(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 494 845 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
10.04.1996 Bulletin 1996/15

(51) Int. Cl.[6]: **A61B 5/14**

(21) Application number: **92830002.9**

(22) Date of filing: **03.01.1992**

(54) **Perforable stopper for evacuated test tubes**

Durchstechbarer Verschluss für evakuierte Proberöhrchen

Bouchon perforable pour tube à essai sous vide

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(30) Priority: **10.01.1991 IT FI910006**

(43) Date of publication of application:
15.07.1992 Bulletin 1992/29

(73) Proprietor: **DIESSE DIAGNOSTICA SENESE s.r.l.**
I-20123 Milano (IT)

(72) Inventor: **Monciatti, Gabriele**
I-53100 Siena (IT)

(74) Representative: **Mannucci, Michele**
Ufficio Tecnico Ing.A. Mannucci,
Via della Scala 4
I-50123 Firenze (IT)

(56) References cited:
CA-A- 1 107 245
DE-B- 1 818 046
US-A- 4 295 572

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 0 494 845 B1

Description

Blood-sampling systems, which are well known and widely used, comprise (see Fig.1) a device 1 with a cylindrical guide structure 1A on the base 1B of which there are connected an external needle 3 for insertion into the vein and an internal needle 5 intended to perforate the rubber stopper T0 of an evacuated test tube P0; the rubber stopper T0 has a diaphragm which is perforable by the needle 5 and a flange expansion (projecting over the rim of the test tube P0) to guide it into the cavity of the cylinder 1A toward the needle 5. The needle 5 is covered in a slidable perforable elastic sheath 7 which forms a sealing valve for the needle 5 and is made to slide back by the diaphragm of the stopper P0 when the test tube with said stopper is inserted in the direction of the arrow fo into the cavity of the cylinder 1A, in order to take the sample; inside the test tube P0 a predetermined vacuum is created, as a result of which - with the insertion of the test tube P0 and the perforation of the diaphragm of the stopper T0 by the needle 5 after the cap 7 has been slid back - blood is brought from the vein through the needles 3 and 7 toward the test tube P0 to obtain the sample of a desired quantity of blood, which depends on the venous pressure, the capacity of the test tube P0 and the degree of vacuum established inside the latter. These sampling systems make it possible to take many samples while the device 1 is kept with the needle 3 in the vein and with no danger to the patient, since the only operation needed for taking a sample is that of inserting the evacuated test tube into the cavity of the cylinder 1A with a gentle axial thrust to perforate the diaphragm and a gentle axial pull to withdraw it. This operation may be repeated many times with new test tubes, while the needle 3 remains in the vein.

Also known is a different sampling system from that above, depicted in Figs 2 and 3, using test tubes into which the sample is drawn by the suction of a plunger which is slid along said test tube. As will be seen in Figs 2 and 3, the double-needle device 11 has an external needle 13 for insertion into the vein and an internal needle contained within a cavity 11A formed by the body of the device 11; here too, the needle 15 has a slidable elastic sheath 17 which is pushed back on perforation and slips forward again to close off the channel formed by the two needles 13 and 15, once the sample has been taken. To take the sample, a test tube P1 is provided, forming a cylinder-plunger system in which the plunger P2 is operated by a rod P3 to draw in the liquid (blood) after the head T1 of the test tube P1 has been inserted into the cavity 11A in such a way as to perforate the diaphragm T6 with the needle 5, the sheath 17 having been slid elastically back up the needle 15; to apply suction with the cylinder-plunger system, the head T1 is provided with pins T3 and the body 11 forming the cavity 11A has L-shaped clefts 11B running in from the rim, to allow bayonet connection of the head T1 after its insertion into the cavity 11A, by means of an angular movement which engages the pins P3 in the innermost extremities of the Ls of the clefts 11B; a reverse angular movement must be made to withdraw the head T1 of the test tube P1 out of the cavity 11A, whereupon the sheath 17 slips forward again. This arrangement has a number of disadvantages due chiefly to the need to make repeated operations - which require much skill - to repeat the functions of connecting and disconnecting the bayonet by rotating the successive test tubes inside the cavity 11A, while the device 11 is kept with the needle 13 in the vein; in particular, there is the danger that the needle 13 may slip out of the vein, or that the vein itself may be traumatized by sudden movements as the test tubes are changed over.

DE-A-1818046 discloses a stopper made of rubber for test tubes intended for the taking of blood samples by vacuum action; said stopper has an external extension, with an axial cavity, which projects from inside the test tube to end in the perforable diaphragm at the extremity of the extension; said extension is insertable into a recess of the internal needle of the sampling device, without the need for bayonet-type connection and disconnection, but with a screws connection system, which anyway needs an angular movement to obtain the connection.

The abovementioned disadvantages or DE-A-1818046 and of the system indicated in Figs.2 and 3 can be overcome by the invention, with the use of an evacuated test tube analogous to the test tube P0, T0, in order to work with the unmodified device 11 and in replacement for the plunger test tube P1, T1.

The invention accordingly relates to a stopper made of rubber - or similar material - for test tubes intended for the taking of blood samples by vacuum suction through a double-needle device 11 having an external needle 13 for insertion into the vein while the other or internal needle 15 is coaxial with and opposed to the first and fitted with a sheath forming a slidable elastic cap 17, and able to perforate the diaphragm of said stopper; the stopper has an external extension, with axial cavity, which projects from inside the test tube to end in the perforable diaphragm at the extremity of the extension; said external extension can be inserted into the recess of the internal needle 15 of the sampling device 11,

According to the invention, said external extension is more or less cylindrical, advantageously frustoconical, with a slight gradual narrowing. No angular movements is required for connection.

The tip of the extension, which defines externally the perforable diaphragm, is advantageously concave in order to hold any microdrop of blood which might form on withdrawal from the internal needle after sampling.

In one possible embodiment, the rubber stopper of the invention comprises a body capable of entering the test tube in order to close it; in said body there may, or equally well may not, be one or more external recesses to enable the vacuum to be established with the body of the stopper partly inserted in the test tube; there also must be a stop flange which remains outside the test tube.

The invention will be understood more clearly by following the description and the accompanying drawing, which latter shows a practical, non-limiting embodiment of said invention. In the drawing:

Fig. 1 shows the known solution discussed above for the use of low-pressure, that is evacuated, test tubes;
Figs 2 and 3 show the solution discussed above for use with test tubes P1 having a cylinder-plunger system for suction;
Figs 4 and 5 show a test tube made for operating under vacuum with the use of the device of Fig. 2, and a view in partial section of the stopper, shown in isolation, of said test tube.

As depicted in the accompanying drawing, with reference to Figs 4 and 5, a test tube P10 - in which a particular degree of vacuum can be pre-established - is fitted with a stopper T10 made of rubber or other equivalent material. This stopper T10 has a body T12 capable of entering the top of the test tube in order to close the test tube (with the help also of the vacuum created in the test tube) and a flange T14 by which it rests against the test tube rim. The body T12 has a slightly frustoconical portion T16 to ensure that it grips with a certain force on the test tube walls and an end section T18 to encourage its insertion into the mouth of the test tube P10; recesses T20 may be made in said section T18 in order that in the production stage the vacuum can be established inside the test tube with the section T18 of the stopper T10 only just inserted into the mouth of said test tube; the final forcible insertion of the section T16 of the stopper T10 into the test tube seals in and maintains the vacuum that has been pre-established in the cavity of the test tube. The stopper T10 projects beyond the flange T14 with an extension T22 which is typically shaped in a frustoconical or more or less slightly narrowing form to enable its insertion into the cavity 11A in the same way as with the extension T1 of the conventional test tube P1, T1. The extension T22 has no projections like those of T3, the bayonet connection of the test tube onto the device 11 being avoided because the test tube T10 contains a vacuum, and no axial movements of a plunger, which would necessitate an axial link between the body 11 and the test tube P1 of the conventional system of Figs 2 and 3, are therefore necessary. An axial cavity 24 extends from the inward extremity of the body T12, which forms the real stopper, into the extension T22 and as far as the extremity thereof where a perforable diaphragm T26 is present, analogous to the diaphragm T6 of the test tube P1, T1; the outward extremity of the extension T22 is concave, T28, in order to hold any microdrop of blood which might form on withdrawal of the test tube P10, T10 from the needle 15 of the device 11.

With the test tube P10, T10 as described, it is possible to use the device 11 - already known for use with plunger test tubes P1 - with a test tube containing a particular calibrated degree of vacuum for drawing in a predefined volume of blood; such a test tube P10, T10 simply requires the extension T22 to be inserted into the cavity 11A, with no need for angular operations to achieve a bayonet connection, nor for suction operations with the rod of a plunger, but simply the operation of inserting and perforating the diaphragm T26 by means of the needle 15, with the sliding back and temporary puckering up of the elastic sheath 17, which reseals the needle 15 as it slips forward once more when the test tube is withdrawn. The sampling operation is therefore reduced, even with the device 11 of Fig. 2, to the simple axial insertion and withdrawal of the test tube P10, T10, as in the known solutions depicted in Fig. 1, and the disadvantages mentioned above, as well as others known with the system of Figs 2 and 3, are avoided.

A further advantage of the test tube P10, T10 fitted with the extension T22 is that it can also be used with the device 1 of known type and already described with reference to Fig. 1.

It will be understood that the drawing shows a non-limiting illustrative embodiment which is given purely as a practical demonstration of the invention, it being possible for said invention to vary as regards shapes and arrangements without thereby departing from the scope of the concept underlying said invention. Any reference numbers appearing in the accompanying claims are intended to facilitate the reading of the claims with reference to the description and drawing, and do not limit the scope of protection represented by the claims.

Claims

1. A stopper (T10) made entirely of rubber, or other similar material, for a test tube (P10) intended for the taking of blood samples by vacuum suction through a doubleneedle device (11) having external needle (13) for insertion into the vein while the other or internal needle (15) is coaxial with and opposed to the first and fitted with a slidable elastic sheath (17), the stopper having a diaphragm (T26) formed at the extremity of an external extension (T22), with axial cavity (T24), which extends from inside the test tube (P10) to end in the said diaphragm (T26) which is perforable by the internal needle; said extension (T22) being insertable into a recess (11A) of the sampling device (11) in which the internal needle (15) is located, characterized in that said external extension (T22) is shaped in a frustoconical form.

2. The stopper as claimed in the preceding claim , characterized in that the tip of the extension (T22), which defines externally the perforable diaphragm (T26), is concave (T28) in order to hold any microdrop of blood which might form on withdrawal from the internal needle (15).

3. The stopper as claimed in the preceding claims, characterized in that it comprises: a body (T12) capable of entering the test tube (P0) and sealing it

off; at least one possible external recess (T20) in said body (T12) to enable the vacuum to be established in the test tube with the body of the stopper partly inserted; a stop flange (T14), which remains outside the test tube; said narrowing external extension (T22); and said axial cavity (T24) which forms the perforable diaphragm (T26) at the extremity of the external extension.

4. A test tube for taking blood samples by vacuum suction, fitted with the perforable stopper as claimed in the preceding claims, capable of being used with doubleneedle sampling devices having an external needle for insertion into the vein and an internal needle for insertion into said test tube containing the vacuum, after perforation of the stopper, in such a way that the blood is transferred from the vein to the test tube through the sole action of the vacuum present in said test tube.

Patentansprüche

1. Vollständig aus Gummi oder aus einem anderen, ähnlichen Material hergestellter Stopfen (T10) für ein Probenröhrchen (P10), das zur Entnahme von Blutproben mittels Unterdruck-Ansaugen durch eine Doppelnadel-Vorrichtung (11) bestimmt ist, die eine äußere Nadel (13) zum Einstechen in die Vene aufweist, während die andere oder innere Nadel (15) koaxial und entgegengesetzt zu der ersten angeordnet und mit einer verschiebbaren und elastischen Hülle (17) versehen ist, wobei der Stopfen am äußersten Ende einer äußeren Verlängerung (T22) eine Querwand (T26) aufweist, die einen axialen Hohlraum (T24) aufweist, der vom Inneren des Probenröhrchen (P10) ausgeht, um an besagter Querwand (T26) zu enden, die von der inneren Nadel durchstochen werden kann, und wobei besagte Verlängerung (T22) in einer Ausnehmung (11a) der Probenentnahmevorrichtung (11), in der die innere Nadel (15) angeordnet ist, einsetzbar ist,
dadurch gekennzeichnet, daß besagte äußere Verlängerung (T22) kegelstumpfförmig ausgebildet ist.

2. Stopfen, wie im voraufgehenden Anspruch beansprucht, dadurch gekennzeichnet, daß die Spitze der Verlängerung (T22), die endseitig die durchstechbare Querwand (T26) bildet, konkav (T28) ausgebildet ist, um jeglichen Mikrotropfen Blut festzuhalten, der sich nach dem Abziehen von der inneren Nadel (15) bilden könnte.

3. Stopfen, wie in den voraufgehenden Ansprüchen beansprucht, dadurch gekennzeichnet, daß er umfaßt: ein Basisteil (T12), geeignet, um in das Probenröhrchen (P10) einzudringen und es zu verschließen, wenigstens eine möglichst endseitige Ausnehmung (T20) im Basisteil (T12), damit im Probenröhrchen ein Unterdruck aufgebaut werden kann, wenn das Basisteil des Stopfens teilweise eingesetzt ist, einen Stopfenflanch (T14), der außerhalb des Probenröhrchens bleibt, besagte sich verjüngenden äußere Verlängerung (T22) und besagten axialen Hohlraum (T24), der die durchstechbare Querwand (T26) am äußersten Ende der äußeren Verlängerung bildet.

4. Probenröhrchen zur Entnahme von Blutproben mittels Unterdruck-Ansaugung, ausgerüstet mit einem durchstechbaren Stopfen, wie in den voraufgehenden Ansprüchen beansprucht, und geeignet zur Verwendung mit einer Doppelnadel-Probenentnahmevorrichtung, die eine äußere Nadel zum Einstechen in die Vene und eine innere Nadel zum Einsetzen in besagtes, Unterdruck aufweisendes Probenröhrchen nach dem Durchstechen des Stopfens aufweist, in der Weise, daß das Blut allein durch die Wirkung des Unterdrucks, der im besagten Probenröhrchen herrscht, von der Vene in das Probenröhrchen befördert wird.

Revendications

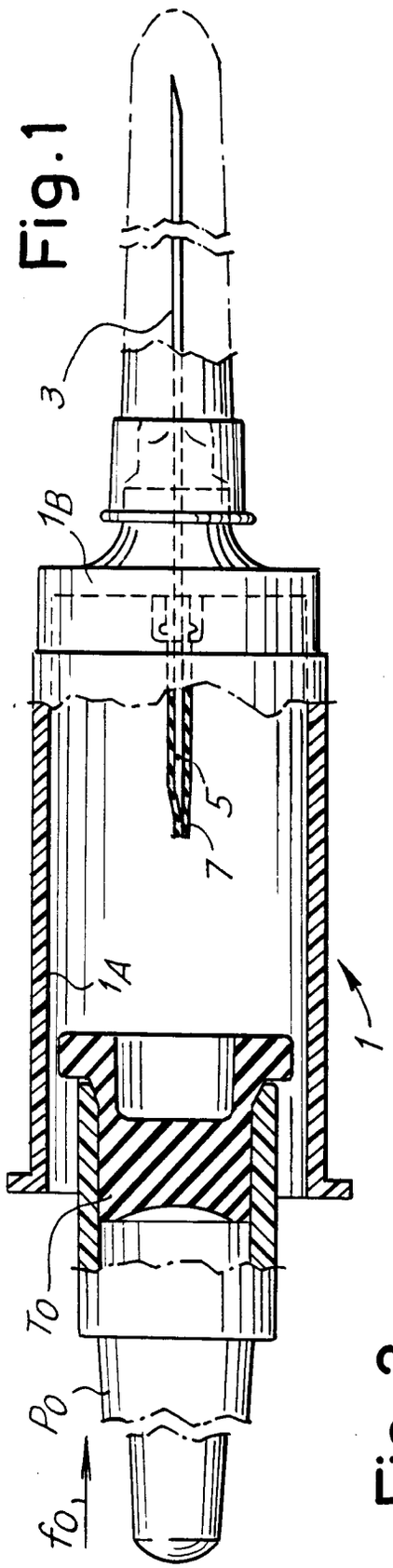
1. Bouchon (T10) réalisé entièrement en caoutchouc, ou en un autre matériau similaire, pour un tube à essai (P10) destiné au prélèvement d'échantillons sanguins par aspiration sous vide, au moyen d'un dispositif à double aiguille (11), avec une aiguille extérieure (13) pour l'introduction dans la veine, tandis que l'autre aiguille, ou aiguille interne (15), est coaxiale et opposée à la première aiguille et munie d'une gaine élastique coulissante (17), le bouchon présentant une membrane (T26) formée sur l'extrémité d'un prolongement extérieur (T22), avec une cavité axiale (T24), qui s'étend depuis l'intérieur du tube d'essai (P10) vers l'extrémité dans la membrane (T26), qui est perforable par l'aiguille interne ; le prolongement (T22) pouvant être inséré dans un évidement (11A) du dispositif d'échantillonnement (11), dans lequel est logée une aiguille interne (15), caractérisé en ce que le prolongement externe (T22) est de forme tronconique.

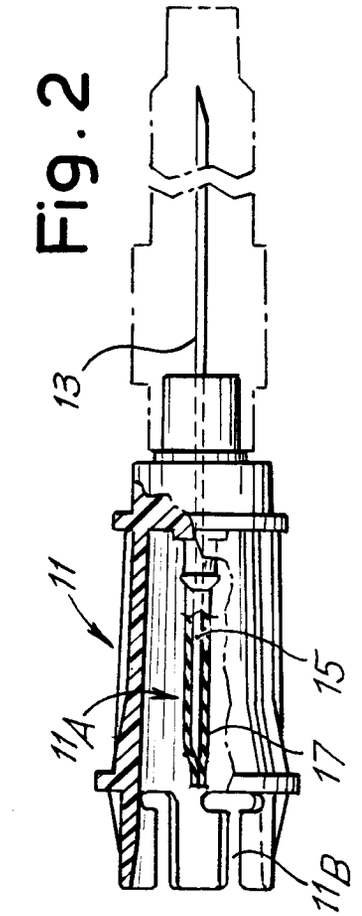
2. Bouchon selon la revendication précédente, caractérisé en ce que la pointe du prolongement (T22), qui définit extérieurement la membrane perforable (T26), est concave (T28), pour retenir toute microgoutte de sang susceptible de se former lors de l'enlèvement de l'aiguille interne (15).

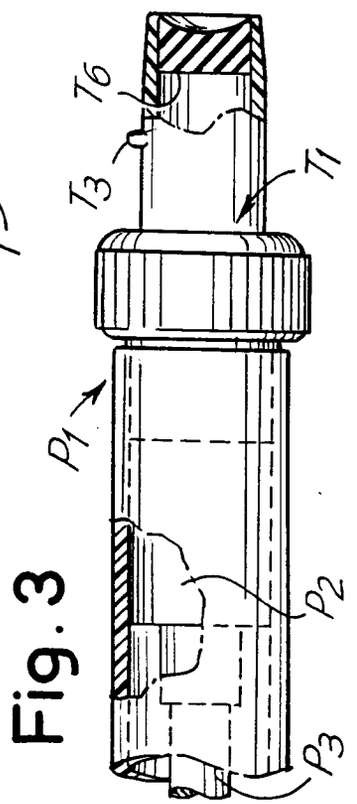
3. Bouchon selon la revendication précédente, caractérisé en ce qu'il comprend : un corps (T12) capable de pénétrer dans le tube d'essai (P0), et de le rendre hermétique ; au moins un évidement externe possible (T20) dans le corps (T12), pour permettre d'établir le vide dans le tube d'essai avec le corps du bouchon partiellement introduit ; un rebord d'arrêt (T14) qui demeure à l'extérieur du tube d'essai ; le

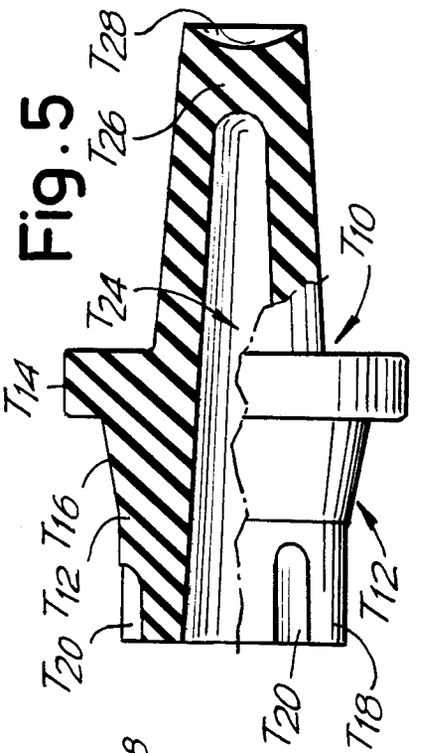
prolongement externe (T22) allant en se rétrécissant ; et la cavité axiale (T24) qui forme le membrane perforable (T26), sur l'extrémité du prolongement externe.

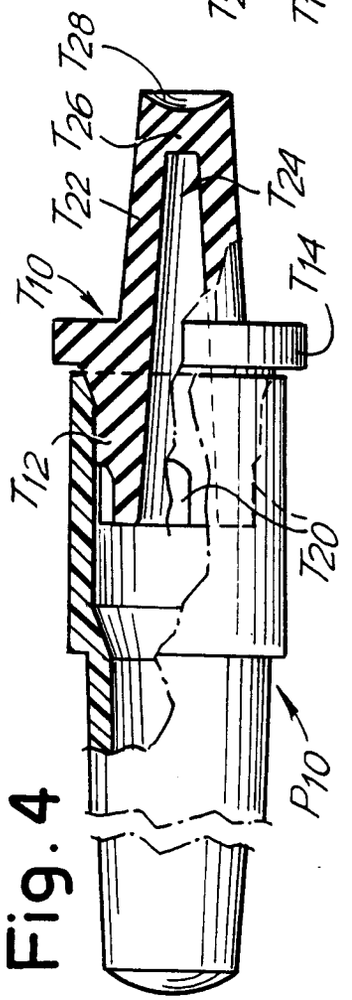
4. Tube à essai pour le prélèvement d'échantillons sanguins par aspiration sous vide, muni du bouchon perforable selon les revendications précédentes, pouvant être utilisé avec des dispositifs d'échantillonnage à double aiguille, comportant une aiguille externe pour l'introduction dans la veine et une aiguille interne pour l'introduction dans le tube d'essai contenant le vide, après perforation du bouchon, de façon à faire passer le sang de la veine au tube d'essai, sous l'effet de la seule action du vide présent dans le tube d'essai.


Fig.1
3
1B
5
7
1A
1
T0
P0
fo


Fig.2
13
11
11A
15
17
11B


Fig.3
T6
T3
T1
P1
P2
P3


Fig.5
T28
T26
T10
T24
T14
T16
T12
T20
T18


Fig.4
T28
T26
T22
T24
T10
T14
T12
T20
P10