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METHOD OF PREPARING A PACKAGED PARENTERAL SOLUTION

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FIG. 1

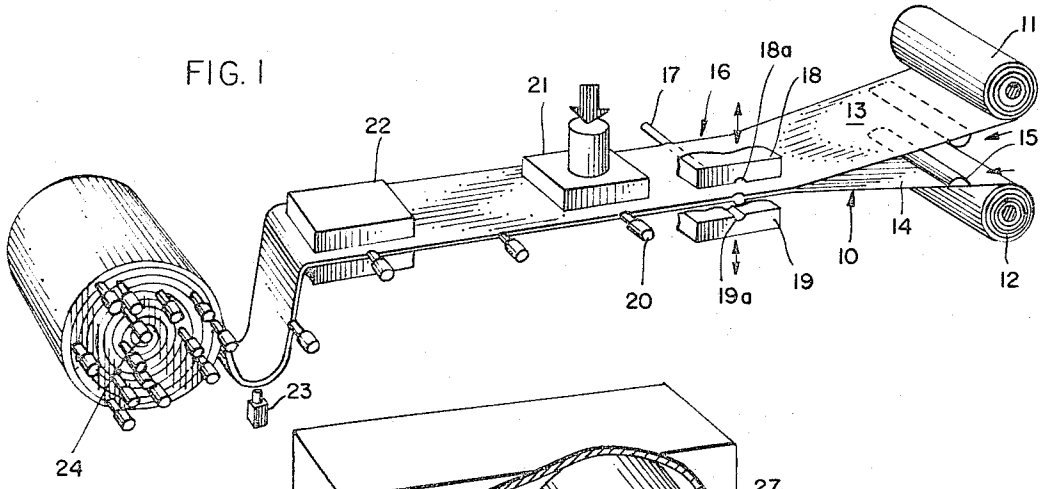
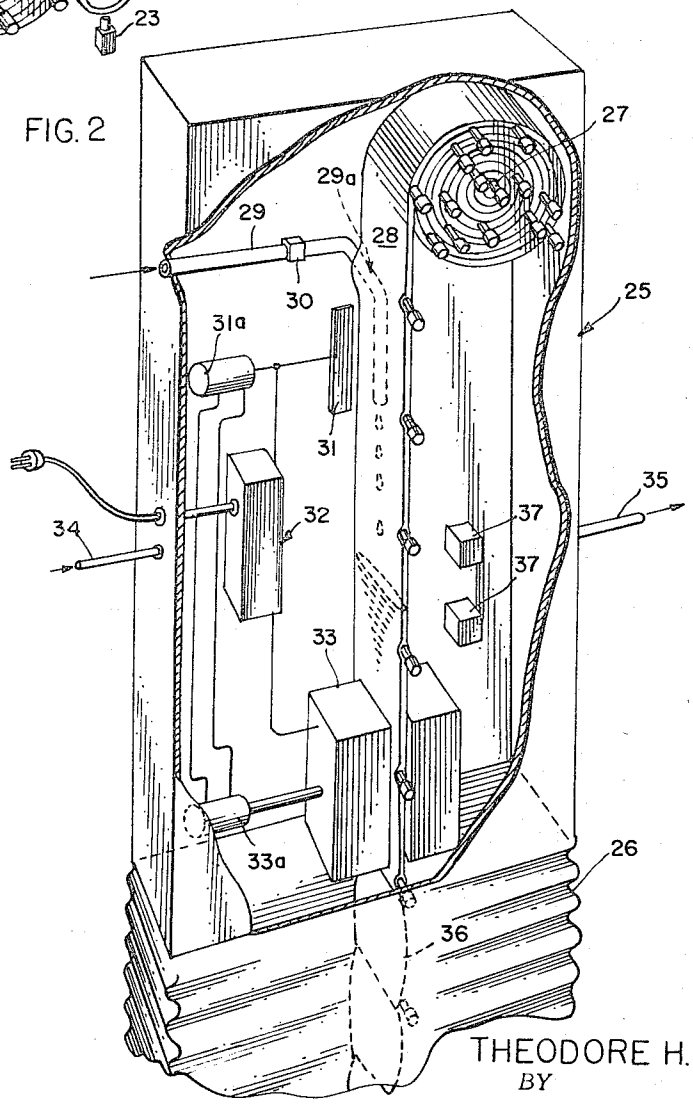


FIG. 2



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METHOD OF PREPARING A PACKAGED PARENTERAL SOLUTION

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This invention relates to a method of preparing a packaged parenteral solution, and, more particularly, to a method utilizing unique conditions of sterilization.

Historically, parenteral solutions have been packaged and sterilized in either of two ways. The first type of packaging employed glass bottles and utilized heat sterilization. This procedure was advantageous in having available the advantages of batch techniques wherein the bottles were filled as a group and then only representative samples checked for sterility. A later development in packaging, and one deemed more desirable from the standpoint of transportation, marketing, etc., is that of using plastic bags. Two outstanding advantages of plastic bags were ability to absorb shock without breakage, and relatively minor disposal problems. However, such plastic bags are severely damaged by the normal method of heat sterilization of the complete units. The plastic material undergoes shrinkage and distortion and the heat also causes leeching of impurities from the bags into the solution. The rate of discards experienced is much higher than can be tolerated commercially. For the reasons, the packaging of intravenous solutions in plastic bags has never become a practical commerical reality in spite of the great desire for such units by hospitals and the armed forces.

Gas sterilization of the filled units is not possible since the solution itself cannot be gas sterilized. Sterile fill techniques have been considered but they would not make available the advantages of batch techniques, particularly insofar as checking sterility is concerned, and the provision of a sterile fill technique which does have available this significant advantage constitutes an important object of the invention.

Other objects and advantages of the invention may be seen in the details of construction and operation set down in this specification.

The invention is explained in conjunction with the accompanying drawing, in which—

FIG. 1 is a schematic perspective view of apparatus for developing the plastic bag utilized in the practice of the invention; and

FIG. 2 is a schematic perspective view of apparatus for sterile filling of the partially-formed bags developed by the apparatus of FIG. 1.

In the illustration given and with particular reference to FIG. 1, the numeral **10** designates generally webbing which is seen to include an upper web **13** derived from a first parent roll **11**, and a lower web **14** developed from a second parent roll **12**. As the webs are unwound from the respective parent rolls, they are cleaned of occluded impurities by vacuum cleaning hoods or shoes **15**. Thereafter, the unwound webs **13** and **14** pass through a sealing station generally designated **16**. Provided as part of the electronic heat-sealing station **16** is a transversely retractable mandrel designated **17** which is adapted to be positioned between the upper heat-sealing shoe **18** and the lower heat-sealing shoe **19**. The shoes **18** and **19** are recessed as at **18***a* and **19***a*, respectively, to accommodate the receipt of the mandrel **17** on which is ensleeved an outlet fitting such as is depicted at **20**, immediately to the left of the heat-sealing station **16**. The fitting **20** can be seen in greater detail in my copending application Ser. No. 493,760, filed Oct. 7, 1965.

The numeral **21** designates a printing mechanism which is arranged to overprint the upper web **13** (now united along the near longitudinal edge to the lower web **14**) as the now-joined webs index forward under the action of a progressive motion pull-through mechanism **22**, or other advancing mechanism such as driven rollers.

The numeral **23** designates a pressure switch arranged to activate a take-up roller **24** which provides the partially united web in reeled form.

A further practice of the invention contemplates utilizing the apparatus generally designated **25** in FIG. 2 which is employed for sterile filling and is seen to include a generally box-like enclosure. The lower portion of the enclosure is designated **26** and includes an airtight storage receptacle for filled bags, the receptacle being collapsible for sterilization. At the extreme upper righthand portion of FIG. 2 the numeral **27** designates an arbor upon which the reeled, partially-formed webbing is mounted, the webbing as it is unwound being designated **28**. Suitable powered unwind means such as pull rolls may be employed—these being omitted for clarity of presentation. The numeral **29** designates a supply pipe which delivers parenteral solutions, i.e., glucose, saline, etc., from a sterile tank (not shown), but wherein the solution can be quickly sterilized by heat so as to prevent caramelization. The numeral **30** designates a valve interposed in the line **29**, the line **29** being seen to be equipped with an elbow **29***a* fitting into the open side of the webbing **28** so as to deliver liquid solution between the webs **13** and **14**. The opposite longitudinal margins (to those already sealed and equipped with the outlet **20**) are sealed by means of a solenoid operated die **31** which operates intermittently to seal the opposite sides together.

The progressive die mechanism, also solenoid operated, is generally designated **32** and is seen to operate a transverse sealing mechanism **33** in addition to the longitudinal sealing mechanism **31**. The mechanism **33** also functions to control the volume of solution in the bags by adjusting the squeeze given to the filled bag or web just prior to sealing. The numerals **34** and **35** indicate ports controlling the flow of sterile air in and out of the system, maintaining the same under suitable pressure.

In the practice of the invention, the reel of partially formed bags is mounted on arbor **27** and arranged so that the pipe **29** is interposed between the confronting webs **13** and **14**. Thereafter, the entire enclosure is sterilized by being subjected to ethylene oxide or like sterilizing gas for a suitable period. Thereafter, the valve **30** is opened and the already heat-sterilized solution delivered to the enclosure **25**, the mechanism **32** operating to simultaneously longitudinally and transversely seal the webbing **28** by actuating the solenoids **31***a* and **33***a*, associated with the dielectric dies **31** and **33** which are suitably connected to a dielectric generator (not shown). This results in a series of filled bags **36**, as are seen in the lower central portion of FIG. 2.

Through the practice of the invention, the parenteral product is now provided in batches which can be tested in the advantageous batch fashion not heretofore available in prior art teachings. Further, the invention makes use of transparent plastic material of substantial thickness so as to stand up in the usual parenteral solution application. The material is strong and heavy and is subjected to dielectric sealing on an intermittent basis, as outlined above. The resultant bag **36** is immediately ready for coupling to the usual parenteral administration set and by adding additional heat-sealing equipment within the enclosure **25**, suitable hangers can be provided on each bag **36**. Fluid height, both maximum and minimum, can be controlled by photocells **37** adjacent the tube **28** for regulating the setting of valve **30**.

While in the foregoing specification a detailed description of an embodiment of the invention has been set down for the purpose of illustration, many variations in the details herein given may be made by those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. A method of preparing a packaged parenteral solution, comprising sequentially installing outlet fittings longitudinally along elongated thermoplastic webbing, reeling said webbing, installing said reeled webbing in apparatus coupable to a source of [heat] sterilized solution, gas sterilizing said apparatus and reeled webbing, and thereafter introducing heat sterilized solution into said webbing while said webbing is formed into bags and while said apparatus is maintained under sterile conditions.

2. The method of claim 1 in which said webbing includes a pair of webs arranged in superposed relation with aligned longitudinal edges, said webs being edge-united incident to installing said fittings.

3. The method of claim 1 in which said bag forming is achieved through intermittent dielectric heat-sealing of transparent plastic materials to allow ready visual inspection.

No references cited.

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