to enter the tip end of the syringe barrel at any time. Entrapped air can cause physiological problems and can add to the number of rejects. All of these factors result in a more costly and inefficient manner of producing prefilled syringes and, therefore, do not contribute to the production of a low cost, effective disposable prefilled syringe.

It would be extremely advantageous to the art if a device and method could be provided for quickly and efficiently filling a syringe barrel with the predetermined dose required, with a minimal danger of air being entrapped in the portion of the barrel containing the medicament. Furthermore, it would also be advantageous if the forward end or tip end of the syringe barrel could be capped at all times during filling procedures and the medicament could be inserted into the barrel through the wider rear open end and then the stopper positioned within the barrel at the desired location. By being able to place the medicament in the syringe barrel through its wide open end, assembly procedures would be accelerated to a great degree, particularly if the desired dose could be quickly inserted and then the

stopper quickly placed within the barrel on top of the medicament. It can be readily seen that assembly of the prefilled syringes would be accelerated thereby reducing assembly line time and resulting in a more economic low cost prefilled syringe lending itself to disposability.

Naturally, in addition to speeding up the filling process, a device and method which simultaneously alleviates the danger of entrapped air within the portion of the syringe barrel containing the medicament would also be extremely advantageous.

SUMMARY OF THE INVENTION

Among the objectives of this invention is to provide a device and a method which will achieve the above mentioned advantageous results and which will alleviate the above mentioned problems. A principal objective is therefore to provide a device and method which permits a prefilled syringe barrel to be filled from the wider opened rear end thereof with the required dose to be administered while the forward tip is in a capped condition and allows the stopper to be properly positioned in engagement with the dosage within the barrel. During the positioning procedure, air within the syringe barrel is allowed to escape through the rear open end of the barrel until the stopper is properly located at the desired depth within the barrel with only medicament between the forward end of the stopper and the forward tip of the syringe barrel, thereby providing an economical, low cost and efficient prefilled syringe barrel which will lend itself for use as part of a disposable prefilled syringe assembly.

The assembling device of the invention includes a stopper holding means on the device to hold the stopper as it is being inserted into the open end of the syringe barrel wherein the barrel contains the desired dose of medicament. The device also includes air escape means to permit air within the barrel to escape from the open end of the barrel as the stopper is being placed therein. When the device is removed from engagement with the stopper and the syringe barrel, the stopper is left in sealing engagement with and properly positioned within the syringe barrel.

With the above objectives in mind, reference is had to the attached drawing for a more detailed description of the device and method of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is an elevation view of the device of the invention shown in engagement with a stopper about to be positioned within a syringe barrel which in turn is shown in a sectional elevation view having its lower end capped;

FIG. 2 is a partially sectional elevation view thereof after the stopper has been positioned within the syringe barrel with an arrow showing the direction of movement of the device and attached stopper;

FIG. 3 is a partially sectional elevation view thereof showing the stopper in position and the device of the invention having been removed from engagement therewith with the arrow showing the direction of movement of the device while it is being disengaged therefrom;

FIG. 4 is a sectional top view thereof taken along the plane of line 4—4 of FIG. 2; and

FIG. 5 is a sectional top view thereof taken along the plane of line 5—5 of FIG. 2.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The assembly tool or device 20 to assemble a stopper to a syringe barrel which has been prefilled to a predetermined level with a liquid includes a body portion 21 of the device 20 which is an elongated member consisting of a plurality of web-like members 22 arranged at approximately right angles to each other. Each web-like member 22 has a threaded outer surface 23, the purpose of which will be discussed below.

Extending from the lower surface of body 21 is a center pin 24 mounted to the body portion 21 in any convenient manner or integral therewith. A longer peripheral pin 25 extends somewhat further below the bottom surface of body portion 21. A circular nut 26 having a centrally located threaded bore 27 therethrough is positioned on body 21 so that the threads of bore 27 engage with threaded surface 23 of webs 22. In this manner, nut 26 may be threaded axially along the length of body portion 21. The purpose of this arrangement will be discussed in detail below.

It might also be noted that the upper surface of body portion 21 has a flanged surface of greater diameter than the web portion of the body to facilitate the presence of a greater engaging surface to force the device downward when pressure is applied thereto. Flange portion 28 also provides a gripping surface to facilitate the removal of the device when a stopper is properly positioned in a syringe barrel.

FIGS. 1 and 2 show how pins 24 and 25 form a stopper holding means for a stopper 29 which is to be positioned within a syringe barrel to form a prefilled syringe. The arrangement of pins 24 and 25 provides sufficient gripping force to hold stopper 29 in position until it has been inserted to the proper depth within the syringe barrel, yet, however, the arrangement permits the pins to be removed entirely from engagement with the stopper and the syringe barrel without disturbing the position of stopper 29. Pin 25 of device 20 serves to provide the air release or escape passage as the stopper is put into position within the syringe barrel. This aspect will also be discussed in greater detail below.

FIG. 1 shows a device of this type holding a stopper 29 in position above a common type of syringe barrel 30 normally constructed of a glass material, although any other common type of syringe barrel material, such as plastic, may be employed equally as well. The rear end of syringe barrel 30 has a wide opening 31 and the forward end of the syringe barrel 30 has a reduced tip 32 having a narrow passage 33 therethrough. As previously explained, normally in filling such a syringe with a predetermined dose, the stopper is positioned within the syringe barrel to its full depth and then is slowly withdrawn to create a vacuum and draw fluid in through small opening 33 until the desired dose is within the syringe. By using the device and method as described in this disclosure to produce a prefilled syringe barrel, no fluid need be introduced into the barrel through opening 33. Therefore, a sealing tip 34 may be positioned in sealing engagement over reduced end 32 to seal opening 33. Sealing tip 34 may be constructed of any common type of sealing material such as rubber which may be easily positioned on tip 32 and also easily removed when it is desired to attach a needle and hub

to the syringe barrel to form a syringe assembly for use.

Turning to operation of the device 20 and the method of filling a syringe quickly and efficiently by use of this device to form a prefilled syringe will now be discussed in detail. Initially, the elements are positioned as shown in FIG. 1 with a rubber stopper 29 held in position by pins 24 and 25. Nut 26 is axially threaded to the desired position on webs 22 so that device 20 may only be extended within syringe barrel 30 until the lower surface 35 of nut 26 contacts the upper lip 36 of syringe barrel 30 thereby locating stopper 29 at the proper and desired depth within syringe barrel 30. The predetermined dose is then introduced into syringe barrel 30 easily and quickly through its open end 31 to a desired depth as previously determined.

The next step in forming the prefilled syringe is demonstrated in FIG. 2 whereby the arrow shows the direction of movement of device 20 to insert stopper 29 within barrel 30. The outer diameter of body portion 21 of device 20 is smaller than the inner diameter of syringe barrel 30 to allow movement of device 20 downwardly into syringe barrel 30. However, the outer diameter of nut 26 is greater than the inner diameter of syringe barrel 30 and forms shoulder 35 as previously described which contacts lip 36 of syringe barrel 30 when stopper 29 is at the correct depth.

As device 20 and stopper 29 are inserted into syringe barrel 30, air is permitted to escape by the action of pin 25 which engages with the inner wall of syringe barrel 30 and slightly deforms the side wall of stopper 29. This provides small passageways as shown in FIG. 5 which permits air to escape out through opening 31 as stopper 29 is being inserted. By proper calculations, when device 20 has been extended to its fullest extent, stopper 29 will be in contact with the upper surface of the fluid within the syringe barrel with no air trapped therebetween. Device 20 may then be removed as shown in FIG. 3.

When stopper 29 is being inserted by device 20, pins 24 and 25 along with the undersurface 38 of body portion 21 assists in holding stopper 29 and moving the stopper as it is inserted within the barrel. Therefore it is not necessary for the pins 24 and 25 to be in tight engagement with stopper 29. The pins are in disengageable association with the stopper. So, as device 20 is removed from the syringe barrel, pins 24 and 25 are disengaged from stopper 29 so that they pull free from the stopper without displacing the stopper from its proper position. The resilient nature of stopper 29 will close openings which had been created by pin 25 as stopper 29 expanded to engage the side walls of syringe barrel 30 around its entire circumference. The resulting sealed syringe barrel will contain a predetermined dosage thereby providing a prefilled syringe barrel portion which may be readily and easily connected to a hub and needle assembly by removing tip 34 to provide a syringe assembly for injection of the dosage within barrel 30. Naturally, as in normal practice, a plunger would be connected to opening 39 in the upper surface of stopper 29 to facilitate its projection to the bottom of syringe barrel 30 and injection of the contained dosage. Opening 39 also provides an opening for pin 24 of device 20 when stopper 29 is initially placed within the syringe barrel 30.

It can be readily seen how adjustment of nut 26 in cooperation with the desired amount of fluid to be positioned within syringe barrel 30 can be regulated so that

a large number of prefilled syringes of this type containing a certain dosage can be quickly and efficiently filled and stoppered in mass quantities by merely pre-setting the nut 26 to the correct axial position on body 21 of device 20.

The device 20 is particularly adapted, but not limited, for use under aseptic conditions. For example, sterile syringe barrels with tip cap 34 are assembled in an upright position within a conditioned, contaminant-free air flow, as, for example, on a work bench swept by a laminar air flow. A sterile device 20 interengages a sterile stopper 29 stored in a tray swept by the laminar air flow. The interengagement can be manual or automatic. An automatic metering device or the like dispenses a predetermined quantity of drug into the syringe barrel through wide opening 31. Thereafter, the stopper is inserted into the syringe barrel and is disengaged, thereby forming a prefilled syringe.

Thus, the above mentioned objects of the invention, among others, are achieved.

I claim:

1. Device for assembling a deformable stopper to a syringe barrel having one open end and being filled to a predetermined level comprising:

stopper holding means on said device to hold said stopper as the stopper is being inserted into the open end of said syringe barrel;

air escape means on said device to permit air within said barrel located between the surface of the contents of the barrel and the open end to escape from the open end thereof as said stopper is being placed therein including means to deform said stopper during insertion into the barrel away from engagement with the barrel in at least one location to form a passageway therebetween;

said stopper holding means releasably engaged with said stopper so that when said stopper is properly positioned within said barrel, said device may be removed from engagement with said stopper and said syringe barrel permitting said stopper substantially immediately to return to normal configuration in complete sealing engagement with and properly positioned within said syringe barrel.

2. The invention in accordance with claim 1 wherein indicating means is on said device to facilitate determination of when said stopper is positioned at the desired depth within said barrel.

3. The invention in accordance with claim 1 wherein said stopper holding means includes a center pin extending from the bottom surface of the body of said device into an opening within the upper surface of said stopper adapted to receive the center pin, a second pin extending downwardly from the peripheral portion of the bottom surface of the body of said device and engaging the outer surface of said stopper, said center pin and second pin holding said stopper firm enough to assure proper positioning of the stopper within the barrel and loose enough to permit removal of said device from said stopper and barrel without displacing said stopper from said proper position.

4. The invention in accordance with claim 1 wherein said air escape means on said device includes a pin extending downwardly from the peripheral portion of the bottom of the body portion of said device, said pin engaging the outer surface of said stopper held by said device and the inner wall of said syringe barrel when said stopper is being positioned within said barrel by said

device thereby providing an air passageway for the air within said syringe barrel to escape and permitting said stopper to enter said syringe barrel.

5. A method of assembling a deformable stopper to a syringe barrel having one open end and being filled to a predetermined level by utilizing a device including stopper holding means to hold the stopper until it is properly positioned within the syringe barrel and then to release the stopper so that the stopper will remain in the proper position in the syringe barrel and air escape means on the device to permit air within the barrel to escape from the open end thereof while the stopper is being positioned therein comprising:

positioning a deformable stopper into engagement with the stopper holding means of said device;

passing the stopper into the barrel of the syringe from the open end thereof with the displaced air within said barrel located between the surface of the contents of the barrel and the open end being allowed to escape from the open end of the barrel by means of said air escape means which deform said stopper during insertion into the barrel away from engagement with the barrel in at least one location to form a passageway therebetween as said stopper and device are moved to the desired position within the syringe barrel; and

removing said device from said stopper and said syringe barrel while said stopper holding means permits said stopper to substantially immediately return to normal configuration in complete sealing engagement with and properly positioned within said syringe barrel.

6. The invention in accordance with claim 5 wherein as the stopper is being placed within the syringe barrel indicating means on the device facilitates the determination of when said stopper is positioned at the desired depth within said barrel.

7. A device for assembling a stopper to a syringe barrel having one open end comprising:

stopper holding means on said device to hold said stopper as the stopper is being inserted into the open end of said syringe barrel;

air escape means on said device to permit air within said barrel to escape from the open end thereof as said stopper is being placed therein;

said stopper holding means releasably engaged with said stopper so that when said stopper is properly positioned within said syringe barrel, said device may be removed from engagement with said stopper and said syringe barrel leaving said stopper in sealing engagement with and properly positioned within said syringe barrel; and

indicating means on said device to facilitate determination of when said stopper is positioned at the desired depth within said barrel comprising a body portion on said device having an elongated shape of a smaller outer diameter than the inner diameter of the syringe barrel, the body portion having a threaded outer surface, a nut having a threaded bore therethrough in interengagement with the threaded surface of said body portion so as to be movable in axial direction with respect thereto, said nut having a larger outer diameter than the inner diameter of said syringe barrel so that when said nut is axially positioned at the desired point on said body portion, said device can only be extended into said barrel until said nut contacts the rim of said barrel thereby indicating that said stopper is positioned at the desired depth.

* * * * *