Spruson & Ferguson

COMMONWEALTH OF AUSTRALIA

THE PATENTS ACT 1952

AUSTRALIA
CONVENTION
STANDARD
PATENT
APPLICATION
FORM
SFP2

CONVENTION APPLICATION FOR STANDARD PATENT OR A STANDARD PATENT OF ADDITION

CP-8184

Full name(s) of Applicant(s)

SECTION 34(4) DIRECTION SEE FORM 2
NAME DIRECTED: STERWOOD MEDICAL COMPANY
OF 1831 OLIVE STREET, ST LOUIS, MISSOURI, 63103
UNITED STATES OF AMERICA

Address(es) of Applicant(s)

hereby apply for the grant of a standard patent ~~patent of addition~~

for an invention entitled

"BLOOD SAMPLE SYRINGE"

Title of Invention

595007

which is described in the accompanying complete specification.

DETAILS OF BASIC APPLICATION(~~S~~)

Number(~~s~~) of Basic Application(~~s~~)

745,855

Name(~~s~~) of Convention Country(~~ies~~) in which Basic Application(~~s~~) was/~~were~~ filed

United States of America

~~(respectively)~~

Date(s) of Basic Application(~~s~~)

17 June, 1985

~~(respectively)~~

SPECIFICATION ACCEPTED AND AMENDMENTS ALLOWED 6.2.90

PATENT OFFICE
A.C.T. SUB-OFFICE
- - 079632
Collector of Public Moneys

LODGED AT SUB-OFFICE
18 JUN 1985

~~My~~/Our address for service is:

C/- **Spruson & Ferguson**
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Dated this 17 day of April 19 86

The Common Seal of
CHESEBROUGH POND'S INC.
was hereto affixed in
the presence of:-

CHESEBROUGH-POND'S INC.
Westport, CT 06881

Robert E. Karlson

Robert E. Karlson, Vice President

To: The Commissioner of Patents

SFP2 11/81

Spruson & Ferguson

COMMONWEALTH OF AUSTRALIA

THE PATENTS ACT 1952

~~CP-8184~~

AUSTRALIA
CONVENTION
STANDARD
& PETTY PATENT
DECLARATION

DECLARATION IN SUPPORT OF A CONVENTION APPLICATION FOR A PATENT

In support of the Convention Application made for a patent for an invention entitled:

Title of Invention

"BLOOD SAMPLE SYRINGE"

I/~~We~~ Robert E. Karlson, Vice President

Full name(s) and address(es) of Declarant(s)

of CHESEBROUGH-POND'S INC.
33 Benedict Place, Greenwich, Connecticut 06830,
United States of America

do solemnly and sincerely declare as follows:–

Full name(s) of Applicant(s)

~~1.--I am/We are the applicant(s) for the patent~~

(or, in the case of an application by a body corporate)

1. I am/~~We are~~ authorised by CHESEBROUGH POND'S INC.

the applicant(~~s~~) for the patent to make this declaration on its/~~their~~ behalf.

2. The basic application(~~s~~) as defined by Section 141 of the Act was/~~were~~ made

Basic Country(ies)

in United States of America

Priority Date(s)

on 17 June, 1985

Basic Applicant(s)

by GARY B. McALISTER and JAMES MALLOY

~~3.--I am/We are the actual inventor(s) of the invention referred to in the basic application(s)~~

Full name(s) and address(es) of inventor(s)

(or where a person other than the inventor is the applicant)

3. GARY BENNETT McALISTER and JAMES PATRICK MALLOY

of 54 Wolfe Avenue, Beacon Falls, Connecticut 06403, and
22 Warncke Road, Wilton, Connecticut 06897, both
in the United States of America

(respectively)

~~is~~/are the actual inventor(s) of the invention and the facts upon which the applicant(~~s~~) is/~~are~~ entitled to make the application are as follows:

Set out how Applicant(s) derive title from actual inventor(s) e.g. The Applicant(s) is/are the assignee(s) of the invention from the inventor(s)

The said applicant is the assignee of the actual inventors.

4. The basic application(~~s~~) referred to in paragraph 2 of this Declaration was/~~were~~ the first application(~~s~~) made in a Convention country in respect of the invention(~~s~~) the subject of the application.

Declared at Westport CT this 17 day of April 1986

CHESEBROUGH-POND'S INC.

Robert E. Karlson

Signature of Declarant(s)

Robert E. Karlson, Vice President

SFP4

To: The Commissioner of Patents

11/81

(12) PATENT ABRIDGMENT (11) Document No. AU-B-58883/86
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 595807

(54) Title
BLOOD SAMPLING SYRINGE WITH PLUG

International Patent Classification(s)
(51)[4] **A61M 005/31** **A61B 005/14** **A61M 005/18** **A61M 005/315**

(21) Application No. : **58883/86** (22) Application Date : **16.06.86**

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(31) Number (32) Date (33) Country
745855 **17.06.85** **US UNITED STATES OF AMERICA**

(43) Publication Date : **24.12.87**

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SPRUSON & FERGUSON

(56) Prior Art Documents
EP 102070
US 4466446
US 4448206

(57) Claim

1. A syringe assembly for obtaining a fixed maximum volume fluid sample which comprises:

a cylindrical syringe barrel open at a first end and adapted to receive a hypodermic needle at a second end;

a cylindrical plug element arranged at a selected longitudinal position in the said syringe barrel defining the said fixed maximum volume for the said sample as the interior volume of the said barrel between the said second end and the said plug element, the said plug element being arranged to permit flow of air therethrough and to prevent flow of fluid therethrough, and a plunger arranged in the said barrel between the said plug element and the said first end, the said plunger including a piston having an air channel therethrough, a plunger rod extending out of the said first end and valve means for closing the said air channel when the said plunger rod is drawn in the direction of the said first end.

8. A method for drawing a fixed maximum volume, air-free blood sample which comprises:

providing a syringe having a plug element at a fixed position in a

syringe barrel, the said plug element being air-permeable and fluid-impermeable and having a plunger arranged in the ~~said~~ side barrel on the said of the said plug element away from the needle end of the said syringe;

inserting the needle of the said syringe into a blood vessel; and drawing the said plunger away from the said plug thereby to draw air through the said plug element until blood fills the said syringe barrel between the said needle and the said plug element.

FORM 10 **SPRUSON & FERGUSON**

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

COMPLETE SPECIFICATION

(ORIGINAL)

FOR OFFICE USE:

58883/86.

595807

Class Int. Class

Complete Specification Lodged:

Accepted:

Published:

Priority:

Related Art:

Name of Applicant: ~~CHESEBROUGH POND'S INC~~. SHERWOOD MEDICAL COMPANY

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Actual Inventor(s): GARY BENNETT McALISTER and JAMES PATRICK MALLOY

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Complete Specification for the invention entitled:

"BLOOD SAMPLE SYRINGE"

The following statement is a full description of this invention, including the best method of performing it known to us

SBR/JS/0031M

ABSTRACT

A syringe assembly for obtaining a fixed maximum volume fluid sample which comprises:

a cylindrical syringe barrel open at a first end and adapted to receive a hypodermic needle at a second end;

a cylindrical plug element arranged at a selected longitudinal position in the said syringe barrel defining the said fixed maximum volume for the said sample as the interior volume of the said barrel between the said second end and the said plug element, the said plug element being arranged to permit flow of air therethrough and to prevent flow of fluid therethrough, and a plunger arranged in the said barrel between the said plug element and the said first end, the said plunger including a piston having an air channel therethrough, a plunger rod extending out of the said first end and valve means for closing the said air channel when the said plunger rod is drawn in the direction of the said first end.

TMR/187u

BACKGROUND OF THE INVENTION

The present invention relates to a novel arterial blood sample syringe for use in connection with blood gas analysis. More specifically, the syringe of the present invention is designed to substantially reduce or eliminate error in blood sampling procedures through the use of a preset means that defines the maximum volume of blood that can be delivered to the syringe either by aspiration or by arterial blood pressure. Further, the syringe of the present invention provides improvement in elimination of air contamination in connection with obtaining an arterial blood sample.

Earlier U.S. Patent No. 4,133,304 discloses an apparatus for obtaining a fixed volume blood sample, which

includes a sample gathering capillary tube which is vented by the use of a fibrous thread, which can be removed to seal the capillary tube. The earlier device in one embodiment provides an arrangement for blood aspiration through the use of a piston which surrounds the capillary tube.

The prior art device has a rather complex construction and is difficult to use in connection with some blood-gas analyzing equipment which require that a blood sample be ejected into the analyzing equipment.

SUMMARY OF INVENTION

According to the present invention, there is provided a syringe assembly for obtaining a fixed maximum volume fluid sample which comprises:

a cylindrical syringe barrel open at a first end and adapted to receive a hypodermic needle at a second end;

a cylindrical plug element arranged at a selected longitudinal position in the said syringe barrel defining the said fixed maximum volume for the said sample as the interior volume of the said barrel between the said second end and the said plug element, the said plug element being arranged to permit flow of air therethrough and to prevent flow of fluid therethrough, and a plunger arranged in the said barrel between the said plug element and the said first end, the said plunger including a piston having an air channel therethrough, a plunger rod extending out of the said first end and valve means for closing the said air channel when the said plunger rod is drawn in the direction of the said first end.

In a preferred embodiment of the invention the air permeable, fluid impermeable plug element has a sealing member formed of a material arranged to allow penetration of fluid into the material prior to sealing and thereby trap a small volume of fluid, such as blood in the sealing material. The material may comprise a porous polyethylene with a pore size which allows entry of fluid and a water soluble sealant additive within the polyethylene.

In accordance with the present invention there is provided a blood sampling device having a syringe barrel and an air- permeable and fluid-impermeable sealing member for obtaining a blood sample using arterial blood pressure in a volume defined by the position of the said sealing member in the said syringe barrel, characterized by a sealing material arranged to allow penetration of blood into the said material prior to sealing thereby to trap a small volume of blood in the said sealing material.

There is still further provided a method for drawing a fixed maximum volume, air-free blood sample which comprises:

providing a syringe having a plug element at a fixed position in a syringe barrel, the said plug element being air-permeable and fluid-impermeable and having a plunger arranged in the said barrel on the side of the said plug element away from the needle end of the said syringe.

inserting the needle of the said syringe into a blood vessel;

and drawing the said plunger away from the said plug thereby to draw air through the said plug element until blood fills the said syringe barrel between the said needle and the said plug element.

BRIEF DESCRIPTION OF THE DRAWING

The figure is a longitudinal sectioned view of a syringe constructed in accordance with a preferred embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The drawing shows a cross-sectional view of a syringe assembly in accordance with the present invention.

The syringe assembly uses a conventional cylindrical syringe barrel 10 which has a first open end 16 and a second end 12 adapated to receive either a hyperdermic needle or a cap, which is not shown. For this purpose, end 12 has a neck 14 for receiving a hyperdermic needle, and in the illustrated embodiment also includes a Luer lock arrangement 18 for securing attachment of a needle or plug to neck 14.

A plug element 20 is arranged at a fixed position within barrel 10. The position of plug element 20 defines a blood sample volume consisting of the interior space of barrel 10 between plug element 20 and neck 14.

Plug element 20 has an exterior member 22 made of Kraton. Member 22 is formed to resiliently engage the interior of barrel 10 to form a seal between barrel 10 and member 22. Interior passage 26 is formed to extend longitudinally through the center of plug element 20. Sealing member 24 is held firmly within an enlarged section of longitudinal passage 26 of member 22.

Sealing member 24 is arranged to pass air through the center of plug 20 but to seal and prevent passage of fluid such as blood. The particular sealing member 20 used in the embodiment shown in the drawing is of special design and arranged to allow blood to penetrate the sealing member to a partial thickness of the member prior to sealing. This arrangement of sealing member 24 provides for relatively complete elimination of air in the sample volume between plug element 20 and neck 14 when blood enters the syringe either by arterial blood pressure or aspiration, as will be further explained.

A suitable material for plug element 24 is porous polyethylene with a relatively large pore size which enables fluid to enter the sealing member 24. Within the polyethylene, there is provided a water soluble sealant additive. The sealant additive is dissolved in the water of a fluid, such as blood, and upon dissolving causes a thickening of the fluid in the interior of sealing member 24 which prevents further flow of blood through the entire thickness of member 24, thereby blocking passage 26. A suitable material for member 24 can be obtained from Porex Technologies of Fairburn, Georgia and has a designation R44-NP10.

The syringe assembly shown in the drawing further includes a plunger 28 having a plunger rod 29 and a piston member 30. Piston 30 includes cylindrical member 31, also made of Kraton and also in sealing engagement around its periphery with the interior of barrel 10. Member 31 includes a longitudinal interior air channel 32. A valve member 34 is arranged within air channel 32 and connected to plunger rod 29 by a non-circular connecting member 36. Accordingly, in the relaxed condition illustrated air can freely flow through piston 30. When plunger rod 29 is drawn outwardly from syringe barrel 10, valve member 34 engages a shoulder on cylindrical member 31 and seals the air channel 32 so that air can no longer enter barrel 10 and a partial vacuum occurs within barrel 10.

The interior of barrel 10, particularly in the sample chamber between plug element 20 and neck 14 is advantageously provided with Heparin coating 38 to prevent blood clotting when a sample is within the sample volume.

When supplied to a technician or nurse who is to obtain a blood sample, the syringe shown in the drawing has plug element 20 at a pre-set position within barrel 10 which defines the volume of blood sample to be obtained. Plunger 28 is at a position where piston 30 is spaced between plug element 20 and opened end 16 of barrel 10. It is important that the technician be instructed not to move plunger 28 into barrel 10 in a manner which would disturb the pre-set positon of plug element 20. A temporary mechanical stop may be provided to reinforce this instruction.

In order to obtain an arterial blood sample, for example for blood gas analysis, a needle is attached to neck 14 and inserted into the patient's artery. For a normal adult patient, with adequate blood pressure, arterial blood pressure is usually sufficient to cause blood to flow into barrel 10 through neck 14. As blood enters, it contacts and becomes mixed with the Heparin coating 38. During the blood collecting process, plug element 20 should be elevated with respect to neck 14 so that air in the sample chamber between element 20 and neck 14 can flow through sealing member 24 and air passage 26 of plug element 20 and also through air channel 32 past valve 34 in piston member 31.

When the level of the blood sample reaches sealing member 24, air within the sample chamber is driven out as the blood enters the sealing member 24. Following partial penetration, for example, approximately 25% of the distance through sealing member 24, the water soluble sealant additive within sealing member 24 causes a thickening of the blood and sealing of the porous passageways, thereby preventing further flow of blood past plug element 20.

Having obtained a blood sample, the technician may remove the needle from the patient's artery and can thereafter use plunger 28 to move plug element 20 toward neck 14 to expel the blood sample through neck 14 into a blood gas analyzer.

It should be noted that during the sampling process, contact between the blood sample and air has been carefully minimized, since air is quickly driven through sealing member 24 and the portion of the blood sample that has contacted air enters sealing member 24 and is trapped therein. The portion of the blood sample injected into the analyzing device has not had contact with air and contains no remnant air bubbles, which might arise in a conventional syringe where there is an air space within neck 14 and the funnel portion of barrel 10 prior to obtaining a sample.

In a second mode of operation, the syringe shown in the drawing can be used to aspirate a blood sample from a patient with inadequate arterial blood pressure. For this purpose a needle is attached to neck 14 and inserted into an artery as in the self-venting operation. In order to draw a blood sample under partial vacuum into syringe barrel 10, plunger 28 is drawn outwardly from syringe barrel 10 causing valve 34 to close air passage 32 within piston 30 and generating a partial vacuum within syringe barrel 10 on the side of piston 30 facing barrel end 12. Because piston 30 starts at a location part-way down barrel 10, a rather gentle vacuum is generated, which is sufficient for drawing the blood sample, but does not cause extraction of gases from the blood sample nor does it cause hemolysis of red blood cells. In the aspiration operation, air is drawn through sealing member

24 thereby eliminating presence of air within the sample chamber once the blood level reaches and enters sealing member 24.

An important advantage of the present invention is the ability of the devices, as described, to provide for a fixed maximum volume of blood sample, determined by the pre-set position of plug element 20, even when the device is used in the aspiration mode. Unlike prior arrangements, plug element 20 does not move within barrel 10 when blood is aspirated using the syringe.

Another important advantage of the invention is that it enables almost total elimination of air within the sample volume. The arrangement illustrated enables natural flow of air, in either the self-venting mode or the aspiration mode, through sealing member 20 until the blood sample actually enters and penetrates the sealing member pushing trapped air bubbles well into the sealing member. Another advantage of the invention is the fact that neither plug element 20 nor piston 30 move into the portion of barrel 10 containing the blood sample until plunger 28 is used to expel the blood sample for analysis. Accordingly, the Heparin coating 38 on the interior of barrel 10 is not disturbed by the passage of a piston element.

While there has been described what is believed to be the preferred embodiment of the present invention, those skilled in the art will recognize that other changes and modifications may be made thereto without departing from the spirit of the invention, and it is intended to claim all such changes and modifications as fall within the true scope of the invention.

The claims defining the invention are as follows:

1. A syringe assembly for obtaining a fixed maximum volume fluid sample which comprises:

a cylindrical syringe barrel open at a first end and adapted to receive a hypodermic needle at a second end;

a cylindrical plug element arranged at a selected longitudinal position in the said syringe barrel defining the said fixed maximum volume for the said sample as the interior volume of the said barrel between the said second end and the said plug element, the said plug element being arranged to permit flow of air therethrough and to prevent flow of fluid therethrough, and a plunger arranged in the said barrel between the said plug element and the said first end, the said plunger including a piston having an air channel therethrough, a plunger rod extending out of the said first end and valve means for closing the said air channel when the said plunger rod is drawn in the direction of the said first end.

2. The syringe assembly as claimed in claim 1 wherein no manual operation of the plug element is required to prevent the flow of fluid therethrough.

3. A syringe assembly as claimed in claim 1 or claim 2 wherein the said plug element comprises a cylindrical resilient member forming an air and fluid seal against the inside of the said barrel and having an internal passageway and a sealing member across the said passageway, the said sealing member being arranged to permit passage of gas and to prevent passage of fluid.

4. A syringe assembly as claimed in claim 3 wherein the said sealing member has a selected thickness in the direction of air flow through the said passageway and is arranged to seal only after fluid has penetrated the said sealing member a distance which is less than the said selected thickness whereby a small volume of the said fluid is trapped in the said sealing member.

5. A syringe assembly as claimed in claim 4 wherein the said sealing member comprises porous polyethylene having a pore size selected to permit entry of fluid and a water-soluble sealant additive within the said polyethylene.

6. A blood sampling device having a syringe barrel and an air-permeable and fluid-impermeable sealing member for obtaining a blood sample

using arterial blood pressure in a volume defined by the position of the said sealing member in the said syringe barrel, characterized by a sealing material arranged to allow penetration of blood into the said material prior to sealing thereby to trap a small volume of blood in the said sealing material.

7. The device as claimed in claim 6 wherein the said sealing material comprises porous polyethylene having a pore size selected to permit entry of fluid and a water-soluble sealant additive within the said polyethylene.

8. A method for drawing a fixed maximum volume, air-free blood sample which comprises:

providing a syringe having a plug element at a fixed position in a syringe barrel, the said plug element being air-permeable and fluid-impermeable and having a plunger arranged in the ~~said~~ side barrel on the said of the said plug element away from the needle end of the said syringe;

inserting the needle of the said syringe into a blood vessel; and drawing the said plunger away from the said plug thereby to draw air through the said plug element until blood fills the said syringe barrel between the said needle and the said plug element.

9. A syringe assembly for obtaining a fixed maximum volume fluid sample substantially as hereinbefore described with reference to the accompanying drawings.

10. A blood sampling device substantially as hereinbefore described with reference to the accompanying drawings.

11. A method for drawing a fixed maximum volume, air-free blood sample substantially as hereinbefore described with reference to the accompanying drawings.

DATED this NINTH day of NOVEMBER 1989
Sherwood Medical Company

Patent Attorneys for the Applicant
SPRUSON & FERGUSON

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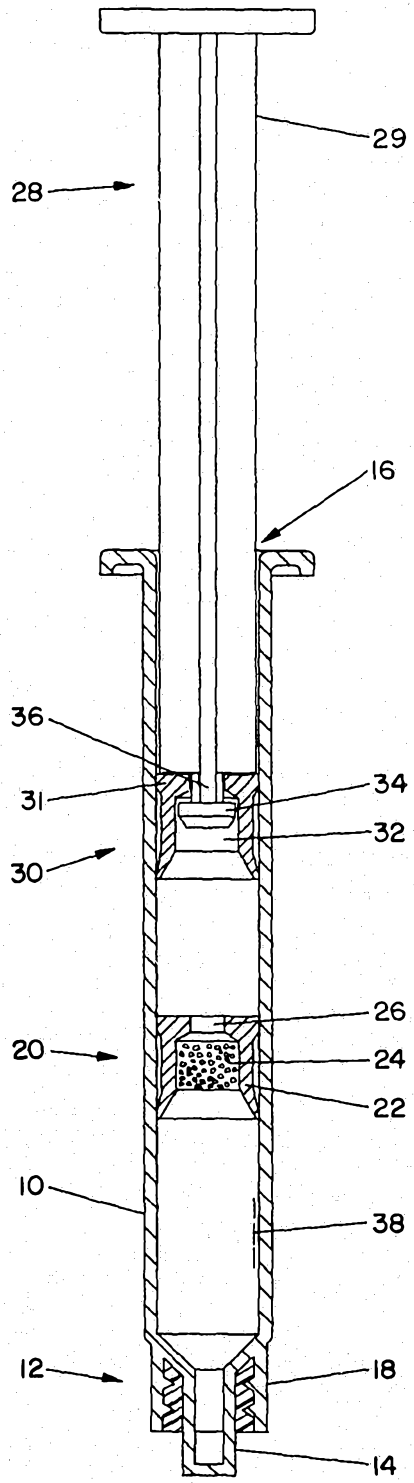
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