United States Patent

[11] 3,550,581

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[45] Patented **Dec. 29, 1970**

[54] **APPARATUS AND METHOD FOR DETERMINING THE TENDENCY TO THROMBOSE**
6 Claims, 12 Drawing Figs.

[52] **U.S. Cl.** **128/2,** 128/275
[51] **Int. Cl.** **A61f 10/00**
[50] **Field of Search** ..... 128/2, 276, 214, 272, 216, 275; 27/24, 24.1(Digest)

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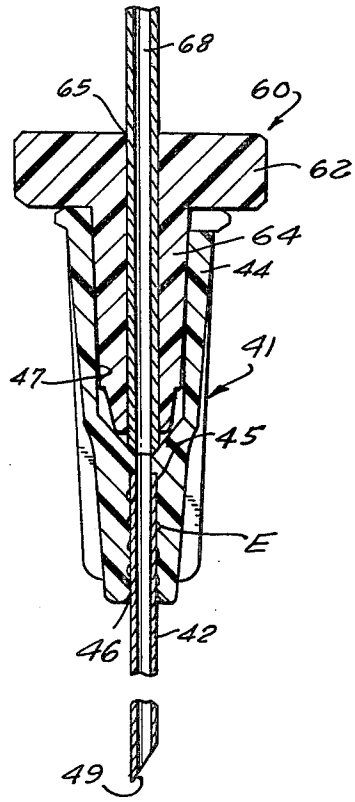
ABSTRACT: A test procedure for determining the tendency to thrombose wherein blood is caused to flow through a substantially uniform passageway from a venipuncture to a collection container. By measuring and recording the volume of blood collected with respect to time until a clot forms within the passageway, the tendency to thrombose may be determined. In carrying out this procedure, an apparatus is provided which includes a needle and removable stylet for effecting venipuncture, and a flexible elongated tube which is removably mounted to the needle after the stylet is removed. The tube is connected to the rear end of the needle in such a manner that the passageway through the needle and tube is substantially uniform in diameter whereby a uniform fluid flow through the apparatus is obtained.



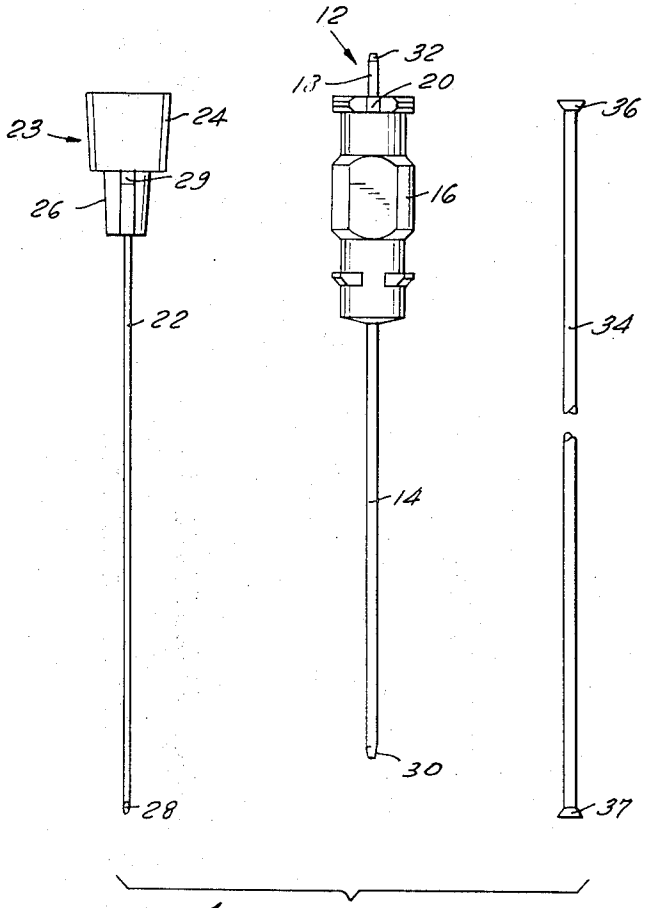
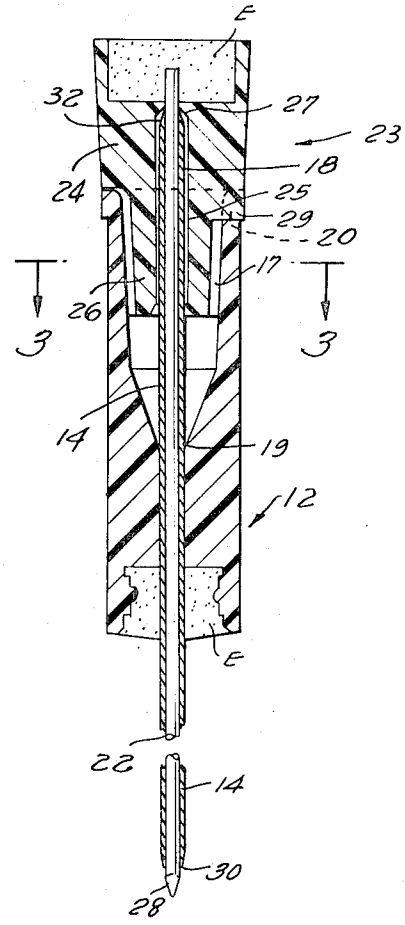


FIG. 1

FIG. 2



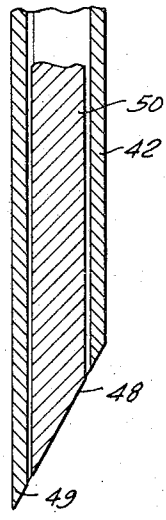


FIG. 4

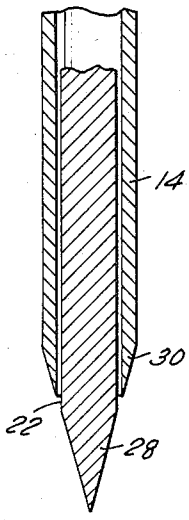
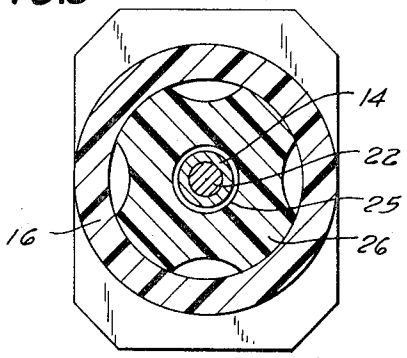


FIG. 5

FIG. 3



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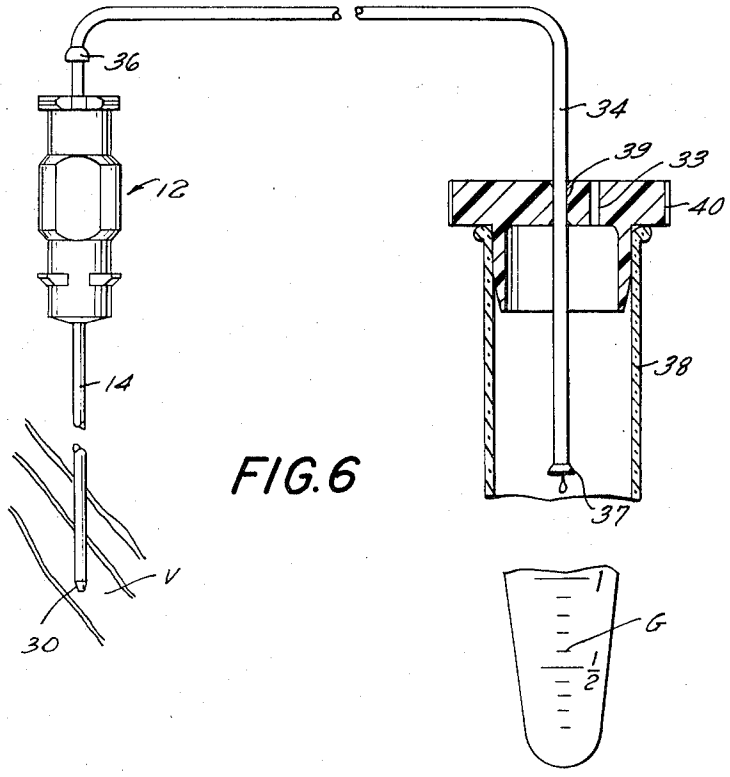

FIG. 6

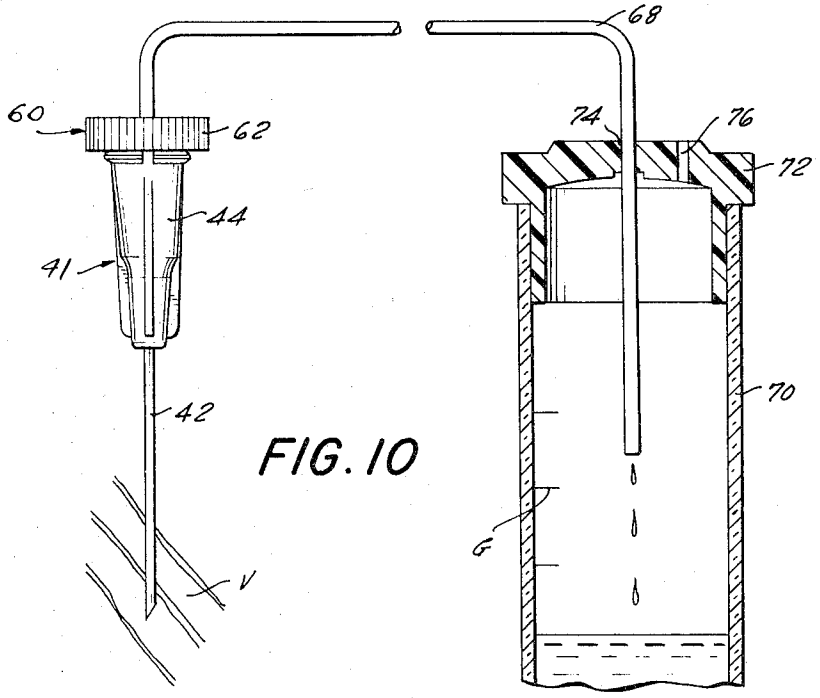

FIG. 10

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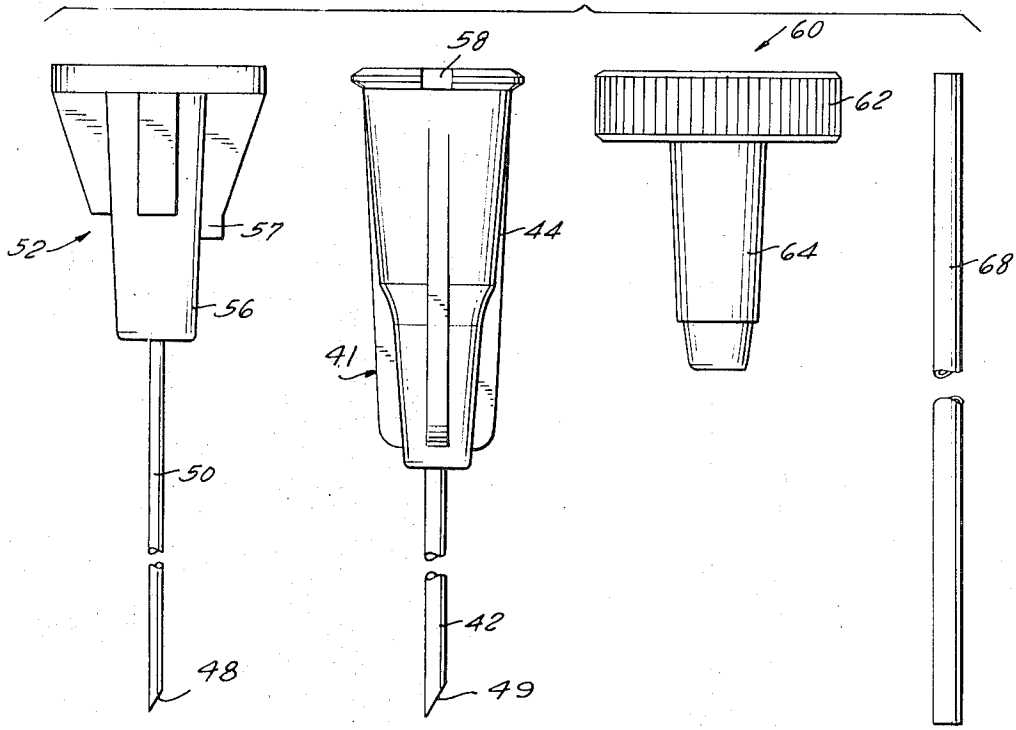
FIG. 7



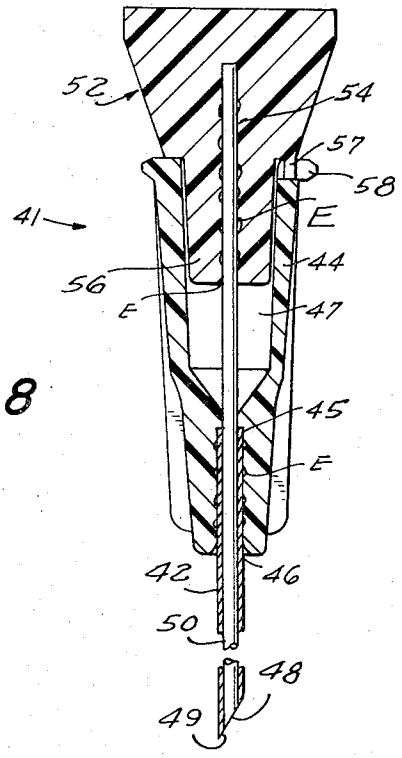


FIG. 8

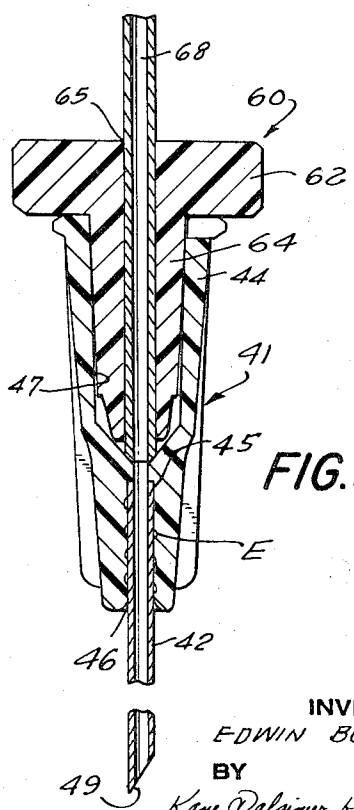


FIG. 9

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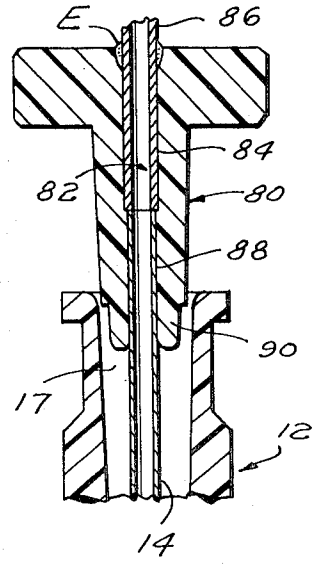

FIG. 11

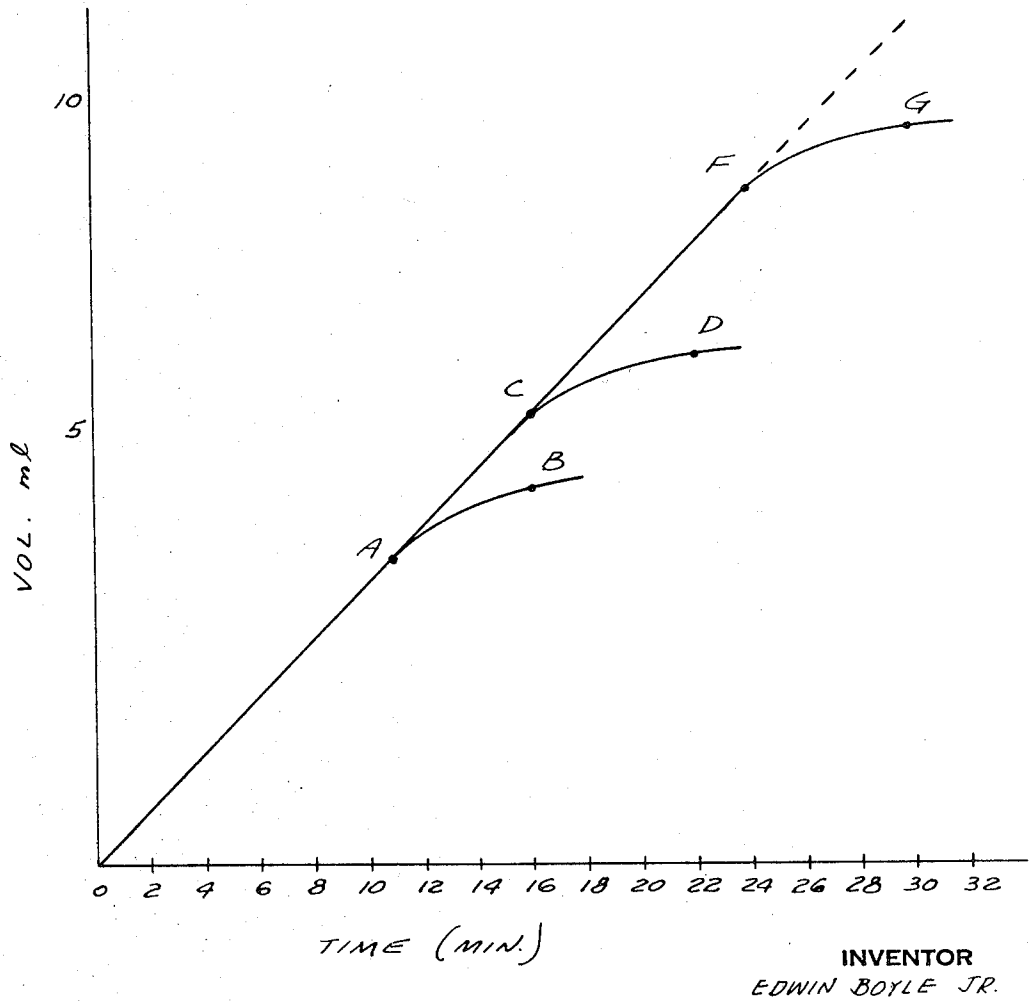

FIG. 12

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APPARATUS AND METHOD FOR DETERMINING THE TENDENCY TO THROMBOSE

This invention relates to an apparatus for determining the tendency to thrombose and the method for employing the apparatus. More particularly, the invention relates to the method and apparatus which provides for controlled flow of blood, free of catalytic agents from surrounding tissue which cause premature clot formation, whereby the tendency to thrombose is determined by blood clot formation in the apparatus.

Clinical apparatus and procedures presently being employed do not specifically determine the tendency to thrombose. Thus, hematology studies to determine clot reaction time, sedimentation rate, hematicrit, coagulation time (Lee and White times), bleeding time, platelet count, prothrombin time, prothrombin consumption time, capillary resistance test, firbrinogen level, partial thromboplastin determination and others are not specific tests to determine the tendency to thrombose, although the results are useful for diagnosis of other malfunctions of the body.

It is therefore an object of my invention to provide an apparatus for determining the tendency to thrombose; also, the method by which the tendency to thrombose is determined by employing such apparatus.

Another object of my invention is to provide a relatively inexpensive apparatus whose component parts are easily manufactured and easily assembled for ready use and which apparatus may be employed by persons with minimal technical skill to determine rather rapidly the tendency to thrombose.

My invention generally contemplates providing a method and apparatus for determining the tendency to thrombose. In carrying out the method, I provide an apparatus comprising a surgical assembly including a tubular needle member with a smooth shank and a needle handle portion mounted adjacent one end thereof. A tight-fitting stylet member having a stylet handle portion at one end is removably mounted within the needle bore so that the stylet handle portion nests within the needle handle portion whereby the members are coaxially disposed. The other end of at least one of the members terminates in a sharp puncture end which is capable of puncturing a blood vessel. A flexible elongated tube is provided having means at one end for mounting the tube on the surgical assembly with the tube being mounted adjacent the needle handle portion upon removal of the stylet so as to form a continuous flow passage through the needle and tube. The tube is formed having an internal diameter at least as large as the internal diameter of the needle so that blood will initially flow through the needle and enter the tube passage in a continuous and at a substantially uniform flow whereby the tendency to thrombose is determined by blood clot formation within the tube passage.

In performing the method for determining the tendency to thrombose, the above apparatus is employed by first puncturing a vein with the surgical assembly of the type having a needle fitted with a stylet. Since the tight-fitting stylet substantially fills the bore of the needle, the entrance of tissue thromboplastin into the bore of the needle, resulting from the puncture, is substantially minimized thereby obviating premature clot formation within the apparatus. After the vein has been punctured, the stylet is removed allowing a small amount of blood to pass through the needle to flush any remaining tissue thromboplastin present in the blood. A flexible tube is mounted on the surgical assembly forming a continuous passage through the needle and tube so that blood will flow therethrough in a continuous and substantially uniform flow. The flow of blood through the apparatus is maintained until a clot forms within the flexible tube whereby the tendency to thrombose is determined.

Other objects and advantages of my invention will become apparent from the following description of the drawings illustrating several variations of the apparatus in which:

FIG. 1 is an elevational view of the component parts of the unassembled apparatus;

FIG. 2 is a vertical sectional view of the surgical assembly;

FIG. 3 is a sectional view taken on the line 3–3 of FIG. 2;

FIGS. 4 and 5 are fragmentary sectional views of two forms of the puncture end of the surgical assembly;

FIG. 6 is an elevational view, partly broken away, of the apparatus depicting blood flowing through the end of the flexible elongated tube into a container;

FIG. 7 is a view similar to FIG. 1 of another embodiment of the apparatus;

FIG. 8 is a vertical sectional view of the surgical assembly of FIG. 7 prior to puncturing the vein;

FIG. 9 is a view similar to FIG. 8 showing the flexible tube, partly broken away, in position for performing the test;

FIG. 10 is a view similar to FIG. 6 employing assembly of FIG. 9;

FIG. 11 is a view in vertical section showing alternative structure for mounting the flexible tube on the apparatus of FIG. 1; and

FIG. 12 is a graph showing a typical plot of readings obtained through the use of the apparatus wherein blood volume in relation to time is recorded.

In the accompanying drawings I have shown several embodiments of different portions of the apparatus for determining the tendency to thrombose. In one embodiment, FIGS. 1—3 and 6, the apparatus is generally indicated by numeral **10**. The apparatus comprises a surgical assembly **12** which includes a tubular needle member **14** formed with a smooth shank and provided with a needle handle portion **16** mounted adjacent end **18** of needle **14** by employing any suitable adhesive material, such as an epoxy resin E. Needle handle **16** is formed having a bore **17** with its outer end surface provided with a slot **20** to form one portion of the lock means of the surgical assembly. Needle **14** is centered in handle portion **16** by bore **19** which communicates with bore **17** so that end portion **18** of needle **14** extends beyond handle **16**. Stylet handle **23** is formed having an upper flanged head **24** and a depending hollow skirt portion **26**. When stylet **22** is positioned in stylet handle **23** it is coaxially spaced from the inner surfaces **25** of skirt **26** and is centered therein through opening **27**. Stylet **22** and stylet handle **23** are mounted in fixed position by any suitable adhesive, such as an epoxy resin E. Stylet **22** is removably mounted within needle **14** so that skirt **26** of stylet handle **23** nests within needle handle portion **16** so that end portion **18** of needle **14** is telescopically positioned within skirt **26** of stylet handle **23** as shown most clearly in FIG. **2**.

Also formed and depending from the outer edge of flanged head **24** is a tab **29** forming the other component of the locking means so that when the stylet **22** is disposed within the needle **14**, the surgical assembly will be locked from axial rotation.

In FIGS. **4** and **5** representative puncturing ends are shown. The former figure depicts a beveled end while the latter figure depicts an end formed into a pencil tip or conical end portion. In FIG. **4** needle **42** provides a sharp beveled puncture point **49**. A stylet, such as stylet **22** or **50**, of complementary end configuration is received within needle **42** so as to substantially close the needle bore opening thereby to form a smooth surface **48** (see FIG. **7**). In FIG. **5**, stylet **22** is formed to provide a sharp conical puncturing tip **28** and extends beyond the beveled end **30** of needle **14**. Both end portions are machined by conventional grinding techniques so as to form a substantially smooth continuous surface. While the embodiment of FIG. **1** provides a puncture end as shown in FIG. **5** it is apparent that the puncture end of FIG. **4** may be substituted in lieu thereof. In a similar manner, the apparatus of FIG. **7** may employ the puncture end of FIG. **5**. Obviously, any suitable configuration may be employed as the puncture end in accordance herewith.

Flexible tube **34** is formed having outwardly extending flanged portions **36** and **37** so that either end may be frictionally mounted over end **32** of needle **14** with relative ease. Also, end **32** of needle **14** is tapered such that a substantially continuous passage is formed when tube **34** is mounted over end **32** of needle **14**. As shown in FIG. **6**, the apparatus is assembled depicting blood flowing from a vein V through needle

14 and flexible tube 34 so that blood is received in container 38. The container is provided with graduations G for determining the volume and rate of blood flow. Tube 34 is positioned within container 38 preferably by passing end 37 through central opening 39 of stopper 40 with tube 34 depending into container 38. An air vent 33 is provided to stopper 40 so as to remove excess air as blood is collected in container 38.

In FIGS. 7—10, another embodiment of my invention is illustrated. Surgical assembly 41 as shown in FIG. 7 comprises a tubular needle member 42 mounted in needle handle portion 44 at end 45 thereof. Needle 42 is centered at end 45 in bore 46 of needle handle 44 and held in position by any suitable adhesive, such as an epoxy resin E. Bore 46 communicates with opening 47 formed in needle handle 44. Stylet 50 is mounted at one end in stylet handle 52 through bore 54 formed therein and is held in position by any suitable adhesive, such as an epoxy resin E. Stylet handle 52 is formed having a depending skirt 56 which is of size substantially equal to the diameter of opening 47 of needle handle 44. When stylet 50 is removably mounted within tubular needle 42, skirt 56 of stylet handle 52 will nest therein. To prevent axial rotation of the stylet within the surgical assembly 41 a depending tab portion 57 is formed in stylet handle 52 and disposed in a complementary formed notch 58 on needle handle 44.

Tube mounting means 60 is formed having a head portion 62 and integrally formed therewith is a depending plug portion 64 which is of a size substantially equal to the diameter of bore 47 of needle handle 44. Tube mounting means 60 is formed having a centrally formed axial bore 65 through depending plug 64 for frictionally engaging one end of flexible tube 68. When flexible tube 68 is mounted in position on surgical assembly 41, tube mounting means 60 frictionally engages the internal surfaces of bore 47 in needle handle 44. Tube 68 is moved forward so as to communicate with bore 46 thus forming a continuous passage from needle 42 through flexible tube 68, as shown most clearly in FIG. 9.

In FIG. 10 the apparatus is assembled depicting blood flowing from a vein V through needle 42 and tube 68 so that blood is received in container 70. Container 70 is similar in construction to the container shown in FIG. 6 and is provided with a stopper 72 having a centrally disposed opening 74 in stopper 72. An air vent 76 is provided in stopper 72 so as to remove excess air as blood is collected in container 70. Container 70 is provided with graduations G so that the volume and rate of blood flow may be determined.

An alternative means for mounting the flexible tube on the surgical assembly of FIG. 1 is shown in FIG. 11. In this FIG. I show a tube mounting means 80 that is similar to the tube mounting means 60 (FIG. 7). Mounting means 80 is formed with an axial bore 82. The upper bore portion 84 is of a diameter substantially equal to the outer diameter of flexible tube 86 and the lower bore portion 88 is of a diameter substantially equal to the outer diameter of needle 14 (FIG. 1).

Tube 86 is received within bore 84 and is retained in the mounted position by any suitable adhesive capable of bonding the flexible tube to the mounting means 80.

The lower portion 90 of mounting means 80 is received within opening 17 of surgical assembly 12 in a manner similar to the receipt of stylet handle 23. Thus, upon mounting the end 18 of needle 14 is frictionally received within the lower bore 88 to abut the end of flexible tube 86 to provide a continuous and substantially smooth flow passage from the needle 14 and into flexible tube 86.

Flexible tube members 34, 68 and 86 are formed of a plastic material, for example, polyethylene, polypropylene, polyvinyl and polyvinyl copolymers, polytetrafluoroethylene, polytrifluoroethylene, or any other suitable elastomeric material which is relatively flexible and which is inert to fluids being passed therethrough, for example, blood. The bore of the flexible tube is preferably formed having an internal diameter that is at least as large as the internal diameter of the needle bore forming a part of the surgical assembly. The internal diameter of the tube may be of a size approximately 0.020 to 0.040 inches, and preferably 0.031 inches. The internal diameter of the needle is preferably substantially equal to the internal diameter of the tube and in its preferred form should be approximately 0.031 inches. It has been found that when using bore dimensions of the preferred size for the tube and needle, thrombosing times generally will be determined within a period of 5 to 10 minutes. By thrombosing time I mean the interval between that time when the blood flow begins to decelerate, i.e., the initiation of thrombose, and the time when the blood flow ceases, i.e., completion of thrombose. Conversely, if the bore of the needle and tube are increased in size, the thrombosing time will likewise increase and, similarly, if the bore of the needle and tube are decreased, the thrombosing time is decreased. In any event, the tube bore should be at least as large as the bore of the needle.

In performing the method employing the apparatus herein, the function of the flexible plastic tube is believed to approximate a small blood vessel outside the body which precipitates the clotting of blood in the pure thrombose form, i.e., without catalytic agent or agents present in normal blood clotting which result from trauma of the skin and blood vessel. The surgical assembly as described above is fitted with a stylet. A puncture is made in the antecubital vein using normal precautions for such a veni puncture, i.e., wiping the area with alcohol and placing a tourniquet above the elbow. The tourniquet is loosened after the surgical assembly is inserted into the antecubital vein, the stylet, which substantially precludes the entrance of tissue thromboplastin into the needle, is removed. To flush any remaining tissue thromboplastin or other catalytic agents resulting from the puncture, a small amount of blood is allowed to flow through the needle prior to mounting the flexible tube, as described above, on the surgical assembly. The other end of the flexible tube is disposed within the blood collecting container having graduations thereon so that the volume and rate of blood flow is determined during the course of the test procedure.

The apparatus is adjusted by placing the antecubital space, i.e., the point of veni puncture, about 3 inches below the sternum of the patient and the distal end of the tube, i.e., the end disposed within the container, about 6 inches below the level of the sternum. It has been found that a flexible tube of approximately 20 inches in length serves adequately for determining blood thrombosing time within a period of from approximately 5 to 10 minutes. Also, in order to prevent clotting of the blood within the needle bore, the needle is formed of a material that tends to prevent premature clotting along the inner bore surface. Needles having a siliconized inner surface have performed well in carrying out the disclosed test procedure.

As the test proceeds, the technician performing the test records volume of blood collected versus time at predetermined intervals. Initially blood flow provides a substantially linear plot until the initiation of a blood clot. At this time, the blood flow begins to decelerate (break time or initiation of thrombose), thereafter the time intervals are continued to be recorded until blood ceases to flow through the tube (termination of thrombose, i.e., complete formation of a blood clot). As stated previously, the thrombosing time is the interval between the initiation and termination of clot formation. Thus, the tendency of a patient to thrombose is determined.

After the blood has ceased to flow, the needle is removed from the antecubital vein and the tubing removed from the needle. The tubing is cut open and histological examination of the clot within the tubing may be made, if desired.

From the foregoing, the graphical representation of FIG. 12 will be apparent. FIG. 12 is a representation of typical plots derived through tests performed on various types of patients employing the apparatus in its preferred dimensions. While performing the method described, plots A—B, C—D and F—G represent, respectively, thrombosing times of hypocoagulable, normal and hypercoagulable patients. The linear curve represents the flow of blood prior to the initiation

of thrombose at points A, C and F. Thus, by recording time (X-axis) and blood volume (Y-axis) the rate of blood flow, the thrombosing time and total volume of blood collected is determined.

From the foregoing, it is obvious that the objects and advantages of the invention are carried out. The invention described herein clearly sets forth a test procedure for determining the tendency to thrombose. The procedure is accomplished by employing rather inexpensive, easily assembled apparatus and requires minimal technical skill by persons performing the test.

It is obvious that many changes and variations in materials and design for forming the apparatus may be made without departing from the spirit and scope of the invention as defined in the appended claims.

I claim:

1. An apparatus for determining the tendency to thrombose comprising a surgical assembly having a passage therethrough and including a tubular needle member having a smooth shank and a needle handle portion mounted adjacent one end of said needle member; said needle member adapted to removably receive a tight-fitting stylet member having a handle portion at one end thereof; the other end of said needle terminating in a sharp puncture end; said end being capable of puncturing a blood vessel; a flexible elongated tube with mounting means on one end thereof and said tube being removably mounted on said one end of the surgical assembly so as to form a continuous passage through the surgical assembly and tube; the inner surfaces of said surgical assembly and said tube forming a continuous passage of substantially uniform diameter throughout the entire length of the assembly and tube including the portion at which the surgical assembly and tube are connected; and a blood collecting means removably mounted to the other end of said tube so that the blood will initially flow through the needle and enter the tube passage in a continuous and substantially uniform flow and be collected in said collecting means whereby the tendency to thrombose may be determined by the rate of blood clotting within said tube passage.

2. An apparatus for determining the tendency to thrombose as set forth in claim 1 wherein the internal diameter of said tube is approximately 0.020 to 0.040 inches.

3. An apparatus for determining the tendency to thrombose as set forth in claim 1 wherein said mounting means is defined by an outwardly extending flanged portion at an end of said tube.

4. An apparatus for determining the tendency to thrombose comprising a surgical assembly including a tubular needle member having a smooth shank and a needle handle portion mounted adjacent one end of said needle member; said needle handle portion having an opening coaxial with said needle member; said needle member adapted to removably receive a tight-fitting stylet member having a handle portion at one end thereof; the other end of said needle terminating in a sharp puncture end; said end being capable of puncturing a blood vessel; a flexible elongated tube with mounting means on one end thereof and said tube being removably mounted on said one end of the surgical assembly so as to form a continuous passage through the surgical assembly and tube; the inner surfaces of said surgical assembly and said tube forming a continuous passage of substantially, uniform diameter throughout the entire length of the assembly and tube including the portion at which the surgical assembly and tube are connected; said mounting means include a connector having a bore therethrough; at least a portion of said connector bore being of a diameter substantially equal to the external diameter of the tube, said connector being mounted at the end of said tube; said connector including a depending plug portion having a diameter substantially equal to the diameter of said opening in said handle portion so as to be frictionally engaged thereby when mounted therein; and a blood collecting means removably mounted to the other end of said tube so that the blood will initially flow through the needle and enter the tube passage in a continuous and substantially uniform flow and collected in said collecting means whereby the tendency to thrombose may be determined by the rate of blood clotting within said tube passage.

5. An apparatus for determining the tendency to thrombose comprising a surgical assembly including a tubular needle member having a smooth shank and a needle handle portion mounted adjacent one end of said needle member; said needle member adapted to removably receive a tight-fitting stylet member having a handle portion at one end thereof; the other end of said needle terminating in a sharp puncture end; said end being capable of puncturing a blood vessel; a flexible elongated tube with mounting means formed at one end thereof and removably mounted on said one end of the surgical assembly so as to form a continuous passage through the surgical assembly and tube; the inner surfaces of said surgical assembly and said tube forming a continuous passage of substantially uniform diameter throughout the entire length of the assembly and tube including the portion at which the surgical assembly and tube are connected; and a blood collecting means removably mounted to the other end of said tube; said blood collecting means including a container fitted with a stopper having a central opening, the other end of said tube received within said central opening to pass blood into the container; said container having indicia thereon for measuring the volume of blood and said stopper having a second opening to expel the displaced air when blood is being collected in said container so that the blood will initially flow through the needle and enter the tube passage in a continuous and substantially uniform flow and collected in said container whereby the tendency to thrombose may be determined by the rate of blood clotting within said tube passage.

6. A method for determining the tendency to thrombose comprising puncturing a vein with a surgical assembly of the type having a needle fitted with a stylet, removing the stylet so that a small volume of blood flows from the vein through the needle so as to flush the needle of catalytic agents which may cause premature clot formation, mounting a flexible tube on the surgical assembly to form a continuous passage through the needle and tube so that blood will flow from the vein through the needle and enter the tube passage in a continuous and substantially uniform flow, collecting the blood which flows through the apparatus until a clot forms within the flexible tube, and measuring and recording the volume of blood collected with respect to time, whereby the tendency to thrombose is determined.