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Morgan

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[54] **EXTRA CORPOREAL BLOOD ACCESS SITE**

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[51] **Int. Cl. A61m 05/00;** A61m 01/03; F16l 11/12

[58] **Field of Search**..... 128/214 R, 214.2; 138/103, 138/151; 285/423, DIG. 16

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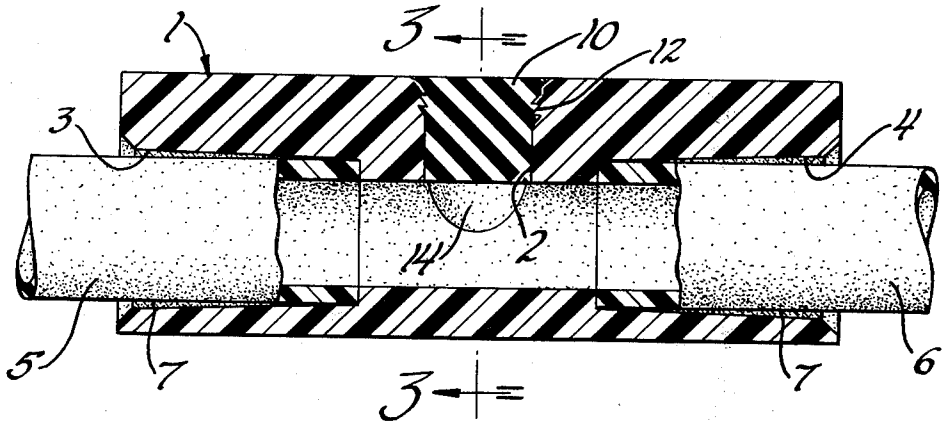
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[57] **ABSTRACT**

In accordance with the invention there is provided an extra-corporeal blood access site comprising a blood-passage tube of rigid material having an opening through a wall thereof and a body of a relatively soft resilient needle-penetrable material in and sealing the opening in the tube, said body being under radially inward compression from substantially the entire periphery thereof.

8 Claims, 3 Drawing Figures



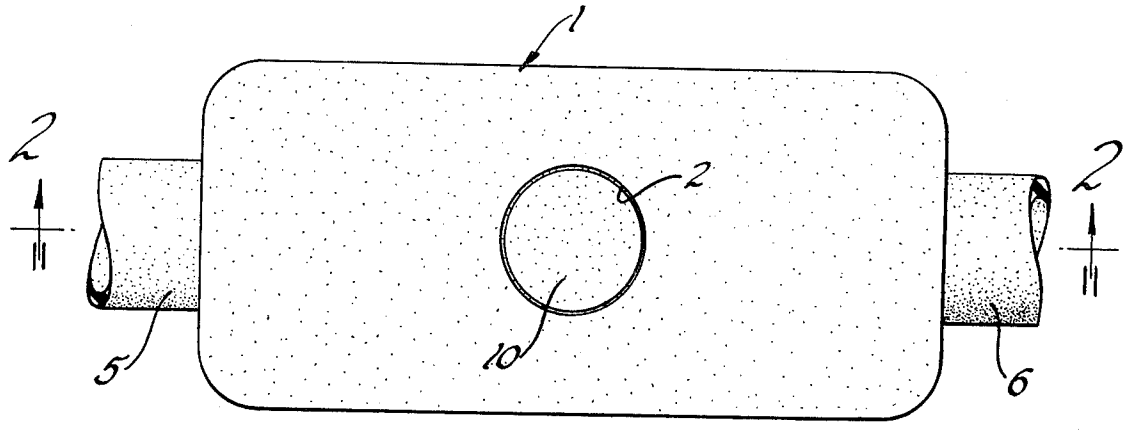


Fig. 1

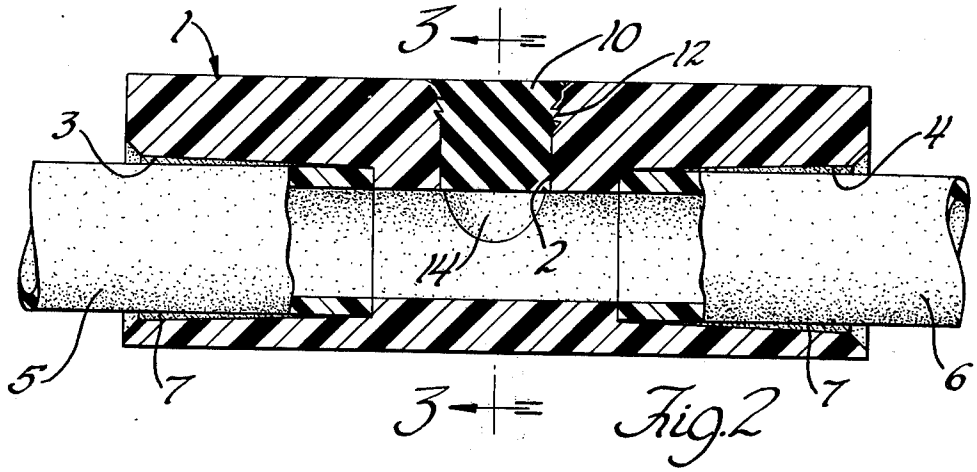


Fig. 2

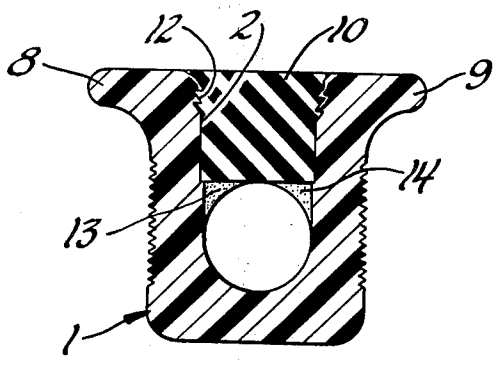


Fig. 3

EXTRA CORPOREAL BLOOD ACCESS SITE

The subject matter of the present invention is an extra-corporeal blood access site for use in withdrawing blood samples from, or in administering medicants to, a patient's blood flowing through a tube external of the patient. Typical uses of the invention are in blood-passage tubes between a patient and an artificial kidney or between a patient and a blood-oxygenator during open heart surgery.

In blood-passage tubing sets provided for or with artificial kidneys, for example, it is desirable, and in fact deemed necessary at the present state of the art, to provide one or more blood access sites to easily enable, by means of a syringe and hypodermic needle, withdrawal of blood samples or the injection of heparin or other medicants into the blood. In the design and construction of such blood access sites it is desirable to accomplish the following to the greatest extent possible. First, the blood access site should enable easy passage of the syringe needle therethrough for withdrawal of the blood sample or injection of the medicant. Second, and as an adjunct to the aforesaid, the site should provide optimum protection against the needle passing entirely through the tube with resultant hazard of the needle entering into the hand of the medical attendant administering the needle. Third, the site should be rapidly self-sealing such that upon withdrawal of the needle there is immediately and thereafer maximum assurance against any leakage of blood through the hole made by the needle and, even more importantly, maximum assurance against any leakage of air into the blood. Fourth, the site should be such that it does not contaminate the blood, this by not just having minimum toxicity but also by providing optimum assurance against there being debris from the needle puncture. Fifth, the construction of the blood access site should be such as to cause minimum turbulence to the flow of the blood past the site since turbulence increases the hazard of blood coagulation.

The principle object of the present invention is to provide an extra-corporeal blood access site which accomplishes the combination of the aforesaid desirable features. Briefly, this is accomplished in accordance with the invention by a blood access site which comprises a blood passage tube of relatively rigid material having an opening in a wall thereof, the opening being sealed by a relatively soft resilient needle-penetrable material which is under radially inward compression from substantially the entire periphery thereof. As will be discussed in detail hereinafter, a key feature of the invention is that the relatively soft resilient needle-penetrable material is in radial inward compression from substantially its entire periphery. This optimizes self-sealing.

FIG. 1 is a top view of a preferred embodiment of the invention;

FIG. 2 is a view taken on the line 2—2 of FIG. 1; and

FIG. 3 is a view taken on the line 3—3 of FIG. 2.

Referring now to the drawings, the blood access site shown comprises a tube 1 of relatively hard material, preferably a rigid organic resin, having a cylindrical opening 2, through a wall thereof. The bore of the tube is enlarged at the ends thereof, as shown at 3 and 4, to accommodate the ends, 5 and 6 respectively, of the tubing through which the blood circulates. The ends of the tubing are secured into the enlarged bore ends by

cement as shown at 7. The bore ends can be slightly tapered, as shown, to facilitate inserting of the ends of the tubing therein and to accommodate the cement. Generally the tubing used is of plasticized polyvinyl chloride and a suitable cement is polyvinyl chloride dissolved in cyclohexanone or other suitable solvent. The diameter of the inner ends of the enlarged bore portions is substantially the same as the outer diameter of the tubing and the diameter of the cylindrical center portion of the bore, into which the opening 2 extends, is substantially the same as the inner diameter of the tubing. Hence, there is no significant change in the diameter of the blood passage as would tend to cause turbulence.

In the preferred embodiment shown, the external shape of the tube 1 is such that it has a T-shaped cross-section, this by reason of a pair of outwardly extending flanges 8 and 9. The flanges provide increased protection for the fingers of the medical attendant administering the syringe needle to the blood access site against accidental puncture by the needle.

Within and sealing the opening 2 is a body 10 of soft resilient needle-penetrable material which is under radially inward compression from the entire cylindrical periphery thereof. This compression is accomplished by forming the cylindrical body 10 to a larger diameter than that of the opening 2 and then forcefully pressing the body into the opening thereby to cause the radial inward compression. The wall thickness of the portion of the tube wall through which the opening 2 extends is substantially the same as that of the body 10.

As can be seen from the drawings, in the most preferred embodiment the thickness of the body 10 (i.e. the dimension axially of the opening) in its compressed state is about the same as the width or diameter of the body. Different ratios can be used but it is preferable that the thickness of the body in its compressed state be at least equal to one-half its diameter but not greater than one and one-half times its diameter. Where the thickness is greater, needle penetration is more difficult with no attendant advantage. If the thickness is less than one-half the diameter, then there can be resultant bulging or arching of the soft resilient body in a direction axially of the opening thereby relieving the radially inward compression on the body. In all cases it is desirable that the thickness of the body 10 in its compressed state be greater than the length of the tapered end portion of the syringe needle used since this assures that at such time as the point of the needle enters the blood, the upper end of the tapered needle portion will be within and hence sealed by the compressed resilient body 10. Taking into account the different sizes of syringe needles that might be used, it is preferred that the thickness of the body in its compressed state be at least about 0.15 inches.

In operation, the syringe needle is caused to pass through the compressed resilient body 10, until the end of the needle is within the bore of the tube 1 and hence in the blood passing through the tube. After the medicant is applied or the blood sample taken, the needle is withdrawn and by reason of the radially inward compression and the resilience of the body, the opening left by the needle upon its withdrawal immediately becomes sealed. To better assure against any withdrawal of the body 10 when the needle is withdrawn, the wall of the opening 2 can be formed with projections, preferably in the form of a spiral thread 12. In the particu-

lar embodiment shown the continuous spiral thread has a tapered cross-section tapered in a direction toward the bore of the tube thereby enabling easy insertion but difficult withdrawal of the body **10.** It will be understood, of course, that prior to insertion into the opening the resilient body **10** need not, and preferably should not, have a thread to mate with that of the opening since the mating shape is impressed into the body upon its insertion into the opening by reason of the resilience of the body. If desired, the body of resilient material can be further secured against withdrawal by cementing it within the opening or by cementing or otherwise securing to the upper surface of the tube **1** a ring which lays over and extends to both sides of the periphery of the opening and the body and thereby mechanically blocks the withdrawal of the body from the opening.

Any of a variety of organic resins, inert with respect to blood, can be used for the tube **1.** Illustrative is polycarbonate resin as, for example, that sold under the trademark "Lexan" by the General Electric Company. Likewise, the resilient body **10** can be any of various organic elastomers, examples being silicone elastomer (silicone rubber) and polyurethane elastomer, the latter being preferred. Of course as is well known in the art, all materials selected for any device having contact with the blood, and hence all the materials selected for the blood access site of this invention, should have minimum toxicity. For this reason natural rubber, though it can be used, is inferior as the elastomer for the body **10.**

For the attainment of a radially inwardly compressed body **10** which provides optimum self-sealing together with relative ease of needle penetration, two factors must be taken into account, namely, (a) the elasticity of the material used for the body, and (b) the amount of compression applied which, in turn, is a function of or determined by the difference in the width of the body prior to and after insertion into the opening **2.** For the ultimate in precise calculation in this respect it would be appropriate to use as the measure of elasticity of the material its modulus of elasticity. However, there is relatively close correlation between modulus of elasticity and durometer resiliency, and as a practical matter, and for simplicity, durometer resiliency on the Shore A scale can be used. The following data and calculations relative to the most preferred embodiment will illustrate.

In the preferred embodiment shown (in enlarged scale) the body **10** is polyurethane elastomer having a durometer resiliency on the Shore A scale of about **65.** The diameter of the cylindrical body **10** prior to insertion into the opening is 0.23 inches (thickness 0.14 inches) and the diameter of the body after insertion into the opening, i.e. the diameter of the opening, is 0.197 inches (thickness about 0.165 inches).

From the aforesaid there can be calculated what will be referred to as the "compressive stress value" (CSV) on the basis of the following formula:

$$CSV = R \times \frac{D_1 - D_2}{D_1}$$

where R is the durometer resiliency on the Shore A scale of the material used for the resilient body, D_1 is the diameter or width of the body prior to its insertion into the opening and D_2 is the diameter or width of the body after its insertion into the opening.

Substituting the values given above for the preferred embodiment there results:

$$CSV = 65 \times \frac{.23 - .197}{.23}$$
$$CSV = 9.3$$

In the practice of the invention it is preferred that the compressive stress value be between **8** and **10.** It will be manifest that to fall within this range, the higher the durometer resiliency of the material used the less should be the compression applied and, vice versa, the lower the durometer resiliency of the material the greater should be the compression applied.

As has been noted above, because the center portion of the bore into which the opening **2** extends is of the same diameter and aligned with the bores of the tubing ends, there is no significant change in the diameter of the passage through which the blood flows and hence minimum turbulence to the blood. Further in this regard it bears mention that it is preferred that the cylindrical body of resilient material be inserted into the opening **2** only to the extent that the center of the bottom surface of the body is aligned with, or in the same plane as, the top (as shown) of the bore. In other words, it is preferred that the bottom end of the body **10** not enter into the bore. Since the bore is cylindrical, this means that if the bottom end surface of the body **10** is flat, there will result two shallow arcuate recesses in the wall portions of the bore immediately below the bottom surface of the body **10,** these shallow recesses being shown at **13** and **14** in FIG. **3.** If it is desired to eliminate these recesses it is only necessary to provide the body **10** with a cylindrical bottom surface of a diameter the same as that of the bore, and preferably also providing a suitable indicia on the top surface of the body, or other means, to assure that when the body is inserted into the opening the cylindrical bottom surface is aligned with the cylindrical bore. However, it is quite satisfactory to use a resilient body with a flat bottom surface, as shown, since the shallow recesses **13** and **14** in the bore cause no significant turbulence, if any turbulence at all, to the blood flow. It will be noted that in the preferred embodiment shown the opening **2** has a narrow radially inwardly extending shoulder lying in the plane of the top surface of the bore and against which the body **10** bottoms thereby better assuring that the body does not extend into the bore.

Because the tube **1,** and hence the bottom wall thereof, is of a relatively rigid material there is assurance against the syringe needle penetrating completely through the tube and into the hand of the medical attendant administering the needle. Further, the blood access site is such that it can be manufactured with relative ease and yet with optimum quality control. The tube **1** can be molded and the body **10** can either be cut from a rod of the resilient material, or molded if desired. But by far a more important feature and advantage is that by way of the radially inwardly compressed body of resilient material, the blood access site enables easy penetration by the syringe needle and yet also provides excellent self-sealing upon needle withdrawal. Still further, where polyurethane is used as the radially compressed elastomeric body, as is preferred, there is

optimum assurance against blood contamination since it has been found that such a body, for reasons not yet fully understood, results in minimum, if any, debris from the needle puncture.

Though by far the chief utility of the invention is as a blood access site, it can find other medical uses such, for example, as an access site in the tubing used for carrying dialysate to or from an artificial kidney or in the tubing used for introducing fluid into a patient's bloodstream. Further, it will be understood that while the invention has been described in detail by reference to a preferred embodiment thereof, various changes may be made all within the full and intended scope of the claims which follow.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An extra-corporeal blood access site comprising a blood-passage tube of relatively rigid material having a cylindrical opening through a wall thereof and a cylindrical body of a relatively soft resilient needle-penetrable material in and sealing the opening in said tube, said body being under radially inward compression from substantially the entire cylindrical periphery thereof, said body having a compressive stress value (CSV) of from **8** to **10** calculated on the basis of the formula $CSV = R\ X[(D_1 - D_2)/D_1]$
where R is the durometer resiliency on the Shore A scale of the material of said body, D_1 is the diameter of said body prior to insertion into said opening and D_2 is the diameter of said body after insertion into said opening.

2. An extra-corporeal blood access site as set forth in claim **1** wherein said body is polyurethane elastomer.

3. An extra-corporeal blood access site as set forth in claim **1** wherein the thickness of said body in its compressed state is at least about 0.15 inches and is from about 0.5 to 1.5 times the diameter of said body and wherein the thickness of the wall portion of the tube through which the opening extends is at least as great as the thickness of said body.

4. An extra-corporeal blood access site as set forth in claim **1** wherein said tube has a center bore portion into which said opening extends and enlarged bore portions at the ends thereof for securing the ends of tubing, said center portion having a diameter substantially the same as the internal diameter of said tubing and said enlarged bore portions being such as to align the ends of said tubing with said center bore portion.

5. An extra-corporeal blood access site as set forth in claim **1** wherein the wall of said opening has projections to assure against accidental withdrawal of said body from said opening.

6. An extra-corporeal blood access site as set forth in claim **5** wherein said projections comprise a spiral thread in the wall of the opening.

7. An extra-corporeal blood access site comprising a blood-passage tube of relatively rigid material having a cylindrical opening through a wall thereof and a cylindrical body of relatively soft resilient needle-penetrable material in and sealing the opening in said tube, said body being under radially inward compression from substantially the entire cylindrical periphery thereof, said cylindrical opening having a spiral thread on the wall thereof which spiral thread is impressed into said resilient body thereby to assure against accidental withdrawal of said body from said opening.

8. An extra-corporeal blood access site as set forth in claim **7** wherein said spiral thread has a tapered cross-section, the taper being in the direction of the bore of the tube.

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