

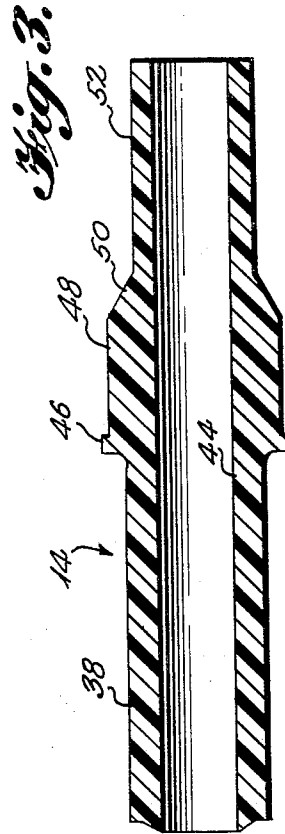
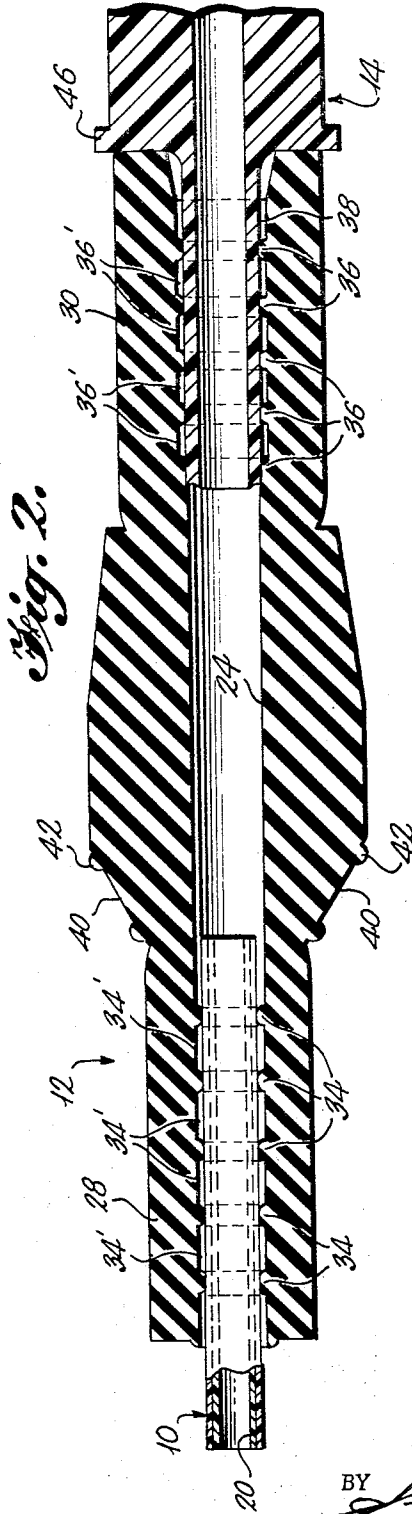
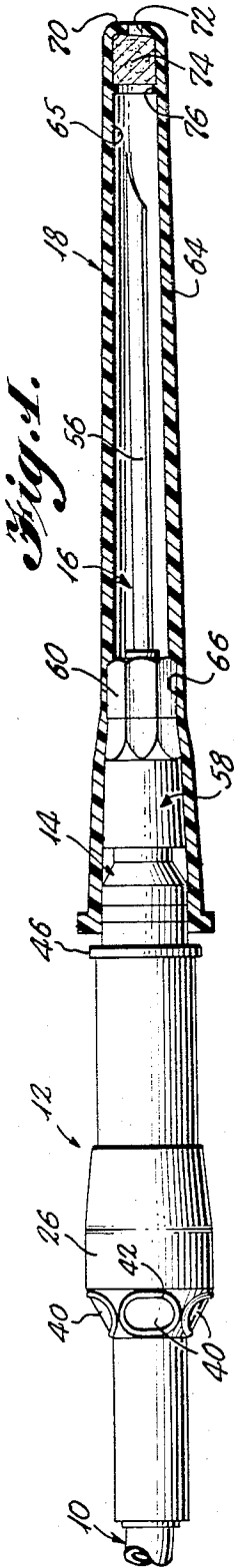
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PIERCING DEVICE GUARD AND CONNECTOR ASSEMBLY

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PIERCING DEVICE GUARD AND CONNECTOR ASSEMBLY

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ABSTRACT OF THE DISCLOSURE

A specific connector means is employed to connect the conduit means with the transparent adapter means in a piercing device. The specific connector means is formed of flexible material and has end sections and a medial section. The sections are traversed throughout by a bore of uniform diameter extending longitudinally therethrough. The bore in the end sections has a plurality of longitudinally spaced radially inwardly directed peripheral ribs semi-circular in cross-section. The medial section of the connector has a thickened wall and the bore therein is unobstructed but collapsible by the application of external pressure.

The present invention relates to a new and novel piercing device guard and connector assembly, and more particularly to such an assembly which is especially adapted for use with blood recipient sets and intravenous injection sets.

The assembly of the present invention includes a connector means which is interconnected with the conduit means or tubing which in turn may be suitably associated with a bottle or a like container having blood or an intravenous solution therewithin. The connector means is interconnected with an adapter means, this adapter means supporting a piercing device such as a hypodermic needle in the illustrated embodiment. A guard means is disposed in surrounding relationship to the piercing device, the guard means being provided with a portion which interengages the adapter means to provide a sterile seal therewith.

The guard means also includes a hole at the outer end thereof through which air is adapted to pass, and a suitable filtering means such as sterile cotton is disposed adjacent this hole for filtering air passing through the hole.

With this over-all arrangement, the sterility of the piercing device is maintained during shipment, storage, and up until the time of use of the assembly.

A particular advantage of the assembly is the fact that the hole in the end of the guard means permits the tubing of the associated blood recipient set or intravenous injection set as well as the connector means and the piercing device to be filled with a suitable fluid such as blood or an intravenous solution without removing the guard from the assembly. This is due to the fact that air may be displaced from the tubing and the associated components through the hole in the end of the guard means.

A further advantage of the present invention is the provision of an arrangement whereby the piercing device and the guard means include interengaging surfaces so that relative rotation therebetween is prevented. This enables the piercing device to be tightened on the associated adapter means without removing the guard means from the assembly and without interfering with the sterile seal provided between the guard means and the adapter means.

Accordingly, when preparing the assembly for venipuncture, the piercing device may be tightened on the adapter means and the air expelled from the assembly and filled with fluid. This of course is essential since air

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embolism is very dangerous and can be fatal to a patient. These preparations may be carried out with the guard in place, and while maintaining the sterility of the apparatus. The guard may then be removed and the apparatus is ready for immediate use.

The connector means of the present invention has a bore extending longitudinally therethrough, this bore including a free and unobstructed space within the central portion of the connector means. The connector means is made of a flexible material which may be readily compressed. When the tubing has been closed by means of the clamp associated therewith and the piercing device has been inserted into a patient, if it is desired to check to make sure that the piercing device is in a vein, the connector means is compressed at the central portion thereof and then released. This release will tend to suck blood back into the assembly to produce what is commonly referred to as "flashback." In the prior art, it has been the general practice to induce flashback into the transparent tubing connected with the assembly. In the present invention, the connector means may not have sufficient capacity to move sufficient blood so that it will be visible in the tubing, and accordingly, certain portions of the adapter means, and even the piercing device may be made of light transmitting material so that such flashback may be observed even when relatively small quantities of blood are sucked back into the apparatus.

A further important feature of the present invention is the particular construction of the connector means. This connector means is provided with a bore extending longitudinally therethrough, one end of the connector means being operatively disposed in surrounding relationship to the tubing or conduit means, and the opposite end of the connector means being operatively disposed in surrounding relationship to a portion of the adapter means. The assembly may in certain instances be under considerable pressure. In some cases, it is simply under gravity pressure, and in other instances, it may be under even greater pressure. When the assembly is subjected to such pressures, there is the ever present danger that the connector means, which is formed of flexible material, may be expanded to such an extent that it will become loose and eventually disconnected from either the tubing or the adapter means with which it is interconnected. Assemblies such as that of the present invention are required to withstand certain standard pressure tests to be acceptable, and the connector means of the present invention is especially designed to pass such pressure tests.

In the prior art, it has been the practice to provide smooth cylindrical bores within such a connector means which in turn are disposed in surrounding relationship to a smooth cylindrical surface formed on the outer surface of plastic tubing or an adapter means or the like. This type of interconnection is not suitable for withstanding some of the extreme hydrostatic pressures encountered in actual practice.

In the present invention, the connector means at each opposite end portion thereof is provided with a plurality of longitudinally spaced peripherally extending radially inwardly directed sealing ribs or rings which engage the outer surfaces of the associated components. These spaced sealing ribs cooperate with the associated members to provide a plurality of annular chambers around the associated members. The pressures in these chambers progressively decrease from the central cavity formed within the connector means. The decreasing pressures which exist in successive chambers toward the outer ends of the connector means enable the ribs which are spaced from the central cavity to provide a very effective seal with the associated members, and the pressure in the outermost chamber so formed is so small that there is virtually no possibility that the sealing engagement will

be impaired. Accordingly, the connector means of the present invention will maintain a very effective seal with the associated members even when under relatively high pressures up to approximately 38 lbs. It will be recognized that this is an important feature of the present invention since if the connector means should become accidentally disconnected from the associated members during use, a very hazardous condition may occur for the patient receiving such treatment.

The connector means of the present invention also includes means whereby suitable injections may be made into the fluid passing through the connector means. Portions of the connector means are adapted to receive a needle, and the connector means is formed of a material which is self-sealing so that when the needle is withdrawn, the connector means will re-seal itself.

An object of the present invention is to provide a new and novel piercing device guard and connector assembly which is especially adapted for use with blood recipient sets and intravenous injection sets.

Another object of the invention is the provision of such assembly which maintains sterility of the piercing device while the assembly and the associated components are being filled with solution and air evacuated therefrom, and further wherein the piercing device may be tightened on the adapter means while maintaining such sterility.

A further object of the invention is to provide such an assembly including light transmitting portions which enable flashback to be observed before the flashback blood reaches the connector means.

Still another object of the invention is the provision of such an assembly including means for ensuring that the connector means maintains an effective sealing engagement with the associated members.

A still further object of the invention is to provide such an assembly wherein the connector means includes means for enabling ready injection of solutions into the solution passing through the connector means.

Yet another object of the invention is the provision of such an assembly which is quite simple and inexpensive in construction, and yet which at the same time is quite efficient and reliable in use.

Other objects and many attendant advantages of the invention will become more apparent when considered in connection with the specification and accompanying drawings, wherein:

FIG. 1 is a view partly in longitudinal section illustrating the assembly of the present invention;

FIG. 2 is a longitudinal section on an enlarged scale through the connector means of the present invention; and

FIG. 3 is a longitudinal section through the adapter means of the present invention.

Referring now to the drawings wherein like reference characters designate corresponding parts throughout the several views, the assembly is shown in FIG. 1 wherein a conduit means or tubing 10 is illustrated, this tubing generally being formed of a transparent flexible plastic material, the end of this tubing being suitably interconnected with other components of blood recipient set or an intravenous injection set as desired. It will be understood that the tubing is generally provided with some sort of clamping means for controlling the rate of flow of liquid through the tubing, and that the tubing is generally empty until suitably interconnected with a container having suitable liquid therein.

The tubing 10 is interconnected with the connector means indicated generally by reference numeral 12 which in turn is operatively connected with an adapter means indicated generally by reference numeral 14. A piercing device indicated generally by reference numeral 16, and which may comprise a relatively conventional hypodermic needle, is operatively mounted upon the adapter means 14, and a guard means 18 is disposed in surrounding relationship to the piercing device,

Referring now particularly to FIG. 2 of the drawings, the connector means 12 is formed of a suitable flexible material which is re-sealable when punctured, and in a typical example may comprise surgical grade rubber latex. The connector means is provided with a bore extending longitudinally therethrough, and the tubing 10 extends within the left-hand end of the bore as seen in FIG. 2. An insert 20 which may be of stiffer material than that of tubing 10 is provided within the tubing 10 only at the end thereof and preferably just within that portion which is disposed within the connector means and perhaps slightly outwardly thereof. This insert 20 serves to reinforce the tubing and to prevent it from collapsing when the connector means is disposed thereabout.

The connector means defines a central substantially unobstructed space 24, and it will be noted that the space in the central portion of the connector means is surrounded by an enlarged wall portion 26, while substantially cylindrical end portions 28 and 30 extend from either side thereof.

Each of these end portions is provided with means for providing an effective seal with the elements associated therewith. End portions 28 and 30 are provided with ribs 34 and 36 which are longitudinally spaced from one another and extend peripherally about the bore formed in the end portions and extend radially inwardly. The inner ends of ribs 34 engage the outer surface of tubing 10 to provide a plurality of annular chambers 34'. In a similar manner, the inner portions of ribs 36 engage the outer surface 38 of the adapter means 14 to provide a plurality of annular chambers 36'.

The inner diameters of ribs 34 and 36 are so dimensioned that the ribs are stretched to place them under tension which serves to provide a very effective seal with the associated members and one that is superior to that which would be obtained if the ribs were simply in light contacting engagement with such members. As pointed out previously, the annular chamber nearest to the central spaced will have the greatest pressure therewithin, while the pressure will decrease in a direction toward the outer ends of the connector means. Accordingly, the pressure in the outermost annular chamber at each end of the connector means is negligible, and accordingly the ribs adjacent such annular chamber will maintain a snug and effective seal with the associated members.

As seen in FIG. 2 of the drawings, the two end portions 28 and 30 have been expanded by forcing them over the ends of tubing 10 and the outer surface 38 of the adapter means respectively. It will be noted that these end portions bulge out slightly from the central portion of the connector means, and this expansion causes pressure to be concentrated on the ribs pressing against the associated members. As noted in FIG. 2, the inner surfaces of the ribs have been flattened due to the pressure applied thereto, it being understood that in their uncompressed free form, these ribs have a generally semi-circular cross sectional configuration.

The connector means is also provided with a plurality of so-called injection targets 40 which may be four in number and which may be defined by outwardly extending ribs 42 to define an area which is generally oval in shape. These injection targets are positioned at an angle of approximately 30 degrees to the longitudinal axis of the connector means, and when a needle is inserted through the central portions of one of these targets and substantially perpendicular thereto, the needle will then properly enter the central space 24 within the connector means to permit a suitable solution to be inserted into the liquid passing through the connector means during normal operation of the apparatus.

The thickened wall portions 26 are of sufficient flexibility to enable the central portion of the connector means to be readily compressed so as to collapse the connector means when it is desired to create a flashback of blood into the apparatus.

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Referring now to FIG. 3, the adapter means of the present invention is illustrated. The adapter means may be formed of a suitable plastic such as translucent polypropylene, polystyrene, or clear transparent rigid plastic material and the like, the adapter means including a longitudinally extending bore 44 formed therethrough. The previously described outer surface 38 joins with a radially outwardly directed flange 46 which limits movement of the adapter means into end portion 30 of the connector means. The flange 46 joins with a generally cylindrical outer surface 48 which in turn joins with an inwardly tapered surface 50 from which extends an outer surface 52 which may comprise a conventional Luer tapered surface.

Referring now to FIG. 1, the piercing device 16 includes a hollow cannula portion 56 and a hub portion 58. These components may both be formed of metallic substance if desired, and in some instances the hub portion as well as the cannular portion may be formed of a plastic. In the present invention, it is anticipated that the hub portion 58 of the piercing device may be formed of a plastic which is light transmitting material so that blood may be observed through this hub portion. The hub portion is also provided with a non-circular outer surface 60 which may be substantially hexagonal in configuration. The hub portion is provided with a recess therewithin which has a Luer taper corresponding to the tapered outer surface 52 so that the hub portion may be tightly fitted on the portion 52 of the adapter means.

As seen in FIG. 1, the guard means 18 comprises an elongated body means 64 formed of plastic material. Body means 64 has a bore 65 formed therewithin and extending throughout the length thereof. Body means 64 includes an inner wall portion 66 which is complementary to the outer surface 60 of the hub of the piercing device, inner wall 66 fitting snugly about portion 60 so that no relative rotation may occur between the guard means and the piercing device in the operative position shown in FIG. 1. The body means 64 flares outwardly toward the left as seen in FIG. 1 and terminates in an open end portion having a flange 68 extending laterally therefrom. This open end portion of the guard means engages the outer surface of the adapter means, and the body means may be provided with a peripherally extending inwardly directed sealing rib similar to that shown in my copending patent application Ser. No. 480,630, filed Aug. 11, 1965, now Patent No. 3,370,588 issued Feb. 27, 1968, such rib engaging the outer surface of the adapter means to provide a sterile seal therewith.

The end wall 70 provided at the outer end of the guard means is provided with a central hole 72. A suitable filter means 74 is disposed adjacent hole 72, and in a typical example may comprise sterile cotton. An inwardly extending peripheral flange 76 is provided in the guard means for maintaining the filter means in the operative position shown.

The sterile cotton filter means will ensure that a sterile seal is maintained within the guard means until the apparatus is ready for use. On the other hand, it should be noted that the filter means will allow air to be expelled from the apparatus when it is being filled with a suitable liquid, thereby maintaining the sterile seal while such operation is taking place.

It is apparent from the foregoing that there is provided according to the present invention a new and novel piercing device guard and connector assembly which is particularly adapted for use with blood recipient sets and intravenous injection sets. The assembly includes a guard means including a sterile filter means which maintains sterility of the piercing device until it is ready to be used, and which enables the escape of air as the set and tubing assembly is being filled with a suitable fluid. In other words, the guard may remain in place while

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this operation is being carried out. In addition, the piercing device may be tightened in operative position on the adapter means without removing the guard means and while maintaining the aforementioned sterile seal. The adapter means, the hub of the piercing device and the guard means may all be formed of suitable light transmitting material such as plastic or the like whereby flashback of blood within the apparatus may be observed once venipuncture has been accomplished. In a typical example, after the clamp has been closed and venipuncture has taken place, the central portion of the connector means may be compressed and then released to draw blood back into the apparatus. The presence of blood may be observed through the adapter means and the hub portion of the piercing device. The connector means is provided with a plurality of longitudinally spaced ribs at either end portion thereof to ensure that the connector maintains an effective sealing engagement with the associated members, and to ensure that the connector means will not become loose or disengaged from such members. The connector means also includes means for enabling the ready injection of other solutions into the liquid passing through the connector means. The apparatus of the present invention is quite simple and inexpensive in construction, and yet at the same time is quite efficient and reliable in use.

As this invention may be embodied in several forms without departing from the spirit or essential characteristics thereof, the present embodiment is therefore illustrative and not restrictive, and since the scope of the invention is defined by the appended claims, all changes that fall within the metes and bounds of the claims or that form their functional as well as conjointly cooperative equivalents are therefore intended to be embraced by those claims.

I claim:

1. A piercing device connector assembly for use in administering parenteral fluids, comprising conduit means, connector means formed of flexible material and having one end portion thereof operatively connected with said conduit means, needle adapter means, the opposite end of said connector means being operatively connected with said adapter means, a hypodermic needle operatively connected with said adapter means, said connector means having end sections and a medial section and a bore of substantially uniform diameter extending longitudinally through said connector from end to end, the inner surface of said bore in said end sections having a plurality of longitudinally spaced radially inwardly directed peripheral ribs substantially semi-circular in cross section adapted to engage the outer surfaces of said conduit means and said adapter means respectively to provide a plurality of annular chambers therewith and to provide an improved seal with the conduit means and the adapter means, and the medial section of said connector having a thickened wall and being unobstructed and collapsible by the application of external pressure.

2. Apparatus as defined in claim 1 wherein said transparent adapter has a thickened portion intermediate its ends formed with a cylindrical outer surface having a stop flange at one end and a tapering surface at its other end.

3. An assembly for use in administering parenteral fluids comprising conduit means, connector means formed of flexible material and having one end portion thereof operatively connected with said conduit means, needle adapter means, the opposite end of said connector means being operatively connected with said adapter means, a hypodermic needle operatively connected with said adapter means, said connector means having end sections and a medial section and a bore of substantially uniform diameter extending longitudinally through said connector from end to end, the inner surface of said bore in said end sections having a plurality of longitudinally spaced radially inwardly directed peripheral ribs substantially

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semicircular in cross section adapted to engage the outer surfaces of said conduit means and said adapter means respectively to provide a plurality of annular chambers therewith and to provide an improved seal with the conduit means and the adapter means.

4. Apparatus as defined in claim 3, wherein the medial section of said connector has a thickened wall and being unobstructed and collapsible by the application of external pressure.

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