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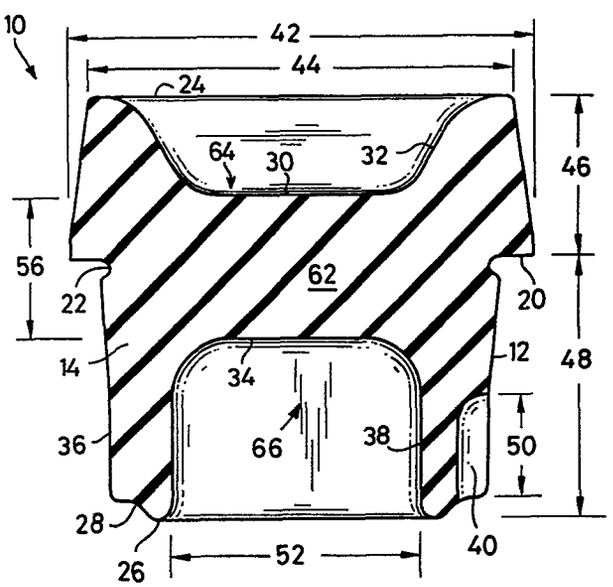
(54) Stopper for test tubes, and the like.

(57) A new stopper (10) is provided for test tubes such as blood collection containers. The stopper (10) ist configured to have a greatly reduced puncture diaphragm thickness than previously contemplated for penetration by a blood collection cannula, with the diaphragm (62) having a substantially constant thickness throughout the diameter thereof so as to avoid needle occlusion. The arrangement of stopper (10) is such that there is a great reduction in the amount of material used for the production of each stopper (10). The reduced diaphragm has the effect, also, of reducing the required cannula penetration force by at least ten percent. Moreover, the overall configuration of stopper (10) herein provides cross-sectional dimensions which reduce to a minimum the bulk of the stopper (10). This has the effect of reducing to a minimum the radial force applied against the adjacent tube lip which, in turn, has the effect of reducing breakage.



EP 0 086 251 A1

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STOPPER FOR TEST TUBES, AND THE LIKE

BACKGROUND AND STATEMENT OF THE INVENTION

Generally speaking, this invention relates to a new stopper for test tubes. More particularly, this invention relates to a new configuration of stopper for blood collection containers such as serum separation tubes, for example. The new stopper, in accordance herewith, is configured to have dimensions relative to the diameter of the cooperating tube wherein the bulk of the stopper is substantially reduced. This, of course, is very important during the mass production of, for example, serum separation tubes wherein the stopper is inserted into the tube partially and a vacuum is applied to evacuate each of the tubes. Subsequent to this application, each stopper is finally seated in its respective tube.

When this procedure takes place, there is substantial radial pressure brought to bear against the lip of the tube. By reducing the bulk of the stopper, in accordance herewith, in the production by mass production techniques in a production line, there is a substantial reduction in the breakage of tubes. Moreover, the continuously applied radial force of the stopper against the adjacent tube lip, once the insertion is made, is at a much lower level during shipment and use. This continuous radial force reduction reduces breakage even further.

As a further important feature of the stopper herein, the cannula penetration diaphragm thereof has a thickness throughout the diameter thereof which is constant. That is, the diaphragm wall does not increase in thickness from the axis thereof radially outwardly of the stopper. The entire diaphragm is substantially constant in its thickness. Because of this, needle occlusion is avoided by the user to a substantial extent during insertion of the needle or cannula into the diaphragm. In essence, the effective area of the diaphragm is substantially increased for use, thus reducing the need for an exacting determination of the insertion point.

In combination with the substantially constant diaphragm thickness, as discussed above, the stopper of the invention provides a penetration diaphragm of substantially less thickness. This, in turn, reduces the penetration force necessary for cannula penetration of the diaphragm by at least ten percent.

As will be appreciated, the reduction in thickness of the diaphragm together with this thickness being constant over the entire diameter of the diaphragm reduces the bulk of the stopper as discussed above and, in accordance with conventional mass production techniques, reduces the quantity of material utilized for each stopper. When one realizes that literally millions of such stoppers are produced for throw-away type serum separation tubes, the amount of savings of materials over a period of production of, for example, one year is substantial.

In producing stoppers for test tubes in the past, and particularly blood collection tubes it is conventional in forming the puncture diaphragm centrally of the stopper for the insertion of a cannula to introduce a blood sample into a serum separation tube, to form a well in the top of the stopper. As will be appreciated, the walls of the well are curved from the top annular edge surface of the stopper to the central lower surface of the well at the axis of the stopper with the walls tapering gradually downwardly in a smooth curve to the axis of the stopper. By the same token, the bottom surface of the prior art stopper includes an undercut area forming a well in the bottom surface of the stopper with generally the same gradually curved walls of the well from the annular bottom edge of the stopper to the axis of the stopper. The opposed wells at the top and the bottom of the stopper cooperate to provide a centrally positioned puncture diaphragm with the thinnest portion thereof being coaxial with the axis of the stopper and generally in the vicinity of the axis of the stopper.

As will be appreciated, such prior art arrangements present a comparatively thin puncture diaphragm area adjacent the axis of the stopper with gradually increased thickness from the axis toward the annular outer edge of the stopper. Practitioners-in-the-art will understand, therefore, that if a needle penetrates the diaphragm adjacent the axis by proper positioning of the cannula for insertion into a blood collection tube, the penetration

force will be desirably small. However, any deviation from the vicinity of the axis of the stopper increases substantially the penetration force and causes, in some instances, an occlusion of the cannula simply because the needle does not penetrate through the area of the puncture diaphragm adjacent the outer annular edge of the stopper.

By contrast, and as discussed above, such problems have been avoided with the new stopper, in accordance herewith, which is configured to maximize the areas of the stopper diameter which are of a thickness to provide a desirable puncture diaphragm area for penetration by a blood collection cannula.

It is, therefore, among the primary objects of this invention to provide a stopper for a test tube, such as a blood collection tube, which stopper has a cannula puncture diaphragm of substantially constant thickness throughout the diameter thereof, for reducing the penetration force necessary for penetration of the diaphragm and for reducing to a minimum cannula occlusion because of incorrect insertion of the cannula coaxially with the stopper.

It is a further object of this invention to provide such a stopper of reduced cost because of substantially reduced bulk of the stopper relative to the size of the stopper and the diameter of the tube for which it is formulated.

It is a further object of the invention to provide such a stopper which, because of its reduced bulk, reduces the radial force against the cooperating lip of the test tube for which the stopper is formulated, thus reducing breakage during insertion and/or shipment of the resulting stoppered tubes.

Before describing this invention in more detail, it may be well to note that the stopper of the invention may be comprised of any conventional elastomer, such as a natural rubber, or a synthetic rubber such as acrylonitrile-butadiene-styrene terpolymer or various known butyl rubbers.

Other objects and advantages of this invention will be apparent from the following description, the accompanying drawings, and the appended claims.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevational view of a test tube stopper illustrating the invention;

Fig. 2 is a top plan view of the stopper of Fig. 1;

Fig. 3 is a bottom plan view of the stopper of Fig. 1; and

Fig. 4 is a cross-sectional view of the stopper of Fig. 3 taken along lines 4-4 of Fig. 3.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, Fig. 1 illustrates the stopper 10 of the invention in a side elevational view showing the body portion 14 of stopper 10 and an upper flange portion 16. The body portion 14 has tapered walls 12 extending from the annular bottom wall 26 of the stopper to a ledge 20. Ledge 20 has a locking groove 22 for cooperating with the lip of a tube into which the body portion 14 of stopper 10 is inserted. Upper annular flange portion 16 of stopper 10 has tapered walls 18 converging toward the axis of stopper 10 from ledge 20 to the annular top edge 24.

As can be seen in Fig. 4, stopper 10 has an annular thin puncture diaphragm 62 defined by an upper cut 64 and an opposed undercut 66. As can be seen further in Fig. 4, the puncture diaphragm 62 has a substantially constant thickness throughout the diameter thereof, with upper wall 30 and lower wall 34 thereof being substantially straight across from the tapered annular wall 32 forming the walls of the upper cut or well 64 and the annular lower wall 38 forming the lower undercut or well 66.

As can be seen further in Fig. 4, annular wall 38 cooperates with annular tapered wall 12 to form an annular skirt 36 which defines the lower third of stopper 10. The bulk and/or thickness of

this skirt 36 is substantially reduced, as will be appreciated, because of the relative vertical walls 38 which, in turn, reduce the resistance of the insertion force necessary to insert stopper 10 into a cooperating test tube. The lower end surface 26 of skirt 36 includes an annular tapered wall 28 which facilitates, also, insertion of stopper 10 into a tube.

In this connection, in the production of serum separation tubes or other evacuated tubes, it is conventional to partially insert a stopper such as stopper 10 into a cooperating test tube only to the extent necessary to hold the stopper in the tube for subsequent production operations. Subsequently, each test tube with a partially inserted stopper is enclosed in an evacuated area and because of the slot 40 formed in annular skirt 36, air can be withdrawn from the partially stoppered tube through the slot 40. Once the tube is evacuated, the stopper is inserted completely into the tube so that the upper lip of the tube is inserted under the annular ledge 20 with the radially extending outer lip of the tube cooperating with the annular groove 22 to lock the stopper 10 into place in the evacuated tube. Of course, ledge 20 prevents further insertion of stopper 10 into the evacuated tube.

As will be appreciated, the dimensions of the stopper, in accordance herewith, as shown in Figs. 1 and 4, may vary, according to the size of the

cooperating test tube for which the stopper is used. However, as illustrative of dimensions which may be utilized in a conventional serum separation tube having a diameter of 16 millimeters (mm), the diameter 42 the stopper 10 may be, for example, 17.42mm. The dimension 44 as shown in Fig. 4 is 16.00mm, the dimension 46 of the upper cap portion 16 of stopper 10 is 6.35mm, while the lower body portion 14 of stopper 10 has a vertical dimension 48 of 10.20mm. The diameter 52 of undercut or lower well 66 in Fig. 4 is 9.32mm, while the vertical thickness 56 of puncture diaphragm 62 is 5.97mm. The radius 60 (Fig. 2) is 7.06mm.

Thus, as will be appreciated from the above description, an improved stopper is provided for test tubes such as blood collection tubes, for example, which includes a puncture diaphragm which is thinner, softer and less resistant to penetration by a cannula. Because of this, it is much easier to penetrate the stopper during veni-puncture and much easier to remove and reinsert the stopper, once the tube is removed to the lab for testing of its contents. As will be appreciated, further, from the above description, the substantially constant thickness of the diameter of the diaphragm of the stopper reduces the possibility of cannula occlusion. This, of course, reduces the accuracy necessary for penetration of the puncture diaphragm of the stopper. Because of the reduced bulk of the stopper there is a built-in reduction in the radial force of the stopper

during its insertion into the tube or during handling or shipping of the tube so that there is a substantial reduction in the breakage of tubes utilizing stoppers, in accordance herewith. Of course, because of the substantial reduction in bulk of the stopper, in accordance herewith, relative to its overall diameter, there is a substantial reduction in the cost of production of each stopper, as will be appreciated.

While the forms of apparatus herein described constitute preferred embodiments of the invention, it is to be understood that the invention is not limited to these precise forms, and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

WHAT IS CLAIMED IS:

1. Stopper apparatus (10) for use with test tubes and the like, comprising

(a) an annular body (14);

(b) an upper annular flange portion (16) integral with said body (14);

(c) said flange portion (16) defining an annular ledge (20) with said body (14) adjacent the junction of said flange portion (16) with said body (14);

the improvement characterized by

(d) an annular upper well (64) in the top surface of said flange portion (16) and coaxial therewith;

(e) the side walls (32) of said upper well (64) being substantially coaxial with said flange portion (16) adjacent the bottom surface (30) of said upper well (64);

(f) an annular lower well (66) in the bottom surface of said body portion (14) and coaxial therewith;

(g) said annular lower well (66) forming a depending skirt portion (36) integral with said body (14);

(h) the annular walls (12) forming said lower well (66) being substantially coaxial with said body (14); and

(i) the bottom surface (30) of said upper well (64) and the top surface (34) of said lower well (66) being substantially flat and cooperating to form a puncture diaphragm (62) in said stopper (10) of constant thickness throughout the entire area thereof.

2. The stopper apparatus (10) of Claim 1, further characterized by
(a) an annular locking groove (22) in said body (14) adjacent said annular ledge (20) for cooperating locking engagement with the lip of a test tube into which said stopper apparatus (10) is inserted.

3. The stopper apparatus (10) of Claim 1, further characterized by
(a) a vertical vent slot (40) in the outer wall of said depending skirt (36).

4. The stopper apparatus (10) of Claim 1, further characterized by
(a) said apparatus comprised of an elastomer selected from the group consisting of natural rubber and synthetic rubber.

5. The stopper apparatus of Claim 1, further characterized by
(a) the diameter of said flange portion (16) is about 16.00 millimeters;
(b) the diameter of said puncture diaphragm (62) is about 9.32 millimeters; and
(c) the height of said stopper apparatus (10) is about 16.55 millimeters.

6. Stopper apparatus (10) for use with test tubes and the like, comprising
(a) an annular body (14);
(b) an annular flange portion (16) integral with said body;

(c) said flange portion (16) defining an annular ledge (20) with said body (14) adjacent the junction of said flange portion (16) with said body (14); the improvement characterized by

(d) an annular puncture diaphragm (62) in said stopper apparatus (10) and coaxial therewith;

(e) the thickness of said puncture diaphragm (62) being substantially less than the thickness of said stopper apparatus (10); and

(f) said thickness of said puncture diaphragm (62) being constant over the entire area thereof.

7. The stopper apparatus of Claim 6, further characterized by

(a) the diameter of said flange portion (20) is about 16.00 millimeters;

(b) the diameter of said puncture diaphragm (62) is about 9.32 millimeters;

(c) the height of said stopper apparatus (10) is about 16.55 millimeters; and

(d) the thickness of said puncture diaphragm (62) is about 5.97 millimeters.

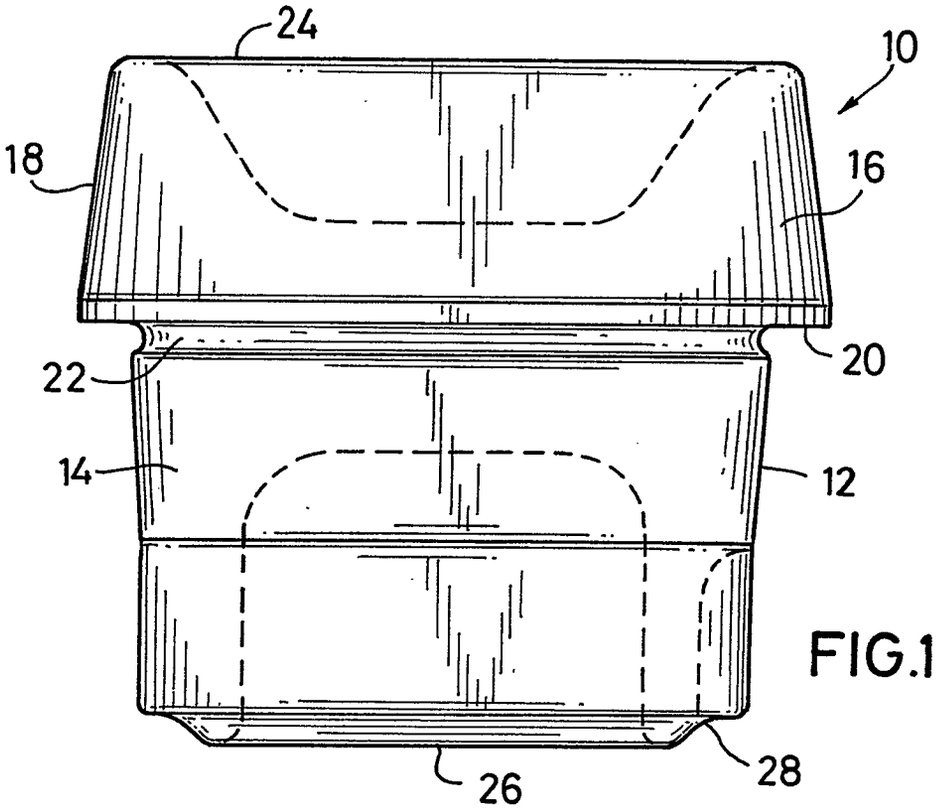

FIG.1

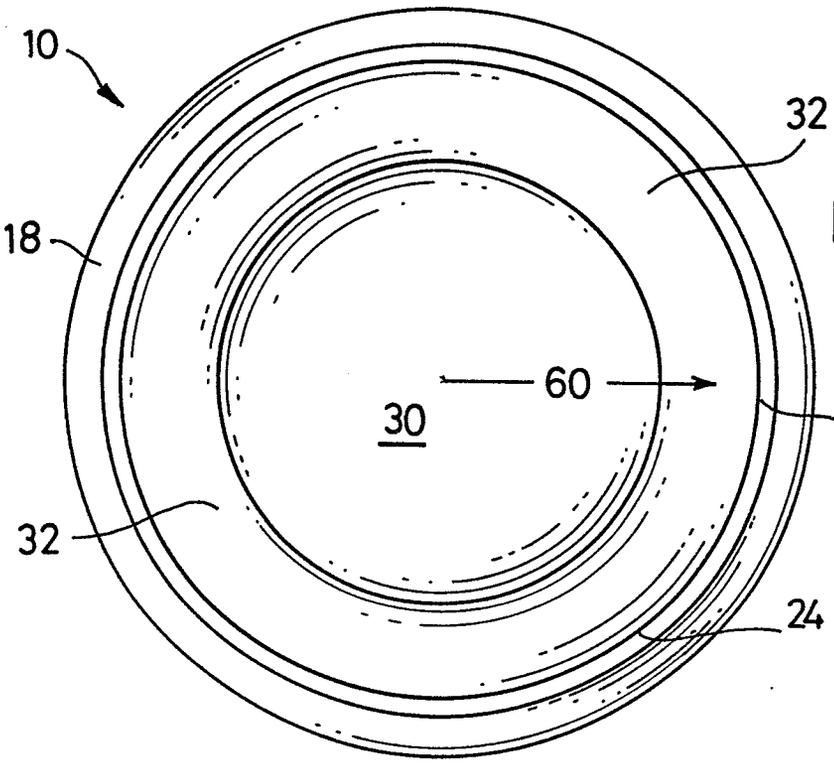

FIG.2

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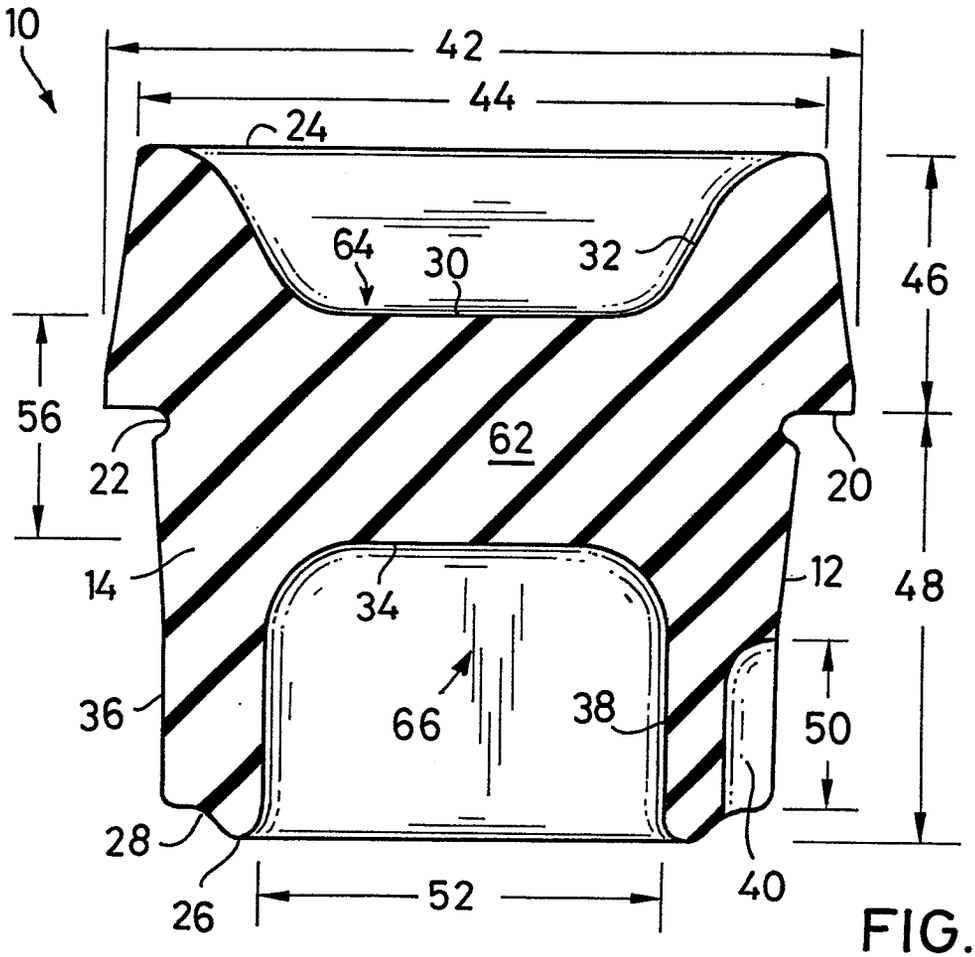

FIG.4

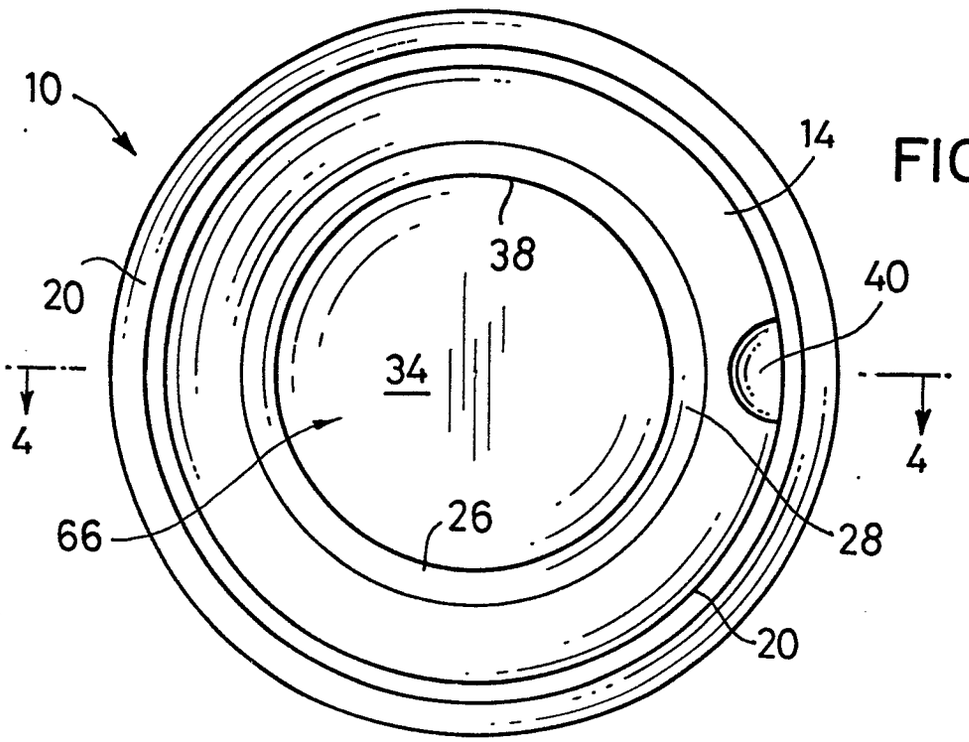

FIG.3

European Patent Office

EUROPEAN SEARCH REPORT

Application number 0086251

DOCUMENTS CONSIDERED TO BE RELEVANT

EP 82107351.7

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. ³)
X	US - A - 3 898 046 (IKEDA et al.) * Totality, especially fig. 1 *	1,4,6	B 65 D 39/04 B 65 D 41/28 A 61 J 1/00
X	GB - A - 1 444 210 (BEUTON) * Totality, especially fig. 1 *	1,4,6	
X	US - A - 3 958 572 (LAWHEAD) * Totality, especially fig. 1, numeral 44; fig. 3; column 3, lines 54-57 *	1,2,4, 6	
P,X	GB - A - 2 081 688 (SHERWOOD MEDICAL) * Totality, especially fig. 1,2; page 1, lines 105-107 *	1,4,6	
A	DE - A1 - 3 106 718 (TAKEDA) * Fig. 13a,b; page 4, lines 17-20 *	1,3,4, 6	
A	GB - A - 2 026 995 (COULTER) * Totality, especially fig. 1,2,3,6; page 3, lines 109-122 *	1,2,4, 5,6,7	

TECHNICAL FIELDS SEARCHED (Int. Cl. ³)

A 61 J 1/00
A 61 M 5/00
B 65 D 39/00
B 65 D 41/00
B 65 D 47/00
B 65 D 51/00
B 65 D 81/00
B 01 L 3/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	13-04-1983	CZUBA

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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