

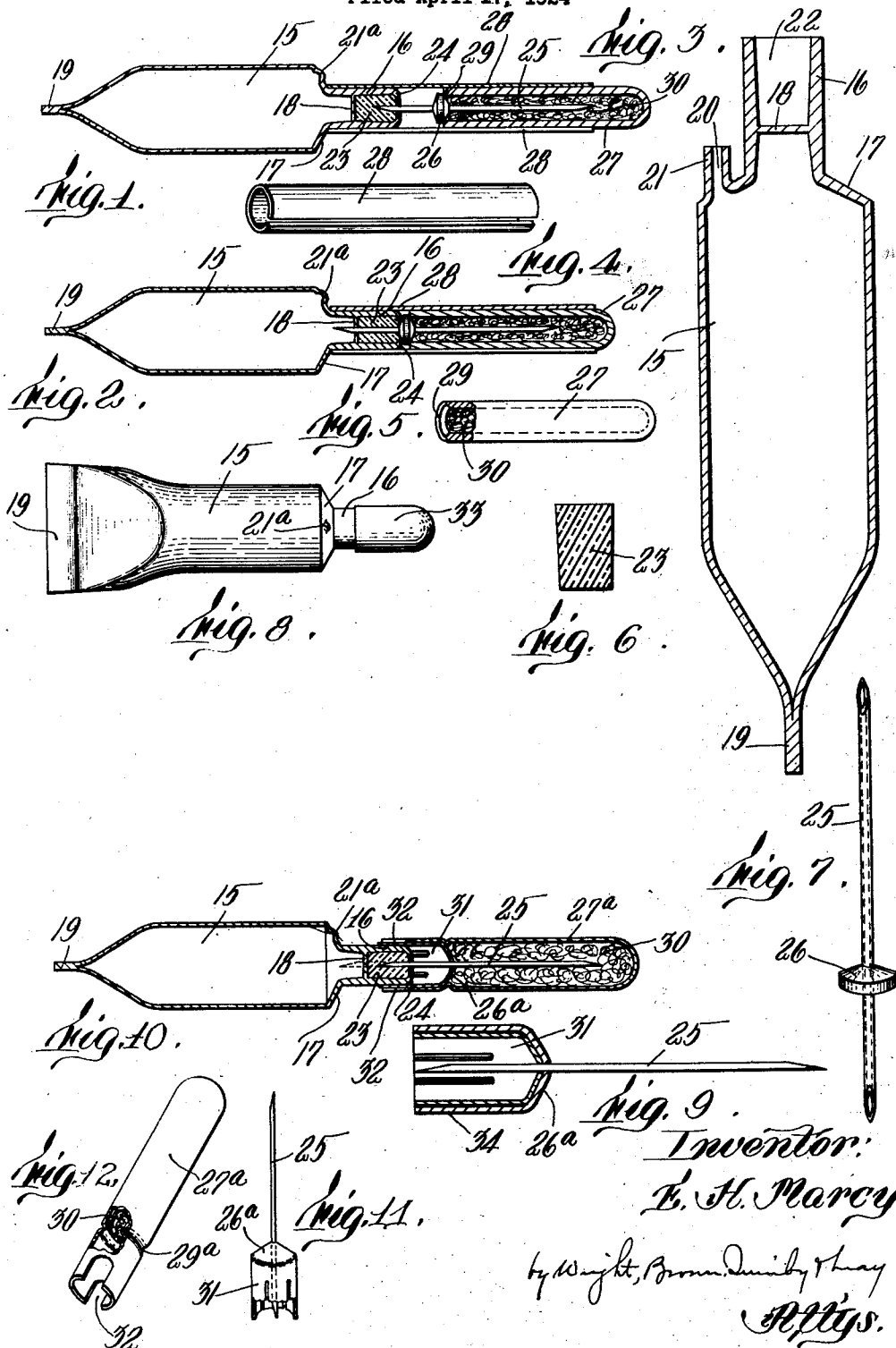
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COLLAPSIBLE AMPUL SYRINGE

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COLLAPSIBLE AMPUL SYRINGE.

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The present invention relates to instruments for hypodermically administering medicines and other liquids; that is instruments which include a tubular needle as the means for conducting the liquid into the veins or tissues of the patient. The main object of the invention is to enable the medicine to be directly administered from a sterile original package or container, and without need of placing the original package in a syringe, or in association with any other device except, in some cases only, a hypodermic needle. The accomplishment of this object involves making the container of flexible and collapsible construction, which in itself is not new with the present invention; but the accomplishment of the further object of delivering the medicine to the user in an assuredly sterile or uncontaminated condition is a new result.

While hypodermic units including collapsible medicine containers have recently gone into extensive use and met with wide favor, such containers as have heretofore been used are subject to one great and serious defect, namely, that they cannot be sterilized. Therefore even in spite of the greatest care to see that before filling the containers are clean and that pure and clean solutions are put into them, yet the impossibility of sterilizing them after filling, or of insuring that they will remain intact from penetration of harmful micro-organisms, has made impossible any assurance that at the time of use, the contained medicine will be perfectly safe to use. By the present invention the element of lack of perfect safety has been removed and I have now made it possible to put up at the manufacturing laboratory a sterile solution in a container from which the solution may be injected hypodermically without transfer to another instrument, and with which assurance may be given that the solution is sterile and will remain so until time of use, however long deferred, provided the solution is not one of those which is liable to change by internal reaction.

In this specification I use the word "sterile" and words of similar import in a generic sense to indicate that condition in which the medicine is free from harmful foreign matter. By the use of these terms I do not mean merely that the solution has been made sterile by destruction of all organisms therein, but I intend to include also that condition of such solutions as biological products in which the

products, while containing organic life, are yet free from deleterious organisms.

A further object is to furnish an improved, simplified, and inexpensive needle and needle protector, in association with a sealed ampul of collapsible character.

The invention consists in a collapsible ampul of the character indicated and in the combination and association therewith of cooperating parts and elements, as above indicated, and as more particularly pointed out in the following specification and claims.

In the drawings:

Figure 1 is a longitudinal section of a hypodermic ampul unit embodying my present invention, filled and in the condition in which it is furnished to users.

Fig. 2 is a similar view of the unit after the same has been made ready for use by putting the needle into connection with the contents of the ampul.

Fig. 3 is a sectional view of the ampul before filling;

Figs. 4 and 5 are detached perspective views of the parts of my ampul needle sheath or protector, the member shown in Fig. 5 being partly broken away;

Fig. 6 is a detail sectional view enlarged of a sealing element adapted to be used with such ampul;

Fig. 7 is a perspective view enlarged, of the new form of hypodermic needle which I have applied to the unit shown in Figs. 1 and 2;

Fig. 8 is a side view of a filled and sterilized ampul embodying the invention and adapted to be used with a separate needle;

Fig. 9 is a sectional view of a hypodermic needle designed and adapted to be used repeatedly in combination with ampules of the sort shown in the preceding figures;

Fig. 10 is a sectional view of an ampul unit similar to that shown in Figs. 1 and 2, but combined with a specifically different needle and protective sheath;

Figs. 11 and 12 are perspective views of the needle and sheath, respectively, shown in Fig. 10.

Like reference characters designate the same parts wherever they occur in all the figures.

Referring first to Fig. 3 which shows in detail the container which is adapted to be filled with medicine, the same consists of a body or shell 15 having at one end a tubular neck 16. This body is made of a material

which will not affect, nor be affected by, the medicine, and one which also, when shaped in hollow form with thin enough walls, may be collapsed by squeezing between the thumb and finger. The metal tin meets these requirements and is eminently suitable for the purpose. But other metals and non-metals may be used, and as an example of a non-metallic substance, I may mention huguloid, which is a special preparation of nitro cellulose. These materials are mentioned as illustrative of many which might be used, and also as those which are best suited for the purpose, but not as an exhaustive catalogue of all that might be used. The neck 16 is preferably cylindrical and of uniform diameter in order that it may receive, in a sliding manner, and be resiliently grasped by, the protecting cap presently described, or the hub or sleeve of a hypodermic needle. It is also preferably of smaller diameter or width than the body, and is joined to the latter by a shoulder 17.

In carrying out my purpose of making an ampul which can be sterilized, I form within the neck 16 an integral partition 18, and I close the opposite end of the shell at 19. The closed end is sealed in such a way that no opening however minute is left through which air and micro-organisms may enter or through which the contained solution may escape; and the seal is also strong enough to sustain a substantial internal pressure, that is, the pressure generated by heating the confined solution to the degree and in the manner of any approved method of sterilization. I prefer to form this sealed closure of the shell by pinching its walls together at the end opposite to that across which the partition lies, and uniting the contiguous parts of such walls in substantially integral union. Such union may be effected in a variety of ways, as by fusion, electro-deposition of metal, or the use of a solvent which will so affect the contiguous walls as to cause them to coalesce. Within the scope of union by fusion: I include that induced by heat (applicable by electric welding electrodes, a hot iron or wire, a concentrated flame, etc.) sufficiently intense and localized to cause melting together of the parts affected, with or without aid from a flux, and that effected by soldering or the like, as well. An ampul hermetically sealed by any of the means above indicated, or by other possible means as well, is within the scope of my claims for an ampul hermetically sealed, or sealed by integral union of its enclosing walls.

While the ampul may be filled through its open end before the latter is closed and sealed, it may, and in some instances should, be filled after closing the end; and in order that it may be so filled, there may be left, at some point in the shell, preferably in the shoulder 17, a small opening 20 surrounded

by a lip or flange 21. This opening is large enough to admit a filling tube of a size comparable to that of a hypodermic needle. The container so made is ready for reception of its charge of medicine, and is completely closed by the substantially integral continuity of all its walls, except for the filling opening 20. The medicinal charge is introduced into the shell through this opening by means of a tube small enough to enter it, and when filled the opening is closed and sealed by fusion, or in the other ways above indicated. The lip or flange 21 which surrounds the opening aids in thus closing and sealing it as it furnishes an excess of material which will melt and flow together across the hole when affected by sufficiently intense concentrated heat. Heat of this character may feasibly be applied by an incandescent wire or by electric spot welding. The trace of the hole thus closed is shown at 21^a in Figs. 1, 2, 3, 8 and 10. Thus when filled and sealed as described, the ampul has a completely integral envelope, without any openings through which the contained solution may escape or through which organisms may enter and having strength sufficient to sustain without rupture the pressure generated in the confined solution by heat great enough to destroy all organisms.

The partition 18 is located back from the mouth of the neck 16, and thus leaves within the neck a space 22 adapted to contain a packing member which will occupy the space between the walls of the neck and an inserted hypodermic needle and prevent leakage around the needle when the ampul is discharged. Such packing member may be variously made and of various materials, as for example a plastic material poured or forced into the space 22 when in liquid or semi-liquid condition, and of such nature it will be solid at sterilizing, and lower, temperatures, but is penetrable by a hypodermic needle. However I prefer to use a plug of solid and substantially infusible, but penetrable and resilient material. A plug 23 made of vulcanized rubber composition and molded in the form shown in Fig. 6, is eminently suitable for the purpose. It is preferably retained, and may be put under compression, in the space 22 by spinning or compressing the edge of the neck partly over its end. Then it is confined between the partition 18, which serves as a supporting ledge for the plug within the neck, and the inturned lip 24 on the end of the neck, such lip being for that purpose a retaining flange. This plug not only seals the needle, as stated, but it also grasps inner end portion of the needle, holding it in place before use and preventing its separation from the ampul during injection and upon withdrawal from the tissues of the patient. To serve these purposes to the best advantage, it should be not

only large enough to fit tightly in the neck 16, but also long enough to be put under compression by turning in of the lip 24.

The hypodermic needle 25 is a capillary tube of the character usual in this art, and is pointed at both ends. It is provided with an external shoulder in the preferred form of the invention, such shoulder being most feasibly made by providing a disk or button perforated at its center and slipped on the needle to the required position, where it is made fast by any suitable means, such as by compressing and so binding it upon the needle, or by soldering or equivalent means. This needle is combined with the ampul and with a protective sheath to make a complete unit, one end of the needle being passed part way through the plug 23, but to a point short of the partition 18 and of the inner end of the plug; that is a position substantially as shown in Figure 1.

The preferred form of sheath is made of two parts 27 and 28, the part 27 being a tube closed at one end and open at the other end, the open end providing a shoulder 29 of smaller diameter than the needle shoulder or abutment 26, whereby it is adapted to bear on the latter and transmit pressure thereto endwise of the needle. The part 28 is a sleeve slotted throughout its length at one side, whereby it is made springy and thereby enabled to grasp resiliently both the ampul neck and the tube part 27. It should be noted that, in order for the sleeve to do this most effectively, the member 27 should be approximately the same in external diameter as the ampul neck 16. The sleeve member 28 can be very economically made by rolling a flat blank of suitable metal into tubular form and to a diameter slightly less than that of the neck and of the tube 27, so that it will be spread when slipped over these parts. Thus it grips both parts resiliently and firmly enough to hold the tubular part 27 in place, but permits the tubular part to be readily moved endwise within the sleeve. The sleeve, being thus held and bearing against the shoulder of the needle, holds the latter in place also, and the needle is additionally held by the pressure of the resilient enveloping plug on its inner end part. Preferably an enveloping mass of fibrous material, such as surgeon's gauze, in sterile condition is placed in the sheath so as to envelop the outer part of the needle and exclude moisture, dust and harmful micro-organisms therefrom.

The complete unit, consisting of the filled and sealed ampul, the needle, and the sheath associated substantially as shown in Figure 1 is furnished to users ready for use. In this condition the end of the sheath member 27 protrudes from the end of the sleeve member 28 by a distance at least as great as the movement of the needle necessary to pass its inner

point through the partition 18 and place its bore in communication with the contents of the ampul; and the distance of the button 26 from the end of the ampul neck is also at least as great as the same distance. It is made ready for use by pushing the needle inward until its inner point punctures the partition 18 and passes therethrough far enough to bring the open bore of the needle inside of the partition. Pressure for this purpose is applied to the protruding end of the sheath member 27, this member sliding easily in the sleeve member 28 and pushing the needle shoulder 26 before it. The unit is now in the condition shown in Figure 2. Finally the sheath is grasped by the sleeve portion and pulled off from the ampul, leaving the needle exposed ready to be passed into the tissues of the patient. The needle does not follow the sheath when the latter is thus removed, because its inner part is grasped more tightly by the enveloping plug than the outer part is grasped by the loose fibrous mass 30; and the grip of the plug upon the needle is also strong enough to pull it out of the muscular tissue after an injection has been performed. The compressed state in which the plug may be put by turning in the lip at the end of the ampul neck, as hereinbefore described, makes it possible to secure as firm a grip on the needle by means of the plug as may be needed for any purpose.

A specifically different construction of needle, or rather association of needle and means for holding and moving it, is shown in Figures 10, 11 and 12. In this form the needle is associated with a cap 31 having a closed end and an open end. The closed end provides a wall through which the needle passes and to which it is secured. The open end is adapted to surround and slide upon the neck of the ampul body. In order that it may fit firmly and at the same time slide freely on said neck, this cap is slotted for a certain distance from its open end, whereby its walls adjacent to the open end are converted into spring tongues or jaws.

When the ampul unit is put out as such, the needle is applied to the ampul by slipping its cap part way on the neck of the ampul. The inner point of the needle, which lies preferably slightly within the open end of the cap, penetrates part way through the sealing plug, but does not reach to the partition 18, as previously described. Its distance from this partition however is less than the distance which the cap may slide on the neck before abutting against the shoulder. Hence the needle can be passed through the partition so as to open a passage for discharge of the medicine, by sliding the cap down or inward on the neck of the ampul.

This unit also is completed as an article of commerce by a sheath, which may be the same as the one already described, but I have

chosen to show here a modified form of sheath containing in principle many of the features of the other sheath, and capable of being used in place of that one upon the unit first described. The modified sheath 27^a is made all in one piece, adapted to slip over the cap of the needle at its open end, and there formed with spring jaws by notches 32, so that it may be retained in place by grasping the sleeve by means of such spring jaws. A shoulder 29^a, adapted to apply pressure to the said cap in moving it to force the inner point of the needle through the partition 18, is formed by indenting a zone of the sheath at a suitable distance from its open end, substantially as shown. Sterile gauze 30, or equivalent material to envelop and protect the needle, may be used here also. The end of the cap then serves as a shoulder 26^a receiving the pressure of the shoulder 29^a.

The same steps are followed in making this unit ready for discharge, and discharging it, as have already been described; that is the sheath is pushed down as far as it will go, and then removed. The needle then penetrates the partition, but it is held on the ampul by the grip of its spring jaws on the neck 16 as well as by the grip of the packing plug on the inner part of the needle.

A characteristic of the ampul which is essential to the coupling of the needle with its interior in the manner set forth, is that the partition must be penetrable by the inner point of the needle. This condition is readily satisfied by making the ampul and its integral partition of tin, or of other materials indicated, and further, by making the partition thin enough. I have found in practice that it is readily feasible to make the partition with these characteristics in ampules produced on a commercial scale.

The parts of the unit thus described may be sterilized separately and assembled, or may be assembled first and then sterilized. Preferably they are first assembled in the condition indicated by Figures 1 and 10. Sterilization of the units thus assembled may be effected by any of the means or methods used by the medical profession and manufacturing chemists, without danger to the integrity of the ampul or its contents. When the unit leaves the laboratory it is sterile, and both the contained medicine and the needle are protected from subsequent contamination in any manner, since no septic matter can reach either the medicine or that part of the needle which is passed under the skin of the patient. Thus the unit may be safely used at any time, no matter how long, after being put up, subject only to the time limitation due to the nature of the medicine itself, as in the case of medicines which deteriorate or change their composition with age. Even in the act of bringing the needle into connection with the medicine, there is no liability of contaminating the

needle, because the pressure for thus moving the needle is applied to the sheath, which is then removed. The operator need not touch the needle or even put his fingers in a position where there is danger of touching it before passing it into the patient. That part of the needle which lies just outside of the plug does not need protection because it never comes into contact with the medicine, but is closely enveloped by the plug when the needle is pushed home.

Ampules having the capacity of sterilization, and being sterile, as herein pointed out, may also be furnished without the additional equipment of needle and sheath which makes the complete unit, but adapted to be used with a separate needle, which latter can be applied successively to a number of ampules. This ampul is constructed, filled, sealed and sterilized substantially as described. The space within the outer part of its neck is provided with a packing medium, and the neck is protected by a cap 33. This cap is slipped over the neck of the ampul in the same manner as the needle cap 31, and it may be made of any suitable material, but the material is preferably a nitro-cellulose compound of the sort previously described, the same being inexpensive and therefore such that it can be thrown away.

The needle used with a succession of ampules has the same characteristics as the second one previously described, and in addition is equipped with an outer cap 34 of such strong and rugged construction that it can be squeezed and otherwise roughly handled without being deformed. It encloses the spring tongues of the inner cap 31 and protects the latter from deformation by the pressure which the operator unavoidably exerts with his fingers in putting the needle on the ampul and removing it, but it does not confine these tongues closely enough to impair in any way their function of resiliently gripping the neck of the ampul. It is effectively made fast to the closed end of the inner cap or to the needle, or both, in any suitable way.

The ampul of this invention combines for the first time the qualities of collapsibility and capacity for sterilization by heat. Heretofore the only ampules which could thus be sterilized and could be relied on to maintain their contents in sterile condition, have been those made of glass. But in order to discharge a glass ampul hypodermically, it is necessary either to transfer the contents first to a hypodermic syringe, or to apply some form of external expelling device, such as a piston or pusher, as well as a hypodermic needle, to the ampul. My ampul may be discharged directly into the tissues or veins of a patient by merely squeezing it.

On the other hand although hypodermic instruments have been used of which the medicine container is collapsible, these con-

ainers have not been capable of efficient and safe sterilization when filled, nor have they been secured against possible contamination of their contents after leaving the laboratory, particularly when left unused for a long time.

I desire to point out that the present invention consists not only of the entire combination involved in the ampul unit hereinbefore described, but includes also the novel features of the several elements of the combination alone, and without limitation by the novel features of other elements. For example, while the hermetically sealed ampul having substantially integral continuity of its enclosing walls throughout, is an important feature of the invention, nevertheless I claim protection for the novel features of the needle, the sheath, etc., as devices adapted to be used with ampules or other character as well as that particularly specified.

What I claim and desire to secure by Letters Patent is:

1. An ampul comprising an elongated collapsible shell having an integral penetrable closing wall at one end and being there adapted for connection with a hypodermic needle, and its walls at the other end being integrally joined together, said shell having between its ends a filling opening adapted to be integrally sealed after filling.

2. A hypodermic ampul unit comprising a collapsible ampul having a neck with an internal transverse partition, a resilient penetrable plug in said neck outside of the partition, a double pointed needle entering said plug and extending toward said partition and having a pressure-receiving shoulder at

a distance from the end of the neck, and a sheath enclosing the outer part of the needle and formed with a shoulder arranged to bear on said needle shoulder, said sheath having a portion embracing the neck and being adapted to slide endwise thereon.

3. A hypodermic unit comprising a collapsible ampul, a hypodermic needle and a sheath, an ampul having an integral stopping means in one end of a character adapted to be penetrated by a hypodermic needle and its walls being joined in integral continuity throughout the needle having points at both ends adapted to penetrate said stopping means and having also an abutment between its ends, and the sheath having a separable mounting on the end of the ampul whereby it embraces the needle when the latter is in line with the penetrably closed portion of the ampul, and said sheath having an internal shoulder portion adapted to engage said needle abutment, and, by applying pressure thereto force the inner point of the needle through said closing means.

4. The combination with a double pointed hypodermic needle having an external shoulder between its ends, of a needle sheath containing a mass of fibrous material in which the inserted needle is enveloped, said sheath including an internal shoulder arranged to engage and impart motion by pressure application to the shoulder of the needle, and having further an open end adapted to embrace the neck of an ampul.

In testimony whereof I have affixed my signature.

ERNEST H. MARCY.