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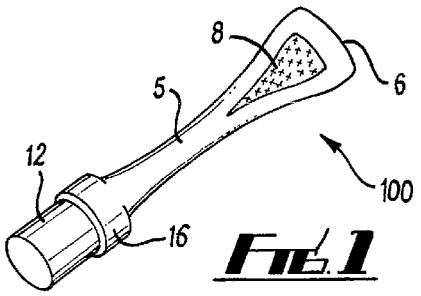

FIG. 1

(57) Abstract: A collector (100) for fluid such as oral fluid having a built in means (12) for collection and an integral indicator in the form of a colour change element (36). The collector operating by total internal reflection or fibre optic means which visually reveals the presence of fluid to the central portion of the collector by the colour change element reacting to wetting. Using a handle (5) as a transmitter by total internal reflection to an observation surface (6) so ensuring the collector has absorbed sufficient fluid for a test to be adequately performed.

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ORAL FLUID COLLECTOR

The present invention relates to oral fluid collection and more particularly fluid saliva collection for forensic or drug testing.

Saliva, or more accurately, oral fluid, is used widely nowadays for a range of tests that include medical screens, hormonal profiles and drug testing. Typically, oral fluid is collected and then transferred to a container for use in a laboratory medical screen, or is applied directly to a test or screening device.

Those conversant in the art will appreciate that collection of oral fluid is difficult in some circumstances. For example when oral fluid is collected for the detection of antibodies to human immunodeficiency virus (HIV) or hepatitis virus, to determine whether someone suffers from one or more of these diseases, the donor often has a compromised hepatic system (especially if they have advanced symptoms of one of these diseases) and therefore have a limited availability of saliva. Similarly if oral fluid is to be collected from the user of an illicit drug or other substance, one effect of the illicit drug may be a dry mouth which makes collection of oral fluid especially difficult in those persons who happen to be of particular interest to drug testing agencies. Moreover, police forces have interest in oral fluid testing for roadside drug testing applications but those practiced in the art will know that many motorists faced with a police presence at a road block or when stopped suddenly by a police car will be nervous and hence will have a dry mouth, making oral fluid collection all the more critical.

The performance and success rate of the test that is carried out with the collected oral fluid also depends to a large extent on the volume and quality of the oral fluid that is collected. If the volume is not sufficient the test will not develop properly or else the laboratory procedure remains incomplete. In certain instances this could result in an erroneous result that could have dire consequences for the patient or the motorist. In certain instances the test

is designed to use a fluid to help extract the oral fluid from the collecting device. This fluid, in the form of a buffer solution, is undesirable because the use of an additive solution dilutes the substances that are being collected and this will produce inaccuracies in the analysis of that substance.

There is therefore a requirement to have a simple system which collects oral fluid and displays the adequate presence of fluid to the supervisor of the test.

Oral fluid may consist of saliva emitted in the mouth from various salivary glands positioned at certain locations within the oral cavity; from sputum; or from nasal mucous and others. For many applications (such as drug testing) any oral fluid would suffice but for other applications (such as hormone analysis or infectious diseases) it is more appropriate to collect sub-crevicular fluid from the gum line.

All collections have to be performed in such a way that the donor does not object to the collection means, and this generally requires that the system is simple, non-invasive and does not require intervention by the supervisor.

The most significant difficulty in collecting oral fluid is a correct assessment of the quantity collected because most individuals are reluctant to put the collection device back in the mouth to collect extra sample especially if the collection device has been handled or if the wet swab is cold having been out of the mouth for a short period. Often, and especially in the case of drug test donors, once the sample has been collected it is not practicable to ask for another sample at a later date once the laboratory realises there was insufficient sample, because the pharmacokinetics of drug or alcohol abuse results in a different level or even an absence of the substance being detected.

It can be seen by those practiced in the art of collecting samples that the problems described above apply equally to other processes that require collection of liquid samples, for example blood, water, effluent, beverages,

and the like, where it is necessary to ensure the correct amount of sample is collected, especially when done remotely such as in a beverage vat or tank.

A review of prior systems includes disclosures such as:

French patent FR2843011 describes a sampling tip with a sliding collector with a filtration system.

U.S. patent 2001008614 describes a collection system incorporating a concentrating system.

Japanese patent JP8299284 describes a vessel with means for collecting volumes of saliva.

Patent WO9502996 describes a testing device incorporating a collection device that consists of a piston and a holding reservoir.

U.S patent 5380492 is a sampling device with a piece of filter paper therein, and U.S. patent US5260031 is a filter paper collector with a visual indicator connected to the holder and filter paper read visually.

Patent DE60222154D is a sample collector with a visually read indicator for fluid adequacy viewed through a hole in the device and thus only readable once removed from the mouth.

U.S. patent. No. 4,150,950 includes a container, a seal, a screw-cap, an elongated element and a specimen collector. After a specimen has been obtained, the specimen collector, which is attached to the screw cap, is forced through the seal into the liquid preservative as the screw cap is fastened onto the container.

U.S. Patent No. 4,774,962 has a resilient absorbent inert body that is chewed by a person and is subsequently introduced into a centrifuge tube.

U.S. Patent No. 4,992,296 describes test papers which have been impregnated with specific test chemicals. The test chemicals are provided for the detection of the drug abuse compounds in animal or human urine.

U.S. Patent No. 4,635,488 is a body fluid sampling device which includes a hollow tube with a solid porous nib mounted in and protrudes from one end of the tube for collecting a sample. The sample may be extracted from the nib for analysis by supplying an extraction fluid to the interior of the tube.

U.S. Patent No. 4,418,702 and U.S. Patent No. 4,580,577 have a flavoured absorbent sponge for mastication and charging it with saliva and then expressing the saliva from the flavoured absorbent sponge. The apparatus for this method includes a barrel-piston arrangement in association with a specimen vial for storage.

U.S. Patent No. 4,817,632 is an oral fluid collection device for placement in the buccal cavity of an individual for the collection and filtering of a saliva fluid. The collection article has a semi-permeable membrane container enclosing an osmotic membrane.

In accordance with aspects of the present invention there is provided a fluid collector comprising a handle having a fluid absorption element at one end and an observation surface, the absorption element located above a colour change element and the handle defines a light path for internal reflection to the observation surface from the colour change element, the light path reflecting incident light along the light path to the colour change element and the observation surface receiving reflected light from the colour change element, the colour change patch activated by absorption of fluid by the absorption element.

Typically, the observation surface is configured to collect ambient light. Possibly, the collector incorporates a light source. Possibly the light source is a torch. Alternatively, the light source comprises a photo luminescent element. Possibly the photo luminescent element is specifically activated

when fluid is collected. Possibly the specific activation is through contact with fluid. Alternatively, the specific actuation involves rupture through squeezing of the handle element of chemical reagents to provide a photo luminescent reaction. Possibly, the light source is arranged to provide a wavelength specifically chosen to highlight the colour change by the colour change element upon incidence of fluid.

Possibly, portions of the handle are silvered to enhance the light path. Generally the handle comprises layers of material having different optical refractance to define the light path.

Possibly the colour change relates to either no reflection or full reflection by the colour change element indicating white or black at the observation surface.

Typically, the collector consists of a transparent moulded handle preferably made from optically clear polymeric material such as polystyrene, onto which is bonded a rigid polyurethane sponge which softens once wet. The end of the handle has a generally smooth region as the observation surface. The sponge has a region which reacts to the presence of the test fluid by changing colour to define the colour change.

In accordance with more specific aspects of the present invention there is provided a collector for fluid such as oral fluid having a built in means for collection and an integral indicator operating by total internal reflection or fibre optic means which visually reveals the presence of fluid to a central portion of the collector using the device as a transmitter by total internal reflection thus ensuring the collector has absorbed sufficient fluid, more particularly consisting of:

a. A handle, stem or transmitting agent consisting of a transparent material such as optically clear polystyrene and capable of transmitting light from one end to the other by total internal reflection, and

b. A sponge collecting device or other suitable absorbing medium attached to the collection end of the handle or stem, and

c. An element at the collection end capable of changing colour in the presence of the collecting fluid such that the presence of fluid causes a colour change to occur that is remotely visible at the operator end of the handle or stem.

Typically, within the collector there is a colour change by the reaction of iodine for example in the form of potassium iodide, and starch thereby forming a sudden colour change from white to dark blue in the presence of the said liquid. Alternatively, the collector may include methyl red or methyl orange with a citric acid in alcohol actuator.

Alternatively, within the collector there is a colour change due to the reaction of a pH indicator such as litmus in the presence of an acid or alkali. Preferably, there is an oral fluid stimulant such as citric acid.

Further alternatively, the collector has a colour change due to a change in light transmission afforded by transmission across an opaque surface at the collector end of the handle or stem by virtue of the presence of a capillary film of the collected fluid.

Additionally the collector has a colour change due to a change in light transmission afforded by a chemical or physical reaction.

When this colour change occurs, the colour is transmitted through the stem of the handle which acts as a 'fibre optic' transmitter through the principle of total internal reflection and can be seen at the end of the handle as evidence that the reaction zone of the colour change element has been wetted with, for example oral fluid. Since this is the region furthermost from the presence of oral fluid in the mouth, as the rigid sponge soaks up oral fluid, complete absorption by the sponge is thus guaranteed.

For the purpose of clarification total internal reflection occurs when light within the device meets the outer edge of the device and the refractance between the device and the outside atmosphere causes reflection within the device such that the light cannot escape. Only when the angle between the light and the surface is significant, such as the end of the device, will light escape. In this way it will be obvious that light originating from one end of the device will bounce around along the handle as a light path and will not be emitted because of total internal reflection until it meets the end of the handle, when it becomes visible through an observation surface. Similarly, illumination from the open end of the handle will travel down the handle by the same principle and will illuminate the portion of the handle designed to change colour even if that portion is in darkness within the oral cavity. Thus a colour change at one end of the handle is clearly observable at the other end.

Embodiments of aspects of the present invention will now be described by way of example and with reference to the accompanying drawings in which:

Figure 1 is a schematic front perspective view of a fluid collector in accordance with aspects of the present invention;

Figure 2 is a schematic end perspective view of the collector depicted in figure 1;

Figure 3 is an end perspective view of elements of the collector depicted in figure 1 and figure 2;

Figure 4 provides schematic illustrations of light change patches or elements in accordance with aspects of the present invention;

Figure 5 is a schematic end view of an alternative colour change patch in accordance with aspects of the present invention;

Figure 6 is a schematic illustration of a further alternative colour change patch in accordance with aspects of the present invention; and

Figure 7 provides a perspective illustration of a collector for impregnated fluids in accordance with aspects of the present invention.

No patents have hitherto referred to the action of a system whereby fibre optic principles of total internal reflections have been utilised as an indicator of sufficient liquid collection.

In the preferred embodiment, shown initially in Fig 1 and Fig 2 schematically for the purposes of identifying individual components, handle (5) provides the internal reflection means and consists of the handle (5), a viewing region (6), a moulded in portion for ease of gripping (8) and a recess suitable for attaching the sponge (12) with adhesive.

The sponge connection is shown in detail in Fig 3 and consists of the handle (5) and wider stem (16) onto which is bonded the sponge (12) covering only zone (22) but leaving a central zone (24) unbonded. Within this central zone (24) is a recess (32) into which locates a reaction pad (36) such as filter paper impregnated with an oral fluid indicator as a colour change element. The degree of sensitivity of the detection system may be adjusted by altering the optical clarity of the region (32) in the handle. In a basic embodiment of a device (100) if this has a polished appearance the optical clarity is optimised and if it is opaque the optical clarity is reduced. Optionally, a particular texture such as ribbed or triangulated-faceted surfaces may be incorporated to improve response from the oral fluid.

When assembled, the viewing or observation surface end (6) of the handle (5) reveals the basic colour of the reaction pad or colour change element by virtue of total internal reflection of light within the plastic handle. The end (6) of the handle (5) permits viewing of the reaction pad (36) or colour change element remotely and at a significant distance and also from a wide range of angles provided the recipient of the oral fluid is generally facing

the donor. Preferably the reaction pad or colour change element is initially white, or a light colour, or has a colour that is significantly different to the colour it will change to once it is wet. This colour can clearly be seen at the end (6) of the handle (5) because of total internal reflection within the plastic, or other material forming the handle or part of the handle. A light path may be further enhanced by silvered surfaces.

When the swab is put in the mouth oral fluid is absorbed by the sponge (12) with colour change element and the fluid penetrates into the core the last portion to be wetted is the core close to the recess (24). As it soaks up into the last portion of the sponge (12) it soaks the reaction pad or colour change element which then changes colour. By this means the recipient of the sample can guarantee that the sponge (12) is adequately absorbed. Advantageously, only the core has the colour change element to show through wetting of the sponge (12).

The total internal reflection property of the plastic or other material forming the handle (5) is also beneficial when the test is administered at night or in poor lighting conditions. Total internal reflection works both ways. In the dark, shining a torch generally towards the person provides illumination of the reaction pad or colour change element because the light from the torch is tunnelled down the plastic of the handle and bounces back by total internal reflection. By this means the colour change of the pad once it is in contact with the oral fluid is very easily observed.

One feature of collection systems for drug abuse is that the donor generally does not want to provide a sample especially if it will show them to have taken an illicit substance, and one common way of avoiding detection is to make collection of an oral fluid sample difficult. They can do this by saying that the sponge is well soaked when in fact it is not. Under these circumstances a collecting device with a readily detectable indicator will be invaluable.

According to the above system several reactions may be used to provide the indication device depending on personal preference.

In one preferred embodiment, Fig 4 shows details of the impregnated device consisting of filter paper of sufficient thickness to provide means for detecting the presence of oral fluid. In this embodiment one layer of filter paper provides for absorption of impregnated starch solution on the handle side of the paper (34) and for absorption of impregnated potassium iodide solution on the reverse side (36). Impregnation by spray mist of a concentrated solution provides for impregnation without intimate mixing of the solutions each side of the paper or membrane. In another embodiment filter papers are soaked and allowed to dry and then sandwiched together with an intermediate plain membrane (39) to prevent intimate contact until oral fluid is present.

When oral fluid is absorbed by the sponge (12) it penetrates into the core and the last portion to be wetted is the region of the core close to the recess (24). As it soaks up the last portion of the sponge (12) it soaks the potassium iodide impregnated on the surface of the pad (36) which, being soluble, is passed through the pad and makes contact with the starch that is impregnated on the surface of the pad at (34). When iodide is mixed with starch, an intensely blue coloured starch/iodine complex is formed. It is thought that the iodine (in the form of I_5^- ions) gets stuck in the coils of beta amylose molecules in the starch). The starch forces the iodine atoms into a linear arrangement in the central groove of the amylose coil. There is some transfer of charge between the starch and the iodine. That changes the way electrons are confined, and so, changes spacing of the energy levels when excited by illumination or other means. The iodine/starch complex has energy level spacings that are just tuned for absorbing visible light- giving the complex its intense blue colour.

The reaction guarantees that the iodide is used up in the reaction, and the starch complex, being now insoluble, cannot escape from the pad and be introduced into the oral cavity of the user.

In another preferred embodiment the sponge is impregnated with citric acid which has the advantage that it stimulates the production of saliva in the mouth of a donor. Fig 5 shows details of the impregnated device consisting of filter paper. In this embodiment the filter paper is impregnated with pH indicator paper that detects the presence or absence of acidic or alkaline substances. When oral fluid is absorbed by the sponge (12) it penetrates into the core and the last portion to be wetted is the core close to the recess (24). As it soaks up the last portion of the sponge (12) it takes with it a concentrate of the citric acid that reacts with the pH indicator paper and that changes colour. For example litmus paper changes from blue to red and this gives a strong colour change that is visible on the end of the handle (5) to the recipient.

In another preferred embodiment the sponge is impregnated with citric acid at one end and methyl red indicator (dissolved in alcohol with a granule of alkali such as sodium hydroxide) spotted or soaked into the sponge. Methyl red is a pale amber colour when slightly alkaline but turns to a vivid scarlet when acidified by traces of the citric acid carried onto the other end of the sponge by oral fluid permeating through to the core of the sponge.

Such a device may conveniently be manufactured by the following method. Dissolve 1 gram of methyl red in 50 ml of ethyl alcohol to which 1 ml of water containing 5 mg of sodium hydroxide has been added. The purpose of the sodium hydroxide is to slightly increase the pH of the indicator solution to prevent adverse reaction of the indicator from any residual acids as may be present on the sponge from manufacture. Apply 20 microlitres of this solution to the centre of the sponge and allow to dry. Attach the sponge to the handle. Take a saturated solution of citric acid in ethyl alcohol and apply 100 microlitres of the solution to the free end of the sponge. Allow to dry. Alternatively apply these chemicals prior to fixing the sponge to the handle provided it can be ensured that the indicator end becomes in contact with the handle and the citric acid end becomes at the free end of the sponge. Figure 7 shows details of this impregnated collector device 51 consisting of

absorbent polyurethane foam 50 capable of absorbing oral fluid and preferably of typical dimensions 12 to 15 mm diameter and 15 to 30 mm length suitable for absorbing between 1 and 4 millilitres of oral fluid, attached to a suitable holding device 54. At the centre of the fixed end of the sponge is impregnated the small amount of methyl red 52 and at the free end of the sponge is impregnated the small area of citric acid 53. In this embodiment, for convenience and desirability, methyl orange is non-toxic and changes from pale yellow colour to a very strong red colour when activated, providing a very marked change in colour intensity and contrast. Also for convenience and desirability citric acid is non-toxic, and is strongly acidic while still being palatable and benefiting from encouraging oral fluid stimulation.

In this embodiment the use of ethyl alcohol assists in easy and consistent impregnation of the sponge without chemicals leaching through the sponge, and assists in fast drying and fixing of the chemicals in the correct location.

In another preferred embodiment shown in Fig 6, the end of the handle in the recess (32) is opaque by virtue of the texture of the plastic and a small, coloured plastic disc (42) is located in the recess. By virtue of the opaque surface the colour of the disc does not transmit well down the stem of the handle by total internal reflection. When oral fluid is absorbed by the sponge (12) it penetrates into the core and the last portion to be wetted is the core close to the recess (24). As it soaks up the last portion of the sponge (12) it enters the crevice between the disc (42) and the recess (32) by capillary action and this bridging of the gap by liquid changes the refractive index of the opaque recess and causes light to bounce off the coloured disc and be transmitted down the handle by total internal reflection and this gives a strong colour change that is visible on the end of the handle (5) to the recipient

In another preferred embodiment the recess (32) contains any chemical that undergoes a strong colour change when exposed to liquid. Other colour change embodiments may be incorporated into this system

without changing the intent of the method of operation of the device working by total internal reflection of the result.

As indicated above aspects of the present invention relate to a fluid collector in which a handle provides a light path between a colour change patch or element and an observation surface. Generally, the colour change patch or element and an absorption element overlaying that colour change patch or element is at one end of the handle whilst the observation surface is at the other. Parts of the handle may be silvered or otherwise formed from concentric or layered portions of plastics or other materials having different optical refractive indexes in order to create internal reflection. Internal reflection along the light path is from the colour change patch to the observation surface. To further enhance its reflection portions of the handle may be silvered as indicated.

In order to identify and notice the colour change in the colour change element as a result of incident fluid absorbed through the absorption element it will be understood that light must reflect along the light path. This light may be ambient light incident about the handle. In such circumstances the observation surface, and possibly other parts of the handle, are configured to collect ambient light and therefore allow presentation of that ambient light to the colour change patch or element such that as observed through the observation surface there is a change in colour indicative of full absorption or desired absorption by the absorption element. The absorption element effectively wets the colour change patch in order to create a chemical or other reaction indicative of a colour change. This reaction may involve changes from white to a colour such as blue or red as described above in relation to iodine/starch complexes or litmus paper reactions to pH changes or otherwise. Alternatively, the colour change may be between black and white in terms of the colour change patch or element going from full reflection to non reflection or vice versa as observed through the observation surface along the light path.

Dependence upon ambient light may be inconvenient particularly if use of the collector is to occur in dark environments. In such circumstances as described above a separate torch may be utilised when viewing the collector through the observation surface. Alternatively, the collector may incorporate a small integral torch comprising an LED and small battery activated by a switch. In such circumstances the fluid collector may remain disposable in that the LED and battery will be relatively cheap. The collector may comprise a separable absorption element with replaceable colour change patch or element. In such circumstances once the colour change collector has been used the absorption element will be removed along with the colour change patch or element and a fresh un-activated and un-wetted absorption element along with colour change patch or element can then be utilised for further testing with the re-assembled fluid collector.

A further alternative would be to provide a photo luminescent element which may be specifically activated when collection of fluid is required. In such circumstances the fluid as presented upon the absorption element may also activate the photo luminescent element to generate light reflection along the light path to indicate changes in the colour change element. Alternatively, the handle may be squeezed to force the rupture of separate bladders incorporating reagents to create photo luminescent reactions. In any event, incident light along the light path may be tuned in terms of wavelength to highlight colour changes in the colour change patch and therefore wetting of the absorption element when that colour change patch is activated.

Claims

1. A fluid collector comprising a handle having a fluid absorption element at one end and an observation surface, the absorption element located above a colour change element and the handle defines a light path for internal reflection to the observation surface from the colour change element, the light path reflecting incident light along the light path to the colour change element and the observation surface receiving reflected light from the colour change element, the colour change patch activated by absorption of fluid by the absorption element.

2. A collector as claimed in claim 1 wherein the observation surface is configured to collect ambient light.

3. A collector as claimed in claim 1 or claim 2 wherein the collector incorporates a light source.

4. A collector as claimed in claim 3 wherein the light source is a torch.

5. A collector as claimed in claim 3 wherein the light source comprises a photo luminescent element.

6. A collector as claimed in any preceding claim wherein the photo luminescent element is specifically activated when fluid is collected.

7. A collector as claimed in claim 6 wherein the specific activation is through contact with fluid.

8. A collector as claimed in claim 6 or claim 7 wherein the specific actuation involves rupture through squeezing of the handle element of chemical reagents to provide a photo luminescent reaction.

9. A collector as claimed in any preceding claim wherein the light source is arranged to provide a wavelength specifically chosen to highlight the colour change by the colour change element upon incidence of fluid.

10. A collector as claimed in any preceding claim wherein portions of the handle are silvered to enhance the light path.

11. A collector as claimed in any preceding claim wherein the handle comprises layers of material having different optical refractance to define the light path.

12. A collector as claimed in any preceding claim wherein the colour change relates to either no reflection or full reflection by the colour change element indicating white or black at the observation surface.

13. A collector as claimed in any preceding claim wherein the collector consists of a transparent moulded handle preferably made from optically clear polymeric material such as polystyrene, onto which is bonded a rigid polyurethane sponge which softens once wet.

14. A collector as claimed in any preceding claim wherein the end of the handle has a generally smooth region as the observation surface.

15. A collector as claimed in any preceding claim wherein the sponge has a region which reacts to the presence of the test fluid by changing colour to define the colour change.

16. A collector for fluid such as oral fluid having a built in means for collection and an integral indicator operating by total internal reflection or fibre optic means which visually reveals the presence of fluid to a central portion of the collector using the device as a transmitter by total internal reflection thus ensuring the collector has absorbed sufficient fluid, more particularly consisting of:

a. A handle, stem or transmitting agent consisting of a transparent material such as optically clear polystyrene and capable of transmitting light from one end to the other by total internal reflection, and

b. A sponge collecting device or other suitable absorbing medium attached to the collection end of the handle or stem, and

c. An element at the collection end capable of changing colour in the presence of the collecting fluid such that the presence of fluid causes a colour change to occur that is remotely visible at the operator end of the handle or stem.

17. A collector as claimed in any preceding claim wherein within the collector there is a colour change by the reaction of iodine for example in the form of potassium iodide, and starch thereby forming a sudden colour change from white to dark blue in the presence of the said liquid.

18. A collector as claimed in any preceding claim wherein the collector may include methyl red or methyl orange with a citric acid in alcohol actuator.

19. A collector as claimed in any preceding claim wherein within the collector there is a colour change due to the reaction of a pH indicator such as litmus in the presence of an acid or alkali.

20. A collector as claimed in any preceding claim wherein there is an oral fluid stimulant such as citric acid.

21. A collector as claimed in any preceding claim wherein the collector has a colour change due to a change in light transmission afforded by transmission across an opaque surface at the collector end of the handle or stem by virtue of the presence of a capillary film of the collected fluid.

22. A collector as claimed in any preceding claim wherein the collector has a colour change due to a change in light transmission afforded by a chemical or physical reaction.

23. A collector substantially as hereinbefore described with reference to the accompanying drawings.

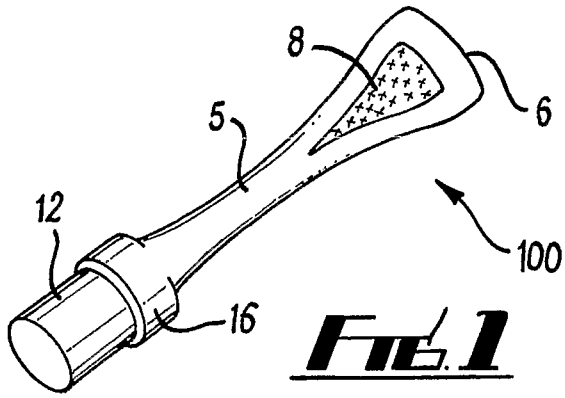

FIG. 1

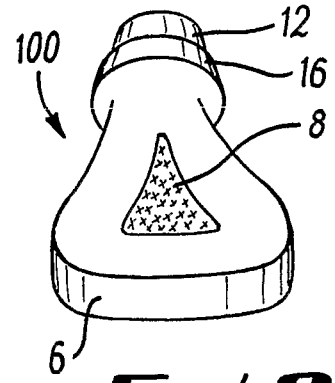

FIG. 2

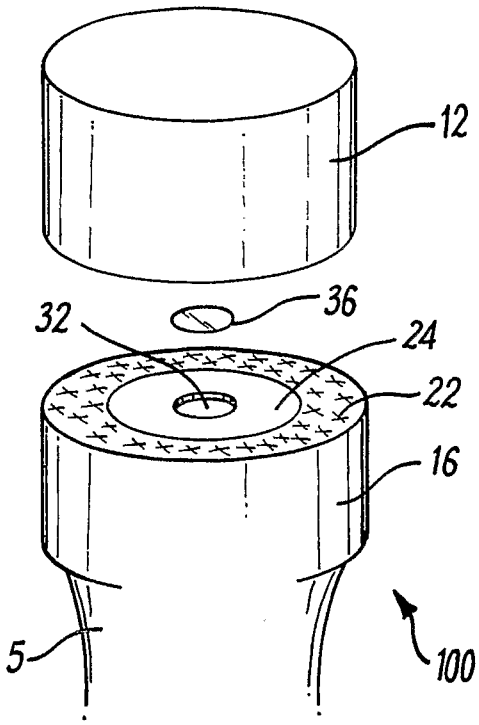

FIG. 3

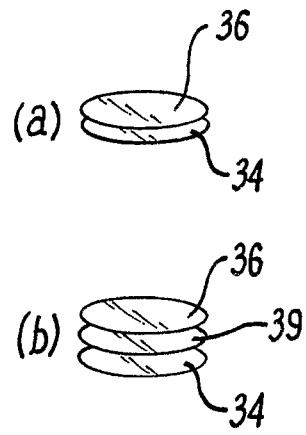

FIG. 4

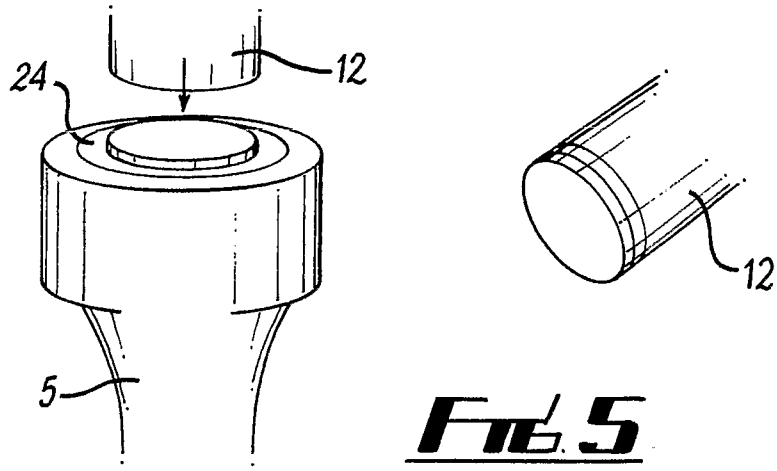

FIG. 5

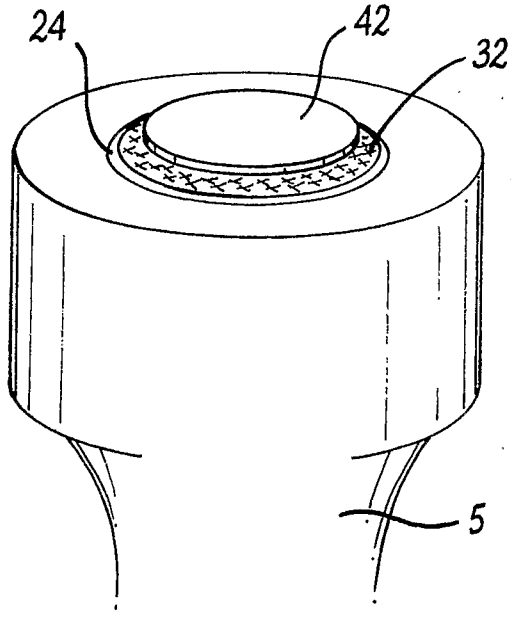

FIG. 6

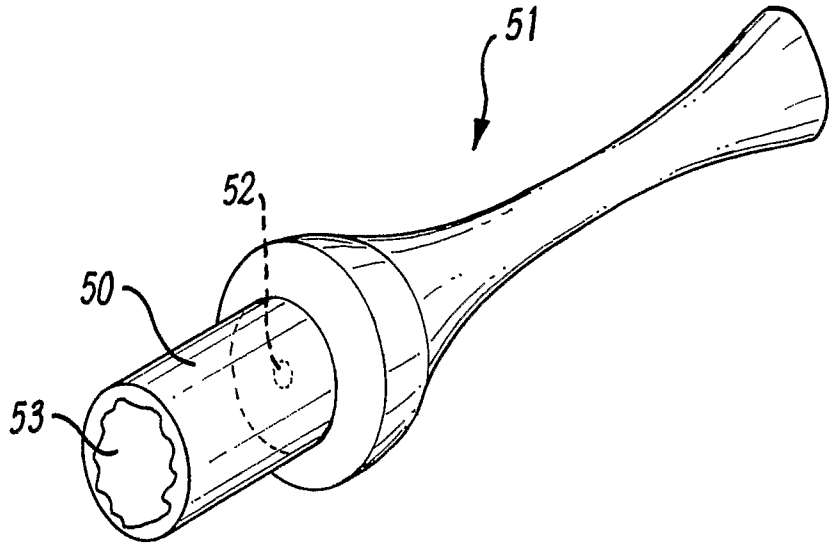

FIG 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/003933

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B10/00
ADD. A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 101 059 404 A (ABON BIOPHARM HANGZHOU CO LTD [CN]) 24 October 2007 (2007-10-24) abstract & WO 2008/139324 A (INVERNESS MEDICAL SWITZERLAND [CH]; DAI JIELIN [CN]; GOU LIJIAN [CN];) 20 November 2008 (2008-11-20) paragraphs [0049], [0069] - [0081]; figures 1-5	1,2, 12-23
X	US 2006/018800 A1 (SLOWEY PAUL D [US] ET AL) 26 January 2006 (2006-01-26) paragraphs [0048], [0058] - [0062]; figures 1-4	1,2,11, 12,15, 21-23

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 February 2009	23/02/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Øen, Petter

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INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/003933

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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