

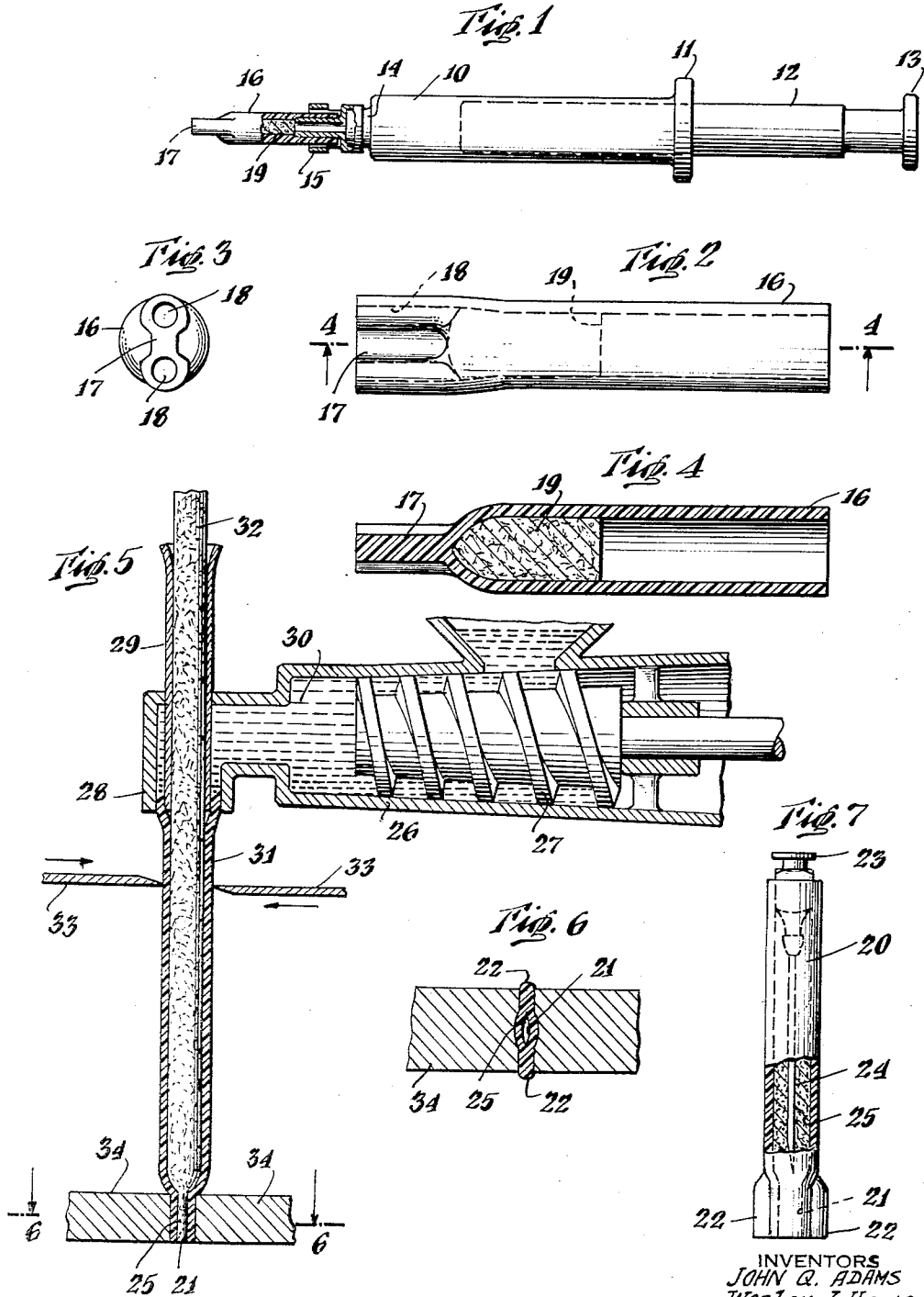
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SHEATH AND METHOD OF MANUFACTURING SAME

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SHEATH AND METHOD OF MANUFACTURING SAME

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5 Claims. (Cl. 128—218)

This invention relates to a structurally and functionally improved sheath especially intended for association with the top of a hypodermic syringe or to enclose the shank of a hypodermic needle. The invention also contemplates an improved method for the manufacture of a shield of this type.

By means of the present teachings, a sheath is furnished which, after the parts have been cleaned, may be applied to a hypodermic syringe barrel or to a cannula. Thereupon, the assembly may be disposed in an autoclave with assurance that complete sterilization will be achieved and no displacement of the sheath will occur. Therefore, in a syringe assembly no conditions of vacuum or pressure buildup will be encountered; the assembly being capable of storage for long periods of time without danger of the parts enclosed within the tip becoming contaminated.

Moreover, a sheath or shield embodying this invention may be manufactured at a relatively nominal figure and by means of procedures which are capable of practice by relatively unskilled operators. The resultant device will be adequately rugged and capable of maintaining a sterile condition of the parts for indefinite periods of time.

With these and other objects in mind, reference is had to the attached sheet of drawings illustrating practical embodiments of the invention and in which:

Fig. 1 is a side elevation of a syringe assembly with the sheath applied thereto;

Fig. 2 is a side elevation in enlarged scale of the sheath illustrated in Fig. 1;

Fig. 3 is an end view of the unit;

Fig. 4 is a longitudinal sectional view taken along the line 4—4 in the direction of the arrows as indicated in Fig. 2;

Fig. 5 is a somewhat diagrammatic sectional side view of apparatus by means of which the method of manufacturing shields may be practiced;

Fig. 6 is a transverse sectional view taken along the line 6—6 in the direction of the arrows as indicated in Fig. 5; and

Fig. 7 is a side elevation of a further shield especially useful when employed to enclose a hypodermic needle.

Referring primarily to Fig. 1, the numeral 10 indicates the barrel of a hypodermic syringe which adjacent its rear and open end is provided with a flange 11. Extending into the fore of the barrel is a plunger 12 having an actuating portion 13. The forward end of the barrel terminates in a tip which is preferably integral with its body. All of these several parts are conveniently formed of glass. The integral tip portion has been indicated at 14 and may amount a fitting 15. That fitting is ordinarily of metal and forms what is commonly known as a Luer coupling to receive and retain the hub of a hypodermic needle.

In order to maintain the sterility of the exterior surfaces it has been customary to mount upon the syringe tip a cap which protects the parts. Aside from the ex-

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pense involved in the manufacture of caps of this nature, difficulties have been experienced with the caps in position during autoclaving operations. This was because the caps when mounted provided tight seals and thus prevented the circulation of relatively high temperature steam or gases through and in contact with the surfaces of the syringe assemblies adjacent the tips thereof. Where attempts were made to apply the caps to the syringe tips after autoclaving, the expense was obviously increased incident to the care which had to be exercised and time necessary to such a procedure.

Where a sheath is involved which is to be applied to the syringe tip, a form of construction found to be especially desirable is illustrated in Figs. 2, 3 and 4. This will involve a body 16 preferably formed of vinyl plastic which will be non-toxic and non-pyrogenic. The rear or tubular end of this body will embrace a diameter such that it may be received within the bore of fitting 15. In any event, it should intimately embrace the tip 14 of the syringe so as to furnish a protective cover for the surfaces of the latter and irrespective of whether a metallic fitting is present or not. The forward end of the sheath may be flattened as at 17 and provide a pair of bores or passages 18, one to each side of the axis of the unit, or holes adjacent the end portion of the tube. The one or more apertures are closed adjacent their inner ends by a pledget 19 of preferably non-absorbent cotton. As especially shown in Fig. 4, this plug will extend rearwardly within the bore of body 16 for a suitable distance, so that it will provide a proper filter in the case of flow of air, gas or steam under pressure. Its length should not be so great that upon application of tube 16 to the syringe tip 14, the edge zone of the latter will substantially compress the pledget.

A similar type of shield has been illustrated in Fig. 7 in which a relatively long tubular body has been indicated at 20. One end of this body is flattened to define a constricted bore portion 21 which may extend in line with its axis and to either side of which constricted zones in the form of fins 22 exist. It will be apparent that the constriction might include numerous other configurations. The opposite end of tube 20 defines a bore diameter such that it may frictionally embrace the hub 23 of a cannula 24. The body of the latter will be housed within the bore of tube 20. Hub 23 may be mounted upon a syringe tip, provide the end of a blood donor assembly be being coupled to the end of a suitable tube, or embrace the sole unit which is initially associated with the needle.

The bore of body 20 may be filled with cotton robing indicated at 25. This material, in common with the pledget, should be preferably non-absorbent. In manufacturing sheaths of this type, as shown in Fig. 7, an apparatus such as has been schematically shown in Fig. 5 may be employed. That apparatus will produce vinyl tubing by what might be an extrusion process. It will include, for example, an encasing member 26 within which a screw 27 turns in any desired and acceptable manner to feed the material. The casing terminates in a discharge nozzle 28 concentrically disposed with respect to and spaced from a tube 29. The latter has its delivery end adjacent the edge of the nozzle. This tube in conjunction with the nozzle will define an annulus such that if the material 30 is expressed from the member 26, a vinyl plastic tube 31 will be formed. This tube will have the required diameter which, due to the characteristics of the material, will enable it to fit (within limits) needle hubs or similar portions embodying different diameters.

There is fed through the tube 29 a body of cotton robing 32, which in the finished unit illustrated in Fig. 7 is identified by the numeral 25. It is apparent that if, as illustrated, this material be arranged in the form of a

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continuous strand, it will completely fill the bore of tube 31. In any event, it will be encased by that tube.

The latter may be severed into suitable lengths as it is discharged from the nozzle by, for example, a pair of cutting blades 33. Conveniently operating in synchronism with these blades are forming jaws 34. The latter, especially as shown in Fig. 6, have their cooperating faces recessed. This will result in the formation of bore portion 21. Also, due to the camming action produced as jaws 34 move towards each other the material of the roving will be constricted within the smaller diameter of bore 21. So constricted it will be held against displacement within the tube body 20.

It is apparent that in both of the sheaths illustrated an adequate passage exists for the escape of gases and the flow of steam into the interior of the shield so that complete sterilization of the parts is assured by an autoclaving procedure. The nonabsorbent cotton filter will function as a barrier to air borne bacteria. With a sheath applied to the syringe tip it becomes unnecessary to individually wrap each syringe assembly after sterilization. Also, expensive containers for the syringes need not be employed. The sheath will maintain the sterility of the parts during storage and when the syringe or contained needle is to be used, it may be stripped off and discarded.

This removal of the sheath will be facilitated due to its flattened configuration which at its end zone will provide a finger grip. The material employed to provide the shield or sheath may specifically be a co-polymer of vinyl chloride. Regardless of whether the shield is applied to the tip 14 of a syringe or the tip defined by a hub such as 23, it should be mounted in sealing relation to the surface in question while the parts are still wet.

In the case of a syringe assembly, the plunger 12 will, of course, be fully projected or seated in the barrel prior to application of the sheath or shield. This will prevent contamination. In the case of the structure shown in Figs. 1 through 4, the passages 18 will furnish openings to either side of the sealed zone 17 to allow for proper venting of air and passage of steam or gas during sterilization. The same will be true of the single passage 21 in the case of the structure shown in Fig. 7.

It will, of course, be understood that various materials might be utilized to provide a sheath and/or filtering structure. For example, nylon could be employed where dry heat sterilization is required. This would involve approximately 320° F. for a period of one hour. Also, with such material, a non-absorbent glass fiber filter would in many instances be satisfactory. Where gas sterilization is to be employed, polyethylene as a sheath material would be satisfactory. Also, non-absorbent cotton robing could be utilized as a filter. In every instance where the pledget is introduced into the sheath after the tubing has been formed, it is definitely preferred that the

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outer sheath end embody a configuration such that this unit be retained against accidental displacement therein.

I claim:

1. A sheath for protecting parts of a hypodermic assembly, said sheath comprising a tubular body having an open end to engage with surfaces of such parts, the sheath being flattened adjacent its opposite end and such flattening being limited to an area such that at least one passage for the flow of gases exists through said opposite end.

2. In a sheath as defined in claim 1, a body of fibrous material within said sheath and parts of said material being constricted within the flattened end zone of said sheath to retain such material against displacement.

3. In combination, a hypodermic needle having a pointed end, a hub secured to said needle in spaced relationship to its point, a tubular sheath having an open inner end, the bore surface adjacent such end sealingly engaging the surfaces of said hub, said sheath extending around and beyond the pointed needle end and being flattened at its outer end and such flattening being limited to an area such that at least one passage for the flow of gases exists through such outer end.

4. In a hypodermic assembly in combination a bored tip structure, a sheath embracing a tubular body receiving said tip structure, said sheath being formed with an opening adjacent that end which is opposite said tip structure and relatively depressed portions integral with said sheath and embracing compressed parts to both sides of said opening.

5. In a hypodermic assembly in combination a bored tip structure, a sheath embracing a tubular body receiving said structure, said sheath being formed with a pair of passages adjacent that end which is opposite said tip structure, and the adjacent end zone of said sheath being flattened to furnish an air-impervious part intermediate said passages.

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