

Nov. 2, 1948.

M. R. FIELDS

2,452,643

DISPOSABLE VENOCLYSIS SET

Filed May 23, 1946

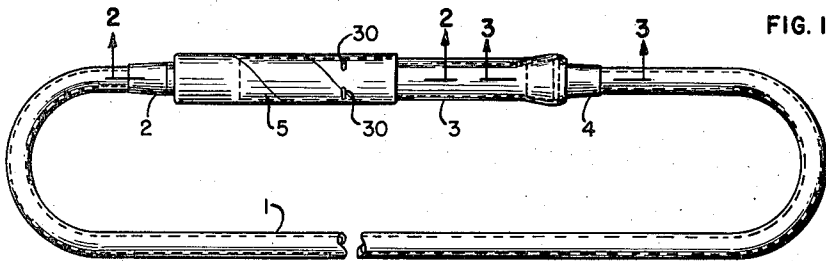


FIG. 1

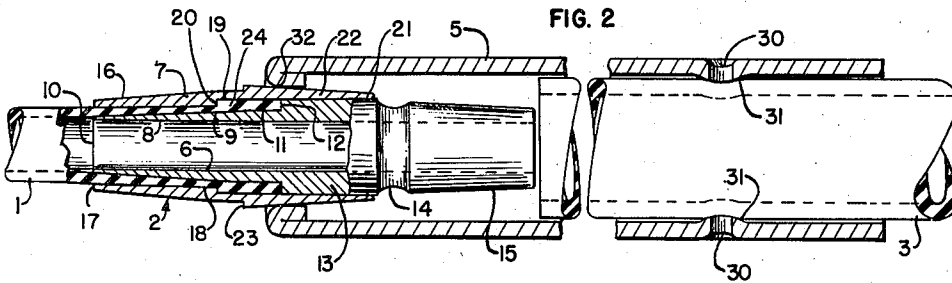


FIG. 2

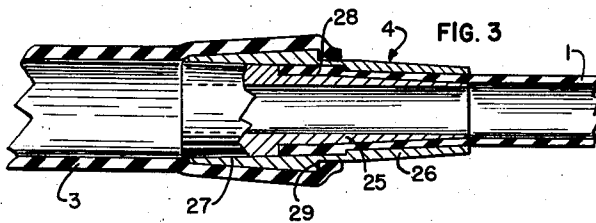


FIG. 3

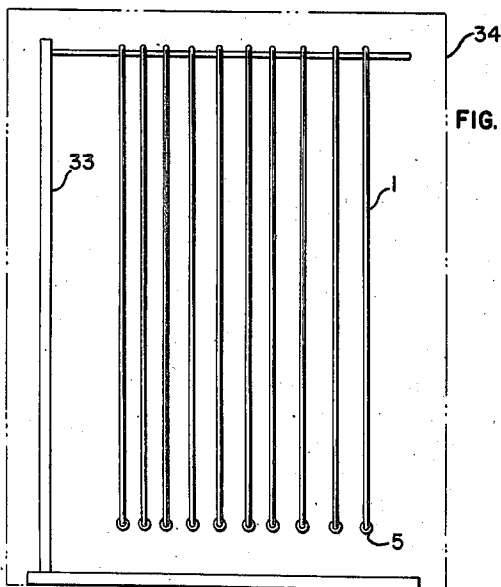


FIG. 4

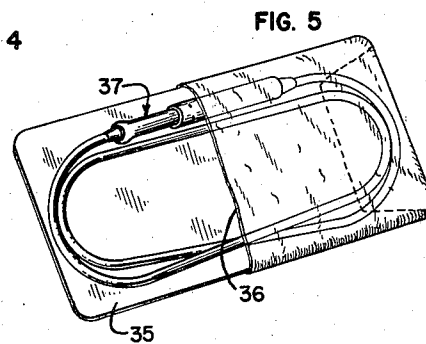


FIG. 5

INVENTOR  
MACK R. FIELDS

BY

*Loans, Pond & Anderson*

ATTORNEYS

## UNITED STATES PATENT OFFICE

2,452,643

## DISPOSABLE VENOCLYSIS SET

Mack R. Fields, Chicago, Ill., assignor to Abbott Laboratories, North Chicago, Ill., a corporation of Illinois

Application May 23, 1946, Serial No. 671,736

5 Claims. (Cl. 128—214)

1

This invention relates to an improvement which may be called a disposable venoclysis set, such as sets comprising sterilizable tubing and fittings which are packaged and delivered to the user in sterile condition ready for the intravenous administration of various solutions or fluids.

High grade natural rubber tubing has commonly been employed for this purpose. Because of its relatively high cost, and because of its scarcity in recent years, it has been uneconomic and impractical to dispose of such tubing after use and it has been the practice to sterilize the tubing from time to time to permit its initial and re-use. Resterilization and re-use of such tubing has been generally considered somewhat objectionable because of uncertainty of the effectiveness of the sterilizing operation and certain adverse effects thereof. Nevertheless, because of a lack of a satisfactory substitute, rubber tubing and repeated sterilization and re-use has been the practice.

Certain relatively inexpensive synthetic thermoplastic tubings have been found to be satisfactory for the purpose so far as their chemical activities are concerned. Such tubing, however, upon being subjected to sterilizing heat tends to lose its resiliency which is required for holding the tube on the discharge nipple of a fluid container and on a needle adapter. Furthermore, small sizes of the thermoplastic tubing could be employed so far as flow capacity is concerned, but such smaller sizes would not permit the application of the tubing to the container nipples or needle adapters which are constructed to receive the rubber tubing which is generally used for the purpose, such tubing normally having an internal diameter of about  $\frac{1}{8}$  of an inch. Thermoplastic tubing having an internal diameter of about  $\frac{3}{64}$  of an inch would provide sufficient flow capacity, and the cost of such tubing would be sufficiently low to permit the same to be discarded after a single use.

The main object of the present invention is to provide a single use disposable venoclysis tubing set, and this object is attained by the provision of fittings whereby small diameter thermoplastic tubing as above referred to may advantageously be employed in the place of the conventional larger rubber tubing.

Other objects of the invention are to provide a disposable venoclysis set which, after production, may be sterilized without impairing the usefulness of the set even though the normal resiliency of the tubing is somewhat impaired by

2

the heat of sterilization; to provide means for handling the set for sterilization purposes and which means will also facilitate effective sterilization of the interior of the elements of the set; to provide a means for facilitating handling of the sterilized set without contaminating any of the vital parts when the set is to be attached to a fluid container and to a needle; to provide a compact, small-sized packaged set of the character indicated which may be made up in sterile condition and of such character as to preserve the sterility of the set until the package is opened.

Other objects and advantages of the invention will be understood by reference to the following specification and accompanying drawing wherein there is illustrated a disposable venoclysis set embodying a selected form of the invention.

In the drawing:

Fig. 1 is a side elevation illustrating the opposite end portions of the improved disposable venoclysis set;

Fig. 2 is a section on the line 2—2 of Fig. 1;

Fig. 3 is a section on the line 3—3 of Fig. 1;

Fig. 4 is a diagrammatic illustration representing a sterilization set up; and

Fig. 5 is a perspective illustrating a form of package which may be employed for distribution of the improved set.

In the drawings there is illustrated a length of relatively small diameter synthetic thermoplastic tubing 1 having secured to one end a fitting 2 which is an adapter for attachment to the usual injection needle, and having secured to its other end a short length 3 of larger diameter rubber tubing such as has been more or less conventionally employed in connection with the giving of large volume intravenous injections from container bottles and the like. The rubber tubing 3 constitutes an adapter for attaching one end of the tubing 1 to the discharge or outlet nipple of the container bottle and a fitting 4 is provided for connecting one end of the tubing 1 to the rubber tube connector or adapter 3.

For purposes which will presently be explained, the needle adapter 2 has an end portion inserted into one end of a paper tube or sleeve 5, and the adapter element 3 similarly has a portion of its length inserted into said tube 5.

The tubing 1, which for most purposes should be about four (4) feet in length, may advantageously be made of any suitable material. Because of cost considerations, tubing made of synthetic thermoplastic material is preferred. Tubing made of such material is also advantageous because of the practicality of producing it with

## 3

a very uniformly dimensioned passageway throughout its length. Such thermoplastic materials are initially flexible and resilient and otherwise rubber-like, and they are available in substantially transparent form. To keep the cost of the set low enough to make it economically practicable to dispose of the unit after a single use, small diameter tubing is desirably employed. In the present instance, tubing of the character indicated having an internal diameter of about  $\frac{7}{64}$  of an inch is employed, the wall thickness of the tubing being .020 inch with a tolerance of plus or minus .005 inch. These sizes are referred to merely by way of example and are not essential or critical.

The needle adapter 2 by which one end of the tube may be connected to the usual injection needle comprises an inner or core member 6 and an outer collar or sleeve member 7, these parts being made of metal such as an aluminum alloy which is non-corrosive and non-oxidizing at standard autoclaving procedure whereby sterilization is effected by super-heated steam at a pressure of fifteen (15) pounds per square inch which gives a temperature of 250° F. The metal should be non-corrosive and non-oxidizing under such autoclaving procedure for a period of at least a half hour.

The core member 6 is in the form of an elongated tube having a constant diameter bore extending from end to end thereof and an end portion 8 of frusto-conical form to provide a tapered external surface 9 which is adapted to be inserted into an end portion of the tube 1 as best shown in Fig. 2. At the inner end 10 of the core part, the thickness of the wall of the part is very small as indicated and said thickness gradually increases until a cylindrical surfaced portion 11 is reached. Said cylindrical portion 11 is of relatively short length and terminates in an outwardly extending shoulder 12 whereby the thickness of the core part is substantially increased to provide a thick intermediate portion 13. Outwardly of the intermediate portion 13, the core part embodies a concave surfaced neck 14 and a tapering outer end portion 15, said neck and outer end portion being of such form as to cooperate with the conventional needle attaching grips.

The outer collar or sleeve portion 7 of the fitting comprises an end portion 16 of frusto-conical form both inside and out. The taper of the inside of the portion 16 is somewhat less than that of the portion 8 of the core, thereby the space between the portions 8 and 16 is gradually reduced as it approaches the median portion of the fitting. The space between the walls at the inner end 17 may be slightly greater than or substantially correspond to the wall thickness of the tubing 10 so that the space at an inwardly disposed point such as represented at 18 will be at least slightly less than the normal wall thickness of the tubing.

The sleeve 7 has an internally recessed portion 19, that is to say that the bore of the member 7 is enlarged at 19 relative to the bore of the portion 16 at the point 18 so as to form a forwardly or outwardly facing shoulder 20. The bore from the shoulder 20 to the outer end 21 of the sleeve is also of frusto-conical form and it is so proportioned that the outer end portion 22 of the sleeve will be a drive or press fit on the correspondingly formed outer surface of the intermediate enlarged core portion 13.

## 4

To assemble the terminal fitting on the tube 1, the sleeve 7 is first threaded over the tube and moved inwardly beyond the end of the tube a short distance. The core part 6 is then inserted until the end of the tube abuts the shoulder 12 or at least closely approaches the same. Then the sleeve member 7 is pulled outwardly to overlap the core part and the tubing portion about the inner end portion of the core part, or, to put it in another way, the tubing with the core element inserted is pushed into the sleeve which may be held or supported by a suitable means engaging an external shoulder 23 formed on the sleeve.

Because of the converging relationship of the inside wall of the inner portion 16 of the sleeve and the outside wall of the inner portion 8 of the core, some of the material of the wall of the tube 1 will be squeezed out into the recess or enlargement formed beyond the internal shoulder 20 of the sleeve. A tube end enlargement 24 will thus be formed on the tube as an integral portion thereof.

When the tube with a fitting as described is subjected to the heat of sterilization in an autoclave as above mentioned, the expanded portion of the tubing between the core and sleeve portions of the fitting will lose a substantial portion, if not all, of its resiliency and will take a set which, in the absence of some positive locking element such as the tube end enlargement 24 and the shoulder 20 on the sleeve, would readily pull off the tapered core portion 8. So long as the tubing maintains its normal resiliency, it has a satisfactory grip on the core part so that the sleeve element 7 together with its function could be dispensed with. However, when the resiliency of the tubing is impaired, and the tubing material becomes set, the grip of the tubing on the core part will usually be so greatly impaired as to preclude reliance on such grip for the purpose of maintaining the tubing in place on the adapter.

By the described sleeve and core construction, the tube is very strongly anchored to the adapter fitting. The sleeve is anchored directly to the core part by the above-mentioned drive fit of the sleeve portion 22 on the core portion 13.

As shown, the tubing 1 is of such size that its external diameter is less than the internal diameter of the bottle adapter tube 3. Cost is thereby kept down. However, this difference in diameters necessitates special provision for interconnecting these elements.

For the purpose of anchoring the bottle adapter tube 3 to the other end of the thermoplastic tube 1, there is provided a fitting which is the same as the above-described needle adapter fitting except that the portions 14 and 15 of the fitting are omitted. This construction is shown in Fig. 3 where the inner or core part is designated 25 and the outer or sleeve part is designated 26. The sleeve part 26 is anchored to the core part by a drive fit indicated at 27 and an enlargement is formed on the tubing 1 as indicated at 28, this enlargement serving to anchor the tubing in the fitting in the same manner that the enlargement 24 anchors the other end of the tubing in the fitting 2.

The bottle adapter tube 3 being of resilient rubber may be slipped over the enlarged end portion of the fitting as shown in Fig. 3 so that it resiliently grips the same and it may be extended beyond the shoulder 29 of the sleeve part 26 to provide an additional grip substantially as illustrated. This provision of a metal (or other hard

material) connector fitting is desirable even though the tubes would be a gripping telescopic fit one within the other, because the rigid fitting positively prevents collapsing of one tube by the other and permits full utilization of the resiliency of the adapter tube to maintain its connection to the end of the smaller diameter tubing.

The paper or fiber tube or case 5 is preferably of spiral construction although any suitable form of tube may be employed. The case 5 may be of such internal diameter that the tube 3 will be an easy frictional fit therein, and to insure retention of the adapter tube 3 in the case, the case may be punched inwardly as indicated at 30 at three or four points around the circumference of the tube. Such inward punching produces inward projections indicated at 31 which more or less bite into or pinch the tube to more effectively hold it in the case.

The end of the case 5 is inwardly rebent as indicated at 32 to provide an end portion on the case of reduced internal diameter which will be such as to snugly fit around the portion 22 of the needle adapter fitting. The fitting may be frictionally held in place in the tube by being pressed tightly into the tube. However, if the case 5 is made of paper board having a varnish or other finish coating of a thermoplastic character on its outside surface, that coating will become softened and tacky due to the heat of sterilization and will upon cooling and setting serve as an adhesive between the surface of the rebent portion 32 of the case and engaged surface of the needle adapter.

The paper tube 5, when pricked inwardly to improve its hold on the rubber adapter tube 3, will present slight but sufficient space between portions of the tube 3 and the interior of the paper tubing to permit leakage of sterilizing steam between the parts and to the interior of the tube and fittings so as to equalize the pressure inside and outside of the set during autoclaving. Circulation within the tube is thereby permitted so that excess moisture will not be trapped inside of the set but will be carried off during the sterilizing process.

A venoclysis set, as above described, or a plurality of such sets, each set constituting in effect an endless belt, may be assembled and supported on any suitable form of stand represented at 33 in Fig. 4, and such an assembly of sets placed in an autoclave chamber represented diagrammatically at 34. In the autoclave, steam is admitted for sterilizing purposes, and it has been found that effective sterilization is produced under about fifteen (15) pounds of steam, i. e. the temperature of 258° F. The heat to which the sets are thus subjected for sterilization purposes tends to soften the coating on the paper board case 5 to effect adhesive bonding of the intumed portion 32 thereof to the needle adapter as already explained. This adhesive bond is, however, readily broken by manual effort when it is desired to remove the needle adapter from the case as when putting the set into use.

A desirable package structure for dispensing and storing the sets is represented in Fig. 5. It consists of a paper board backing member or card 35 and an envelope 36 of suitable transparent material, preferably heat sealable Cellophane or like material which will be capable of enclosing the card 35 and one of the venoclysis sets as represented at 37 in Fig. 5. The package may be produced under sterile or aseptic conditions or it may in its entirety be subjected to sterilization

if desired so as to insure the desired sterile condition of the venoclysis set enclosed in the package.

When the unit is to be placed in use, the envelope 36 is suitably opened and the venoclysis set removed from the package. Then the rubber tubing bottle adapter is withdrawn from the protective case 5, this being readily done while gripping the case in one hand and the exposed portion of the bottle adapter tube in the other. Thus, it is unnecessary to touch and possibly contaminate either the end portion of the needle adapter or the free end portion of the bottle adapted tube which may be easily applied to the outlet nipple or a sterile dispensing bottle cap. While these operations are being performed, the needle adapter remains enclosed in the protective case 5 so that there is practically no danger that such needle adapter will become contaminated. When the unit is properly attached to the dispensing cap, the needle adapter is withdrawn from the protecting case 5 and the required needle applied to the needle receiving portions 14 and 15.

The thermoplastic tubing need not be transparent to the extent that the tubing is clear, but its transparency is desirably such that when the needle is properly inserted into a vein, the back flow of blood through the needle and into the tubing can be readily sighted. Thus it can be made certain that the needle is properly inserted into a vein before starting the flow of material into the vein. The rate of flow of solution from the bottle into the vein may conveniently be adjusted by means of a pinchcock applied to the rubber tubing bottle adapter element in preference to the application of a clamp to the less resilient thermoplastic tubing.

By means of adapter fittings such as described, the thermoplastic tubing may supplant rubber tubing in various arrangements to thereby eliminate the economic necessity for sterilizing and reusing the rubber tubing. The substitution of the inexpensive disposable thermoplastic tubing for the relatively costly tubing is advantageous not only from a cost standpoint, but also from a pathological standpoint for the reason that it has been found to be quite difficult to effectively sterilize long lengths of rubber tubing, and for the further reason that there is some evidence that the heat of sterilization tends, in some cases, to cause the formation on the surface of the rubber, of material which may have an adverse effect on the fluid being injected into a patient or on the patient.

Changes in the described arrangement may be made without departing from the invention.

I claim:

1. A venoclysis set comprising a length of tubing and a terminal fitting on one end of said tubing, said terminal fitting having a tubular core part and a sleeve part, said core part having a stem portion inserted into one end of said tubing and a diametrically enlarged portion projecting from said tubing end, there being a laterally extending shoulder interconnecting the outer surfaces of said stem and enlarged portion of the core part and said shoulder being operative to limit insertion of said stem portion into the tubing by engaging the end of the tubing, said sleeve part being disposed around at least a portion of both said stem portion and said diametrically enlarged portion of said core part with the tubing interposed between said stem portion and the surrounding portion of said sleeve, one end portion of said sleeve having a larger diameter bore than the other end portion and the

larger diameter portion fitting tightly on said diametrically enlarged portion of the core part so as to anchor the sleeve part in fixed relation to the core part, the smaller diameter portion being disposed around said stem portion of the core part, there being a laterally extending shoulder interconnecting the large and small diameter portions of said bore of the sleeve and said last mentioned shoulder being disposed intermediate the length of said stem part, said stem part and the surrounding small diameter bore portion of said sleeve being so proportioned relative to each other as to be operative to squeeze the tubing tightly therebetween and to deform the tubing so as to form an enlargement on the tubing intermediate said shoulders to thereby anchor the tubing in said fitting.

2. A venoclysis set comprising a length of flexible resilient tubing, an adapter tube of flexible resilient material having a larger internal diameter than said length of tubing, and a needle adapter, said adapter tube and said needle adapter being secured respectively to the opposite ends of said length of tubing, said needle adapter having a stem portion inserted into one end of said length of tubing and a portion projecting from said tubing, and a tubular connector interconnecting said adapter tube and said length of tubing, said connector having a stem portion seated tightly in the other end of said length of tubing and a portion projecting from said last mentioned tubing end, said projecting portion of said connector having an external diameter which is larger than the internal diameter of said adapter tube and being inserted into said adapter tube with the latter stretched around and resiliently gripping said projecting portion of said connector.

3. A venoclysis set comprising a length of flexible resilient tubing, an adapter tube of flexible resilient material having a larger internal diameter than said length of tubing, and a needle adapter, said adapter tube and said needle adapter being secured respectively to the opposite ends of said length of tubing, said needle adapter having a stem portion inserted into one end of said length of tubing and a portion projecting from said tubing, and a tubular connector interconnecting said adapter tube and said length of tubing, said connector having a stem portion seated tightly in the other end of said length of tubing and a portion projecting from said last men-

tioned tubing end, said projecting portion of said connector having an external diameter which is larger than the internal diameter of said adapter tube and being inserted into said adapter tube with the latter stretched around and resiliently gripping said projecting portion of said connector, and a protector for the free end portion of said adapter tube and said projecting portion of said needle adapter, said protector comprising a member having tubular end portions, one end portion being of larger internal diameter than the other, the end portion of larger internal diameter enclosing said free end portion of the adapter tube and having gripping engagement with the latter to retain its free end portion within said protector, the protector and portion of smaller diameter enclosing the projecting portion of said needle adapter and having gripping engagement with a portion thereof to retain the same within said protector.

4. Venoclysis equipment according to claim 3, in which the protector has a thermoplastic coating on the portion thereof which grips the needle adapter, the set including said protector in assembled relation as set forth in claim 3 being heat sterilized and said thermoplastic coating being thereby made tacky and caused to adhesively unite said needle adapter and protector so as to more securely retain said projecting portion of the needle adapter within said protector.

5. Venoclysis equipment according to claim 4, wherein the protector consists of a paper tube having a rebent intumed portion forming said protector end portion of smaller internal diameter, the outer surface of said paper tube having a thermoplastic coating thereon which, on the intumed rebent portion, contacts said needle adapter to provide said adhesive attachment of the needle adapter to the protector.

MACK R. FIELDS.

#### REFERENCES CITED

The following references are of record in the file of this patent:

#### UNITED STATES PATENTS

| Number    | Name     | Date          |
|-----------|----------|---------------|
| 16,450    | Phillips | Jan. 20, 1857 |
| 2,346,334 | Shaw     | Apr. 11, 1944 |
| 2,367,806 | Shaw     | Jan. 23, 1945 |