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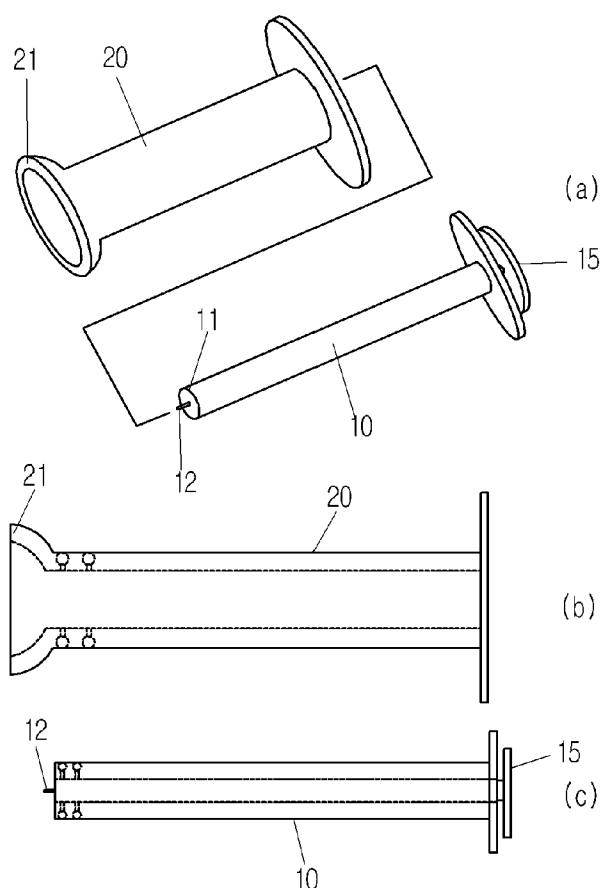
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[Continued on next page]

(54) Title: A MICRONEEDLE DEVICE AND METHODS FOR APPLYING IT



(57) Abstract: Disclosed are a microneedle device and a method for applying the same. The inventive microneedle device locally deforms highly elastic skin prior to rendering a microneedle to pierce the skin, thereby allowing the skin to be more readily and efficiently pierced. Therefore, the inventive microneedle device can be used in painless drug delivery, extraction of a sample to be analyzed, such as blood, and biopsies.

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FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL,
PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM,
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Description

A MICRONEEDLE DEVICE AND METHODS FOR AP- PLICATING IT

Technical Field

- [1] The present invention relates to a microneedle device which can minimize elasticity of skin, thereby allowing easy penetration of the skin, and which enables delivery of a drug and extraction of a sample to be analyzed. The present invention also relates to application of such a microneedle device.

Background Art

- [2] In general, microneedles are used for delivering a drug into a living body, extracting body fluid to be analyzed, and conducting biopsies. Microneedle devices developed until now are different from each other in material, type, and application. In addition, various microneedle devices, each of which has a specific purpose, have been developed. Biovalve Technology Inc. has proposed a simple microneedle device with a microneedle attached to the microneedle device instead of a microneedle of a disposable syringe which is frequently used for delivery of a drug (International Patent Publication No. WO 0245771 entitled "Microneedle Adapter". Similar microneedle devices are also available from Georgia Tech. (U.S. Unexamined Patent Publication No. 20030208167 entitled "Microneedle Drug Delivery Device"). 3M Innovative Properties Co. has proposed a novel development for delivery of a liquid drug which is superior to the above-mentioned inventions, wherein the liquid drug is delivered through three steps, i.e., locking of the drug, inflow of the drug, and injection of the drug (International Patent Publication No. WO 2004009172 entitled "Microneedle Device and Microneedle Delivery Apparatus"). The above three inventions can be easily manufactured and are easy to apply. However, they have limitations regarding penetration of highly elastic skin. In this regard, Prausnitz of Georgia Tech has proposed a method of minimizing the elasticity of skin, and a device for penetrating skin with the aid of a method of using the elasticity of skin (U.S. Unexamined Patent Publication No. 2005013751 entitled "Devices and Methods for Enhanced Microneedle Penetration of Biological Barriers"). The proposed technical idea using the elasticity of skin for the purpose of penetration of skin is worthy of notice. However, they have limitations regarding delivery of a drug after penetration of the skin. Recently, there has been proposed a method of thermally treating skin as well as a microneedle device so as to make it easy to penetrate skin (International Patent Publication WO 2006004595 entitled "Method and Device for Thermal Treatment"). Like this, all of the above-mentioned microneedle devices have been manufactured for

the purpose of rendering the microneedle devices suitable for employing microneedles developed by the manufacturers of the microneedle devices. Therefore, what is needed is a novel microneedle device suitable for characteristics of a newly developed microneedle.

- [3] After having proposed a biodegradable solid type microneedle improved in external shape and hardness (PCT Patent Application No. PCT/KR2007/003506 entitled "A Solid Type Microneedle and Methods for Preparing It") and a hollow type microneedle (PCT Patent Application No. PCT/KR2007/003507 entitled "A Hollow Type Microneedle and Methods for Preparing It"), wherein the microneedles are fabricated through a drawing process, the inventors have made efforts to increase the utilization of such microneedles, and consequently completed the present invention overcoming the drawbacks of the prior art.

Disclosure of Invention

Technical Problem

- [4] Accordingly, the present invention has been made in order to solve the above-mentioned problems, and the present invention is intended to provide a microneedle device without the above-mentioned drawbacks.
- [5] In addition, the present invention is intended to provide a method of applying such a microneedle device.

Technical Solution

- [6] In order to achieve the above-mentioned objects, there is provided a microneedle device, to which a microneedle produced through a drawing process is attached, wherein the microneedle device is adapted to minimize elasticity of skin so as to render the skin suitable for penetration by the microneedle.
- [7] According to a first aspect of the present invention, there is provided a biodegradable microneedle device including a cylinder with a concave end part, and a piston with a plunger head, to which a biodegradable microneedle is attached. The concave end part of the cylinder deforms skin convexly, thereby minimizing the elasticity of the skin, and the piston should be freely moved up and down by the thumb when the cylinder is grasped by a hand, wherein the piston is designed to be readily removed from the cylinder. The piston is pushed to its end position until the biodegradable microneedle comes into contact with the skin, the piston is anchored by springs, and then a pusher is further pushed, so that the microneedle penetrates the skin.
- [8] According to a second aspect of the present invention, there is provided a microneedle device including a biodegradable microneedle which is not patterned, but separated, and a microneedle inserter. The biodegradable microneedle inserter includes

a cylinder with a concave end part, a piston movable up and down within the cylinder, and a push pin connected to the distal end of the piston. A biodegradable microneedle is introduced into the concave end part of the cylinder, the concave end part deforms skin convexly, thereby minimizing the elasticity of the skin, and then the proximal end of the piston is pressed so that the push pin at the distal end of the piston is moved to the end of the concave end part. If so, the biodegradable microneedle is inserted into the skin.

[9] According to a third aspect of the present invention, there is provided a microneedle inserter including: a top member, to which a plurality of biodegradable solid microneedles are attached; and a bottom member formed with a plurality of holes at the positions corresponding to the biodegradable solid needles, the top and bottom members being connected with each other through one or more springs, wherein if the bottom member comes into contact with skin so that the skin is deformed convexly at the areas of the holes, and then the top member is pressed downward, the biodegradable solid microneedles are inserted into the skin at the areas deformed convexly within the holes.

[10] According to a fourth aspect of the present invention, there is provided a hollow type microneedle device including: a first cylinder with a concave end part for deforming skin convexly, thereby minimizing the elasticity of the skin; a second cylinder inserted into the first cylinder and having a plunger head, to which a hollow type microneedle is attached, the second cylinder also serving as a piston; and a second piston inserted into the second cylinder. Like the above-mentioned microneedle devices, the elasticity of the skin is minimized with the aid of the concave end part, the second cylinder is pushed to the end of the interior of the first cylinder so that the hollow microneedle penetrates the skin, and then the second cylinder is anchored by springs. Then, the liquid drug contained in the second cylinder is introduced into the skin and a blood vessel by using the second piston.

[11] According to the present invention, there is also provided a method of using a microneedle device including steps of: i) deforming skin convexly by using a cylinder with a concave end part, thereby minimizing the elasticity of the skin; ii) inserting a piston with a plunger head, to which a biodegradable microneedle is attached, into the cylinder, and pushing the piston so that the biodegradable microneedle penetrates the skin; iii) holding the biodegradable microneedle penetrating the skin by anchoring the piston and the cylinder; and iv) further pushing the biodegradable microneedle (or rendering a hollow type microneedle to be inserted into the skin by using a second piston), so that a liquid drug is delivered into the skin and a blood vessel.

[12] A microneedle applicable to the present invention is a degradable solid microneedle or a hollow type microneedle. The biodegradable solid needle serves to pierce skin so

as to allow a drug to be absorbed through the skin, and the hollow type microneedle is used for piercing skin so as to extract a sample to be analyzed or for delivering a drug into a blood vessel. Microneedle devices introduce drugs in different ways, depending on the types of microneedles employed in the microneedle devices. However, the present invention is not limited by such ways.

[13] According to the present invention, when skin is penetrated, the elasticity of skin can be reduced through a concave end part of a cylinder of a microneedle device or by directly pinching a part of the skin. However, the present invention is not limited to this.

[14] The term "cylinder" of a microneedle used herein means a body within which a piston is movable up and down.

[15] The term "concave end part" used herein means a tip end of a cylinder, which is formed in a concave shape so as to compactly collect skin, thereby reducing the elasticity of the skin.

[16] The term "plunger head" used herein means a part formed at the distal end of a piston inserted into a cylinder, wherein a microneedle is attached to the plunger head.

[17] The term "push pin" used herein means the distal end part of a piston of a microneedle inserter provided so as to apply force to the proximal end of a separate biodegradable microneedle so that the biodegradable microneedle can pierce skin.

[18] The term "second cylinder" used herein means a cylinder for use in extracting a sample to be analyzed and for use in delivering a liquid drug, wherein the second cylinder also serves as a first piston for piercing skin.

[19] The term "microneedle inserter" used herein means a device employing a separate microneedle instead of a gold needle, wherein such a microneedle inserter is configured by combining a concave end part of a microneedle device and a basic shape of a gold thread inserter.

[20] Hereinafter, the present invention will be described in detail with reference to several exemplary embodiments. The embodiments described below are presented in order to illustrate the present invention but not intended to limit it. Of course, it is intended that all the features apparent to an ordinary skilled person in the technical field of the present invention from this specification are included in the scope of the present invention. All the documents described herein are incorporated into the specification of the present application by reference.

Advantageous Effects

[21] According to the present invention, it is possible to fabricate a microneedle device and a microneedle inserter including a biodegradable solid microneedle and a hollow type microneedle, which are fabricated through a drawing process. The inventive mi-

microneedle device minimizes the elasticity of skin, thereby allowing easy penetration of the skin. In addition, the inventive microneedle device renders it possible to deliver a biodegradable solid drug as well as a liquid drug into skin and a blood vessel of a human body, and to extract a sample to be analyzed.

Brief Description of the Drawings

- [22] The above and other objects, features and advantages of the present invention will be more apparent from the following detailed description taken in conjunction with the accompanying drawings, in which:
- [23] FIGs. 1a to 1c show the construction of a biodegradable microneedle device according to the present invention;
- [24] FIGs. 2a to 2c show the action of the biodegradable microneedle device shown in FIGs. 1a to 1c;
- [25] FIGs. 3a to 3c show the construction and action of a biodegradable solid microneedle inserter according to the present invention;
- [26] FIGs. 4a to 4c show the construction and action of a composite biodegradable solid microneedle device according to the present invention;
- [27] FIGs. 5a to 5d show the construction of a hollow type microneedle device according to the present invention; and
- [28] FIGs. 6a to 6c show the action of the hollow type microneedle device shown in FIGs. 5a to 5d.

Mode for the Invention

[29] EXAMPLES

- [30] FIGs. 1a to 1c show the construction of a biodegradable microneedle device according to the present invention. Referring to FIGs. 1a to 1c, a piston 10 with a plunger head 11 and a cylinder 20 with a concave end part 21 are provided, a biodegradable solid microneedle 12 being attached to the plunger head 11, wherein the biodegradable solid microneedle 12 has a distal end diameter of about 5 to 10 μ m, a proximal end diameter of about 200 μ m, and an effective length of about 500 to 2,000 μ m (PCT Patent Application No. PCT/KR2007/003506 entitled "A Solid Type Microneedle and Methods for Preparing It"). FIGs. 2a to 2c show the action of the biodegradable microneedle device according to the present invention. Now, the action of the inventive microneedle device will be described in detail with reference to FIGs. 2a to 2c. As shown in the drawings, the piston 10 is inserted into the cylinder 20. If the concave end 21 of the cylinder 20 presses and deforms skin 30 convexly, thereby reducing the elasticity of the skin 30, the piston 10 is pressed so that the plunger head 11 is anchored by springs and the biodegradable microneedle 12 comes into contact with the convexly deformed skin 30. Thereafter, the biodegradable microneedle 12

comes into contact with the skin 30 by pushing the piston 10 to its end position, and then the biodegradable microneedle 12 pierces the skin 30 by further pushing a pusher 15.

[31] FIGs. 3a to 3c show the construction and action of a biodegradable solid microneedle inserter according to the present invention. The biodegradable solid microneedle inserter is a device for inserting a separate biodegradable solid microneedle 12 through skin 30. Herein, there is also provided a cylinder 20 with a concave end part 21, and a push pin 13 is additionally provided so as to insert the separate biodegradable solid microneedle 12 into the skin 30, wherein the push pin 13 has a diameter of about 300 μ m, which is larger than the proximal end diameter of about 200 μ m of the biodegradable solid microneedle 12.

[32] FIGs. 4a to 4c show the construction and action of a composite biodegradable solid microneedle device according to the present invention. As shown in the drawings, the composite microneedle device has a bottom member 50 formed with a plurality of holes 51, each hole having a diameter of about 2 mm, and a top member 60 provided with a plurality of biodegradable solid microneedles 12, the microneedles being attached to the top member 60 at the positions corresponding to the holes 51, wherein the bottom member 50 and the top member 60 are connected with each other via springs 70, each spring having a length of about 1 cm. The bottom member 50 comes into contact with the skin 30, and then the skin 30 is deformed convexly by the holes 51, thereby reducing the elasticity of the skin 30. Then, the top member 60 is pressed so that the biodegradable solid microneedles 12 pass through the holes 51 and penetrate the skin 30. The springs 70 are pressed and deformed to a length of about 5 mm and are tightly received within spaces formed at the respective corners of the top member 60, so that the top member 60 and bottom member 50 come into contact with each other. As such, the biodegradable solid microneedles 12, each of which has an effective length of about 500 to 2,000 μ m, can be inserted into the skin 30.

[33] FIGs. 5a to 5d show the construction of a hollow type microneedle device. As shown in the drawings, the hollow type microneedle device includes: a first cylinder 20 with a concave end part 21 for deforming skin convexly, thereby minimizing the elasticity of the skin; a second cylinder 80 with a plunger head 81, to which a hollow type microneedle 82 (PCT Patent Application No. PCT/KR2007/003507 entitled "A Hollow Type Microneedle and Methods for Preparing It") is attached, the second cylinder 80 being inserted into the first cylinder 20; and a piston 10 inserted into the second cylinder 80 and configured to be readily separated from the second cylinder 80. In order to penetrate skin 30, the hollow type microneedle 82 is attached to the plunger head 81 of the second cylinder 80. FIGs. 6a to 6c show the action of the hollow type microneedle device according to the present invention. Referring to FIGs. 6a to 6c, the

action of the hollow type microneedle device will be described in detail. After introducing a liquid drug into the second cylinder 80, the second cylinder 20 with the concave end part 21 is applied so as to reduce the elasticity of the skin 30, and the second cylinder 80, which also serves as a piston, is anchored in the first cylinder 20 by springs so that the hollow type microneedle 12 penetrates the skin 30. Subsequently, the liquid drug contained within the second cylinder 80 is delivered into the human body with the aid of the piston 10.

- [34] While the invention has been shown and described with reference to certain preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

Industrial Applicability

- [35] According to the present invention, it is possible to fabricate a microneedle device and a microneedle inserter including a biodegradable solid microneedle and a hollow type microneedle, which are fabricated through a drawing process. The inventive microneedle device minimizes the elasticity of skin, thereby allowing easy penetration of the skin. In addition, the inventive microneedle device renders it possible to deliver a biodegradable solid drug as well as a liquid drug into skin and a blood vessel of a human body, and to extract a sample to be analyzed.

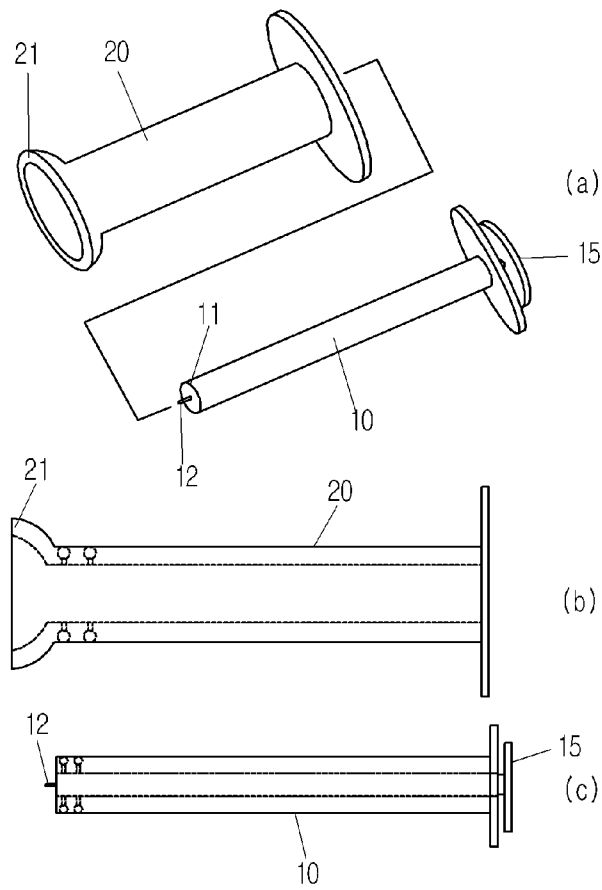
[36]

Claims

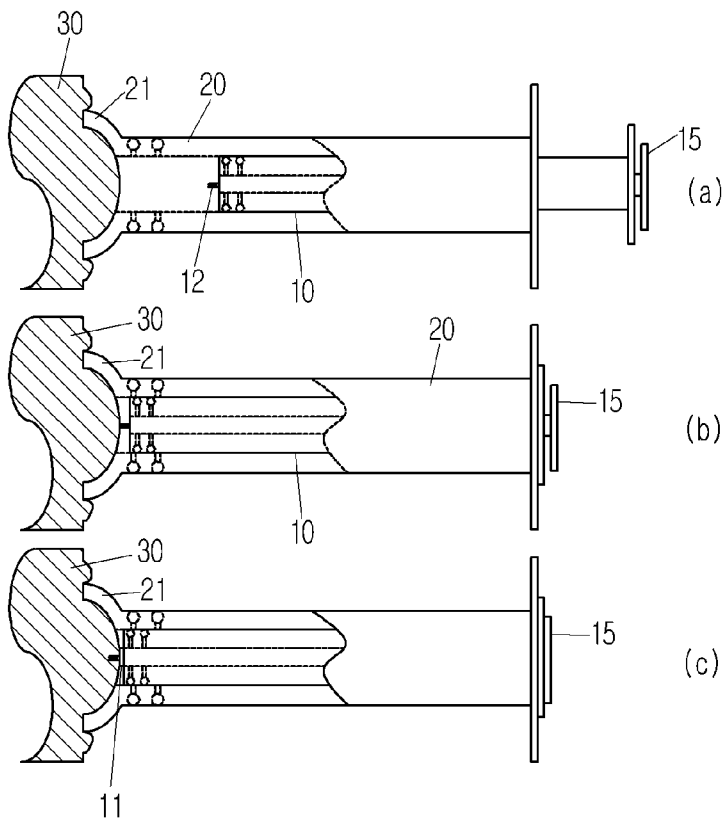
- [1] A biodegradable microneedle device comprising:
a cylinder with a concave end part for deforming skin convexly, thereby minimizing the elasticity of the skin;
a piston inserted into the cylinder and configured to be readily removed from the cylinder; and
a plunger head positioned at the end of the piston, a biodegradable microneedle being attached to the plunger head, wherein the piston has a construction capable of being freely moved up and down by the thumb when the cylinder is grasped by a hand.
- [2] The biodegradable microneedle device as claimed in claim 1, wherein, the piston is pushed to the end position so that the biodegradable needle comes into contact with the convexly deformed skin, the piston is anchored by springs, and then a pusher is further pressed, so that the biodegradable needle penetrates the skin.
- [3] A microneedle inserter comprising:
a cylindrical cylinder;
a concave end part extending from the distal end of the cylinder, the concave end part adapted to deform skin convexly, thereby minimizing the elasticity of the skin;
a piston movable up and down within the cylinder; and
a push pin connected to the distal end of the piston and capable of being moved to the tip end of the concave end part, a microneedle being inserted into the distal end of the push pin, wherein the concave end part deforms skin convexly, thereby minimizing the elasticity of the skin, and then the proximal end of the piston is pushed, thereby moving the push pin positioned at the distal end of the piston to the tip end of the concave end part, so that the microneedle penetrates the skin.
- [4] A biodegradable microneedle inserter comprising:
a top member, to which a plurality of biodegradable solid microneedles are attached;
a bottom member formed with a plurality of holes at the positions corresponding to the solid needles; and
one or more springs interposed between the top and bottom members, wherein the bottom member comes into contact with skin, thereby deforming the skin at the areas of the holes, and then the top member is pressed downward, so that the biodegradable solid microneedles penetrate the skin deformed convexly into the holes.

- [5] A hollow type microneedle device comprising:
a first cylinder with a concave end part for deforming skin convexly, thereby minimizing the elasticity of the skin;
a second cylinder inserted into the first cylinder and having a plunger head, to which a hollow type microneedle is attached, a liquid drug being contained in the second cylinder; and
a piston inserted into the second cylinder and configured to be readily removed from the second cylinder, wherein the elasticity of the skin is minimized with the aid of the concave end part, the second cylinder is pushed to the end of the interior of the first cylinder so that the hollow microneedle penetrates the skin, the second cylinder is anchored by springs, and then the liquid drug contained in the second cylinder is delivered into the skin and a blood vessel by pushing the piston.
- [6] A method of using a microneedle device comprising steps of:
i) deforming skin convexly by using a cylinder with a concave end part, thereby minimizing the elasticity of the skin;
ii) inserting a piston with a plunger head, to which a microneedle is attached, into the cylinder and pushing the piston so that the microneedle penetrates the skin;
iii) holding the microneedle penetrating the skin by anchoring the piston and the cylinder; and
iv) further pushing the biodegradable microneedle or rendering a hollow type microneedle to penetrate the skin by using a second piston so that a liquid drug is delivered into the skin and a blood vessel.

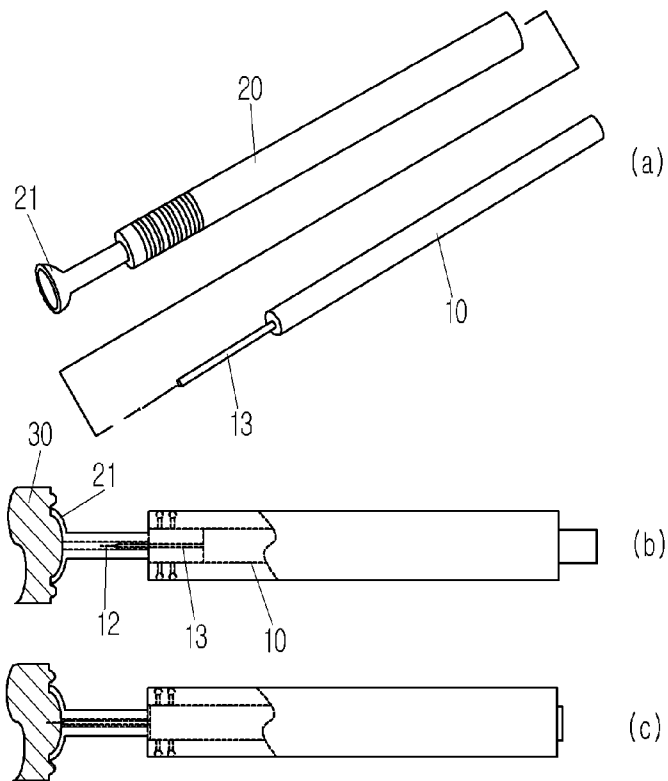
[Fig. 1]



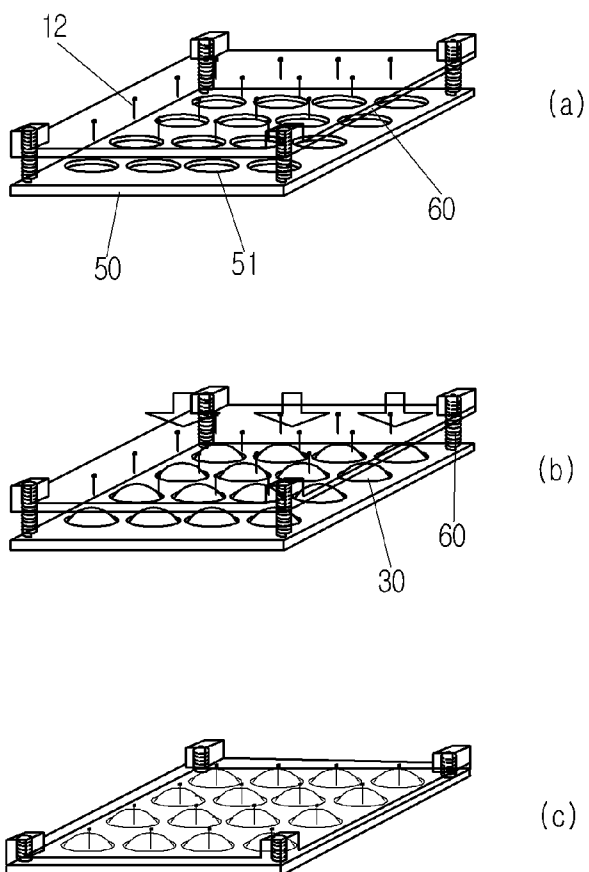
[Fig. 2]



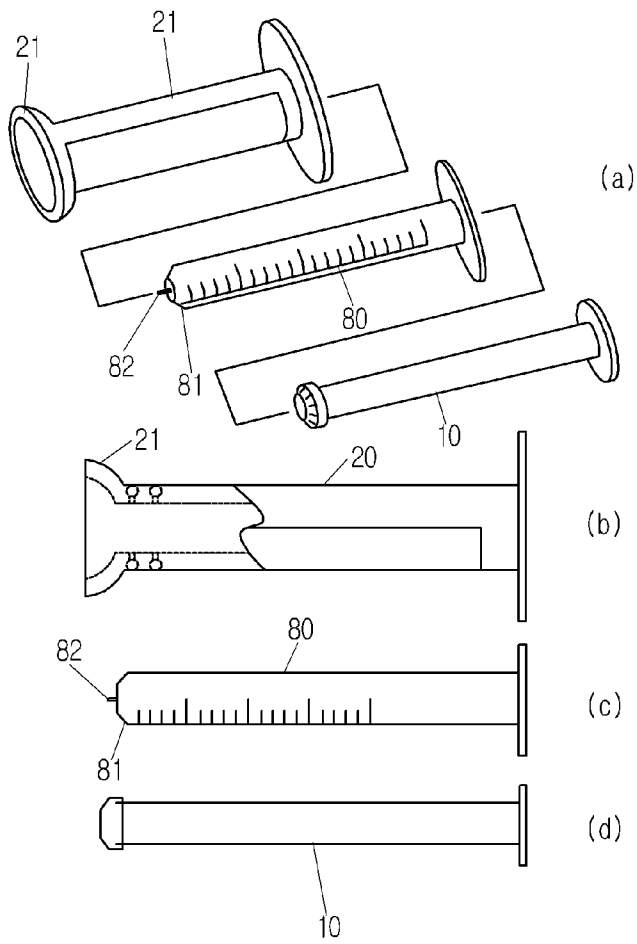
[Fig. 3]



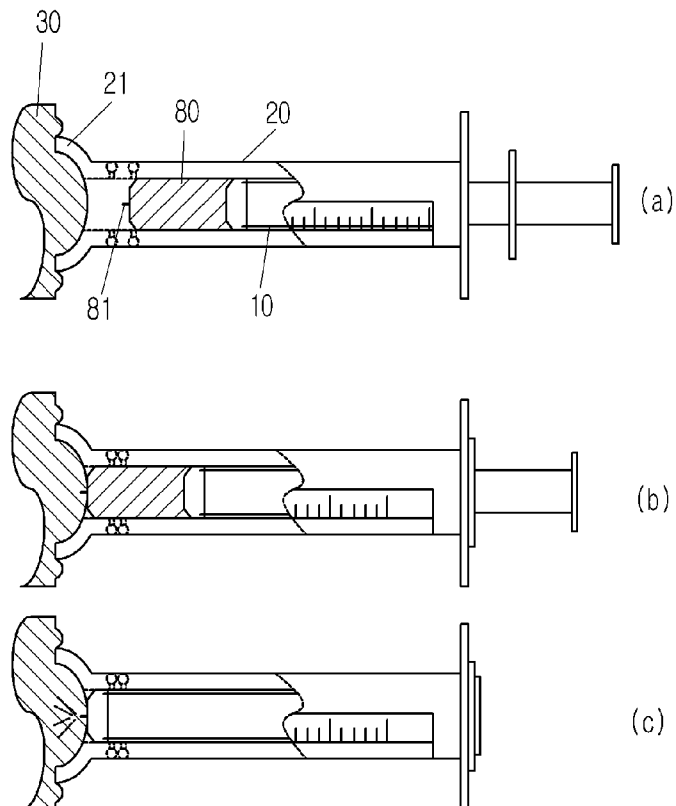
[Fig. 4]



[Fig. 5]



[Fig. 6]



INTERNATIONAL SEARCH REPORT

International application No.

PCT/KR2007/006276**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

I. Claims 1-3, 5 and 6 (group 1) relate to a microneedle device which includes a cylinder with a concave end part and a piston inserted into the cylinder which has a construction capable of being freely moved up, and methods for applying it.

II. Claim 4 (group 2) relates to a microneedle inserter comprising a top member having a microneedle, and a bottom member with a plurality of holes.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2007/006276**A. CLASSIFICATION OF SUBJECT MATTER****A61M 37/00(2006.01)i**

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)

IPC 8 A61B, A61H 15/00, A61H 15/02

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

Korean Utility Models and Applications for Utility Models since 1975

Japanese Utility Models and Applications for Utility Models since 1975

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKIPASS(KIPO internal), esp@cenet, Delphion "needle, cylinder, piston, and concave"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US20050137525 A1 (Becton, Dickinson and Company) 23 June 2005 See Paragraphs 12-16; Figs 3, 7.	1-6
A	US 06743211 B1 (Georgia Tech Research Corporation) 1 June 2004 See column 13, line 31 - column 15, line 12; Figs. 13-14.	1-6
A	US06537242 A (Becton, Dickinson and Company) 25 March 2003 See the abstract.	1-6



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

20 FEBRUARY 2008 (20.02.2008)

Date of mailing of the international search report

20 FEBRUARY 2008 (20.02.2008)

Name and mailing address of the ISA/KR

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gu, Daejeon 302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

KIM, Byeong Pil

Telephone No. 82-42-481-5594



INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/KR2007/006276

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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