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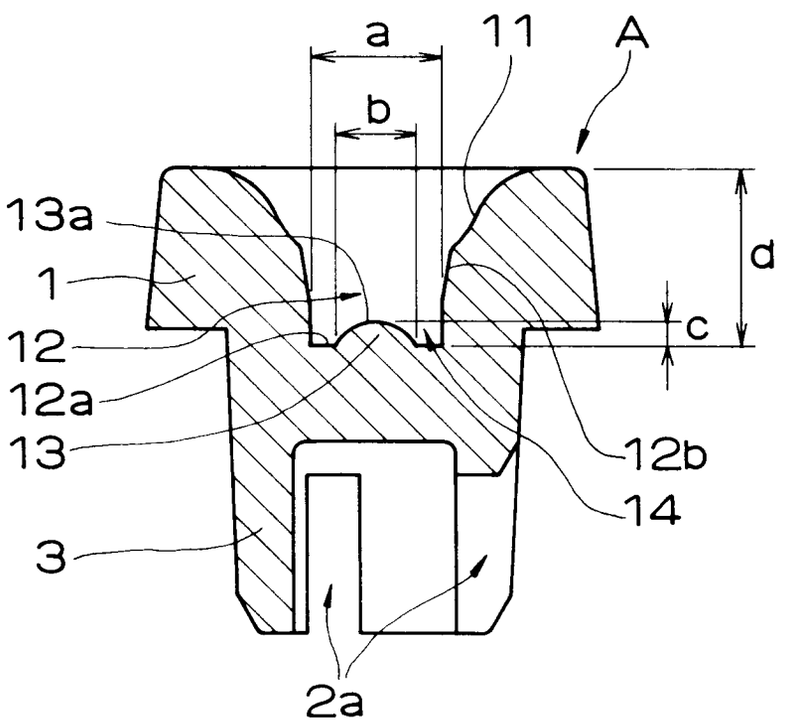
(54) Stopper for evacuated blood collecting tube.

(57) A stopper for an evacuated blood collecting tube having a head (1) provided with a recess (12) in the center of a head cavity (11) and a projection (13) formed on the center of the bottom of the recess. The diameter (6) of the projection (13) is smaller than the inner diameter (9) of the recess (12), and the center portion projects upward and the surrounding portion declines toward the periphery of the projection.

Fig.2



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The present invention relates to a stopper for an evacuated blood collecting tube or bottle, and particularly, to a stopper which do not disturb test data even if some blood remain on the stopper when blood is sampled from the evacuated blood collecting tube.

In operation of an automatic instrument for hemanalysis, a blood sampling needle is pierced directly into the stopper without removing the stopper from the tube in order to protect the operator from infection through the blood. And then, the blood in the evacuated blood tube is sampled with a blood sampling needle through the stopper.

As shown in Fig.4, there has been hitherto known a stopper 50 comprising an enlarged head 52 and a leg portion 53 extending from the head 52 and having a recessed portion 54. The stopper 50 has an upper surface provided with a cavity 55 for receiving a rubber seal of the back end side of a blood collection needle 56.

Further, as shown in Fig.5, there has been known another stopper 51 having a deep hole or recess 57 at the center of the cavity 55 in order to reduce penetration force by the blood collection needle 56.

Blood to be tested is collected from a human body in a tube sealed with those stoppers 50, 51 through a blood collection needle 56. And the blood collected in the tube is further sampled to a test cup or the like through a sampling needle of an automatic instrument for hemanalysis. That is to say, in such case that blood is collected in a tube sealed with the stopper 50 of Fig.4, a sampling needle (not shown) of the automatic instrument for hemanalysis is pierced in the center portion 55a of the cavity 55. Then the blood is sucked, and the sampling needle is pulled out. In another case that a tube sealed with the stopper 51 of Fig.5 is used, the sampling needle is inserted into the recess 57 and pierced in the bottom surface 57a of the recess 57. Then the blood is sucked, and the sampling needle is pulled out.

However, there is some problem in such sampling of blood from the evacuated blood collecting tube sealed with the stopper 50 or 51. That is to say, when the blood collection needle 56 is pulled out from the stopper 50 or 51, some drops of blood may fall onto the cavity 55 of the stopper 50 or 51 from the blood collection needle 56. Then the drops of blood gather in the center portion 55a of the cavity 55 or the recess 57 in the cavity 55, and the blood coagulates and sticks to the surface of the center portion 55a or the recess 57. Under the above-mentioned condition, when a sampling needle is pierced through the center portion 55a of the stopper 50 or the bottom surface 57a of the recess 57 of the stopper 51 in order to suck the blood with an automatic instrument for hemanalysis, the sampling needle takes the coagulation blood at first.

As a result, measurement error happens, and choke or clog of a nozzle happens and causes a trouble of the instrument.

Under the above situation, the main object of the present invention is to provide a new type of stopper which does not cause measurement error and trouble of instrument during hemanalysis. Another object of the present invention is to provide a stopper which does not easily bring coring of the blood collection needle.

According to the present invention, there is provided a stopper for an evacuated blood collecting tube, having an enlarged head and a leg portion extending from the head, in which the head has an upper surface provided with a cavity for receiving a rubber seal of a back end side of a blood collection needle, and the cavity has a bottom provided with a recess at the center of the cavity, and a projection is formed at the center of the bottom of the recess. The projection has a top surface and the remaining surrounding portion declining toward periphery thereof.

The stopper is preferably made of an elastomeric material. Further, the recess preferably has an inner diameter of 3 to 12 mm, and has a depth from an upper surface of the head of 4 to 9 mm. The inner diameter of the recess is preferably gradually enlarged toward the upper side. Further, the projection has preferably a semi-spherical shape.

The stopper of the present invention constructed as mentioned above has an annular groove around the projection, since the outer diameter of the projection is smaller than the inner diameter of the recess. Further, since the projection has a slope declining toward the periphery, the drops of blood easily flow toward the periphery. Therefore, when the blood is collected from a human body and then the blood collection needle is drawn from the stopper, even if blood falls from the tip of the blood collection needle to the cavity of the head of the stopper, the blood quickly flows from the top of the projection toward the periphery and is gathered in the annular groove surrounding the projection. Therefore, the quantity of the coagulation blood sticking on the top surface of the projection is little. Then, when the blood in the evacuated blood collecting tube is sampled with the automatic instrument for hemanalysis, the sampling needle piercing in the top of the projection of the stopper does not take such amount of the coagulation blood that might influence the measurement value. As a result, problems of the measurement error and trouble of instrument can be deleted.

Further, since the projection is formed on the bottom of the recess formed at the center of cavity in the head of the stopper, the thickness of the portion to be pierced with the blood collection needle is small. Therefore, trouble such as coring do not occur, and the needle can be easily pierced into the stopper.

In addition, even if large amount of blood stays in the recess, for example, due to breakage of the rubber

seal of the back end side of the blood collection needle, the blood can be easily removed by means of an applicator (a stick with cotton wool) or the like, since the inner diameter of the recess is sufficiently large.

Hereinafter, embodiments of the present invention will be described with reference to the following drawings.

Fig.1 is a partially-cut-off perspective view showing an embodiment of a stopper for an evacuated blood collecting tube of the present invention;

Fig.2 is a longitudinal sectional view showing an embodiment of a stopper of the present invention;

Fig.3A is a longitudinal sectional view showing a step for drawing a blood collecting step of Fig.3A;

Fig.4 is a longitudinal sectional view showing an example of a conventional stopper 50 for an evacuated blood collecting tube; and

Fig.5 is a longitudinal sectional view showing another example of a conventional stopper 51.

Fig. 1 and Fig. 2 show a stopper A which is an embodiment of the present invention. The stopper A has generally a head 1 and a leg portion 2 extending from the lower side of the head 1. The stopper A is made of an elastomeric material such as a butyl rubber as one body. The leg portion is a part to be fitted into an upper opening of a collecting tube B so as to seal the tube (see Fig. 3B), and the head 1 is a flange-like part to be abutted against the upper end of the tube B. A recessed portion 3 is formed at the lower surface of the leg portion 2.

A cavity 11 for receiving a rubber seal of the back end side of a blood collection needle 56 is formed at the center of the upper surface of the head 1, and a recess 12 is formed at the center of the bottom of the cavity 11. A projection 13 is formed at the center of the bottom 12a of the recess 12. The projection 13 has a diameter smaller than the inner diameter of the recess 12, and the center portion of the projection 13 is the highest portion among the upper surface.

The configuration of the cavity 11 is the same as that of the conventional stoppers 50, 51 shown in Fig. 4 and Fig.5. The recess 12 has inner diameter a of about 3 to 12 mm and depth d from the upper surface of the head 1 of about 4 to 9 mm. Further, the inside wall of the recess 12 has a conically inclined face 12b such that the inner diameter a is enlarged from the lower side toward upper side, and the upper end of the inclined face 12b is connected to the bottom of the cavity 11. Though such inclined face 12b is not always necessary, it is preferable to form the inclined face 12b such that cleaning of the recess 12 becomes easy. The projection 13 has outer diameter b of about 2 to 11 mm and projecting height c of about 0.25 to 5 mm. Further, the projection 13 has preferably a spherical surface such that blood do not easily stick on the top portion 13a of the projection 13, and that the blood collection needle 3 can be easily pierced through the stopper A. The outer diameter b of the projection 13 is smaller than the inner diameter a of the recess 12 such that an annular groove 14 is formed around the projection 13. The groove 14 is made of the periphery of the projection 13, the lower side of the inner wall and the bottom of the recess 12.

The above-mentioned leg portion 2 and the recessed portion 3 might be the same as that of the conventional stoppers 50 and 51 of Fig.4 and Fig.5. The leg portion 2 is provided with cut portions 2a arranged radially. The recessed portion 3 is connected to the outside through the cut portions 2a, and therefore, the stopper can be easily fitted into an upper end opening of the tube.

Hereinafter, referring to Figs.3A and 3B, method for collecting blood C into an evacuated blood collecting tube B sealed with a stopper A which is an embodiment of the present invention will be explained.

At first, the front end side (not shown) of a blood collection needle 5 is inserted into a vane or the like of a human body. Then, as shown in Fig. 3A, the pointed end 4a of the blood collection needle 4 is pierced into the top portion 13a of the projection 13 of the head 1 of the stopper A. That is, when the pointed end 4a of the needle 4 is pushed against the top portion 13a of the projection 13, the needle 4 penetrates the rubber seal 4b of the back end side of the needle 4 and the projection 13. The rubber seal 4b is pushed up with the bottom of the cavity 11. Then, blood flows into the evacuated tube B through the blood collection needle 4 by virtue of the negative pressure in the tube B.

After the collection of the blood, the blood collection needle 4 is drawn from the head 1 of the stopper A. Just then, as shown in Fig.3B, some drops of the blood C_1 stained to the pointed end 4a fall to the top portion 13a of the projection 13 from the pointed end 4a. In the case, the blood C_2 which drops on the top portion 13a flows down along the surrounding slope 13b and is gathered in the annular groove 14 around the projection 13. Therefore, only very small amount of blood C_2, if any, can stick and coagulate on the top portion 13a of the projection 13.

Under the above situation, when the blood C in the tube is sampled with a sampling needle of an automatic instrument for hemanalysis after the above collection of blood, the sampling needle piercing in the top portion 13a does not take such amount of coagulation blood that may influence the measurement value. Therefore, any measurement error and trouble of instrument do not occur.

When the inner diameter a of the recess is designed as such dimension that an applicator can be suffi-

ciently inserted therein, the blood C staying in the groove 14 can be easily removed by means of the applicator or the like. Further, if a large amount of blood C_2 stays in the recess 12 due to breakage of the rubber seal 4b of the back end side of the blood collection needle 4, the blood C_2 can be easily removed by means of an applicator or the like. Further, the thickness of the portion to be pierced with the blood collection needle 4, that is, the thickness from the top portion 13a of the projection 13 to the upper bottom of the recessed portion 3, is small, since the projection 13 is situated at the bottom of the recess 12. Therefore, coring by a needle do not easily occur when piercing the blood collection needle 4 into the stopper. And further, the needle 4 can easily pierce the stopper.

Hereinafter, a concrete example of a stopper A of the present invention will be explained with reference to experimental data.

The stopper A of Example 1 used in the experiment has the following dimensions. The diameter of head is 17 mm, inner diameter a of the recess is 5.5 mm, depth d of the recess is 6.7 mm, height c of the projection 13 is 1 mm, and diameter b of the projection 13 is 5 mm. Further, the stopper A of Example 1 is made of butyl rubber available from Japan Butyl Co. Ltd. (Type number: HT=1066).

The stopper of Reference Example 1 has a construction shown in Fig.4. That is to say, the stopper has neither recess 12 nor projection 13. The remainder is the same as the stopper A of Example 1.

The stopper of Reference Example 2 has a shape shown in Fig.5. That is to say, the stopper does not have projection 13, and the remainder is the same as the stopper of Example 1.

Evacuated blood collecting tubes which were sealed with the stoppers of Example 1 and Reference Examples 1 and 2 were prepared, and a blood of a specified human (man) was collected in the respective tube. Then, the blood was sampled from each tube, and corpuscler components (leukocyte (white blood corpuscle), red blood corpuscle and blood platelets) were counted by means of an automatic corpuscle counter.

The used counter is Automatic Corpuscle Counter MEK-7108 available from NIHON KOHDEN CORPORATION. The sampled blood was diluted to 200 times (1 to 200) for leukocyte. Then, the diluted blood was further diluted to 40000 times (original 1 to solution 40000). The number of corpuscle of subject human which had been accurately previously counted is 73×10^2 for leukocyte, 460×10^4 for red blood corpuscle, and 124.5×10^4 for blood platelets. Those values exist within normal range for a man, that is 6600 ± 1300 for leukocyte, 450 to 510×10^4 for red blood corpuscle and 11 to 34×10^4 for blood platelets. The test was repeated 100 times for each example.

The counted values and the ranges of fluctuation thereof obtained by the above test are shown in the following Table 1.

Table 1

	Leukocyte ($\times 10^2$)	Red Blood Corpuscle ($\times 10^2$)	Blood Platelets ($\times 10^4$)
Example 1	73± 2	460± 9	24.5± 1.5
R.Example 1	72± 3	470± 16	26.1± 1.9
R.Example 2	74± 3	475 ± 17	26.6± 2.0

It can be understood from Table 1 that the stopper A of Example 1 of the present invention provides smaller range of fluctuation. However the stoppers of Reference Examples 1 and 2 provide large range of fluctuation. Further, in the case of Reference Examples, especially for red blood corpuscle, it is expected that abnormal data happen to come out for a subject human who has high corpuscle member, since choke or clog of the blood collection needle or the like might happen.

The main effect of the present invention will be explained bellow.

Since the quantity of coagulation blood sticking on the top surface of the projection is very small, the blood sampling needle does not take such amount of the coagulation blood that influences measurement value. Therefore, measurement accuracy can be increased, and machine trouble can be deleted. Further, since the thickness of the portion to be pierced with a blood collection needle is small, no coring of the needle happens. Further, even if large amount of blood stays in a recess formed at the center of the cavity of the head of the stopper, in case that inner diameter of the recess is designed to sufficient size, the blood can be easily removed with an applicator or the like. Therefore, work efficiency can be increased.

Though several embodiments of the invention are described above, it is to be understood that the present invention is not limited to the above mentioned embodiments, and various change and modifications may be made in the invention without departing from the spirit and scope thereof.

Claims

1. A stopper for an evacuated blood collecting tube, comprising;
an enlarged head;
a leg portion extending from the head;
the head having an upper surface provided with a cavity for receiving a rubber seal of a back end side of a blood collection needle;
the cavity having a bottom provided with a recess having a bottom, at a center of the cavity; and
a projection formed on the center of the bottom of the recess and having center top surface and a surrounding surface declining toward periphery thereof.

2. The stopper of Claim 1 made of an elastomeric material.

3. The stopper of Claim 1 wherein inner diameter of said recess is 3 to 12 mm.

4. The stopper of Claim 1 wherein depth of said recess from the upper surface of the head is 4 to 9 mm.

5. The stopper of Claim 1 wherein inner diameter of said recess is gradually enlarged toward upside.

6. The stopper of Claim 1 wherein said projection has a shape of semi-spherical shape.

Fig.1

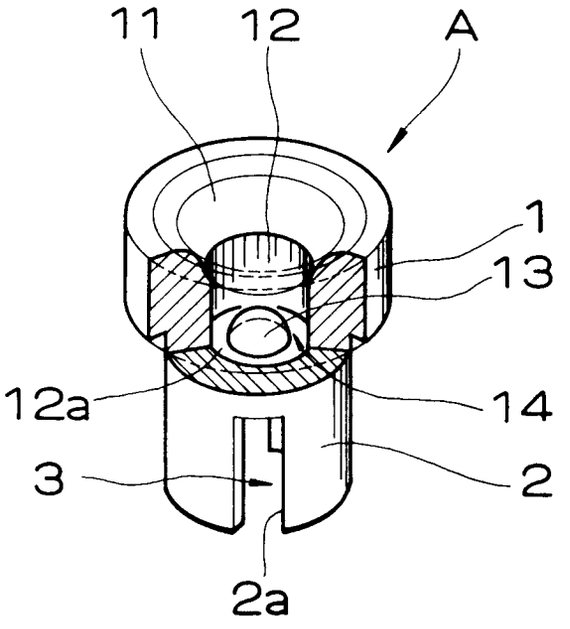


Fig.2

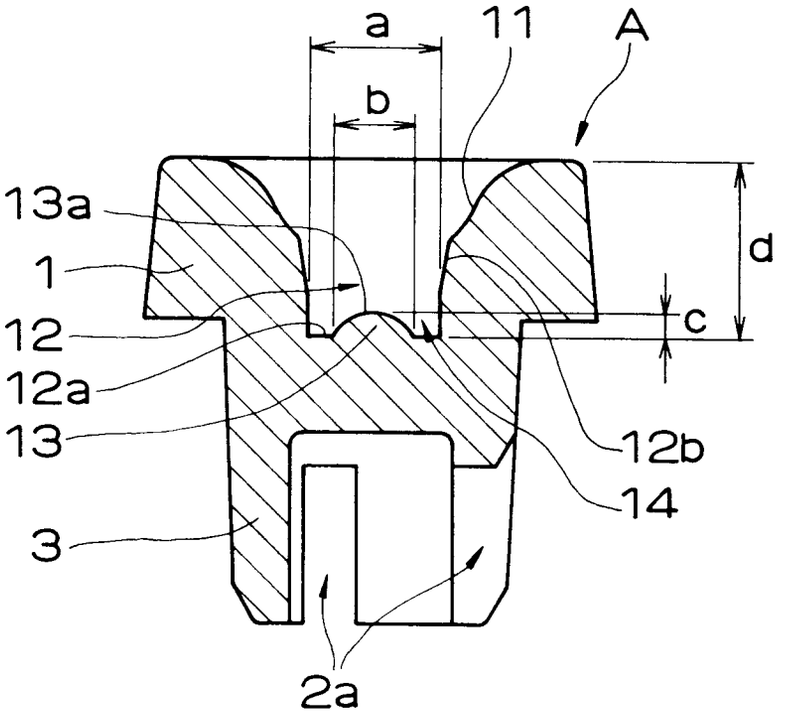


Fig.3A

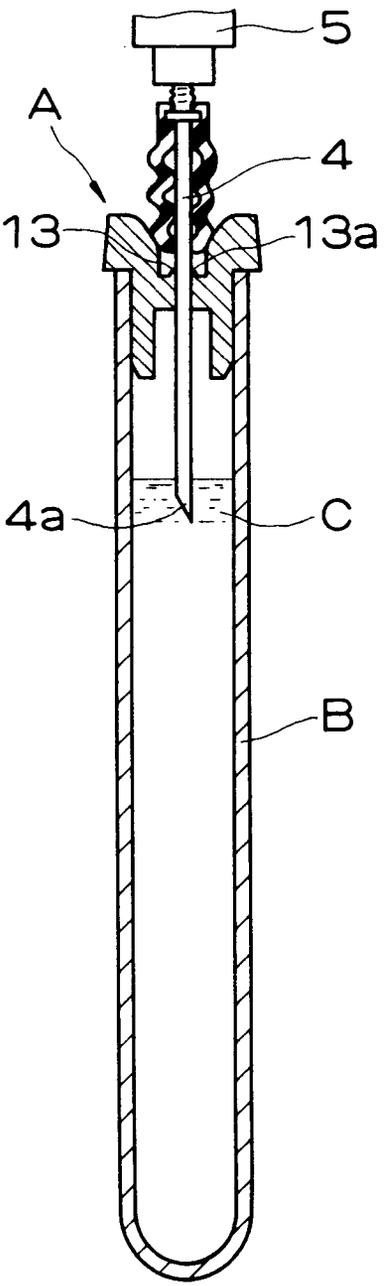


Fig.3B

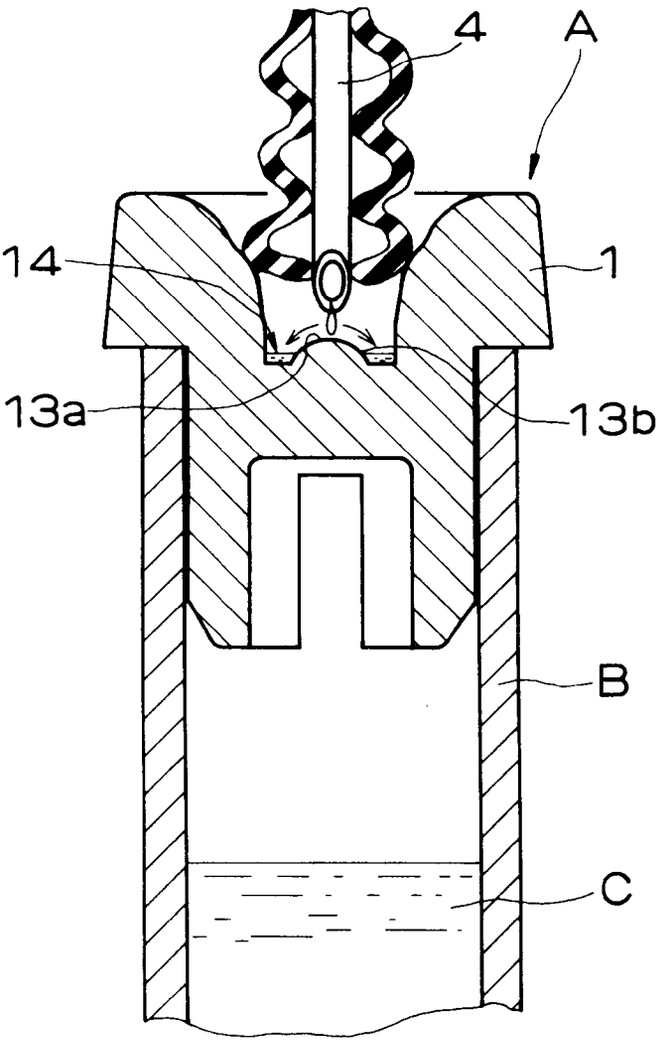


Fig.4
PRIOR ART

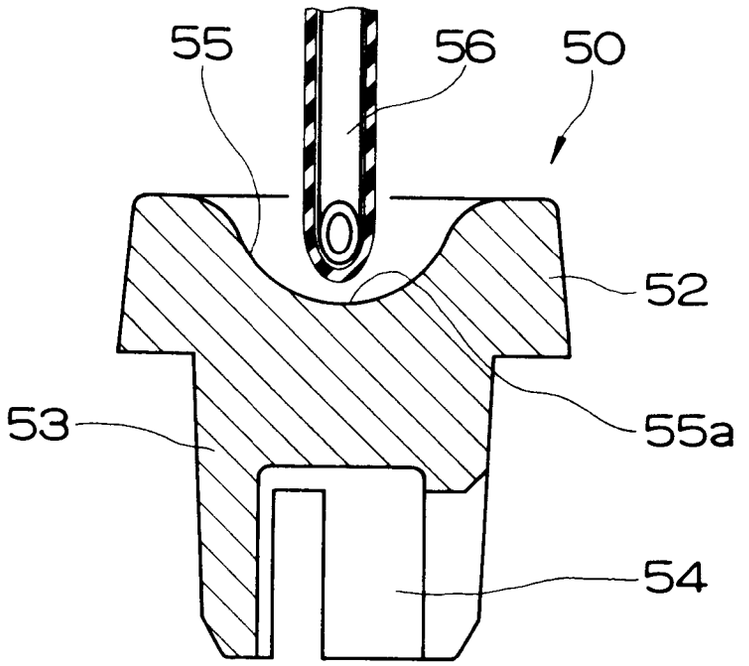
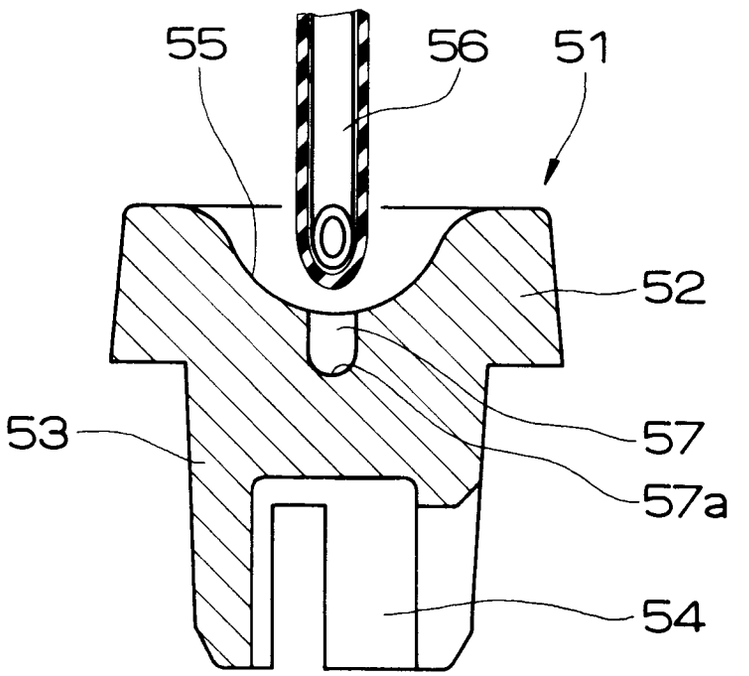


Fig.5
PRIOR ART



European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 92 40 2932

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	FR-A-2 468 514 (BECTON DICKINSON AND CO.) * page 2, line 32 - page 3, line 33; figures 1-4 *	1,2,6	B01L3/14 A61B5/14 B65D51/00 A61J1/00
Y	FR-A-2 291 107 (G.D. SEARLE & CO.) * page 2, line 18 - line 28; claims 1,2; figure *	1,2,6	
A	BE-A-876 606 (STAYNE-PRODUCTS) * page 4, line 19 - line 25; figure 1 *	1,2,6	
A	GB-A-2 108 943 (TERUMO) * page 1, line 1 - line 22; figure 5 *	1,2	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

B01L
B65D
A61J

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	27 JANUARY 1993	MILLS J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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