ROLLING CLAMP FOR PARENTERAL SOLUTION EQUIPMENT

Cyrus R. Broman, Evanston, III., assignor to Baxter Laboratories, Inc., Morton Grove, Ill., a corporation of Delaware

Filed Apr. 14, 1960, Ser. No. 22,234
4 Claims. (Cl. 251—6)

This invention relates to parenteral solution equipment and, more particularly, to clamps means for regulating fluid flow during dispensation thereof in parenteral solution equipment.

Parenteral solutions are ordinarily provided in what is known as bulk containers—containers having a volume in the range of 150-2000 ml. In the past, these containers have uniformly been constructed of glass, but a contemporary trend is to provide the same in the form of flexible plastic bags or containers. Notwithstanding the form of the container, dispensing has been conventionally achieved by suspending the container in an inverted condition, i.e., mouth-downwardly, for gravity discharge of the fluid. The container or "bottle" is connected to the patient by means of an administration set, alternatively termed a "tube and needle set," which includes a length of tubing of the order of about four feet equipped with needles or connectors at the tube ends.

Because the fluid can be utilized only slowly by the body, the rate of flow must be restricted. Depending upon the therapy indicated, the rate of infusion may vary over the range of one-half to eight hours for administering a half liter of solution. Even the fast rates are slow compared with the free gravity flow through the tubing when the same is unrestricted. Some means, therefore, must be provided to regulate the flow and ascertain its actual rate. In the past, this has been done by the use of a clamp for the tubing such as a hemostat, and a drip tube or drop-counting device for ascertaining the rate of flow.

The drip tube construction involves an air conning chamber interposed in a length of tubing through which drops fall in a manner so that the drops are readily counted. The drop-forming tube is usually carefully constructed so as to develop drops of uniform size, i.e., 1/64 ml. Thus, the nurse attending the patient can accurately determine the rate initially and vary it during the course of administration merely by adjusting the clamp or other valve means to provide the requisite number of drops per minute.

Inasmuch as the infusion set up is static—there is an insignificantly small variation in hydrostatic head over the course of an administration, the infusion program should be able to be organized with a high degree of accuracy. This organization, however, has been frustrated because of the inadequacy of the valving means. To maintain the desired static organization, there should be no disturbance of the condition of the valving means, but in the past this has been extraordinarily difficult of achievement—primarily because of the unreliability of the valving means. A change in the valve condition during the administration may result in a significant and undesirable change in system operation. This possibility of change in condition has been tolerated in the past because it was mandatory to provide inexpensive valves or clamps. An expensive valve would necessarily have to be retained between infusions, and this raises a problem of non-availability at a critical time. Consequently, it has been found necessary to provide a valve or clamp with each administration set, the set itself being sufficiently inexpensive to be disposed of after a single use. This, of course, is desirable from the standpoint of savings in cleaning, sterilization, etc.

For a considerable period, the art workers have employed a "roller clamp" as the above-mentioned valve. This is essentially a knurled roller movably trunnioned in a tube-way, the roller being positioned relative to an inclined wall to exert varying degrees of pressure on the tubing. The principle of operation of this type of clamp was eminently suited to its intended purpose inasmuch as the "wedge"-type of action effectively extended the clamping stroke to provide a fine degree of control.

However, the roller clamps employed in the past have not measured up to the standards to which they were believed to be capable. Their principal drawback was that there was a tendency of the setting of the clamp to drift, i.e., shift of the roller, and always to a position permitting greater fluid flow. This was manifestly undesirable, since it could even result in danger to the patient's health.

Since the operation of the roller clamp necessarily comprehends a frictional contact between the roller and the tube-way to maintain the roller stationary, it was necessary to maintain this frictional engagement to achieve substantial immobilization of the roller. However, this could not be done without making the roller difficult to manipulate so as to achieve the proper setting. Thus, a compromise was struck, with the emphasis being on making the roller readily adjustable within the tube-way, which necessarily permitted the undesirable shift mentioned above. Any jiggling of the tubing being clamped promoted this undesirable shift, and this is not uncommon where the tubing is connected to the arm of the recipient.

It is a principal object of this invention to provide an apparatus for parenteral solution equipment that overcomes the problems outlined above and more particularly is characterized by a "drift-free" operation.

Another object is to provide a roller clamp uniquely constructed of a resilient plastic material which is effective to maintain a given flow setting irrespective of changes in physical conditions of the administration set with which the clamp is employed.

Still another object is to provide a roller clamp in which a tube-way is employed, the tube-way being constructed of a resilient plastic material and in which the tube-way is constructed to deform slightly in operation so as to maintain a predetermined setting.

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

The invention will be described in conjunction with an illustrative embodiment thereof, in the accompanying drawing, in which—

FIG. 1 is a fragmentary elevational view of parenteral solution equipment featuring the inventive clamp;
FIG. 2 is a perspective view of the clamp seen in FIG. 1;
FIG. 3 is a top elevational view of the clamp of FIG. 2; and
FIG. 4 is an enlarged cross-sectional view of the body portion of the clamp of the previous views.

In the illustration given, the numeral 10 designates the mouth portion of a parenteral solution bottle which is illustrated only in fragmentary form, since such structures are well known to the art. As pointed out previously, the bottle having the mouth portion 10 may be provided in a number of sizes, the more widely used sizes being 500 ml and one liter. As such, the bottles are intended for gravity dispensing through an administration set generally designated 11 and which is equipped at its upper end with a plug-in connector 12. The connector 12 extends into a passage 13 provided by a stopper or closure 14. Ordinarily, the stopper 14 is equipped with a second passage 15 in which is mounted an air tube 16. The air tube extends to a point adjacent the...
bottom of the bottle 10 (the bottom being uppermost when the bottle 10 is in the operative position seen in the drawings) and permits the entry of air to replace the liquid exiting through the administration set 11. The distal end of the set (designated 17) is adapted to be coupled to a hypodermic needle (not shown) so as to establish communication with the body of a patient undergoing parenteral therapy.

The administration set 11 includes as operative elements a drip housing 18 and a length of small bore tubing 19. The drip housing is usually only partially filled with liquid (as designated by the liquid level 20) so that a drop 21 falling from the drop-forming tube 22 can be readily seen as it passes through the air space portion 23 of drop tube housing 18. Again, all of the foregoing is conventional in the art, and the description thereof is set forth only for purposes of illustration.

For the purpose of regulating the flow of liquid through the set 11, the tubing 19 is equipped with a valve or clamp generally designated 24 and which is shown in further detail in the remaining views, i.e., FIGS. 2–4, of the drawing. The clamp 24 constitutes an improvement of a basic type known as a roller clamp, in which a knurled roller 25 is movably mounted. The clamp 24 includes a unitary body 26 (designated only in FIG. 2) which is constructed of a polypropylene resinous plastic material such as marketed by Hercules Powder Co. under the name of “Profax.” The body 26 may be conveniently molded as an integral unit, or alternatively by gluing mating portions together, if desired. The roller 25 may also be constructed of plastic material being provided at the time of fabrication with the knurls or ridges 27.

The body 26 is seen to have a pair of side walls 28 and 29 integrally joined with a bottom wall 30 so as to form a trough-like shape. As can be appreciated from FIG. 3, the top of the clamp 24 is open as at 31, as are the ends as at 32 in FIG. 4 and 33 in FIG. 2. Thus, the body 26 may be regarded as being essentially three-dimensional pyramid shape, having one open side and open ends.

The side walls 28 and 29 are each equipped with a longitudinally-extending recess, the recesses being designated by the numerals 34 and 35, respectively, and shown most clearly in FIG. 4.

Mounted for movement in the recesses 34 and 35 is the cooperating recesses 34 and 35 are notched at as 36 and 37 (seen only in FIG. 3) to provide for the insertion of the trunnions 36 and 37.

The lower end of the body 26 (the end characterized by the opening 33) is equipped with stationary jaws 40 (see FIG. 2), which permit the removable receipt of the tubing 19 as at 19a in FIG. 1. This effect a complete shut-off of fluid flow through the tubing 19 inasmuch as the tubing is clamped at 19b about the end of the lower wall 30 adjacent the opening 33. This clamping edge is designated by the numeral 41 in FIG. 4. As can be seen most clearly from a consideration of FIG. 4, the juncture between the side walls 28 and 29 and the bottom wall 30 is filleted as at 42. The fillets 42 have been found effective to maintain the angle between the side walls 28 and 29 and the bottom wall 30 against deformation, i.e., in the illustration given, about a right angle. Thus, any deformation of the bottom wall 30 by virtue of the clamping action exerted by the roller 25 tends to bring the side walls 28 and 29 together at the ends thereof remote from the bottom wall 30 and creates an additional pressure at 37 and at points adjacent to the roller 25. This results in an advantageous stabilization of the roller 25 against accidental dislodgement.

Additionally cooperating in reinforcing the body 26 are the integral struts 43 and 44 which are provided, respectively, at the large and small ends of the body 26. The top edges of the side walls 28 and 29 are parallel, as can be appreciated from a consideration of FIG. 1, and the strut 44 is positioned above the top edges, which are designated 45 in FIG. 1, while the strut 44 is positioned therebelow but still in a position effective to interconnect the top portions of the side walls 28 and 29. Additionally, the bottom wall 30 is provided with a recess or cut-out portion 46 (see FIG. 3) which is effective to provide the previously-mentioned clamping edge 41.

In the fabrication of the device, the body 26 is molded as a unit to provide the clamp support. A typical clamp body or support for conventional set tubing might have an overall length of about 17/8", a width of 5/8", and a maximum height of about 1 1/4". The trough-like body 26 may be conveniently installed on the tubing by threading the tubing 19 through the openings 22 and 23, with the smaller end 32 positioned remote from the connector 12. Thus, the pressure exerted by the liquid flowing in the tubing 19 does not tend to move the roller 25 to a position of greater flow. Thereafter, the roller 25 can be conveniently inserted into the ways provided by recesses 34 and 35 through the openings 38 and 39.

In the operation of the arrangement, the tubing 19 is clamped as by pressing the roller 25 toward the smaller end 32 by loop the tubing around the clamping edge 41 into the configuration designated by the numerals 49a and 49b in FIG. 1. Thereafter, the connector 12 is inserted into the parenteral solution bottle 10 and the set 11 filled with liquid. The filling is performed in a conventional fashion so as to preserve the air space 23 in the drip housing 18. If the housing 18 is constructed of a resilient plastic material, this material can be flexed in order to displace a portion of the air and to fill the housing 18 partially with liquid. Thereafter, the clamp 24 is opened so that all air is expelled from the set below the level 20. Thereafter, the clamp 24 is again closed and the vein puncture made. This effectively precludes the inadvertent administration of air to a patient receiving the parenteral therapy. The clamp is then opened to the position providing the desired flow rate, this being determined by counting the number of drops 21 falling per minute. As pointed out previously, the flexure of the configuration of the body 26 is preferentially achieved in the central portion of the bottom wall 30 so as to provide an advantageous immobilization of the roller 25. This is attended by additional pressure exerted on the top inner portions of the trunnions 36 and 38 by virtue of the inward shifting of the wall portions 34a and 35a (see FIG. 4).

While in the foregoing specification, I have set forth a detailed description of an embodiment of the invention for the purpose of illustrating thereof, many variations in the details herein given may be seen by those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. A flow control device for use with resilient tubing comprising a unitary body constructed of resilient plastic material, said body having elongated parallel side walls having top edges and a bottom wall angularly related to the plane of said top edges at the junction of said side and bottom walls and effective to maintain the angle between the side walls and bottom wall against deformation, said body having open ends and an open top, integral struts at each end of said body connecting the top positions of said side walls together, each of said side walls being further equipped with an elongated recess parallel to said plane, said recess projecting outwardly from said side walls and a trunnion-equipped roller member slidably, rotatably mounted in said recesses and operative to compress a resilient tube against said bottom wall and to slightly deform said bottom wall.
3,099,429

bringing the side walls together at the ends thereof remote from the bottom wall thus creating a pressure upon the trunnion roller and stabilizing said roller within said body.

2. The structure of claim 1 in which said angularly-related bottom wall necessarily results in open ends of different heights, the strut at the shorter of said open ends being positioned below said plane and the other of said struts being positioned above said plane.

3. A "drift-free" roller clamp comprising a unitary elongated body of resilient plastic material said body having an elongated interconnected bottom and side walls to define an open-ended, open top structure, fillets provided at the junction of said side and bottom walls and effective to prevent deformation of the angles formed by the side walls and the bottom, an elongated, laterally-extending recess in each side wall angularly inclined relative to said bottom wall and thereby being convergent with said bottom wall and a trunnion-equipped roller movably mounted in the side recesses and cooperating with said bottom wall to compress a tubing included therebetween to restrict flow through said tubing and to slightly deform said bottom wall thereby bringing the sidewalls together at the ends thereof remote from the bottom wall thus exerting sufficient pressure upon the roller to prevent variation in the position of the roller relative to the ends of the elongated body.

4. In a clamp for parenteral administration equipment and the like, a trough-like holder for a resilient tubing, said holder being equipped with a pair of parallel side walls and a bottom wall and a slot in each side wall inclined relative to said bottom wall and extending in parallel relation with each other, said slots being equipped with closure walls spaced outwardly from said walls and being integral therewith, and strut members interconnecting said side walls spaced from said bottom wall at opposite ends of said holder; a length of resilient tubing, a section of said tubing intermediate its length residing in said trough-like holder; a trunnion-equipped roller slidably, rotatably mounted in said recesses and operative to urge said resilient tubing against said bottom wall, and a pair of outwardly extending stationary jaws provided integral with said bottom wall whereby a section of said tubing extending beyond said trough-like holder may be folded back along said bottom wall and retained by said pair of jaws in a complete shut-off of fluid flow position without effecting the position of said roller in said trough-like holder.

References Cited in the file of this patent

UNITED STATES PATENTS

1,411,731 Kemper ---------------- Apr. 4, 1922
2,595,511 Butler ---------------- May 6, 1952
2,603,237 Van Huyning -------- July 15, 1952
2,902,248 Barton -------------- Sept. 1, 1959

FOREIGN PATENTS

36,527 Germany ---------------- of 1885