United States Patent [19]

Waterman

[11] **3,915,167**

[45] **Oct. 28, 1975**

[54] **INTRAVENOUS CLAMP**

[75] Inventor: **Neil S. Waterman,** Stamford, Conn.

[73] Assignee: **Atlantic Design & Development Corporation,** Stamford, Conn.

[22] Filed: **May 23, 1974**

[21] Appl. No.: **472,633**

[52] **U.S. Cl.** ..... **128/214 R;** 251/9

[51] **Int. Cl.²** **A61M 5/00;** F16K 7/06

[58] **Field of Search** ..... 128/214 R, 214.2, 227, 128/274; 251/4, 6, 9

[56] **References Cited**

UNITED STATES PATENTS

2,595,511	5/1952	Butler	251/6
3,135,259	6/1964	Evans	128/214 R
3,550,900	12/1970	Rolin	251/9
3,630,481	12/1971	McGay	251/6
3,724,818	4/1973	Roger	251/9

Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Buckles and Bramblett

[57] **ABSTRACT**

An adjustable fluid flow valve clamp is formed of a one-piece molded plastic body part provided with a slidably adjustable cam follower member integrally formed therewith and connected thereto by an elongated thin flexible strip of plastic material. By a first rolling and folding operation of the flexible strip the cam follower member is inserted into a longitudinal slot formed in the open planar top portion of the body part, the plastic tubing of an intravenous set is then laid into an open trough in the body part of the clamp member, the said trough having an inclined ramp formed in the bottom thereof, and by a second folding operation the planar top portion, which is connected to the body portion by an integrally formed plastic hinge, is closed and locked into the body to complete the adjustable clamp assembly.

5 Claims, 11 Drawing Figures

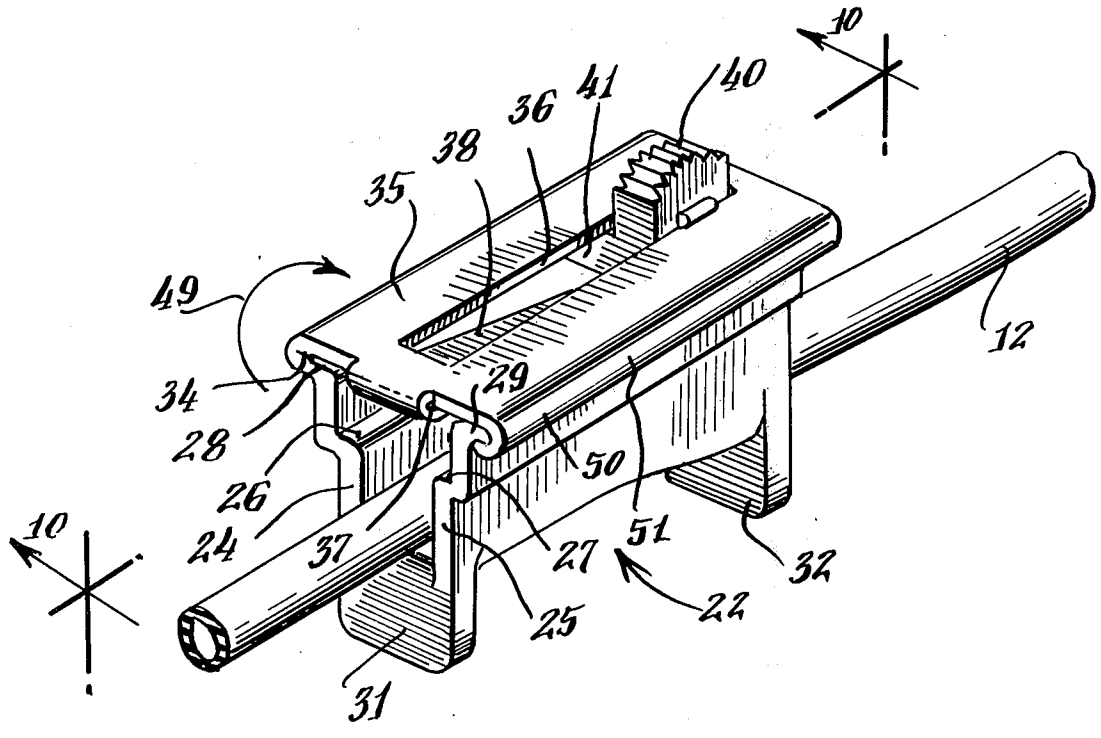


Fig. 1.
PRIOR ART

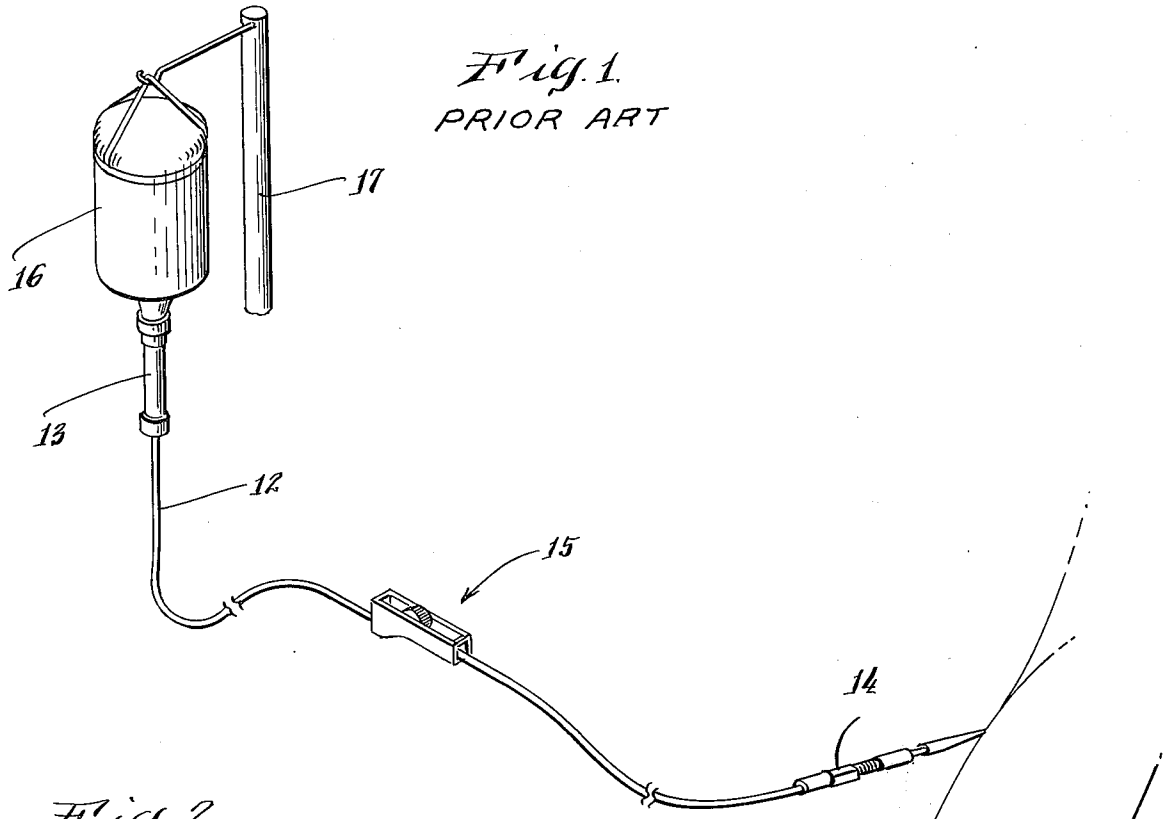


Fig. 2.

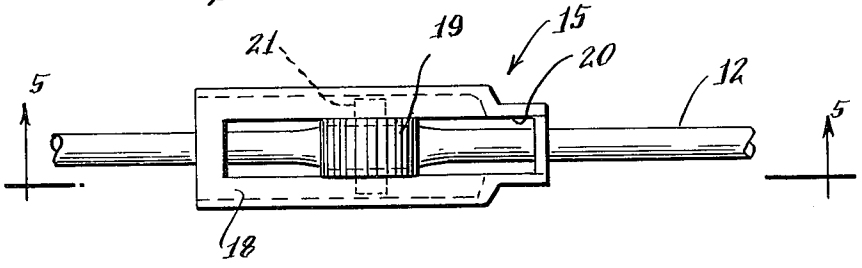


Fig. 3.

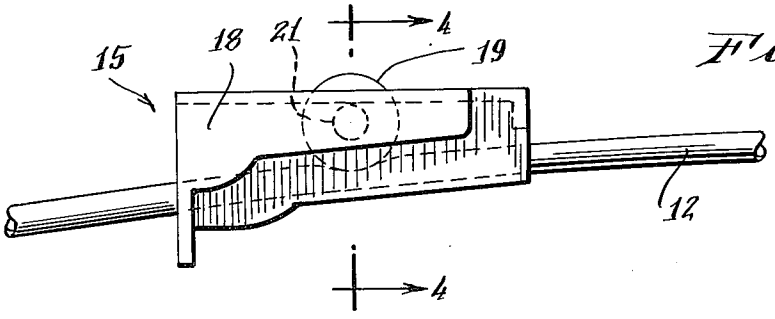


Fig. 4.

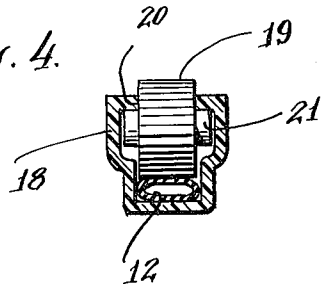


Fig. 5.

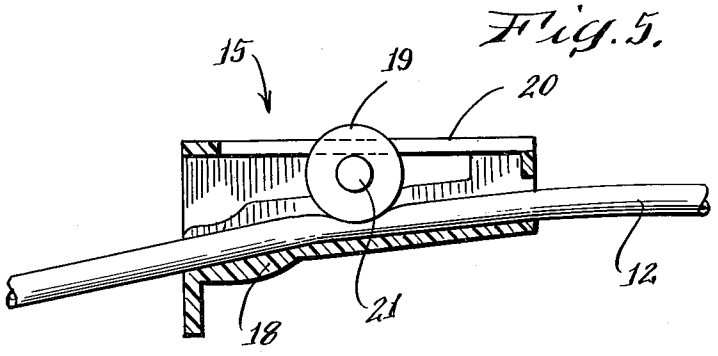


Fig. 6.

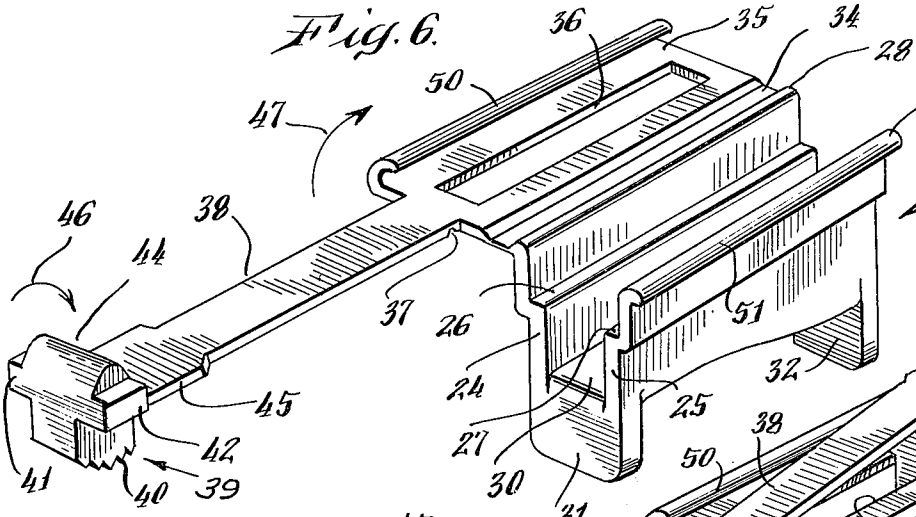


Fig. 7.

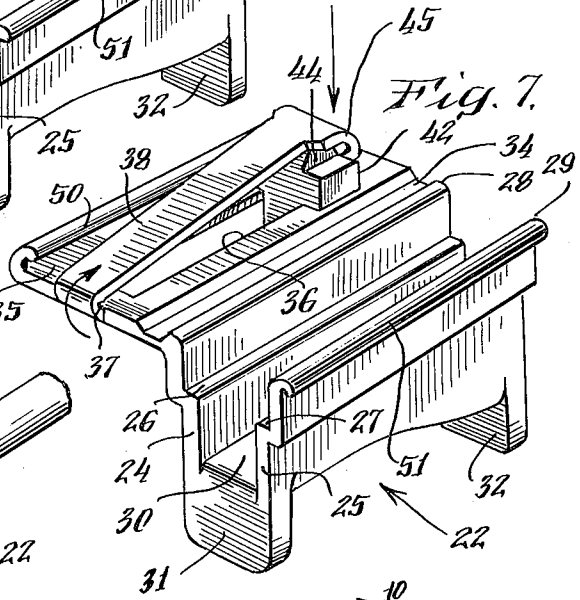
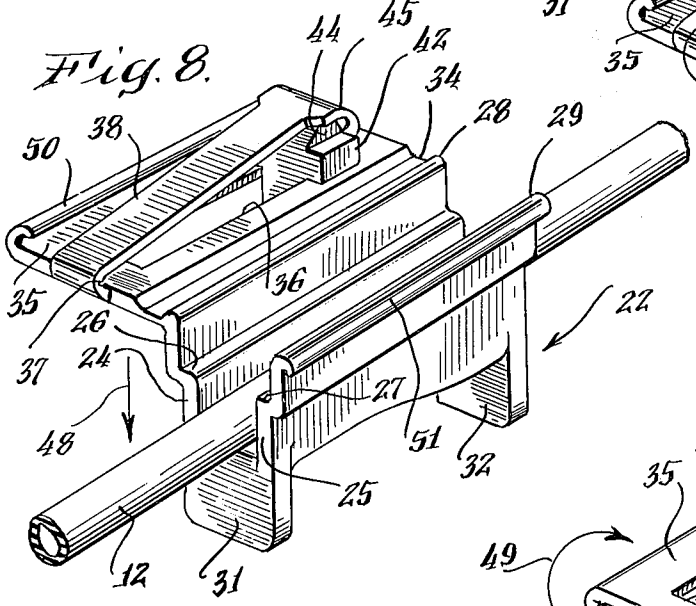


Fig. 8.



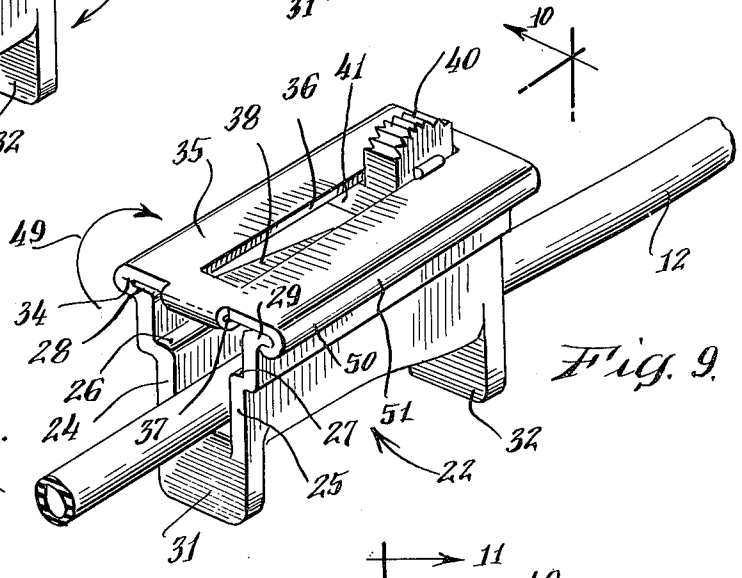
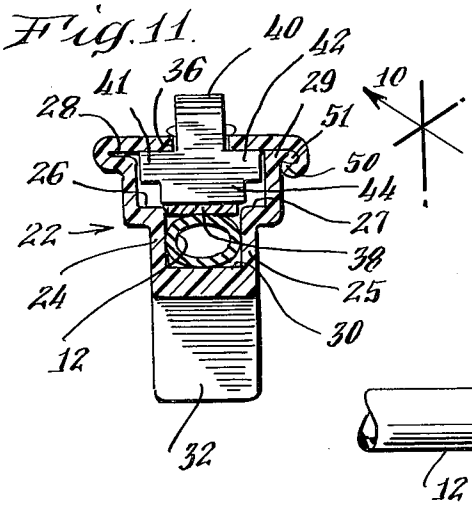


Fig. 9.

Fig. 11.



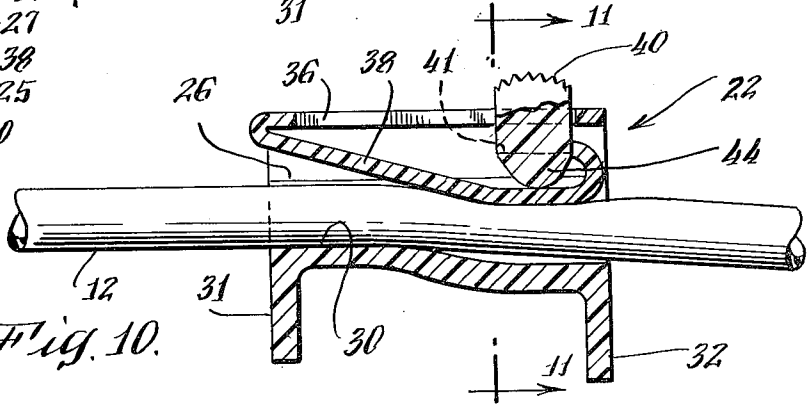


Fig. 10.

INTRAVENOUS CLAMP

BACKGROUND OF THE INVENTION

Disposable intravenous infusion equipment, widely known in the medical art as "I.V. Sets", are employed by the hundreds of millions annually for the administration of glucose, blood plasma, or medications in solution for intravenous injection into patients. Regardless of the type of fluid to be injected into a patient it is imperative that the I.V. set include a fluid flow valve or control clamp for regulating the rate at which fluid is admitted into the patient's veins. Because it is also imperative that the entire apparatus be maintained sterile and nonpyrogenic, it is impracticable to reuse I.V. sets, and so they are disposed of following each administration. This is the reason for the great volume of production and usage, and also the reason that the cost of manufacture of such apparatus must be maintained as low as possible.

PRIOR ART

The most recent, and most widely used, form of prior art I.V. set as illustrated by FIG. **1** of the drawings comprises a length of flexible transparent plastic tubing **12** having a "drip chamber" **13** connected to one end thereof, a needle adaptor **14** connected to the opposite end, and a manually operable clamp **15** therebetween. The drip chamber **13** has a spike at its outer end (not shown) which connects it with a solution container **16,** which in turn is suspended from a bedside stanchion **17** above the patient. An intravenous infusion needle is affixed to the needle adaptor **14** and inserted into the vein of a patient's arm as shown.

As shown in detail by FIGS. **2** through **5** the prior art clamp comprises a hollow body member **18** having a knurled roller wheel **19** within a longitudinal slot **20,** the wheel **19** being retained substantially within the cavity of body **18** by a rolling trunion **21,** with the inner surface of wheel **19** bearing upon the surface of the flexible tubing **12** which is passed through the longitudinal cavity of body **18.** The inner bottom surface of the cavity within body **18** slopes upwardly from one end to the other toward the top slotted portion, as shown in FIGS. **3** and **5.** Thus, as the wheel **19** is manually rolled from left to right, as shown in the drawing, it applies increasing constricting pressure on the flexible tubing **12,** thereby restricting fluid flow therethrough. If rolled all the way to the right the wheel **19** completely closes the tubing **12,** while if rolled to the extreme left the tubing is unrestricted and fully opened for maximum fluid flow. In normal practice during the administration of intravenous infusions the wheel **19** will be located somewhere intermediate these extreme positions, depending upon the prescribed drip rate as observed in chamber **13.** Once the desired drip rate has been established it is important that the setting of the clamp valve **15** remain unchanged throughout the administration of infusion, which may continue for several hours.

While the prior art apparatus of FIGS. **1** through **5** has served the medical profession admirably for some time it is nevertheless subject to some drawbacks and is therefore susceptible of improvement. One problem is that any relative longitudinal motion between the tubing **12** and the clamp **15** will result in changing the preset drip rate, because the friction between the engaged surface of the tubing and the knurled surface of

wheel **19** will cause the wheel to roll within its slot in either direction, depending upon the direction in which the tubing is pulled with respect to the clamp body. Such undesired motion may be caused inadvertently, for example, by nurses aides rendering other services to the patient, or by a somnolent or delirious patient unattended.

Another problem with the prior art is the cost of manufacture and assembly. Because of the high volume production requirements, and the desirability of keeping the unit costs as low as possible, large multi-cavity molds are employed for the molding of approximately one gross (**144**) clamp bodies at a time. Also because the clamps of the prior art are two price devices a separate mold is required for the plastic wheel part which, because of its smaller size may be molded in quantities of approximately **250** units per mold. The degree of precision required for molding two interfitting parts with tolerance for rolling motion therebetween after assembly is such that very costly molds and very costly molding operations are necessary. Even so, a very high percentage of parts must be rejected because of dimensional variations which prevent proper interfitting assembly.

A further disadvantage of the prior art device is that after the two parts (wheel and trough) have been assembled manually, it is then necessary to remove the needle holder from the end of the I.V. tube set and to laboriously manually fit the tube end through the assembled valve beneath the roller wheel, and then reassemble the needle holder on the tubing end. All of this labor adds to the end cost of the completed prior art I.V. sets.

A further drawback to the prior art as suggested above is that any inadvertent or accidental motion of the valve with respect to the tubing on which is is mounted will result in a change in the valve setting by reason of the fact that the tubing rides directly against the roller wheel. In other words, the drip rate set by the I.V. nurse is not locked into the valve but may be accidently or inadvertently changed by other attendants or by the patient.

BRIEF DESCRIPTION AND OBJECTS OF THE INVENTION

The improvement which is the heart of the invention is a unitary one-piece molded plastic valve clamp which can be manufactured at substantially lower cost than the prior art structure and which provides the operational advantage of remaining securely set at any position to which it is adjusted.

An important object of the invention is to provide an improved intravenous infusion set which can be more readily manufactured and more easily assembled, at a lower cost, than heretofore.

Another equally important object of the invention is to provide an improved fluid flow clamp valve for I.V. sets which is more reliable in maintaining any preselected setting to which it may be adjusted.

An overall object is to achieve the above objects by means requiring less manual labor in assembly of I.V. sets.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

The invention accordingly comprises an article of manufacture possessing the features, properties, and the relation of elements which will be exemplified in

the article hereinafter described, and the scope of the invention will be indicated in the claims.

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description taken in connection with the accompanying drawings, in which:

BRIEF DESCRIPTION OF DRAWINGS

As described above under "Prior Art" FIGS. 1 through 5 disclose what is believed to be the most pertinent prior art.

FIG. 6 is a perspective view of one embodiment of my improved molded plastic clamp part as it comes from the injection mold;

FIG. 7 is a similar perspective view of the same part as in FIG. 6 but with the cam follower end member rolled over the elongated strap portion and inserted into a slot formed in the top cover portion;

FIg. 8 is another perspective view like FIG. 7 but showing the plastic tubing of an intravenous infusion set placed in the open trough portion of the body part;

FIG. 9 is a further perspective view similar to FIG. 8 but showing the top cover member folded over and locked to the body portion to engage the tubing therein, thus completing the assembly;

FIG. 10 is a vertical cross-section taken along the line 10—10 of the completed assembly of FIG. 9; and

FIG. 11 is an end sectional view taken along the line 11—11 of FIG. 10.

Similar reference numbers identify corresponding parts in all views of the drawings.

DETAILED DESCRIPTION

Referring now in greater detail to FIG. 6 of the drawings, the one-piece molded plastic part which forms the clamp valve for an intravenous infusion set comprises a substantially rigid body portion indicated generally at 22, having opposed parallel sidewalls 24 and 25, on the inner surface of which are formed parallel shoulders 26 and 27 extending longitudinally throughout the length of the body 22. Above the off-set shoulders 26 and 27 the sidewalls extend vertically and parallel to upper edges 28 and 29 which are parallel to each other and to the shoulders 26 and 27. The sidewalls 24 and 25 are joined by a generally flat bottom surface 30 which is not parallel to the shoulders 26 and 27 but which slopes downwardly from the open end of the body 22 as seen in FIG. 6 to the opposite end of the body which is also open. The surface 30 thus forms an inclined ramp in the bottom of an open ended trough formed between sidewalls 24 and 25. A forward depending protrusion 31 and a similar protrusion 32 at the opposite end provide added rigidity to the body 22 and also facilitate gripping the assembled clamp in the fingers of one hand.

Still referring to FIG. 6, affixed to the edge 28 by a relieved thin portion 34 is a top cover member 35 in which is formed an elongated rectangular slot 36. Joined to one edge of cover member 35, as shown in FIG. 6, by a relieved hinge portion 37, is an elongated thin strap 38 which extends parallel to and is somewhat wider than slot 36. However, the width of strap 38 is somewhat less than the width of the body trough between sidewalls 24 and 25 of the body member 22. Affixed to (and molded integrally with) the opposite end of strap 38 is a solid slider member indicated generally at 39 which is formed with a knurled protruding handle portion 40, a pair of opposed extending shoulders 41 and 42, and a curved camming surface 44, all as shown clearly in FIG. 6. The end of the strap 38 adjacent slider member 39 is relieved by a plurality of parallel grooves 45 to make it more flexible in this area and to facilitate rolling the slider member tightly thereover in the direction indicated by the arrow 46 in FIG. 6.

In assembling the clamp, slider 39 is first rolled over onto the relieved portion 45 of strap 38, in the direction indicated by arrow 46, the rolled strap is then folded over the cover member in the direction indicated by the arrow 47, about the relieved hinge portion 37, and the protruding handle portion 40 of the slider member 39 is inserted through the slot 36 as shown in FIG. 7 of the drawings. All of these folding operations can be performed automatically by machine. The next assembly operation, which can also be done by machine, is the dropping of a length of flexible plastic tubing 12, in the direction indicated by arrow 48 in FIG. 8, into the open trough of the clamp body 22. The final step of assembly is shown in FIG. 9 wherein the top cover member 35 is folded over along the relieved hinge 34 in the direction indicated by the arrow 49 in FIG. 9. Locking means such as a curled edge 50 (FIG. 6) on top member 35 engages with corresponding means such as lip 51 on the opposite sidewall of body member 22 to permanently secure the assembled clamp valve in its final operating condition as illustrated by drawings 9, 10 and 11. Alternatively, if desired, the closed edges 50–51 may be sealed by heat fusion, or by ultrasonic welding, or in any other suitable manner.

Among the advantages achieved by the present invention are the fact that the one-piece construction of the valve clamp eliminates the prior problems of interfitting separate parts. Furthermore, an intravenous tube complete with end fittings of drip chamber and needle adaptor can be laid in the open trough of the clamp before the cover is closed, thus eliminating the need for laboriously fitting the tube end through a narrow orifice. Additionally the flexible strap construction of the clamp with integral molded plastic sliding cam follower eliminates contact between the valve adjuster and the plastic tubing, thereby preventing any transmission of motion between tubing and valve regardless of the valve setting. Thus the valve adjuster of my new device remains effectively and securely located in any position to which it is set and cannot be inadvertently or accidentally changed.

An overall advantage is that the device of the invention is less expensive to manufacture as the entire assembly can be accomplished by machine.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above article without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention which, as a matter of language, might be said to fall therebetween.

Having described my invention, what I claim as new and desire to secure by Letters Patent is:

1. An adjustable clamp valve for intravenous infusion control comprising in combination, a one-piece molded plastic body having an elongated open trough formed therein, the bottom surface of said trough forming an incline with respect to the upper edges thereof, a foldable planar top portion joined to one upper edge of said trough by a first integrally molded hinge portion, a longitudinal slot formed in said planar top portion, a thin flexible strap portion joined to one end of said top portion by a second integral hinge and extending longitudinally in alignment with said slot, an enlarged cam follower member formed at the opposite end of said strap portion and joined thereto by a third integrally formed rollable hinge portion, and a first engaging portion on the edge of said top portion opposite said first integral hinge portion engageable with a corresponding second engaging portion on the opposite edge of said trough when said top portion is folded along said first hinge portion to cover said trough.

2. The structure of claim 1 wherein said cam follower member is rolled over said third hinge portion, said strap portion is folded over said second hinge portion, said cam follower member is inserted into said longitudinal slot, said planar top portion is folded along said first hinge portion to cover said trough, and said first and second engaging portions are engaged in locking relationship.

3. The combination of claim 2 including a length of flexible plastic tubing inserted longitudinally in said trough beneath said closed top portion, whereby longitudinal sliding motion imparted to said cam follower member causes said strap portion to press said flexible tubing against the inclined bottom surface of said trough to construct fluid flow through said tubing.

4. An adjustable fluid flow valve clamp for flexible tubing comprising in combination a tubing receiving hollow body having an inclined inner surface against which a length of flexible tubing is disposed, a pair of opposed side walls of said body restraining said tubing therewithin, a substantially planar wall of said body opposite said inclined inner surface, a longitudinal slot formed in said planar wall, an elongated flexible plastic strap having one end thereof joined to said planar wall, said strap disposed within said body between said slot and said tubing, and a manually adjustable slider member connected to the opposite end of said strap and mounted in said slot to protrude therethrough, a smooth inner surface of said slider member bearing against said strap, whereby when said slider member is moved from one end of said slot toward the opposite end thereof said tubing is compressed against said inclined surface to constrict the flow of fluid therethrough.

5. An intravenous infusion set including a length of flexible plastic tubing having means at one end thereof connectable to a container of solution to be infused and means at the opposite end connectable to a venous infusion needle, and a fluid flow control clamp member insertable therebetween comprising in combination a molded plastic-body structure having an elongated open trough for receiving said tubing, a bottom surface of said trough inclined at an angle with respect to the upper edges thereof, a cover member joined to one edge of said trough by a flexible hinge, locking means on the opposite edge of said cover member engageable with corresponding locking means on the opposite edge of said trough when said cover is closed thereover by folding said hinge, a longitudinal slot formed in said cover member parallel to said trough, an elongated thin flexible plastic strap joined at one end to an edge of said cover member and at the opposite end thereof to a manually adjustable moveable member, said moveable member being inserted into said slot for applying constrictive compression to said tubing when said cover member is closed thereover in locking engagement with said body, whereby said entire clamp member is formed as a unitary molded plastic part.

* * * * *