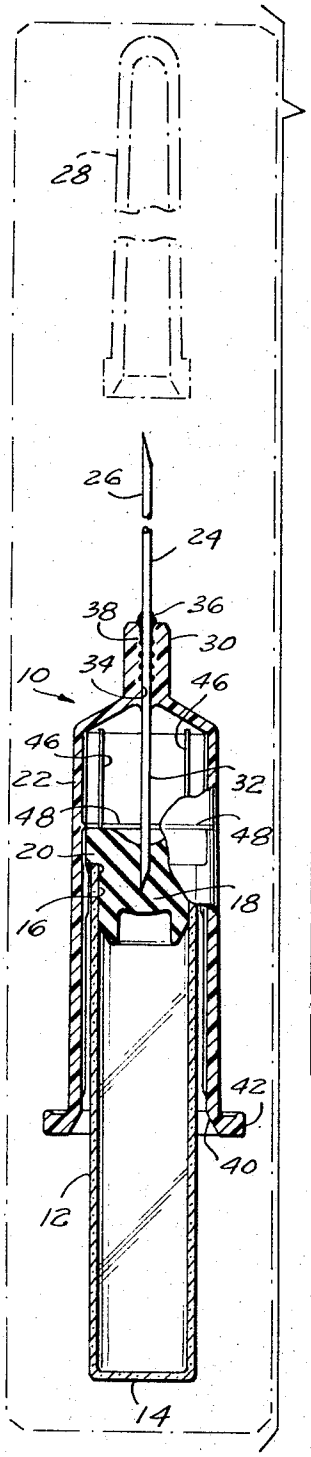
Jan. 30, 1968 G. H. KELLER 3,366,103

BLOOD COLLECTING ASSEMBLY

Filed June 24, 1965

FIG. 1



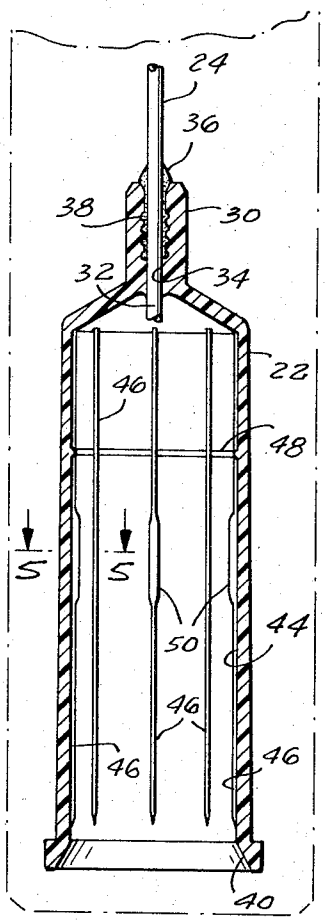


FIG. 2

FIG. 3

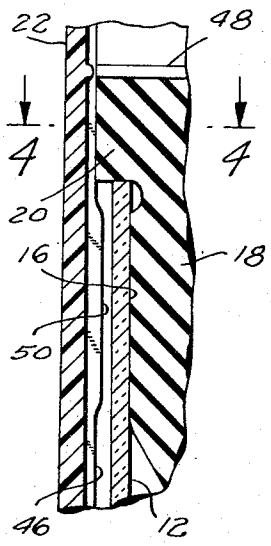


FIG. 4

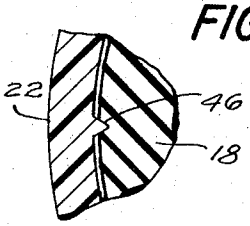
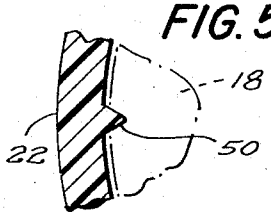


FIG. 5



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BLOOD COLLECTING ASSEMBLY

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ABSTRACT OF THE DISCLOSURE

An improved blood collecting assembly including a cylindrical, air-evacuated container provided at one end with a resealable penetrable stopper and a holder having a double ended cannula. The holder has circumferentially spaced ribs extending inwardly, each rib having an intermediate portion of increased height which engages with the periphery of the stopper thereby holding the container to the holder while permitting the container to be longitudinally shifted therein by applying a deliberate force thereto, thereby causing one end of the cannula to penetrate the stopper when the force is applied.

The present invention relates to a structurally and functionally improved blood collecting assembly and, more particularly, to an assembly of this type having a novel and superior holder construction.

In the medical, biological and laboratory fields, assemblies employing evacuated tubes and containers are frequently used in the collection of blood. Assemblies of this type are disclosed in U.S. Patent No. 2,460,641 granted Feb. 1, 1949, U.S. Patent No. 3,136,440 granted June 9, 1964, and U.S. Patent No. 3,141,460 granted July 21, 1964. The evacuated containers are suitably sealed by a stopper made of elastomeric material and not only adapted to provide the desired seal but permit the insertion and removal of the inner end of a double ended cannula. This cannula is attached to the forward end of the container holder which, at the same time, serves to slidably retain the stopper end of the container therein. In this connection, a number of different approaches have been suggested for retaining the container in the holder in the desired position relative to the inner end of the cannula both prior to actual use of the assembly or during its manipulation during the blood collecting cycle prior to the complete penetration of the stopper by the inner cannula end.

It is a principal object of this invention to provide a blood collecting assembly in which an improved holder is employed; and in this regard, the holder is adapted to retain the container therein to thereby provide a ready-to-use unit while keeping the frictional resistance between inner surfaces of the holder and the stopper at a minimum thereby permitting relatively easy insertion of the sealed container into the holder during assembly and also at the selected period following the initial penetration of the stopper by the inner cannula end while minimizing danger of disassociation of the stopper from container upon retraction of the evacuated container relative to the holder.

Another object is to provide a disposable holder and united needle thereby affording extreme convenience in field use by having a unit ready to use without concern for assembly and even disassembly during use; this design not only permitting the packaging of an evacuated tube and holder-needle unit assembled into a ready-to-use unit but also permits the holder-needle unit to be placed in individual packages with evacuated containers packaged in selected groups in larger evacuated cans.

In accordance with the present invention, a typical evacuated container, closed at one end and open at the other end, is employed for the blood collecting technique.

The open end of the container is sealed by a penetrable stopper which is adapted to maintain the internal vacuum and then reseal itself upon penetration and withdrawal of a cannula following the blood collecting process. This container is adapted to be conveniently held in a holder-needle unit. The holder is essentially cylindrical in configuration having a rear open end into which the penetrable stopper end of the container is adapted to be inserted. The other end of the holder is reduced or restricted and formed with a reduced bore. A double ended cannula is disposed in this bore with its inner penetrating end projecting inwardly of the bore of the holder. A bonding material is interposed between the cannula and the restricted holder end whereupon this material is adapted to adhere with the material of the cannula and the material of the holder. This bonding material may embrace the typical epoxy bonding systems and, as such, may not possess the optimum bonding affinity desired with the resin materials employed in the fabrication of the holder. In such cases, the bond is supplemented by a mechanical interlock which is provided by the penetration of the bonding material into recesses formed in the bore of the holder restricted end. The internal diameter of the holder is larger than the external diameter of the container as well as the stopper. The desired holding or gripping action between the holder and the container is obtained by a series of circumferentially spaced and radially inwardly extending ribs of a sufficient height to engage with the periphery of the stopper. In this manner, the desired holding pressure is obtained between the holder and the container while, at the same time, permitting sliding movement therebetween and maintaining the frictional forces at a minimum. Intermediate portions of a selected number of these ribs are enlarged to increase the holding or gripping pressure on the stopper at such location. This location is at a position in which the penetrable stopper is in close proximity with the inner penetrating end of the cannula. In this manner, an indication is provided for the locating as well as the presence of the stopper at this position. The ribs, forwardly of this location as was the case rearwardly thereof, are reduced but, nevertheless, provide sufficient gripping pressures on the stopper while permitting the escape of air around the stopper during penetration thereof by the cannula. In the packaging of the holder-needle unit either separately from the container or assembled therewith, the outer penetrating end of the cannula will be protected by a shield adapted to engage with the outer surfaces of the restricted holder end.

Other objects and advantages will become apparent from the following detailed description which is to be taken in conjunction with the accompanying drawings illustrating a somewhat preferred embodiment of the invention and in which:

FIG. 1 is a longitudinal sectional view of the assembled blood collecting assembly with the cannula shield shown in phantom and with a proposed sealed package also shown in phantom for maintaining the interior thereof and the assembly in sterile condition;

FIG. 2 is another longitudinal sectional view of the holder-needle unit with a proposed sealed package shown in phantom for maintaining the interior thereof and the enclosed unit in sterile condition;

FIG. 3 is an enlarged, fragmentary sectional view showing the relationship of the stopper and retaining ribs when the parts are assembled as shown in FIG. 1;

FIG. 4 is an enlarged fragmentary section taken along the line 4—4 of FIG. 3; and

FIG. 5 is a similar sectional view taken along the line 5—5 of FIG. 2 showing the enlarged ribs for increasing the grip with the stopper of the container at a location in which the stopper is in close proximity with the inner penetrating end of the cannula.

In the drawings, a blood collecting assembly **10** is shown and is adapted to be supplied commercially in a pre-packaged sterile condition ready for use to be ultimately discarded following the blood collecting operation. The assembly includes an evacuated container **12** having a rear closed end **14** and a forward open end **16** closed and sealed by a penetrable stopper **18**. The container **12** and the stopper **18** is disclosed and described in detail in U. S. Patent No. 3,136,440. Suffice it to say that the container **12** is evacuated and substantially light transparent to facilitate the observation of the interior particularly during the blood collecting operation. The stopper **18**, on the other hand, is of such proportion and formed from an elastomeric material which assures its retention in the open end of the container **12** during substantially all stages of use. As will be observed, the outer end of the stopper **18** includes a circumferentially extending enlarged periphery **20** which, together with the end **16** of the container **12**, is inserted into and suitably retained by a holder-needle unit **22** which comprises a holder **22** and double ended needle **24**.

Referring now to the holder-needle unit, it should be understood initially that this unit may be supplied commercially separately from the evacuated container **12** to be eventually assembled in the field. In this manner, the holder-needle unit will be separately packaged under sterile conditions with the forward penetrating end **26** of the cannula **24** protected by the shield **28** adapted to be frictionally mounted on the restricted forward end **30** of the holder **22**.

The double ended needle **24** is conveniently secured to the restricted forward end **30** of the holder **22** with its inner penetrating end **32** disposed inwardly of the bore of the cylindrical holder **22**. In this regard, the intermediate portion of the cannula **24** is disposed in the bore **34**. A bonding material **36** is interposed between the cannula **24** and the bore defining surfaces of the restricted end **30**. The bonding material may be of the type disclosed in U.S. Patent No. 3,186,408 granted June 1, 1965, as well as the disclosures mentioned therein. A contemplated bonding material will, accordingly, embrace an epoxy bonding system. Such systems have acceptable bonding affinity with the usual metals employed for cannulas **24** but, in a number of instances, have less than the required amount of bonding affinity for the resin material employed for the holder **22**. In such cases, the bonding action is supplemented by means of a mechanical interlock which is provided by one or more recesses **38** forming part of the bore **34** of the restricted end **30** of the holder **22**.

Referring now to the holder **22**, it will be appreciated that a substantially elongated cylindrical configuration is present with the rear open end **40** having a radially outwardly extending and interrupted flange **42** which is adapted to be engaged by the forefinger and index finger of the hand of the operator during the manipulation and handling of the assembly **10**. The material employed for the holder **22** may be selected from a wide variety of materials including polypropylene or one of the materials disclosed in U.S. Patent No. 3,186,408 or the disclosures mentioned therein. Suffice it to say that the holder material should be sufficiently light transparent to permit observation of the flow of liquid or blood from the inner penetrating end **32** into the container **12**.

The internal bore **44** of the holder **22** is proportioned and constructed to facilitate the entry therein of the container **12** and stopper **18** and, at the same time, assure against undesirable or unintentional removal thereof. Under the circumstances, the internal diameter of the bore **44** is greater than the external diameter of the container **12** as well as the periphery **20** of the stopper **18**. These components are conveniently and adequately held and gripped relative to the holder **22** by a series or network of ribs extending between the stopper **18** and the holder **22**. These ribs may assume any one of a number of selected patterns and, as disclosed in the exemplary embodiment, may be of substantially elongated form and in a circumferentially spaced pattern. These ribs **46** are integral with the internal surfaces of the holder **22** and extend radially inwardly for a sufficient distance to engage and grip the circumferentially extending periphery **20** of the stopper **18**. The pressure created by this engagement is sufficient to hold the container **12** and stopper **18** within the bore **44** of the holder **22**. At the same time, this engagement is not sufficiently great to create frictional forces that will serve to hinder or deter the desired and efficient insertion of the container **12** and stopper **18** into the holder **22** particularly during the actual blood collecting operation. It will be appreciated that, with this arrangement, air is permitted to escape or flow around the circumferentially extending periphery **20** during the shifting of the stopper **18** within the holder **22**.

A circumferentially extending rib **48** is provided on the face of the bore **44** to serve as an indicator of a fixed or certain relative disposition of the stopper **18** and inner end **32** of the cannula **24**. In other words, when the front face of the stopper **18** is aligned with this rib **48**, the inner penetrating end **32** of the cannula **24** is either proximal the stopper or embedded therein in a manner shown in FIG. 1. When the front face of the stopper **18** is forced across this rib **48** during the blood collecting operation, the lumen of the cannula **24** will then be in communication with the vacuum present in the container **12**.

As explained in the above, the container **12** and stopper **18** may be assembled with the holder **22** to provide a pre-packaged unit and offered or merchandised in a single packaged unit. In some instances, the evacuated container may be packaged separately but once assembled with the holder **22** will be either held or stored in this condition for prolonged periods of time. It will then be desirable, if not necessary, to assure the retention of the evacuated container within the holder **22**. This assurance is provided by an enlarged portion **50** of a selected number of the ribs **46**. Thus, these enlarged ribbed portions **50** served to increase the frictional force and grip of the ribs **46** on the circumferentially extending periphery **20** of the stopper **18**. In addition, an abutting beveled shoulder is thereby provided against which the rear face of the periphery **20** is adapted to engage when the front face of this periphery is aligned with the rib **48**. This relationship is clearly shown in the enlarged fragmentary representation of FIG. 3.

While the present assembly **10** may be used in diverse applications, as explained it is primarily intended to be employed in the collection of blood. If not preassembled in the same package, an evacuated container will be mounted in a holder **22** with the front face of the stopper **18** aligned with the indicating rib **48**. During this insertion, the periphery **22** of the stopper **18** will yieldingly bear to a slight extent against the ribs **46** and, to a greater extent, as the enlarged ribbed portions **50** are traversed. During this insertion, the ribs **46** in cooperation with the periphery **20** will assure the proper alignment of the evacuated container relative to the holder and cannula **24**. The embedding of the full point of the inner end **32** of the cannula avoids blood leakage on entry into a vein and will also prevent premature loss of vacuum. With the shield **28** removed, the operator will now grasp the holder **22** and introduce the outer penetrating end **26** of the cannula **24** into the vein of a donor. Immediately thereafter, the puncture of the stopper **18** by the inner end **32** of the cannula is completed to thereby communicate the lumen of the cannula with the interior of the container. Blood will flow immedaitely upon insertion of the outer end **26** of the cannula in the selected vein. Therefore, aside from venus pressure, the vacuum within the container **12** will assist in the aspirating of blood through the lumen of the cannula to thereby fill the container interior to the desired extent. Thereupon, the

container **12** together with stopper **18** may be retracted to the position at which the front face of he stopper **18** is aligned with the rib **48** or else may be entirely withdrawn from the holder **22** and the outer end **26** of the cannula withdrawn from the vein of the donor.

Thus, among others, the several aforenoted objects and advantages are most effectively attained. Although a single somewhat preferred embodiment of this invention has been disclosed and described in detail herein, it should be understood that this invention is in no sense limited thereby and its scope is to be determined by that of the appended claims.

I claim:

1. A liquid collecting assembly comprising a substantially elongated cylindrical air evacuating container having a closed end and an open end, a penetrable stopper extending across the container open end to seal the interior thereof, a substantially elongated cylindrical container holder having an open end and restricted end disposed about the container open end and the stopper thereat in substantial coaxial relationship therewith, the internal diameter of said holder being relatively greater than the exterior diameter of said container whereby the holder is spaced radially outwardly relative to the container, the container closed end extending beyond the holder open end, the holder restricted end having a coaxial bore, a double ended cannula disposed in said bore and having an outer penetrating end and an inner penetrating end disposed within said holder bore, connecting means for connecting the cannula to the holder restricted end, holding means for holding the stopper and consequently the container within the holder bore and at selected positions therein while permitting the container to be longitudinally shifted therein by applying a deliberate force to the closed end of the container and while maintaining the frictional resistance between the stopper and the holder at a minimum, said holding means comprising integral, circumferentially spaced ribs extending radially inwardly into engagement with the outer periphery of the stopper, wherein certain opposed ribs each include an intermediate portion of increased height to increase the holding pressure on the stopper to thereby assure its retention in the holder, said intermediate portion being at the position at which the inner penetrating end of the cannula is in a predetermined position relative to the stopper, said stopper being at said intermediate portion when said container and the holder are assembled prior to collecting liquid.

2. The invention in accordance with claim **1** wherein the maximum outer diameter of the stopper is less than the internal diameter of the holder to permit rearward escape of air around the stopper during shifting of the container toward the holder restricted end.

3. The invention in accordance with claim **1** wherein the connecting means include a bonding material interposed between the cannula and restricted end and being adhered thereto, the bore of said restricted end including recessed portions in which said bonding material is partially disposed to thereby provide a mechanical interlock supplementing the action of the bonding material.

4. A holder for a liquid collecting assembly comprising a substantially elongated cylindrical container holder having an open end and restricted end and adapted to receive an air evacuated elongated container having a penetrable stopper sealing one of its ends, the internal diameter of the container and stopper whereby the container and stopper are adapted to be spaced radially inwardly relative to the holder, the holder restricted end having a coaxial bore adapted to receive a double ended cannula having an outer penetrating end and an inner penetrating end for disposition internally of the holder bore, holding means adapted to hold the stopper and consequently the container within the container bore and at selected positions therein while permitting the container to be longitudinally shifted therein by applying a deliberate force to the container and while maintaining the frictional resistance between the stopper and holder at a minimum, said holding means comprising integral, circumferentially spaced ribs extending radially inwardly and adapted to engage with the outer periphery of the stopper, wherein certain opposed ribs each include an intermediate portion of increased height to increase the holding pressure on the stopper to assure its retention in the holder, said intermediate portion being at a position at which the inner penetrating end of the cannula is at a predetermined position relative to the stopper.

5. The invention in accordance with claim **4** wherein connecting means are provided for connecting the cannula in the restricted end of the holder, the connecting means includes a bonding material interposed between the cannula and restricted end and being adhered thereto, the bore of said restricted end including recessed portions in which said bonding material is partially disposed to thereby provide a mechanical interlock supplementing the action of the bonding material.

6. The invention in accordance with claim **5** wherein a shield is mounted on the holder restricted end and protectively about the outer penetrating end of the cannula.

7. The invention in accordance with claim **4** wherein a sealed package surrounds the holder, the holder together with the interior of the package being substantially sterile, and means for permitting the removal of the package to permit use of the holder.

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