Innovation, Sciences et Développement économique Canada
Office de la Propriété Intellectuelle du Canada

Innovation, Science and Economic Development Canada
Canadian Intellectual Property Office

CA 3200013 C 2024/04/23

(11)(21) 3 200 013

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(86) Date de dépôt PCT/PCT Filing Date: 2021/10/28
(87) Date publication PCT/PCT Publication Date: 2022/05/05
(45) Date de délivrance/Issue Date: 2024/04/23
(85) Entrée phase nationale/National Entry: 2023/04/27
(86) N° demande PCT/PCT Application No.: US 2021/056965
(87) N° publication PCT/PCT Publication No.: 2022/094020
(30) Priorités/Priorities: 2020/10/28 (US63/106,793); 2021/04/07 (US63/171,995); 2021/04/21 (US63/177,515); 2021/08/13 (US17/402,413); 2021/09/07 (US17/468,132)

(51) Cl.Int./Int.Cl. *A61B 50/20* (2016.01), *A61B 50/00* (2016.01), *A61B 50/22* (2016.01), *A61B 50/33* (2016.01)

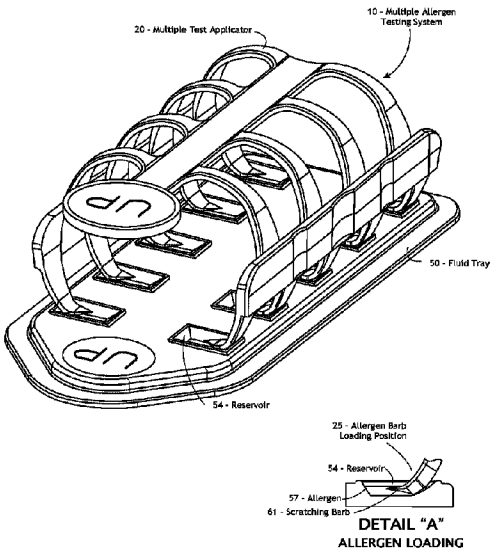
(72) Inventeur/Inventor:
PRINCE, TY L., US

(73) Propriétaire/Owner:
PRINCE, TY L., US

(74) Agent: SMART & BIGGAR LP

(54) Titre : SYSTEMES, APPLICATEURS ET PROCEDES POUR ADMINISTRER DE MULTIPLES ALLERGENES DANS LA PEAU D'UN PATIENT

(54) Title: SYSTEMS, APPLICATORS, AND METHODS FOR ADMINISTERING MULTIPLE ALLERGENS INTO THE SKIN OF A PATIENT



(57) Abrégé/Abstract:
Systems, applicators, and methods for administering a plurality of allergens into the skin of a patient uses a multiple test applicator in cooperative engagement with a fluid tray. The applicator has a plurality of scratching barbs each aligned with a plurality of reservoirs in the fluid tray each filled with an allergen. During allergen barb loading, a different allergen is loaded onto each respective scratching barb from each respective reservoir. Each scratching barb is designed to retain a trace amount of allergen. The applicator fits into one hand of a technician administering the test enabling one-handed operation. The applicator is removed from the fluid tray and repositioned onto the skin of the patient for allergen deposition. Then, each scratching barb pierces the epidermis at each respective test site as a trace amount of each respective allergen seeps into each respective test site from each scratching barb.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
05 May 2022 (05.05.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/094020 A1

(51) International Patent Classification:
A61B 50/20 (2016.01) *A61B 50/22* (2016.01)
A61B 50/00 (2016.01) *A61B 50/33* (2016.01)

(21) International Application Number:
PCT/US2021/056965

(22) International Filing Date:
28 October 2021 (28.10.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

63/106,793	28 October 2020 (28.10.2020)	US
63/171,995	07 April 2021 (07.04.2021)	US
63/177,515	21 April 2021 (21.04.2021)	US
17/402,413	13 August 2021 (13.08.2021)	US
17/468,132	07 September 2021 (07.09.2021)	US

(72) Inventor; and
(71) Applicant: **PRINCE, Ty, L.** [US/US]; 6824 Stone Mill Drive, Knoxville, TN 37919 (US).

(74) Agent: **BLACK, Gerald, R.**; 6690 W. Maple Rd., Ste. 2221, West Bloomfield, MI 48322 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) **Title:** SYSTEMS, APPLICATORS, AND METHODS FOR ADMINISTERING MULTIPLE ALLERGENS INTO THE SKIN OF A PATIENT

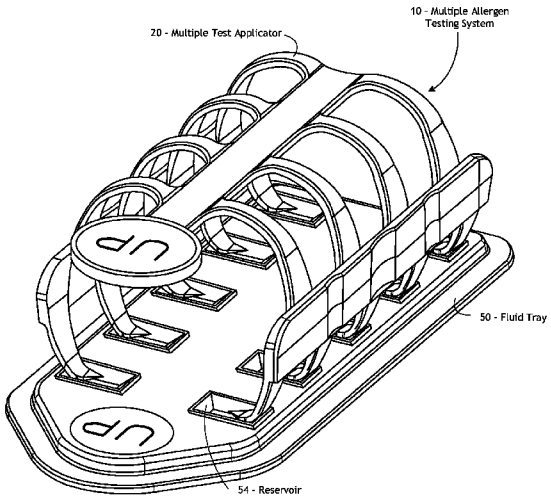
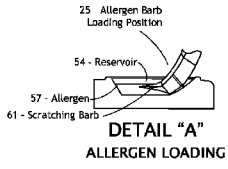


FIGURE 1



(57) **Abstract:** Systems, applicators, and methods for administering a plurality of allergens into the skin of a patient uses a multiple test applicator in cooperative engagement with a fluid tray. The applicator has a plurality of scratching barbs each aligned with a plurality of reservoirs in the fluid tray each filled with an allergen. During allergen barb loading, a different allergen is loaded onto each respective scratching barb from each respective reservoir. Each scratching barb is designed to retain a trace amount of allergen. The applicator fits into one hand of a technician administering the test enabling one-handed operation. The applicator is removed from the fluid tray and repositioned onto the skin of the patient for allergen deposition. Then, each scratching barb pierces the epidermis at each respective test site as a trace amount of each respective allergen seeps into each respective test site from each scratching barb.

WO 2022/094020 A1

SYSTEMS, APPLICATORS, AND METHODS FOR ADMINISTERING MULTIPLE ALLERGENS INTO THE SKIN OF A PATIENT

FIELD OF USE

The present invention relates to new systems, applicators, and methods used in administering multiple allergens into the skin of a patient, and more particularly, to new systems, applicators, and methods for conducting multiple allergy scratch tests.

BACKGROUND OF THE INVENTION

There is an increasing population of allergy disease sufferers. Accordingly, there is a growing need to identify these people and diagnose their specific allergies and allergic disorders.

The medical technician administering these skin tests may often need to apply a relatively large number of different allergens to the skin of a patient. To perform skin tests of this type, the medical technician removes the skin-test device with a small amount of allergen deposited on the sharp pointed testing tips and applies the allergen to the patient in a predetermined sequence.

Some skin testing methods known to treat patients include:

U.S. Patent No. 6554777 (Hein, Jr.) discloses a multi-site skin-test system. The system includes a reservoir tray and strips of interconnected reservoir caps inserted into upper portions of the reservoirs. The caps each include a generally conically shaped hole. Connection members connect the caps of a strip to one another. The strips of caps are pressed into tightly fitting upper portions of reservoirs having upwardly facing ledge surfaces for supporting downwardly facing bottom surfaces of the caps. The outer side surfaces of the caps and the inner surfaces of the upper portions of the reservoirs are substantially the same size to provide a tight fit.

U.S. Patent No. 9597030 (Smollar) depicts an allergy testing kit containing a plurality of allergy testing applicators, an allergy testing tray, and a plurality of allergen bottles each containing an allergen. Each of the applicators contains an elongated handle, a plurality of arms extending from the elongated handle and disposed in an asymmetrical

configuration, and a plurality of legs with tines extending from each of the arms. The allergy testing tray contains a main body having an underside and a top surface, a cover for locking with the main body and a plurality of reservoirs extending from the underside of the main body. The reservoirs each have a chamber with an opening extending from the top surface. The reservoirs are disposed in different groups and each group has an asymmetrical configuration matching that of the applicator.

U.S. Patent Application - Serial No. 11/885086 (Schindlbeck; et al.) depicts a device for performing an allergy test. The device comprises a container assembly including several containers designed to receive the allergens, and a mark transferable onto the skin which is used to associate specific allergens to specific allergy sites on the skin of a living being undergoing an allergy test. The device aims at improving so that the allergy test sites on the skin can be constantly marked very legibly, and so that the corresponding marks can be readily eliminated from the skin immediately after the allergy test.

U.S. Patent Application - Serial No. 10/558943 (Ronborg; et al.) discloses an allergy tester for delivering a diagnostic agent to the skin or mucosa of a patient. A chamber filled with the diagnostic agent is separate from the housing with a rod capable of transferring the diagnostic agent to the animal. The chamber is connected to the housing with the rod before transfer of diagnostic agent.

Since many different allergens need to be screened for a particular patient, it becomes necessary to minimize patient discomfort while accumulating patient data so that the proper course of treatment can be identified.

What is needed are methods for administering multiple allergens that will replace needle pricks that are commonly used: a simple, economical, and reliable scratch testing method in which multiple allergens can be tested simultaneously on the skin of a patient which minimizes any cross contamination of the allergens, that simplifies the handling of the applicator device and provides results that are easily observable.

The objects of this invention are to provide system, applicators, and methods that significantly reduce the possibility of errors in reading the test results while reducing false

positives, and minimizing patient discomfort, that is cost-effective, and is easy to use and manufacture.

Certain other objects will become apparent to those skilled in the art from the following description of preferred embodiments of the invention taken in connection with the accompanying drawings.

SUMMARY OF THE INVENTION

The systems, applicators, and methods for administering multiple allergens of the present invention address these needs.

The system of the present invention uses a multiple test applicator that is in cooperative engagement with a fluid tray to administer a plurality of allergens into the skin of a patient

The multiple test applicator has a plurality of scratching barbs positioned on the multiple test applicator each being aligned with one of a plurality of reservoirs. Each reservoir in the fluid tray preferably contains an allergen fluid or some other testing fluid.

The method of the current invention involves allergen barb loading (when the scratching barbs are loaded with allergen fluid) followed by allergen barb deposition (where trace amounts of each allergen are deposited into a scratch on the epidermis layer of the skin of the patient created by the scratching barb).

During allergen barb loading, a different allergen is loaded onto each respective scratching barb from each respective reservoir. Each scratching barb is designed to retain a trace amount of the allergen fluid.

The multiple test applicator fits into one hand of a medical technician administering the test enabling one-handed operation.

The medical test applicator is then removed from the fluid tray and repositioned onto the skin of the patient for allergen barb deposition.

During allergen barb deposition, each scratching barb pierces the epidermis layer of the skin of the patient at each respective test site as a trace amount of each respective allergen seeps into each respective test site from each scratching barb.

The multiple test applicator is preferably made of a compressible material, the multiple test applicator having a relaxed state and a compressed state. The multiple test applicator is in the relaxed state while in allergen barb loading position when the multiple test applicator is cooperatively engaged with the fluid tray. The multiple test applicator preferably includes a first finger grip disposed on a first side frame and a second finger grip disposed on an second side frame.

Pressure applied by a thumb positioned on the first finger grip disposed on the first side frame and an index finger of the same hand disposed on a second finger grip disposed on the second side frame enable repositioning of the multiple test applicator from the relaxed state to the compressed state.

In a first preferred embodiment, the scratching barbs project in an upward direction relative to the fluid tray. The allergen barb deposition occurs when the multiple test applicator is repositioned onto the skin of the patient and the multiple test applicator is in the compressed state.

In a second preferred embodiment, the scratching barbs project in a downward direction relative to the fluid tray. The multiple test applicator is repositioned from a compressed state when placed onto the skin of the patient in the allergen barb deposition position.

For allergies to initially develop, the body must be exposed to an allergen, that prompts the body to initiate an immune response.

Another aspect of the present disclosure relates to a method for administering a plurality of allergens into skin of a patient, said method comprising: a. positioning a multiple test applicator during allergen loading onto a fluid tray, said multiple test applicator having first and second scratching barbs, said multiple test applicator being cooperatively engageable with said fluid tray, said fluid tray having a first allergen retainable in a first reservoir, said fluid tray having a second allergen retainable in a second reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir, said second scratching barb retaining some of said second allergen when removed from said second reservoir, said multiple test applicator having a relaxed state and a compressed state, said first scratching barb moving away from said second scratching barb when said multiple test applicator changes from said compressed state to said relaxed state, said multiple test applicator being held by one hand of a medical technician during said allergen loading; and b. relocating said multiple test applicator during allergen deposition onto said skin of said patient, said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited into said first scratch, said second scratching barb generating a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch, said multiple test applicator being held by one hand of said medical technician during said allergen deposition.

Date Reçue/Date Received 2023-08-22

Another aspect of the present disclosure relates to a method for administering a plurality of allergens into skin of a patient, said method comprising: a. positioning a multiple test applicator during allergen loading onto a fluid tray, said multiple test applicator being cooperatively engageable with said fluid tray, said multiple test applicator including a first and second scratching barb, said multiple test applicator having a first side frame, said multiple test applicator having a second side frame, said first side frame opposing said second side frame, said multiple test applicator including a first finger grip disposed on said first side frame, said multiple test applicator including a second finger grip disposed on said second side frame, said fluid tray having a first allergen retainable in a first reservoir, said first scratching barb retaining some of said first allergen when removed from a first reservoir, said fluid tray having a second allergen retainable in said second reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir during said allergen loading, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading, said multiple test applicator having a relaxed state and a compressed state, said multiple test applicator being in said relaxed state during said allergen loading, said first scratching barb moving toward said second scratching barb when said multiple test applicator repositions into said compressed state; and b. relocating said multiple test applicator during allergen deposition onto said skin of said patient, said first scratching barb generating a first scratch onto said skin of said patient as said some of said first allergen is deposited into said first scratch, said second scratching barb generating a second scratch onto said skin of said patient as said some of said second allergen is deposited into said second scratch, said multiple test applicator scratching said skin of said patient without applying downward pressure.

Another aspect of the present disclosure relates to a method for administering a plurality of allergens into skin of a patient, said method comprising: a. positioning a multiple test applicator during allergen loading onto a fluid tray, said multiple test applicator having a first scratching barb positionable on a first applicator leg, said multiple test applicator having a second scratching barb positionable on a second applicator leg, said first scratching barb of said multiple test applicator being cooperatively engageable with a first reservoir of said fluid tray during said allergen loading, said second scratching barb of said multiple test applicator being cooperatively engageable with a second reservoir of said fluid tray, said fluid tray having a first allergen retainable in said first reservoir, said fluid tray having a second allergen retainable in said second reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir during said allergen loading, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading, said first scratching barb projecting upwards when positioned in said fluid tray, said second scratching barb projecting upwards when positioned in said fluid tray; and b. relocating said multiple test applicator from said fluid tray onto said skin of said patient during allergen deposition, said first scratching barb generating

Date Reçue/Date Received 2023-08-22

a first scratch onto said skin of said patient as said first allergen is deposited from said first scratching barb into said first scratch while said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited from said second scratching barb into said second scratch.

Another aspect of the present disclosure relates to a method for administering a plurality of allergens into skin of a patient, said method comprising: a. positioning a multiple test applicator during allergen loading onto a fluid tray, said multiple test applicator having a first scratching barb disposed on a first applicator leg, said multiple test applicator having a second scratching barb disposed on a second applicator leg, said first scratching barb opposing said second scratching barb, said first scratching barb of said multiple test applicator being cooperatively engageable with a first reservoir of said fluid tray during said allergen loading, said second scratching barb of said multiple test applicator being cooperatively engageable with second reservoir of said fluid tray, said fluid tray having a first allergen retainable in said first reservoir, said fluid tray having a second allergen retainable in said second reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir during said allergen loading, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading, said first and said second scratching barbs pointing downward toward said fluid tray, said multiple test applicator having a relaxed state and a compressed state, said multiple test applicator being in said relaxed state during said allergen loading; b. removing said multiple test applicator from said fluid tray, repositioning said multiple test applicator from said relaxed state to said compressed state prior to placing said multiple test applicator on said skin of said patient; and c. relocating said multiple test applicator from said fluid tray onto said skin of said patient during allergen deposition, where said first scratching barb generates a first scratch onto said skin of said patient as a portion of said first allergen is deposited from said first scratching barb into said first scratch while said second scratching barb generates a second scratch onto said skin of said patient as a portion of said second allergen is deposited from said second scratching barb into said second scratch, said first scratching barb moving away from said second scratching barb as said first scratch and said second scratch are formed.

Another aspect of the present disclosure relates to a multiple test applicator for administering onto skin of a patient a first and a second allergen used in allergy skin testing, said multiple test applicator including: a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray as a second scratching barb is cooperatively engageable with a second reservoir on said fluid tray, said fluid tray having said first allergen retainable in said first reservoir and said second allergen retainable in said second reservoir, said multiple test applicator having an expanded position and a compressed position, said first scratching barb retaining some of said first allergen when removed from said first reservoir as said second

Date Reçue/Date Received 2023-08-22

scratching barb retains some of said second allergen when removed from said second reservoir during allergen loading; and a first side handle and a second side handle, a first finger grip being disposed on said first side handle, a second finger grip being disposed on said second side handle, said first finger grip opposing said second finger grip, a squeezing together of said first finger grip and said second finger grip using only one hand decreases a distance between said first scratching barb and said second scratching barb, during allergen deposition said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited into said first scratch, while said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch.

Another aspect of the present disclosure relates to a multiple test applicator for administering onto skin of a patient a first and a second allergen used in allergy skin testing, said multiple test applicator comprising: first scratching barb cooperatively engageable with a first reservoir in a fluid tray, said fluid tray having said first allergen retainable in said first reservoir, said first scratching barb pointing upwards when disposed in said fluid tray, said first scratching barb retaining some of said first allergen when removed from said first reservoir during allergen loading; and a second scratching barb cooperatively engageable with a second reservoir in said fluid tray, said fluid tray having said second allergen retainable in said second reservoir, said second scratching barb pointing upwards when disposed in said fluid tray, said multiple test applicator having an expanded position and a compressed position, during allergen deposition said first scratching barb generating a first scratch on said skin of said patient as said first allergen is deposited into said first scratch while said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch.

Another aspect of the present disclosure relates to a multiple test applicator for administering onto skin of a patient a first and a second allergen used in allergy skin testing, said multiple test applicator comprising: a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray, a first allergen being retainable in said first reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir during allergen loading; and a second scratching barb being cooperatively engageable with a second reservoir on said fluid tray, said fluid tray having a second allergen retainable in said second reservoir, said second scratching barb being disposed in said fluid tray during said allergen loading, said multiple test applicator having an expanded position and a compressed position, said multiple test applicator being in said expanded position during said allergen loading, said multiple test applicator being in said compressed position during allergen deposition, during said allergen deposition said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited into said first scratch as said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch.

Date Reçue/Date Received 2023-08-22

Another aspect of the present disclosure relates to a multiple test applicator for administering onto skin of a patient a first and a second allergen used in allergy skin testing, said multiple test applicator comprising: a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray, said fluid tray having said first allergen retainable in said first reservoir; and a second scratching barb being cooperatively engageable with a second reservoir on said fluid tray as said first scratching barb is cooperatively engageable with said first reservoir on said fluid tray, said second allergen being retainable in said second reservoir, said multiple test applicator having an expanded position and a compressed position facilitating movement of said multiple test applicator from said expanded position during allergen loading to said compressed position prior to placement onto said skin of said patient, during allergen deposition said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited into said first scratch as said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch.

Another aspect of the present disclosure relates to a multiple test applicator comprising: a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray during allergen loading, a first allergen being retainable in said first reservoir, said first scratching barb retaining some of a first allergen when removed from said first reservoir during said allergen loading; a second scratching barb being cooperatively engageable with a second reservoir on said fluid tray during said allergen loading, said second scratching barb opposing said first scratching barb, said second scratching barb cooperatively engaging with said first scratching barb, a second allergen being retainable in said second reservoir, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading; and a first side handle secured to said first scratching barb, a second side handle secured to said second scratching barb, said first side handle opposing said second side handle, said first side handle and said second side handle configured to fit into one hand of an operator, said first side handle cooperatively engaged with said second side handle as inward pressure is applied on said first side handle and said second side handle after said allergen loading is completed and prior to allergen deposition, where said first scratching barb and said second scratching barb are placed on skin as said inward pressure is released during said allergen deposition such that said first scratching barb moves across a first section of said skin as said second scratching barb moves across a second section of said skin away from said first scratching barb, said first scratching barb generating a first scratch depositing a portion of said first allergen into said first scratch as said second scratching barb generates a second scratch depositing a portion of said second allergen into said second scratch.

Another aspect of the present disclosure relates to a multiple test applicator comprising: a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray during allergen loading, a first

Date Reçue/Date Received 2023-08-22

allergen being retainable in said first reservoir, said first scratching barb retaining some of a first allergen when removed from said first reservoir during said allergen loading; a second scratching barb being cooperatively engageable with a second reservoir on said fluid tray during said allergen loading, said second scratching barb opposing said first scratching barb, said second scratching barb cooperatively engaging with said first scratching barb, a second allergen being retainable in said second reservoir, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading; and a first side handle secured to said first scratching barb, a second side handle secured to said second scratching barb, said first side handle opposing said second side handle, said first side handle and said second side handle configured to fit into one hand of an operator, said first side handle cooperatively engaged with said second side handle such that application of pressure on said first side handle and said second side handle during allergen deposition causes said first scratching barb to move across a first section of skin as said second scratching barb moves across a second section of said skin, said first scratching barb generating a first scratch in said first section of said skin depositing a portion of said first allergen into said first scratch as said second scratching barb generates a second scratch depositing a portion of said second allergen into said second scratch.

In intradermal skin testing, a medical professional injects a tiny amount of allergen between the epidermis and the dermis of the patient. The immediate positive skin reaction reaches a peak in about fifteen minutes, and is a pale central area surrounded by redness (a flare) and a bump or swelling (a wheal).

In addition to the allergens in question, skin testing is also performed with a positive control (histamine) that should always cause a skin reaction, and a negative control (saline), that should not cause a reaction. A test is positive if the allergen causes a wheal 3 mm greater than the negative control, and if the skin has a response to the histamine, as well.

Date Reçue/Date Received 2023-08-22

The allergic reaction is measured 15 to 20 minutes after the application of the allergen. The information is a direct measure of the allergy reaction occurring under the skin. The information on each site is presented to the physician to compare against visual observations. A determination of the patient susceptibility to each allergen is determined by the physician and a course of future action is planned. A positive skin test does not predict the severity of an allergic reaction. A negative skin test usually means the patient is not allergic.

In general, allergy skin tests are reliable for diagnosing allergies to airborne substances, such as pollen, pet dander and dust mites. Skin testing may help diagnose food allergies, but because food allergies can be complex, additional procedures may be required.

The multiple allergen testing system of the present invention is designed to minimize any cross contamination of the various allergens.

For a complete understanding of the systems, applicators, and methods for administering multiple allergens into the skin of a patient, reference is made to the accompanying drawings and description in which the presently preferred embodiments of the invention are shown by way of example. As the invention may be embodied in many forms without departing from spirit of essential characteristics thereof, it is expressly understood that the drawings are for purposes of illustration and description only and are not intended as a definition of the limits of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts an assembly view of a first preferred embodiment of the multiple allergen testing system of the present invention comprising a first preferred embodiment of the multiple test applicator having ten applicators cooperatively engaged with a fluid tray, the multiple test applicator being disposed on the fluid tray; and DETAIL "A" depicting an exploded side view of the scratching barb projecting upward relative to the fluid tray disposed in a reservoir of the fluid tray during allergen loading, the reservoir being partially filled with an allergen.

FIGURE 2 depicts the first preferred embodiment of the multiple test applicator of FIGURE 1.

FIGURE 3 depicts a detailed assembly view of the fluid tray of the multiple allergen testing system of FIGURE 1 complete with ten reservoirs.

FIGURE 4 depicts the first preferred embodiment of the multiple test applicator of FIGURE 2 held in one hand by a medical technician, with the thumb positioned on a first finger grip on a first side frame and the index finger of the same hand positioned on a second finger grip on a second side frame, the first side frame opposing the second side frame.

FIGURE 5 depicts the first preferred embodiment of the multiple test applicator of FIGURE 2 held in one hand of the medical technician as the allergens are deposited under the skin on a forearm of a patient.

FIGURE 6A is a front view of the multiple test applicator of FIGURE 2, the multiple test applicator being in an expanded position, the scratching barbs resting upon the skin of the patient.

FIGURE 6B is a front view of the multiple test applicator of FIGURE 6A, the multiple test applicator now being in a compressed position, the pair of opposed scratching barbs resting upon the skin of a patient with each of the scratching barbs disposed at two test sites of the patient, with the skin having been lifted upwards between the pair of opposed scratching barbs.

FIGURE 6C is a front view of the multiple test applicator of FIGURE 6B, the multiple test applicator still being in a compressed position, the pair of opposed scratching barbs now being raised from the skin of the patient with scratches now appearing on each side of the raised skin of the patient and allergy testing fluid being deposited into each scratch.

FIGURE 7A is an exploded assembly view of the first preferred embodiment of the scratching barb pointed upward toward the spine of the multiple test applicator of FIGURE 2, a tip break-off section also being depicted.

FIGURE 7B is an exploded assembly view of a second preferred embodiment of the scratching barb pointed upward toward the spine of the multiple test applicator of FIGURE 2, the scratching barb including an aperture and a channel for retaining a trace amount of the allergen, a tip break-off section also being depicted. Skin lifting pads are shown

on each side of the barb, the skin lifting pads lifting the skin and limiting the depth of the scratching barb.

FIGURE 7C is an exploded assembly view of a third preferred embodiment of the scratching barb pointed upward toward the spine of the multiple test applicator of FIGURE 2, the scratching barb including a vial and a channel for retaining a trace amount of the allergen, a tip break-off section also being depicted. Skin lifting pads are shown on each side of the barb, the skin lifting pads lifting the skin and limiting the depth of the scratching barb.

FIGURE 8 depicts an exploded side view of a pair of scratching barbs being raised upward on a portion of the skin of a patient that has been pulled together as the scratching barbs generate a pair of scratches, a pair of skin lifting pads being positioned, one on each side of each skin scratching barb, the skin lifting pads lifting the skin and limiting the depth of the scratching barb penetration and the degree of downward pressure.

FIGURE 9 depicts an assembly view of a second preferred embodiment of the multiple allergen testing system of the present invention comprising a second preferred embodiment of the multiple test applicator of the present invention having nine scratching barbs, and a single test applicator with a one scratching barb, all being cooperatively engaged with ten fluid reservoirs disposed in the fluid tray depicted in FIGURE 3.

FIGURE 10A depicts an assembly view of the single test applicator of FIGURE 9, and FIGURE 10B depicts an end view of the single test applicator of FIGURE 10A.

FIGURE 11 depicts an assembly view of a third preferred embodiment of the multiple allergen testing system of the present invention comprising a third preferred embodiment of the multiple test applicator having ten scratching barbs cooperatively engaged with ten reservoirs of a fluid tray, the multiple test applicator being disposed on the fluid tray of FIGURE 3; and DETAIL "B" depicting an exploded side view of the scratching barb positioned in a reservoir of the fluid tray pointing downward relative to the fluid tray, the reservoir being partially filled with allergen.

FIGURE 12 depicts the third preferred embodiment of the multiple test applicator of FIGURE 11.

FIGURE 13A is a front view of the multiple test applicator in an expanded position with the scratching barbs, the scratching barbs now being loaded, and each scratching barb including a trace of their respective allergens and are now prepared for allergen deposition.

FIGURE 13B is a front view of the multiple test applicator of FIGURE 13A, the multiple test applicator now being in a compressed position. The scratching barbs are resting upon the skin of a patient with the each of two scratching barbs pointed downward.

FIGURE 13C is a front view of the multiple test applicator of FIGURE 13B, the multiple test applicator now being in an expanded position, the scratching barbs now have generated a pair of scratches at a pair of test sites as the scratching barbs move away from each other.

FIGURE 14A is an exploded assembly view of the first preferred embodiment of the scratching barb pointed downward away from the spine of the multiple test applicator of FIGURE 12, a tip break-off section also being depicted.

FIGURE 14B is an exploded assembly view of a second preferred embodiment of the scratching barb pointed downward away from the spine of the multiple test applicator of FIGURE 12, the scratching barb including an aperture and a channel for retaining a trace amount of the allergen, a tip break-off section also being depicted.

FIGURE 14C is an exploded assembly view of a third preferred embodiment of the scratching barb pointed downward away from the spine of the multiple test applicator of FIGURE 12, the scratching barb including a vial and a channel for retaining a trace amount of the allergen, a tip break-off section also being depicted.

DETAILED DECRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, FIGURE 1 depicts an assembly view of a first preferred embodiment of the multiple allergen testing system [10] of the present invention. A multiple test system [10] of the present invention is for administering onto skin of a patient multiple allergens used in allergy skin testing. The multiple test system [10] comprises a multiple test applicator [20] and a fluid tray [50].

The multiple allergen testing system [10] comprises a first preferred embodiment of the multiple test applicator [20] having ten scratching barbs [61] in cooperative engagement with ten reservoirs [54] of a fluid tray [50], each reservoir [54] preferably retaining a different liquid for skin testing.

When allergens [57] are placed into respective reservoirs [54] in the fluid tray [50], care is taken to avoid using excess amounts of the allergens [57] which may cause cross contamination of allergens. The size of the reservoirs [54] and the distance between adjacent reservoirs [54] are designed to minimize any cross contamination of the allergens [57].

DETAIL "A" depicts an exploded side view of a scratching barb [61] positioned in a reservoir [54] of the fluid tray [50] while in the allergen barb loading position [25]. The reservoir [50] is partially filled with allergen [57]. While in the allergen barb loading position [25], the scratching barbs [61] are dipped into the allergen [57] setting in the reservoirs [54].

FIGURE 2 depicts the first preferred embodiment of the multiple test applicator [10] as shown in FIGURE 1. Each of the ten scratching barbs [61] is in cooperative engagement with one of the ten reservoirs [54] of the fluid tray [50].

In a first preferred embodiment, the scratching barbs [61] projects in an upward direction relative to the fluid tray [50] when disposed in the first reservoir. The allergen barb depositing position [92] occurs when the multiple test applicator [20] is repositioned on the skin of the patient [90] and the multiple test applicator [20] is in a compressed state.

FIGURE 3 depicts a detailed assembly view of the fluid tray [50] complete with ten reservoirs [54]. The multiple test applicator is made of compressible material, the multiple test applicator [20] having a relaxed state and a compressed state. The materials of choice are preferably engineering grade polymers, since the multiple test applicator needs to be sterilized in an autoclave prior to use, the material must be stable at elevated temperatures.

Allergens are inserted into containment reservoirs in the loading tray (the trays may also be preloaded). The preferred embodiment of the method for administering multiple allergens into the skin of a patient [90] uses a multiple skin test system [10] of the present

invention. The multiple allergen testing system [10] is removed from its sterile package. The method for administering a plurality of allergens into skin of a patient involves a two-stage positioning process: (1) an allergen barb loading process, and (2) an allergen barb depositing process.

The applicator [20] is removed from the fluid tray [50] and placed onto the skin of the patient [90]. The testing arms are pulled toward the center of the applicator from both sides, raising up the skin of the patient. The pair of skin lifting pads [45] are sandwiched about each scratching barb [61]. The scratching barbs [61] lift the skin and limit the depth of penetration of each scratching barb [61]. From this position, the scratching barb [61] is pulled up and away from the skin of the patient [90]. This action creates a small scratch [91] on the skin of the patient [90] inserting a small amount of allergen [57] under the skin.

While in the allergen barb loading position, the multiple test applicator [20] is in the relaxed state.

FIGURE 4 depicts the first preferred embodiment of the multiple test applicator [20] held in one hand by a medical technician, with the thumb positioned on a first finger grip [30] on a first side frame [35] and the index finger of the same hand positioned on a second finger grip [31] on a second side frame [36], the first side frame [35] opposing the second side frame [36].

The multiple test applicator [20] is in the relaxed state while in allergen barb loading position [25] when the multiple test applicator [20] is in cooperative engagement with the fluid tray [50]. The multiple test applicator [20] is preferably sized to be held in one hand of a medical technician administering the allergen skin testing. The pair of finger grips [35 and 36] are positioned on opposing sides of each opposing applicator frame [30 and 31]. The medical technician grasps the applicator [20] by the pair of opposing finger grips [35 and 36] in her/his hand during the allergen barb loading process and the allergen barb depositing process by placing her/his thumb on one finger grip [35] and her/his forefinger of the same hand on the other finger grip [36]. The method involves one hand of a medical technician [96] positioning a multiple test applicator [20] onto a loading tray [50] during the allergen barb loading.

The use of the finger grips [35 and 36] to move the multiple test applicator [20] from the relaxed state to the compressed state and then back again to the relaxed state enables one-handed operation by the medical technician. During allergen barb depositing position [92], the medical technician uses the same hand as in the allergen barb loading enabling one-handed operation throughout the entire process.

Multiple allergens are retainable in the reservoirs [54] of the fluid tray [50]. Allergens are initially selected and placed into the individual containment reservoirs [54] of the fluid tray [50], and care is taken not to use an excess amount of the allergens. The multiple test applicator [20] has multiple scratching barbs [61]. During the allergen barb loading each scratching barb is positioned in a reservoir [54] containing an allergen [57].

FIGURE 5 depicts the first preferred embodiment of the multiple test applicator [20] held in one hand of the medical technician as the allergens are deposited under the skin on a forearm, upper arm, leg or back of a patient [90]. The method for administering a plurality of allergens into skin of a patient [90] then uses the same hand of the medical technician [96] to relocate the multiple test applicator [10] onto the skin of the patient [90] during allergen deposition.

During allergen barb depositing position [92], the medical technician uses the same hand as in the allergen barb loading enabling one-handed operation throughout the entire process. The first scratching barb facilitates a first scratch on a first epidermis layer of the patient while in the allergen barb depositing position [92] relative to the skin of the patient [90]. The second scratching barb facilitates a second scratch on a second epidermis layer of the patient while in the allergen barb depositing position [92] relative to the skin of the patient [90].

After being repositioned from the barb allergen loading position [25] once the first and scratching barbs are loaded with some of the allergens. The multiple test applicator [20] is primed to deposit the allergens in the scratches on the skin of the patient [90]. A first scratch is generated by a first scratching barb once the multiple test applicator [20] is repositioned onto the skin of the patient [90]. A second scratch is generated by a second scratching barb once the multiple test applicator [20] is repositioned onto the skin of the patient [90].

Then, the multiple test applicator [20] is pulled up and away from the skin of the patient [90]. The medical technician then waits between 10 to 20 minutes to determine how the patient has reacted to each of these allergens [57]. After the testing has been completed, the physician analyzes the test results to determine the next course of treatment.

FIGURES 6A, 6B, and 6C depict the first embodiment of the multiple test applicator [20] of the present invention during allergy barb deposition. When subsequently repositioned upon the skin of the patient [90], the scratching barbs [61] contact both sides of the raised portion of the skin [94] of the patient. The skin of the patient [90] is raised by the pair of skin lifting pads [45], one positioned on each side of each scratching barb [61]. Also, the skin lifting pads [45] are positioned relative to each scratching barb [61] to limit the depth that each scratching barb [61] as it penetrates the skin of the patient [90]. The multiple test applicator [20] generates a scratch [91] at each test site essentially simultaneously as the medical technician manipulates the multiple test applicator [20] upward or downward, as trace amounts of each respective allergen [57] seep into each respective scratch [91] at each test site.

FIGURE 6A is a front view of the multiple test applicator [20] in an expanded position, with the scratching barbs [61] resting upon the skin of a patient [90]. The scratching barbs [61] each include a trace of their respective allergens and are prepared for allergen barb deposition.

FIGURE 6B is a front view of the multiple test applicator [20]. The multiple test applicator is now being in a compressed position by use of the pair of finger grips [35 and 36]. The scratching barbs [61] are resting upon the skin of the patient [90] with the each of two scratching barbs [61] disposed about a portion of the skin of a patient [90] that has been lifted upwards [94] between the pair of opposed scratching barbs [61]. The multiple test applicator [20] is in the allergen deposition position.

FIGURE 6C is a front view of the multiple test applicator of FIGURE 5B. The multiple test applicator [20] is still being compressed. The scratching barbs [61] now have been raised upward from the skin of the patient [90] with a pair of scratches [61] now appearing on each side of the portion of the skin of the patient that was lifted upwards [94].

With the scratching barbs [61] now positioned on the skin of the patient [90], the multiple test applicator [20] is moved from the relaxed state to the compressed state and pulled upwards away from the raised skin. In so doing, the scratching barbs [61] will break the skin of the patient [90] and generate a plurality of small scratches [91]. A trace amount of each allergen [57] has been retained on each scratching barb [61] and is inserted into each scratch [91] on the skin of the patient [90].

The method of administering the plurality of allergens using the multiple test system of the present invention requires allergen barb loading (the position [25] being depicted in DETAIL "A" of FIGURE 1) and allergen barb deposition (the position [92] being shown in FIGURE 5).

FIGURE 7A is an exploded assembly view of the first preferred embodiment of the scratching barb pointed upward [61] toward the spine [21] of the multiple test applicator [20]. A barb break-off section [44] is also shown.

FIGURE 7B is an exploded assembly view of a second preferred embodiment of the scratching barb pointed upward [62] toward the spine [21] of the multiple test applicator [20]. The scratching barb [62] includes an aperture [47] and a channel [46] for retaining a trace amount of the respective allergen [57]. A barb break-off section [44] is also shown. A pair of skin lifting pads [45] are sandwiched about each scratching barb [61]. The pair of skin lifting pads [45] lift the skin and limit the depth of the scratching barb [62]. The pair of skin lifting pads [45] controls the depth of the penetration of the scratching barbs [62] and ensures accuracy and repeatability of the testing.

FIGURE 7C is an exploded assembly view of a third preferred embodiment of the scratching barb [63] pointed upward toward the spine [21] of the multiple test applicator [20]. The scratching barb [63] includes a vial [48] and a channel [46] for retaining a trace amount of the respective allergen [57]. A barb break-off section [44] is also shown. A pair of skin lifting pads [45] are sandwiched about each scratching barb [63]. The pair of skin lifting pads [45] lift the skin and limit the depth of the scratching barb [63]. The pair of skin lifting pads [45] control the depth of the penetration of the scratching barbs [63] and ensure accuracy and repeatability of the testing.

FIGURE 8 depicts an exploded side view of a pair of scratching barbs [61] being raised upward on a portion of the skin of a patient [90] that has been pulled together and raised [94] to prepare the site for a pair of scratches [91] from the pair of scratching barbs [61]. Skin lifting pads [45] are shown on both sides of the scratching barb [61], that lift the skin and limit the depth of penetration of the scratching barb [61].

The scratching barb [61] is subsequently transferred to the skin of the patient [90]. Once the scratching barb [61] of the multiple test applicator [20] is on the skin of the patient [90], the applicator [20] is moved in such a way, as to lift the skin in front of the scratching barb [61]. The next action is to lift the multiple test applicator [20] perpendicular to the skin of the patient [90], causing the scratching barb [61] containing a trace amount of allergen [57], to scratch the skin through the epidermis in a way so not to penetrate the dermis.

FIGURE 9 depicts an assembly view of a second preferred embodiment of an allergy testing system [110] comprising a second preferred embodiment of the multiple test applicator [120] having nine scratching barbs, and a single test applicator [180] with a single scratching barb, all being in cooperative engagement with ten fluid reservoirs [54] in the fluid tray [50]. The multiple test applicator is also compatible with multiple single test applicator units [180] when aligned with a fluid tray [50] that is properly sized with the number and alignment of fluid reservoirs (not shown).

FIGURE 10A depicts an assembly view of the single test applicator [180] of FIGURE 9, and FIGURE 10B depicts an end view of the single test applicator [180] of FIGURE 10A.

Again, in this second preferred embodiment, the multiple test applicator [120] is in the relaxed state while in allergen barb loading position [25] when the multiple test applicator [120] is in cooperative engagement with the fluid tray [50]. The multiple test applicator [120] is preferably sized to be held in one hand of a medical technician administering the allergen skin testing. The pair of finger grips [35 and 36] are positioned on opposing sides of each opposing applicator frame [30 and 31]. The medical technician grasps the applicator [120] by the pair of opposing finger grips [35 and 36] in her/his hand during the allergen barb loading process and the allergen barb depositing process by placing her/his thumb on one finger grip [35] and her/his forefinger of the same hand on the other finger

grip [36]. The method involves one hand of the medical technician [96] positioning a multiple test applicator [120] onto a loading tray [50] during the allergen barb loading.

The use of the finger grips [35 and 36] to move the multiple test applicator [20] from the relaxed state to the compressed state and then back again to the relaxed state enables one-handed operation by the medical technician. During allergen barb depositing position [92], the medical technician uses the same hand as in the allergen barb loading enabling one-handed operation throughout the entire process.

FIGURE 11 depicts an assembly view of a third preferred embodiment of multiple allergen testing system [210] comprising of a third preferred embodiment of the multiple test applicator [220] having ten scratching barbs applicators [61] in cooperative engagement with ten reservoirs [54] in a fluid tray [50].

DETAIL "B" depicts an exploded side view of the scratching barb [261] positioned in a reservoir [54] of the fluid tray [50] while in the allergen barb loading position. The reservoir [54] is partially filled with allergen [57]. Here, the scratching barbs [261] project in a downward direction relative to the fluid tray [50]. The multiple test applicator [20] is enabled to reposition from the compressed state to the relaxed state when placed on the skin of the patient [90] in the allergen barb depositing position [92].

And again, in this third preferred embodiment, the multiple test applicator [220] is in the relaxed state while in allergen barb loading position [25] when the multiple test applicator [220] is in cooperative engagement with the fluid tray [50]. The multiple test applicator [220] is preferably sized to be held in one hand of a medical technician administering the allergen skin testing. The pair of finger grips [35 and 36] are positioned on opposing sides of each opposing applicator frame [30 and 31]. The medical technician grasps the applicator [220] by the pair of opposing finger grips [35 and 36] in her/his hand during the allergen barb loading process and the allergen barb depositing process by placing her/his thumb on one finger grip [35] and her/his forefinger of the same hand on the other finger grip [36]. The method involves one hand of the medical technician [96] positioning a multiple test applicator [220] onto a loading tray [50] during the allergen barb loading.

The use of the finger grips [35 and 36] to move the multiple test applicator [220] from the relaxed state to the compressed state and then back again to the relaxed state enables

one-handed operation by the medical technician. During allergen barb depositing position [92], the medical technician uses the same hand as in the allergen barb loading enabling one-handed operation throughout the entire process.

FIGURE 12 depicts the third preferred embodiment of the multiple test applicator [220].

FIGURES 13A, 13B, and 13C depict an alternate embodiment of the method for administering multiple allergens of the present invention, each of the scratching barbs [261] of the multiple test applicator [220] downward toward the fluid tray [50] when disposed in the fluid tray [50]. The fluid tray [50] contains multiple allergens, generally test fluid in each reservoir [54]. Allergens [57] are initially selected and placed into containment reservoirs [54] in the fluid tray [50], and care is taken not to use an excess amount of the allergens. After allergen barb loading is completed, the medical technician lifts the multiple test applicator [220] out of the fluid tray [50], the multiple test applicator [10] being in the relaxed state. Using the pair of opposing finger grips [30 and 31], the medical technician applies pressure moving the multiple test applicator [220] to a compressed state before placing the applicator [220] upon the skin of the patient [90] in the allergen deposition position, the medical technician pushes lightly upon the applicator [220] and slowly releases the finger grips [30 and 31]. This generates a scratch [91] at each test site essentially simultaneously on the skin of the patient [90]. Trace amounts of each respective allergen [57] then seep into each respective scratch [91]. The use of the finger grips [30 and 31] to move the multiple test applicator [220] from the relaxed state to the compressed state and then back again to the relaxed state enables one-handed operation by the medical technician. Then, the multiple test applicator [220] is pulled up and away from the skin of the patient [90].

FIGURE 13A is a front view of the multiple test applicator [220] in an expanded position, with the scratching barbs [61]. The scratching barbs [61] have been loaded and each include a trace amount of allergen and are prepared for allergen deposition. FIGURE 13B is a front view of the multiple test applicator [220], which is now in a compressed position. The scratching barbs [261] are resting upon the skin of a patient [90] with the each of two scratching barbs [261] pointed downward. FIGURE 13C is a front view of the multiple test applicator [220], which is now in an expanded position. The scratching barbs [61] now

have generated a pair of scratches [91] on the skin of the patient [90] at a pair of test sites as the scratching barbs [61] have separated from each other.

Then, the medical technician waits between 15 to 20 minutes to determine how the patient has reacted to these allergens. After the testing has been completed, the physician analyzes the test results to determine the next course of treatment.

FIGURE 14A is an exploded assembly view of the first preferred embodiment of the scratching barb [261] pointed downward away from the spine [21] of the multiple test applicator [220]. A barb break-off section [44] also being shown.

FIGURE 14B is an exploded assembly view of a second preferred embodiment of the scratching barb [262] pointed downward away from the spine [21] of the multiple test applicator [210], the scratching barb [262] including an aperture [47] and a channel [46] for retaining a trace amount of the allergen [57]. A barb break-off section [44] also being shown.

FIGURE 14C is an exploded assembly view of a third preferred embodiment of the scratching barb [263] pointed downward away from the spine [21] of the multiple test applicator [220], the scratching barb [263] including a vial [48] and a channel [46] for retaining a trace amount of the allergen [57], a break-off section also being shown. A barb break-off section [44] also being shown.

Application barb loading is like the procedure already discussed in detail. Once allergen barb loading is completed, the multiple test applicator [10] is removed from the fluid tray [50] and repositioned onto the skin (i.e. - arm, back, or leg) of the patient [90].

In the allergen deposition position, the multiple test applicator [20] is compressed, and each allergen [57] is deposited into each respective scratch [91] generated by each respective scratching barb [61] on the skin of the patient [90] for further analysis as needed by the treating physician.

After the prescribed time between 10 to 20 minutes the test operator records the skin condition with an evaluation form or a photo of each scratch site. The applicator includes break-off features for the arms, legs, and tips enabling more efficient disposal of the device after use with a patient. The break-off features for the tips enable this part of the

applicator to be disposed of in a biohazard sharps container. The leg break-off points enable the legs to be broken off from the spine and the legs and spine to be disposed of in a separate container from the tips. The fluid tray can also be disposed of in the same container. This increases the packing density of the discarded material and a much lower disposal cost.

Also, the multiple test applicator [20] of the multiple allergen testing system [10] has the advantage of breaking the skin of the patient without downward pressure. This diminishes chances of the mast cells (histamine containing cells) releasing the histamine secondary to pressure causing a false positive. This is a critical factor with percutaneous allergy testing.

The single and multiple allergen testing system [110] enables testing for a single allergy or multiple allergies in the same device. The allergen testing applicator [120] simulates the best practice in a controlled procedure. The multiple-allergen testing system is designed around a multiple allergen testing system [120] that enables the accurate and repeatable placement of allergy testing fluid, either in a tray or on the skin of a patient. The testing procedure also controls the scratching or pricking of the skin, to introduce the allergen in a more controlled manner.

The multiple test applicator [20] and the fluid tray [50] are preferably made of engineering grade polymers that are sterilized prior to use in an autoclave, or other standard sterilization procedures. Hence, the materials preferably are made of plastics that are stable at higher temperatures. The multiple test applicator [20] is depicted having ten scratching barbs. The multiple applicator unit may also have two, four, six, eight, twelve, and any of a wide variety of configurations, as needed.

It is critical during use that the allergens [57] for the various reservoirs [54] do not become intermixed as this contamination will affect the test results. The suggested minimum distance between two neighboring scratching barbs extending from the same side frame is preferably at least three-quarters of an inch.

It is critical that the multiple test applicator unit be held in one hand of the medical technician who is administering the test. This will enable the other hand to be free to

take notes, to assist the patient, or do whatever becomes necessary during the administration of the procedure.

Accordingly, the multiple test applicator [20] preferably has ten scratching barbs as depicted and is preferably about 2" (height) X 2" (width) X 5" (length). If the multiple test applicator has eight scratching barbs (2 X 4), the length is preferably 3.75" to 4.50" in length, if the multiple test applicator has twelve scratching barbs (2 X 6), the length is about 5.00 to 5.50", etc. It is to be understood that while the multiple allergen testing device as depicted in the accompanying drawings depicts a unit with ten testing devices, one skilled in the art can readily modify this geometry to include 4, 6, 8, 12, 16, 20, 24, 30, 36, or any other combination of multiple testing devices, this disclosure is being limited to 10 for purposes of illustration only.

The multiple test applicator [20] enables testing for multiple allergies in one device and one test procedure or one test with the single tester and one allergy testing fluid. The most consistent results have been achieved by inserting a drop of allergy testing fluid on the skin and then scratching the skin with a simple needle (best practice). The multiple test applicator [20] of the present invention duplicates the best practice but in a controlled, repeatable, and reproducible way. The system built around the devices enables the accurate and repeatable placement of the allergy testing fluid, in a tray and transfers this fluid to the multiple test applicator [20] or the single test applicator [180], by placing the testing end of the device, into the fluid tray [50].

After the prescribed time between 10 to 20 minutes the medical technician records the skin condition. The applicator includes break-off features for the arms, legs, and tips enabling more efficient disposal of the device after use with a patient. The break-off features for the tips enable this part of the applicator to be disposed of in a biohazard sharps container. The leg break-off points enable the legs to be broken off from the spine and the legs and spine to be disposed of in a separate container from the tips. The fluid tray [50] can also be disposed of in the same container. This increases the packing density of the discarded material and a much lower disposal cost.

Also, the multiple test applicator [20] has the advantage of breaking the skin of the patient [90] without downward pressure. This diminishes chances of the mast cells (histamine

containing cells) releasing the histamine secondary to pressure causing a false positive. This may be a critical factor with percutaneous allergy testing.

Throughout this application, various Patents and Applications are referenced by number and inventor, in order to more fully describe the state of the art to which this invention pertains.

It is evident that many alternatives, modifications, and variations of the systems, applicators, and methods for administering multiple allergens into the skin of a patient of the present invention will be apparent to those skilled in the art in lieu of the disclosure herein. It is intended that the metes and bounds of the present invention be determined by the appended claims rather than by the language of the above specification, and that all such alternatives, modifications, and variations which form a conjointly cooperative equivalent are intended to be included within the spirit and scope of these claims.

Date Reçue/Date Received 2023-08-22

PARTS LIST

10. Multiple Allergen Testing System - 1st Embodiment
20. Multiple Test Applicator - 1st Embodiment
21. Spine
22. Spine Arm
25. Allergen Barb Loading Position
30. and 31. Side Frame/Handle
32. Handle Arm
35. and 36. Finger Grip
44. Barb Break-Off
45. Skin Lifting Pad
46. Channel
47. Aperture
48. Vial
50. Fluid Tray
54. Reservoir
57. Allergen
61. Scratching Barb
62. Scratching Barb
63. Scratching Barb
90. Skin of Patient
91. Scratch
92. Allergen Barb Depositing Position
94. Raised Skin
96. Hand of Medical Technician
110. Multiple Allergen Testing System - 2nd Embodiment
120. Multiple Test Applicator - 2nd Embodiment
180. Single Unit Applicator
210. Multiple Test Applicator - 3rd Embodiment
220. Multiple Allergen Testing System - 3rd Embodiment
225. Allergen Barb Loading Position
261. Scratching Barb
262. Scratching Barb
263. Scratching Barb

CLAIMS:

1. A method for administering a plurality of allergens into skin of a patient, said method comprising:

a. positioning a multiple test applicator during allergen loading onto a fluid tray, said multiple test applicator having first and second scratching barbs, said multiple test applicator being cooperatively engageable with said fluid tray, said fluid tray having a first allergen retainable in a first reservoir, said fluid tray having a second allergen retainable in a second reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir, said second scratching barb retaining some of said second allergen when removed from said second reservoir, said multiple test applicator having a relaxed state and a compressed state, said first scratching barb moving away from said second scratching barb when said multiple test applicator changes from said compressed state to said relaxed state, said multiple test applicator being held by one hand of a medical technician during said allergen loading; and

b. relocating said multiple test applicator during allergen deposition onto said skin of said patient, said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited into said first scratch, said second scratching barb generating a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch, said multiple test applicator being held by one hand of said medical technician during said allergen deposition.

2. A method for administering a plurality of allergens into skin of a patient, said method comprising:

a. positioning a multiple test applicator during allergen loading onto a fluid tray, said multiple test applicator being cooperatively engageable with said fluid tray, said multiple test applicator including a first and second scratching barb, said multiple test applicator having a first side frame, said multiple test applicator having a second side frame, said first side frame opposing said second side frame, said multiple test applicator including a first finger grip disposed on said first side frame, said multiple test applicator including a second finger grip disposed on said second side frame, said fluid tray having a first allergen retainable in a first reservoir, said first scratching barb retaining some of said first allergen when removed from a first reservoir, said fluid tray having a second allergen retainable in said second reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir during said allergen loading, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading, said multiple test applicator having a relaxed state and a compressed state, said multiple test applicator being in said relaxed state during said allergen loading, said first scratching

Date Reçue/Date Received 2024-01-18

barb moving toward said second scratching barb when said multiple test applicator repositions into said compressed state; and

b. relocating said multiple test applicator during allergen deposition onto said skin of said patient, said first scratching barb generating a first scratch onto said skin of said patient as said some of said first allergen is deposited into said first scratch, said second scratching barb generating a second scratch onto said skin of said patient as said some of said second allergen is deposited into said second scratch, said multiple test applicator scratching said skin of said patient without applying downward pressure.

3. A method for administering a plurality of allergens into skin of a patient, said method comprising:

a. positioning a multiple test applicator during allergen loading onto a fluid tray, said multiple test applicator having a first scratching barb positionable on a first applicator leg, said multiple test applicator having a second scratching barb positionable on a second applicator leg, said first scratching barb of said multiple test applicator being cooperatively engageable with a first reservoir of said fluid tray during said allergen loading, said second scratching barb of said multiple test applicator being cooperatively engageable with a second reservoir of said fluid tray, said fluid tray having a first allergen retainable in said first reservoir, said fluid tray having a second allergen retainable in said second reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir during said allergen loading, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading, said first scratching barb projecting upwards when positioned in said fluid tray, said second scratching barb projecting upwards when positioned in said fluid tray; and

b. relocating said multiple test applicator from said fluid tray onto said skin of said patient during allergen deposition, said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited from said first scratching barb into said first scratch while said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited from said second scratching barb into said second scratch.

4. A method for administering a plurality of allergens into skin of a patient, said method comprising:

a. positioning a multiple test applicator during allergen loading onto a fluid tray, said multiple test applicator having a first scratching barb disposed on a first applicator leg, said multiple test applicator having a second scratching barb disposed on a second applicator leg, said first scratching barb opposing said second scratching barb, said first scratching barb of said multiple test applicator being cooperatively engageable with a first reservoir of said fluid tray during said allergen loading,

Date Reçue/Date Received 2024-01-18

said second scratching barb of said multiple test applicator being cooperatively engageable with second reservoir of said fluid tray, said fluid tray having a first allergen retainable in said first reservoir, said fluid tray having a second allergen retainable in said second reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir during said allergen loading, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading, said first and said second scratching barbs pointing downward toward said fluid tray, said multiple test applicator having a relaxed state and a compressed state, said multiple test applicator being in said relaxed state during said allergen loading;

b. removing said multiple test applicator from said fluid tray, repositioning said multiple test applicator from said relaxed state to said compressed state prior to placing said multiple test applicator on said skin of said patient; and

c. relocating said multiple test applicator from said fluid tray onto said skin of said patient during allergen deposition, where said first scratching barb generates a first scratch onto said skin of said patient as a portion of said first allergen is deposited from said first scratching barb into said first scratch while said second scratching barb generates a second scratch onto said skin of said patient as a portion of said second allergen is deposited from said second scratching barb into said second scratch, said first scratching barb moving away from said second scratching barb as said first scratch and said second scratch are formed.

5. A multiple test applicator for administering onto skin of a patient a first and a second allergen used in allergy skin testing, said multiple test applicator including:

a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray as a second scratching barb is cooperatively engageable with a second reservoir on said fluid tray, said fluid tray having said first allergen retainable in said first reservoir and said second allergen retainable in said second reservoir, said multiple test applicator having an expanded position and a compressed position, said first scratching barb retaining some of said first allergen when removed from said first reservoir as said second scratching barb retains some of said second allergen when removed from said second reservoir during allergen loading; and

a first side handle and a second side handle, a first finger grip being disposed on said first side handle, a second finger grip being disposed on said second side handle, said first finger grip opposing said second finger grip, a squeezing together of said first finger grip and said second finger grip using only one hand decreases a distance between said first scratching barb and said second

Date Reçue/Date Received 2024-01-18

scratching barb, during allergen deposition said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited into said first scratch, while said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch.

6. The multiple test applicator of Claim 5, wherein said multiple test applicator is in said expanded position during said allergen loading and in said compressed position during said allergen deposition.

7. The multiple test applicator of Claim 5, wherein said first scratching barb is positioned farther away from said second scratching barb during said allergen loading than during said allergen deposition.

8. The multiple test applicator of Claim 5, wherein said first and second scratching barbs project upward when positioned in said fluid tray.

9. The multiple test applicator of Claim 5, wherein said first scratching barb moves away from said second scratching barb during said allergen deposition.

10. The multiple test applicator of Claim 5, wherein said multiple test applicator being cooperatively engageable with a single test applicator and said fluid tray for testing a single allergen, said single test applicator including a single scratching barb, said single scratching barb retaining some of a single allergen when removed from a single reservoir of said fluid tray, said multiple test applicator enabling testing of said first allergen, said second allergen, and said single allergen in one device.

11. A multiple test applicator for administering onto skin of a patient a first and a second allergen used in allergy skin testing, said multiple test applicator comprising:

a first scratching barb cooperatively engageable with a first reservoir in a fluid tray, said fluid tray having said first allergen retainable in said first reservoir, said first scratching barb pointing upwards when disposed in said fluid tray, said first scratching barb retaining some of said first allergen when removed from said first reservoir during allergen loading; and

a second scratching barb cooperatively engageable with a second reservoir in said fluid tray, said fluid tray having said second allergen retainable in said second reservoir, said second scratching barb pointing upwards when disposed in said fluid tray, said multiple test applicator having an expanded position and a compressed position, during allergen deposition said first scratching barb generating a first scratch on said skin of said patient as said first allergen is deposited into said first scratch while said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch.

Date Reçue/Date Received 2024-01-18

12. The multiple test applicator of claim 11, wherein said multiple test applicator is in said expanded position during said allergen loading and in said compressed position during said allergen deposition.

13. The multiple test applicator of Claim 11, wherein said multiple test applicator has an expanded position and a compressed position, said first scratching barb being disposed nearer said second scratching barb in said compressed position, said first scratching barb being disposed farther from said second scratching barb in said expanded position.

14. A multiple test applicator for administering onto skin of a patient a first and a second allergen used in allergy skin testing, said multiple test applicator comprising:

a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray, a first allergen being retainable in said first reservoir, said first scratching barb retaining some of said first allergen when removed from said first reservoir during allergen loading; and

a second scratching barb being cooperatively engageable with a second reservoir on said fluid tray, said fluid tray having a second allergen retainable in said second reservoir, said second scratching barb being disposed in said fluid tray during said allergen loading, said multiple test applicator having an expanded position and a compressed position, said multiple test applicator being in said expanded position during said allergen loading, said multiple test applicator being in said compressed position during allergen deposition, during said allergen deposition said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited into said first scratch as said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch.

15. The multiple test applicator of Claim 14, wherein said first scratching barb is positioned farther from said second scratching barb in said expanded position than in said compressed position.

16. A multiple test applicator for administering onto skin of a patient a first and a second allergen used in allergy skin testing, said multiple test applicator comprising:

a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray, said fluid tray having said first allergen retainable in said first reservoir; and

a second scratching barb being cooperatively engageable with a second reservoir on said fluid tray as said first scratching barb is cooperatively engageable with said first reservoir on said fluid tray, said second allergen being retainable in said second reservoir, said multiple test applicator having an expanded position and a compressed position facilitating movement of said multiple test applicator

Date Reçue/Date Received 2024-01-18

from said expanded position during allergen loading to said compressed position prior to placement onto said skin of said patient, during allergen deposition said first scratching barb generating a first scratch onto said skin of said patient as said first allergen is deposited into said first scratch as said second scratching barb generates a second scratch onto said skin of said patient as said second allergen is deposited into said second scratch.

17. The multiple test applicator of Claim 16, wherein said first scratching barb moves away from said second scratching barb as said first scratch and said second scratch are formed.

18. A multiple test applicator comprising:

a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray during allergen loading, a first allergen being retainable in said first reservoir, said first scratching barb retaining some of a first allergen when removed from said first reservoir during said allergen loading;

a second scratching barb being cooperatively engageable with a second reservoir on said fluid tray during said allergen loading, said second scratching barb opposing said first scratching barb, said second scratching barb cooperatively engaging with said first scratching barb, a second allergen being retainable in said second reservoir, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading; and

a first side handle secured to said first scratching barb, a second side handle secured to said second scratching barb, said first side handle opposing said second side handle, said first side handle and said second side handle configured to fit into one hand of an operator, said first side handle cooperatively engaged with said second side handle as inward pressure is applied on said first side handle and said second side handle after said allergen loading is completed and prior to allergen deposition, where said first scratching barb and said second scratching barb are placed on skin as said inward pressure is released during said allergen deposition such that said first scratching barb moves across a first section of said skin as said second scratching barb moves across a second section of said skin away from said first scratching barb, said first scratching barb generating a first scratch depositing a portion of said first allergen into said first scratch as said second scratching barb generates a second scratch depositing a portion of said second allergen into said second scratch.

19. A multiple test applicator comprising:

a first scratching barb being cooperatively engageable with a first reservoir on a fluid tray during allergen loading, a first allergen being retainable in said first reservoir, said first scratching barb

Date Reçue/Date Received 2024-01-18

retaining some of a first allergen when removed from said first reservoir during said allergen loading;

a second scratching barb being cooperatively engageable with a second reservoir on said fluid tray during said allergen loading, said second scratching barb opposing said first scratching barb, said second scratching barb cooperatively engaging with said first scratching barb, a second allergen being retainable in said second reservoir, said second scratching barb retaining some of said second allergen when removed from said second reservoir during said allergen loading; and

a first side handle secured to said first scratching barb, a second side handle secured to said second scratching barb, said first side handle opposing said second side handle, said first side handle and said second side handle configured to fit into one hand of an operator, said first side handle cooperatively engaged with said second side handle such that application of pressure on said first side handle and said second side handle during allergen deposition causes said first scratching barb to move across a first section of skin as said second scratching barb moves across a second section of said skin, said first scratching barb generating a first scratch in said first section of said skin depositing a portion of said first allergen into said first scratch as said second scratching barb generates a second scratch depositing a portion of said second allergen into said second scratch.

Date Reçue/Date Received 2024-01-18

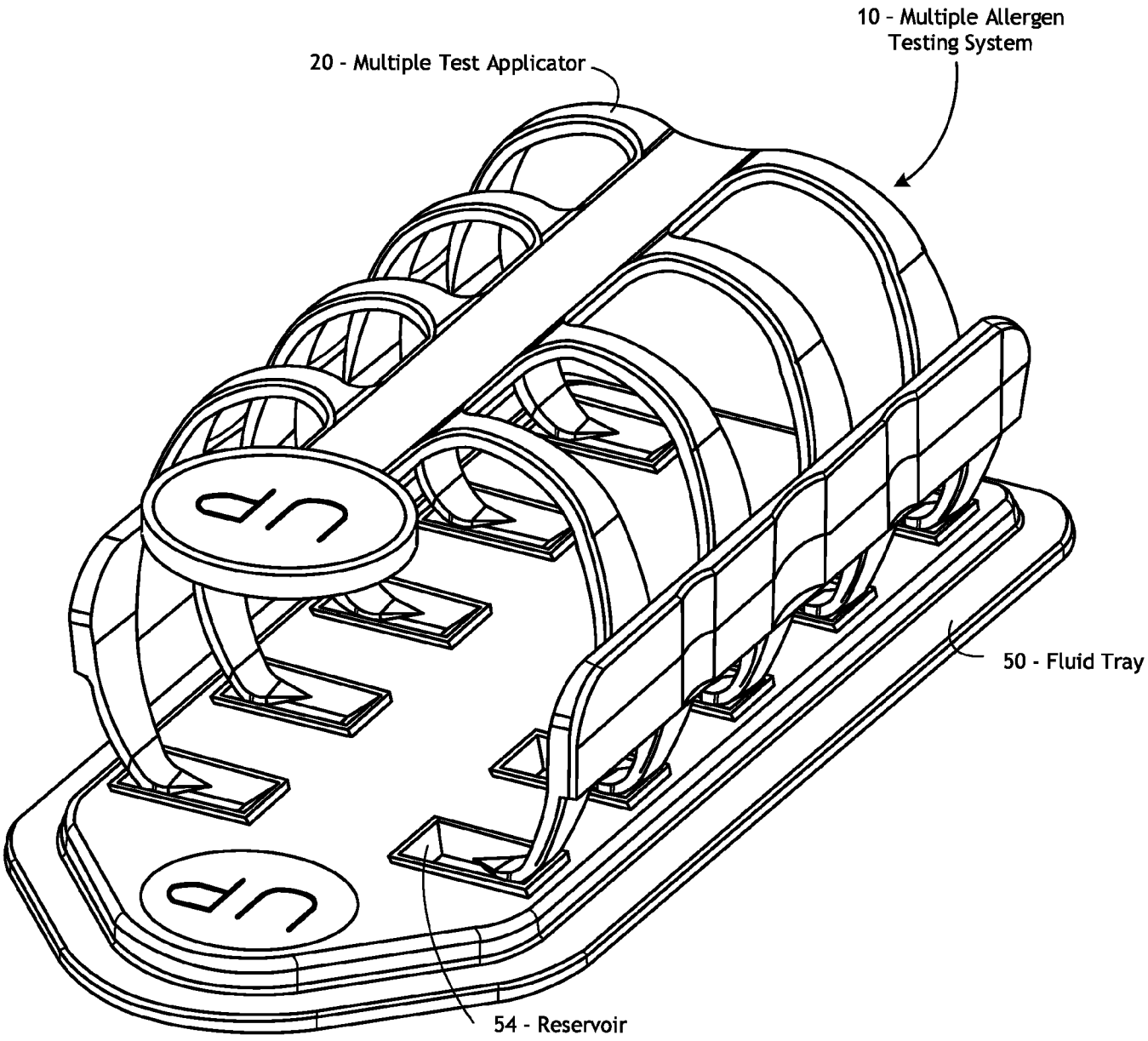
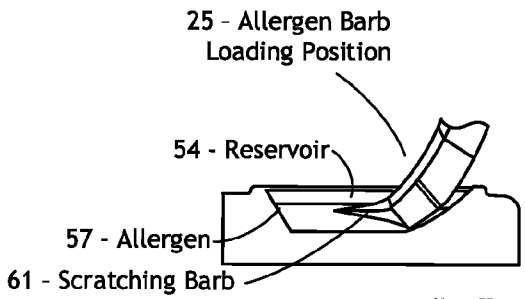


FIGURE 1



DETAIL "A"
ALLERGEN LOADING

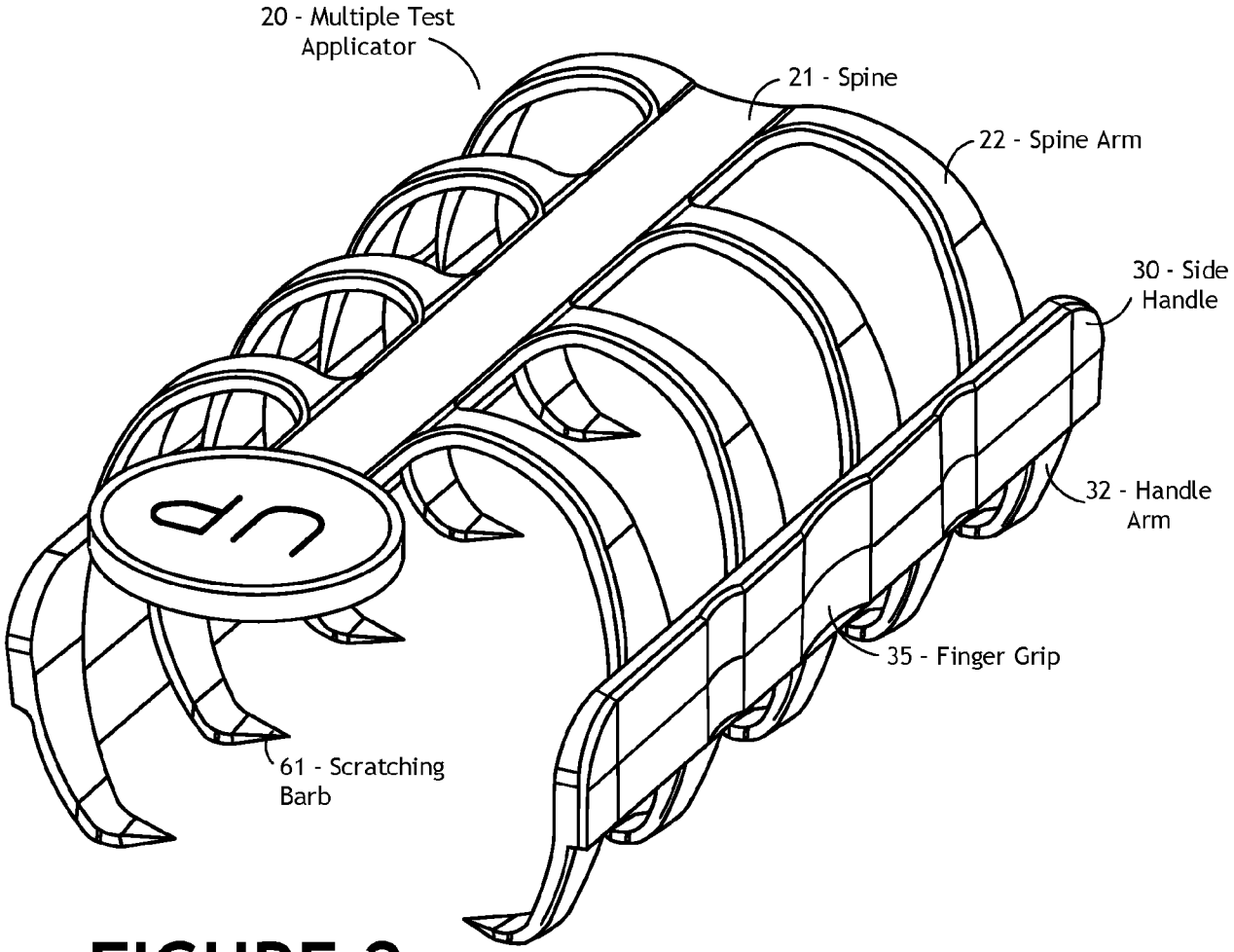

20 - Multiple Test Applicator
21 - Spine
22 - Spine Arm
30 - Side Handle
32 - Handle Arm
35 - Finger Grip
61 - Scratching Barb

FIGURE 2

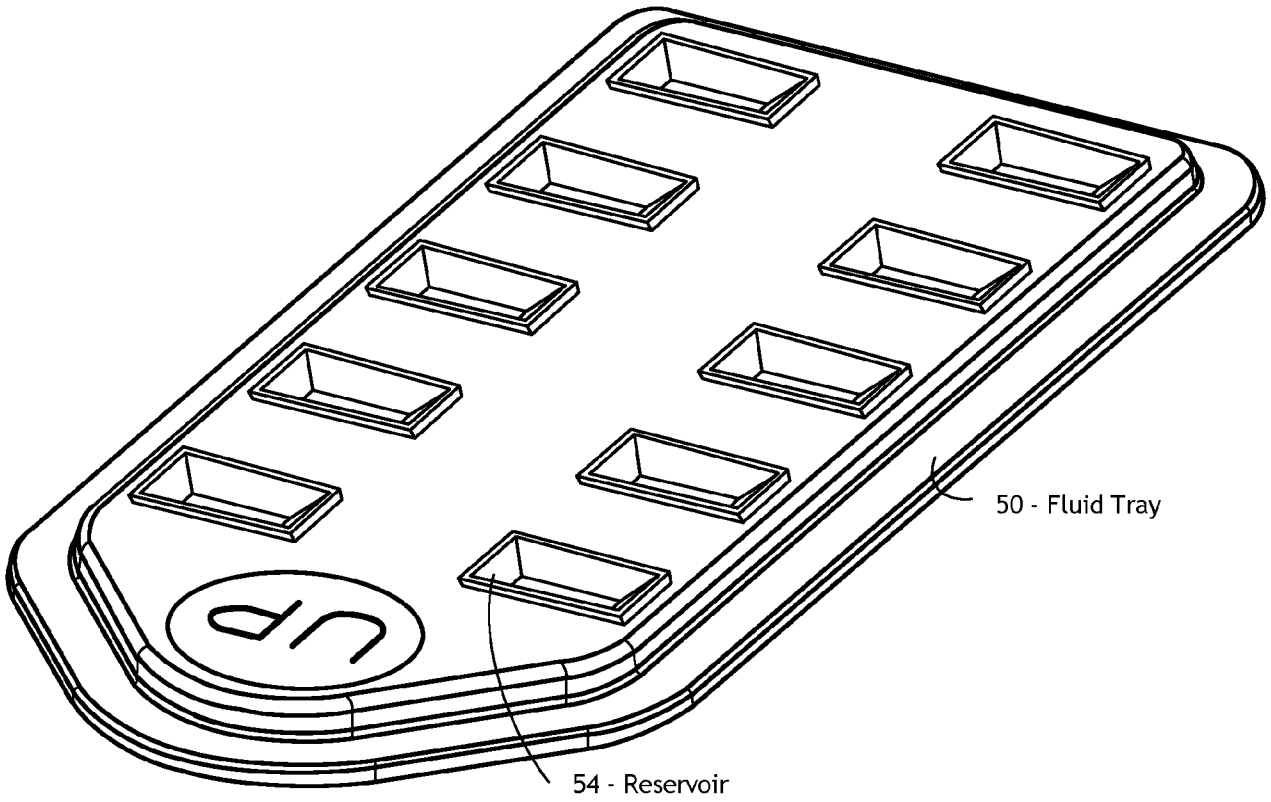


FIGURE 3

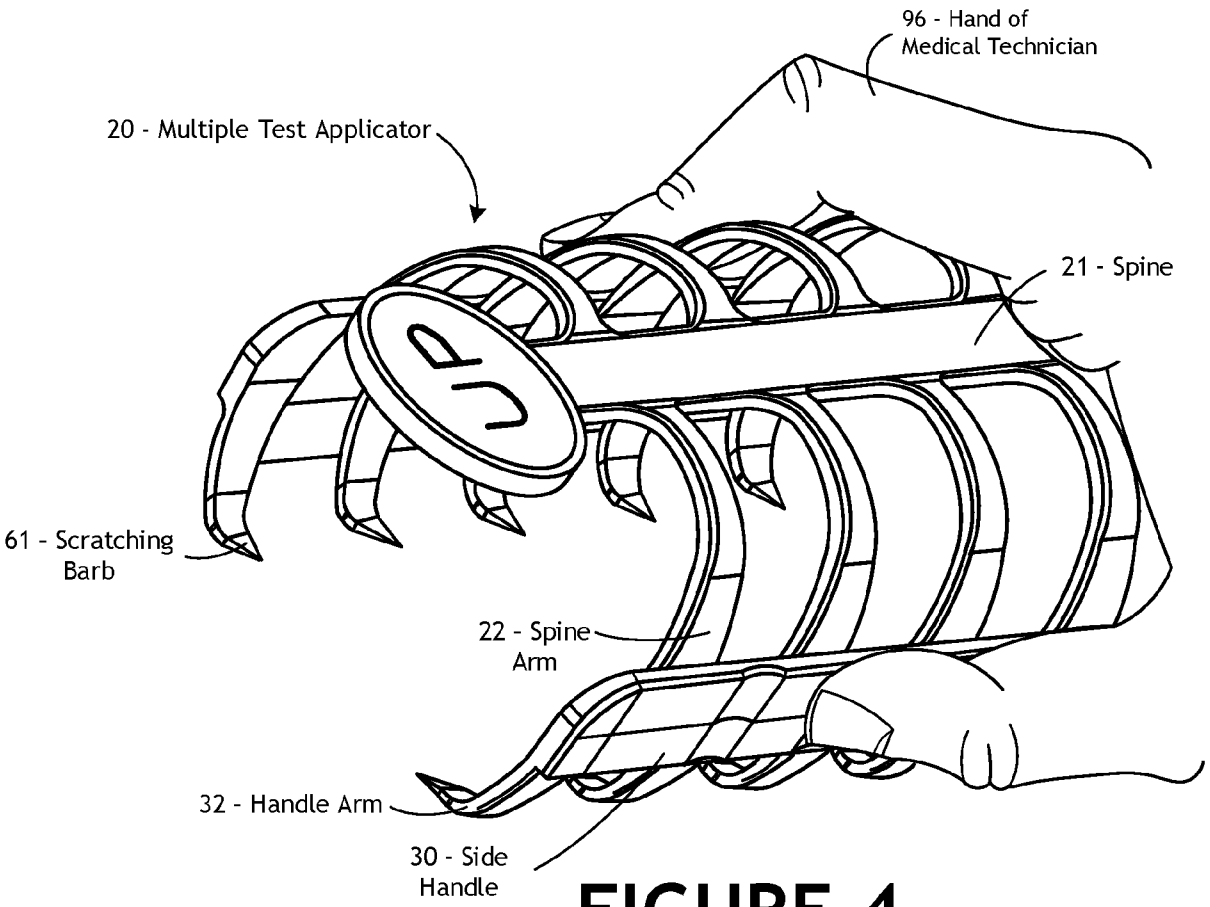

96 - Hand of Medical Technician
20 - Multiple Test Applicator
21 - Spine
61 - Scratching Barb
22 - Spine Arm
32 - Handle Arm
30 - Side Handle

FIGURE 4

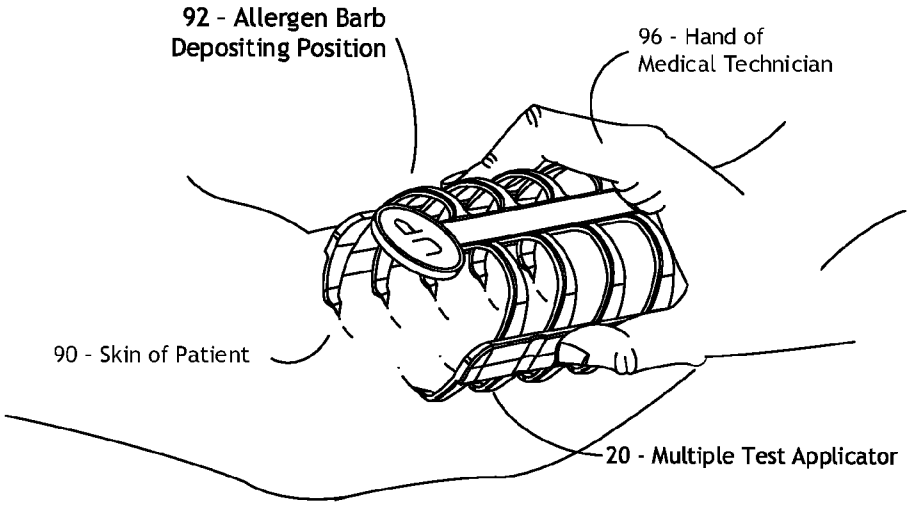


FIGURE 5
ALLERGEN DEPOSITION

FIGURE 6A
RELAXED STATE

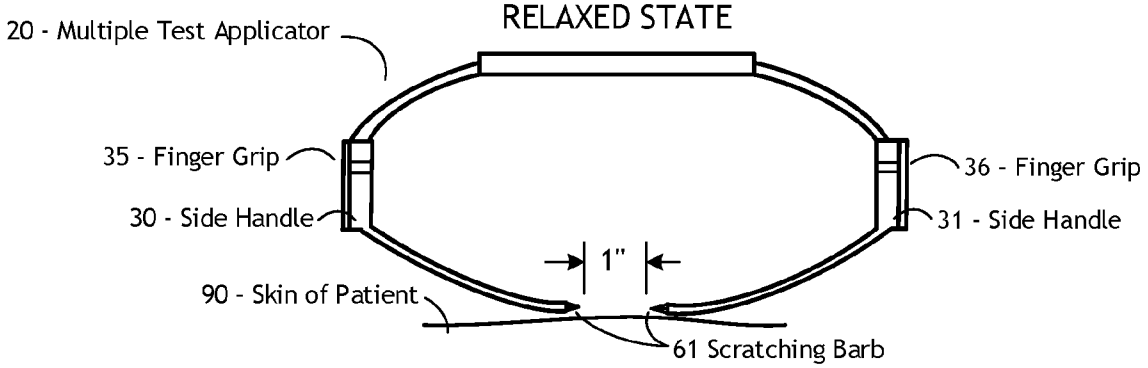


FIGURE 6B
COMPRESSED STATE

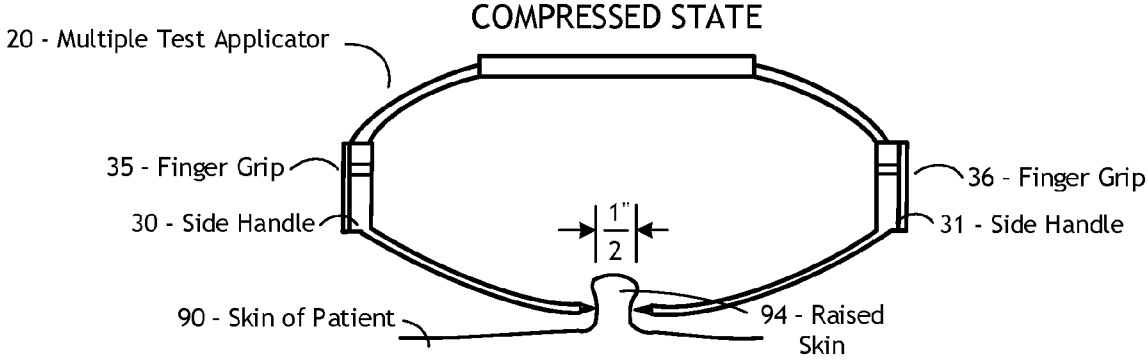
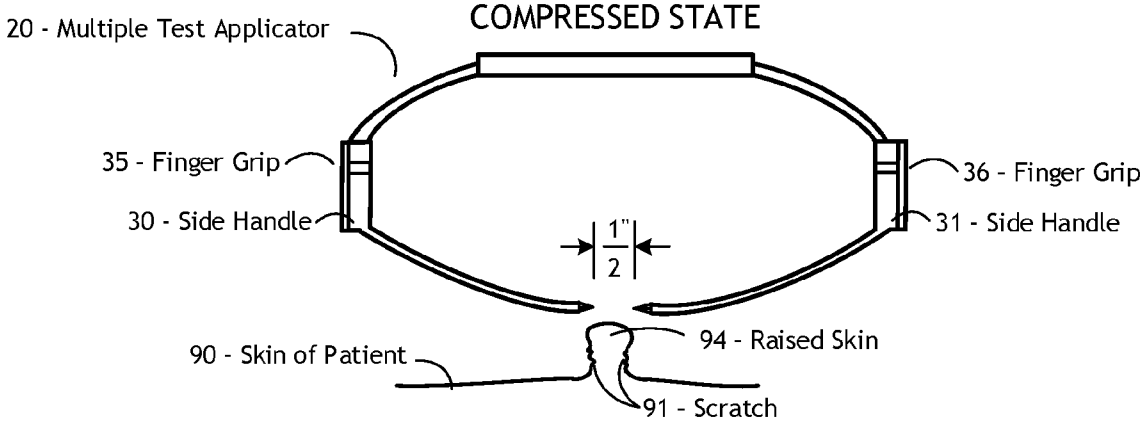


FIGURE 6C
COMPRESSED STATE



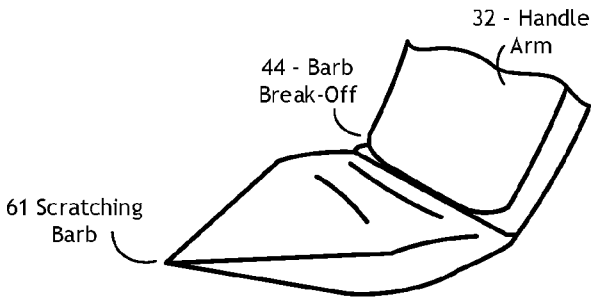


FIGURE 7A
BARB TILTED UP

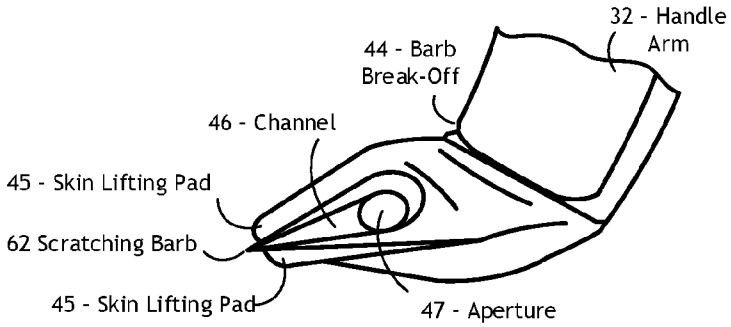


FIGURE 7B
BARB TILTED UP

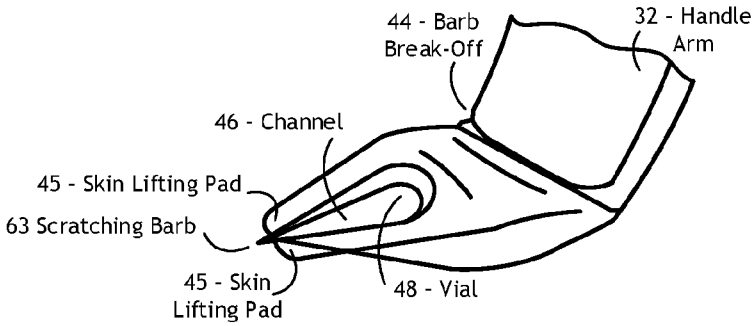


FIGURE 7C
BARB TILTED UP

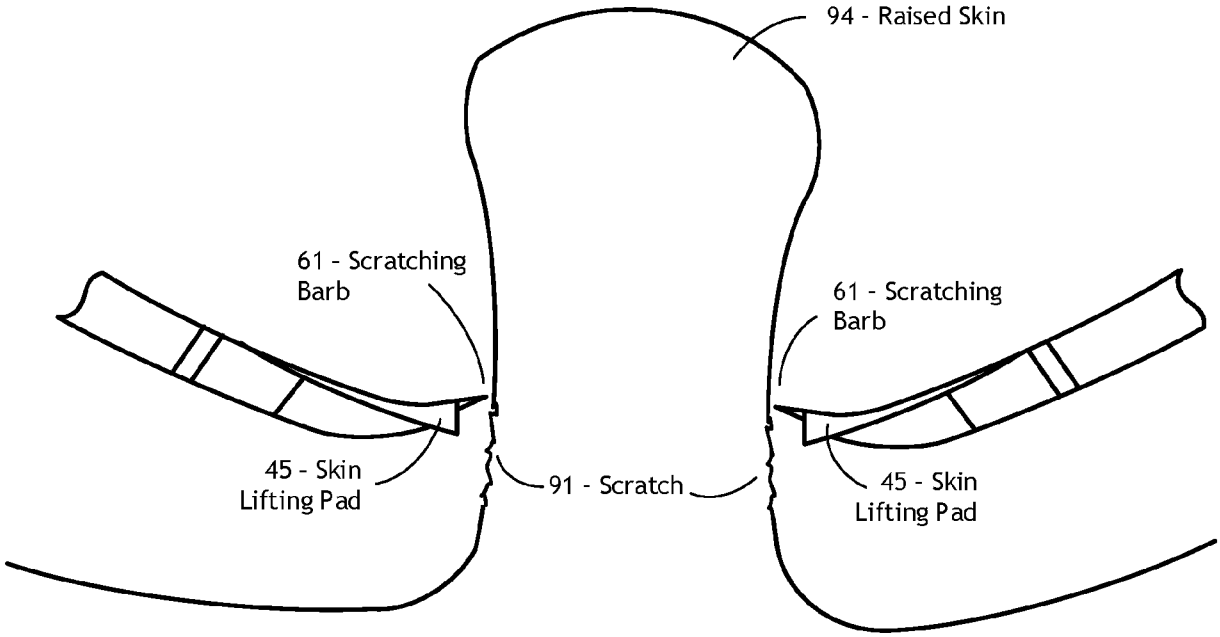

94 - Raised Skin
61 - Scratching Barb
61 - Scratching Barb
45 - Skin Lifting Pad
91 - Scratch
45 - Skin Lifting Pad

FIGURE 8

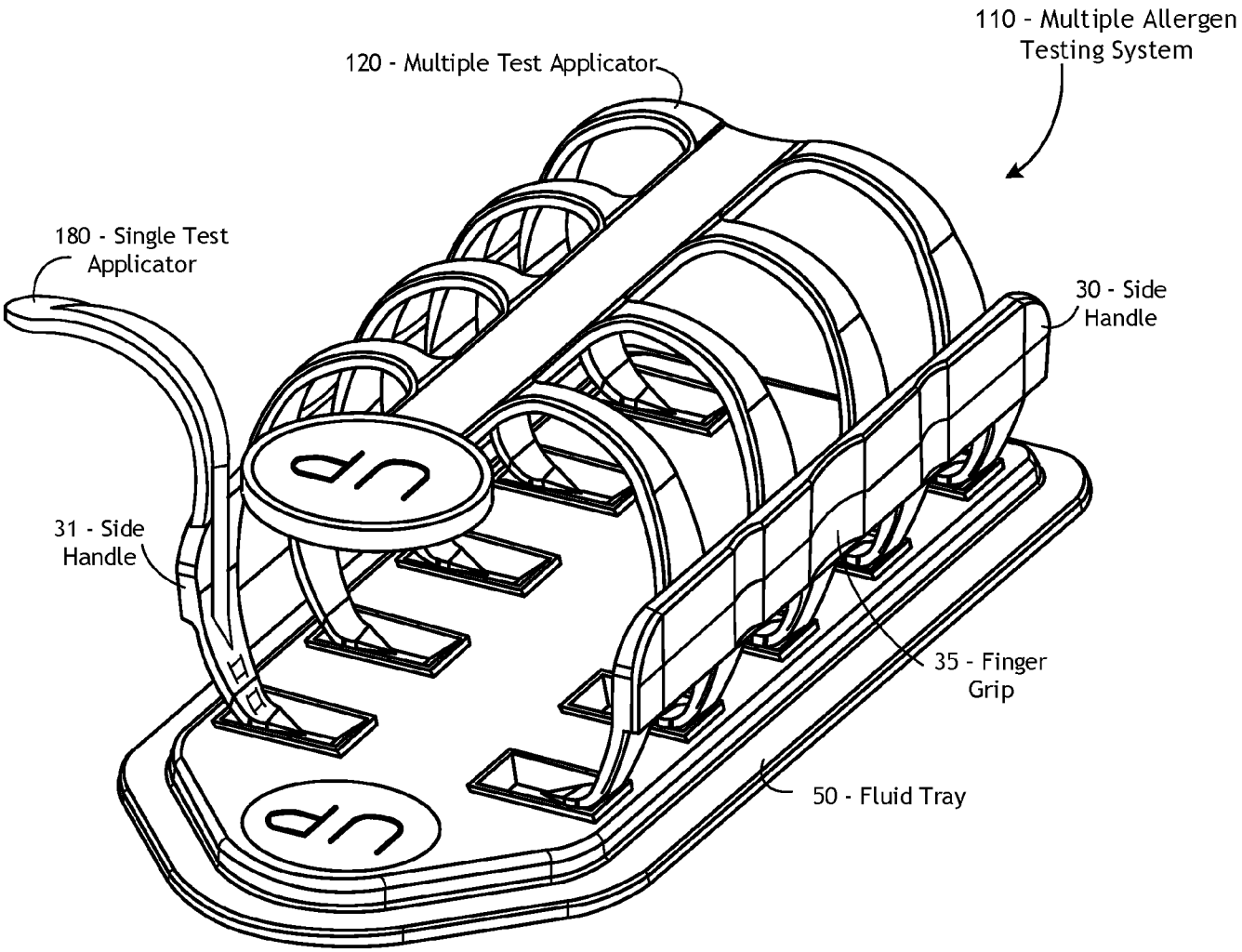


FIGURE 9

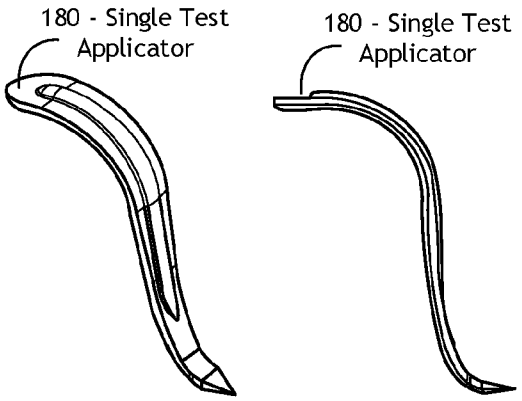


FIGURE 10A

FIGURE 10B

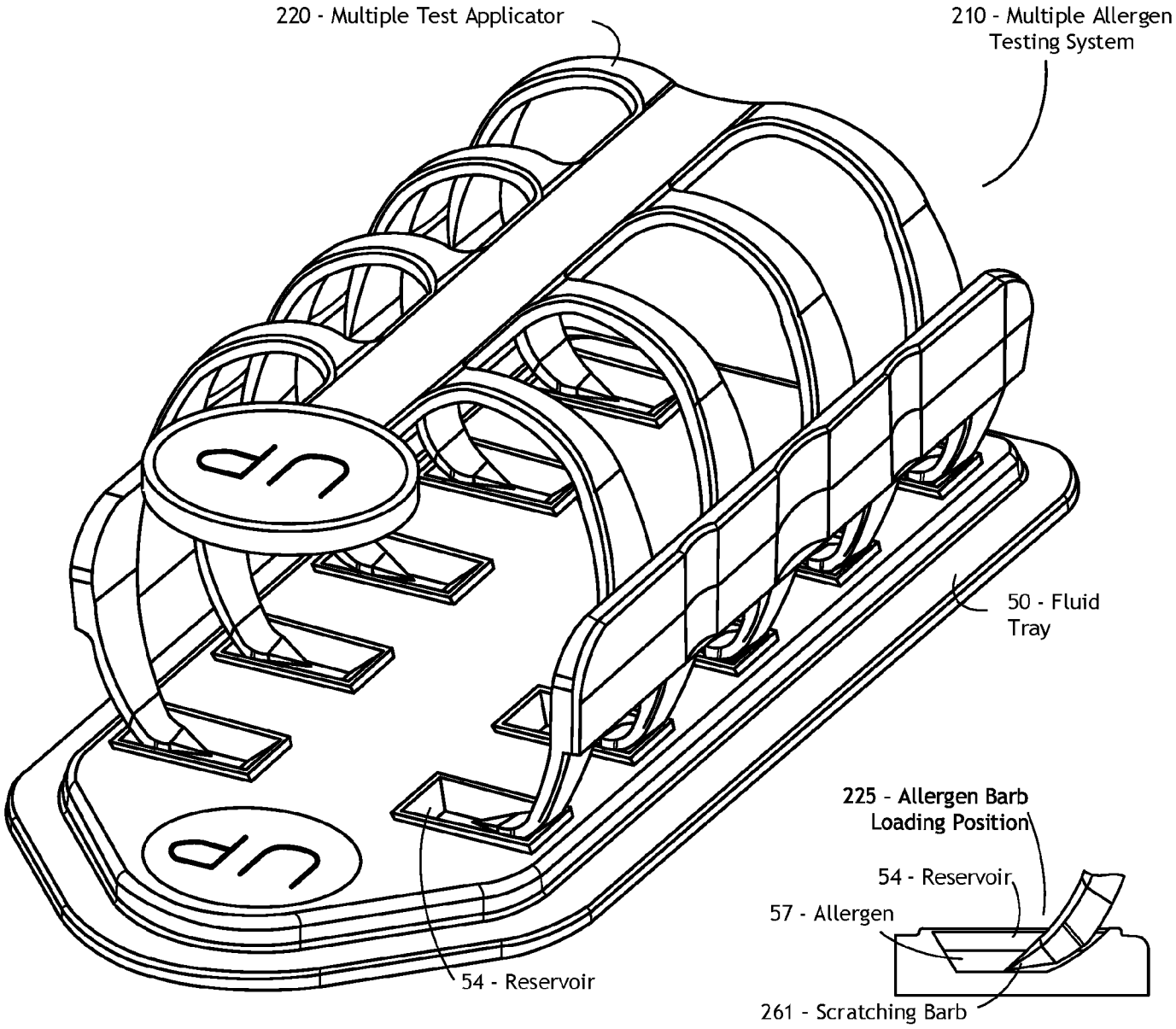


FIGURE 11

DETAIL "B"
ALLERGEN LOADING

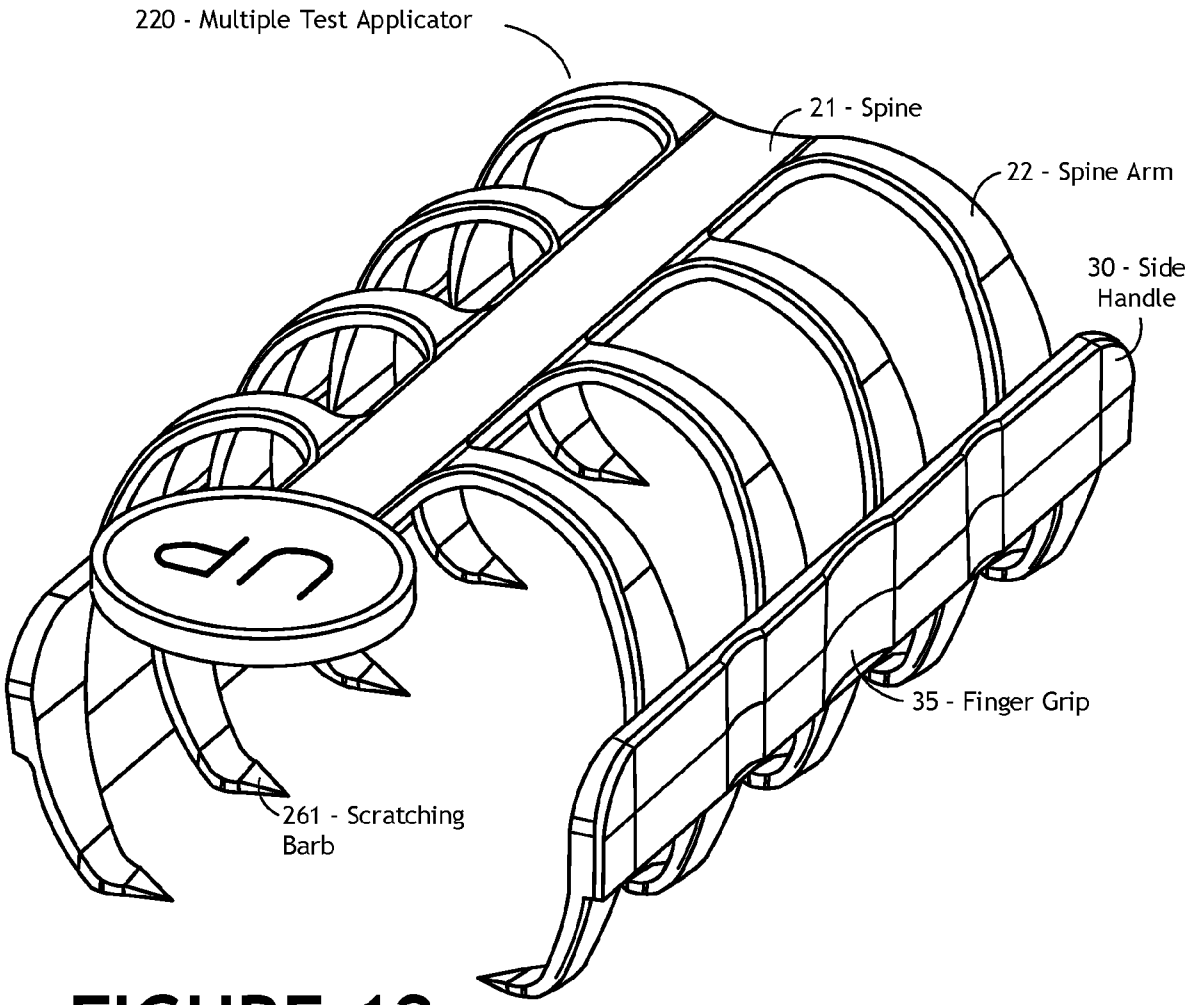

220 - Multiple Test Applicator
21 - Spine
22 - Spine Arm
30 - Side Handle
35 - Finger Grip
261 - Scratching Barb

FIGURE 12

FIGURE 13A
RELAXED STATE

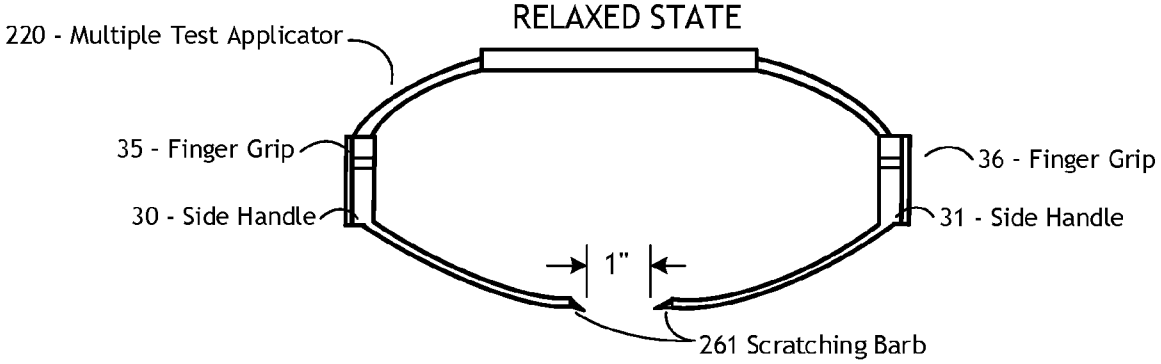


FIGURE 13B
COMPRESSED STATE

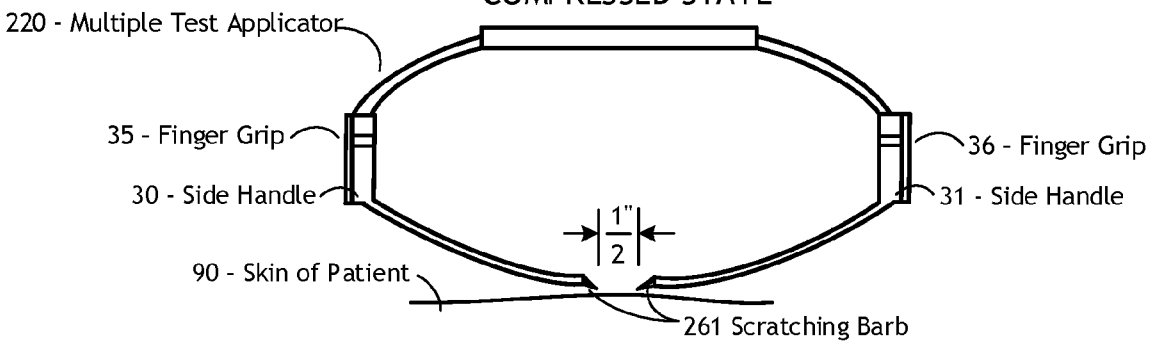
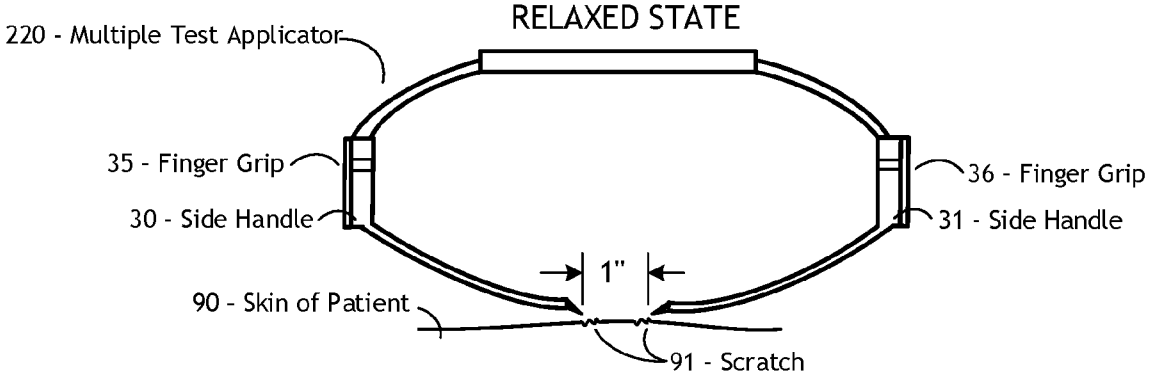


FIGURE 13C
RELAXED STATE



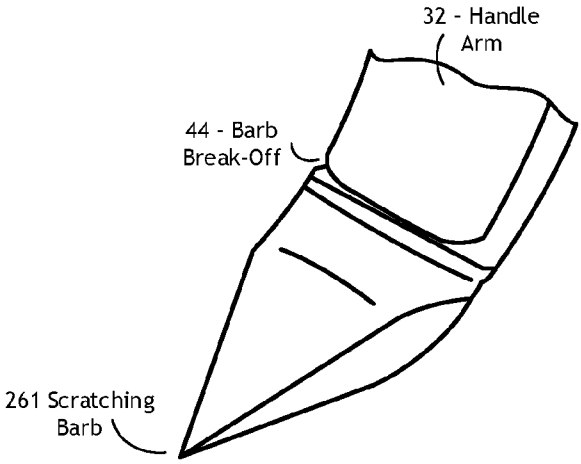


FIGURE 14A
BARB TILTED DOWN

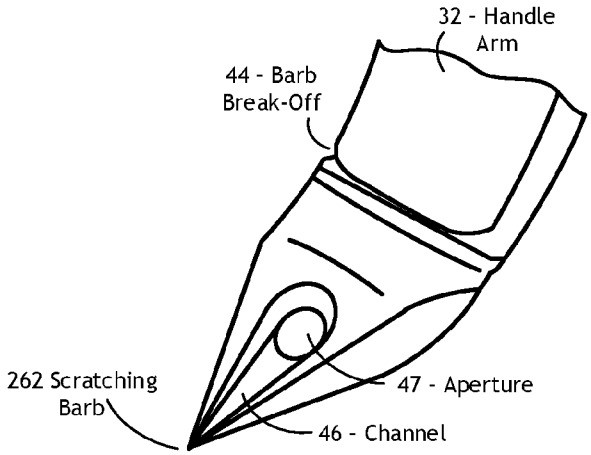


FIGURE 14B
BARB TILTED DOWN

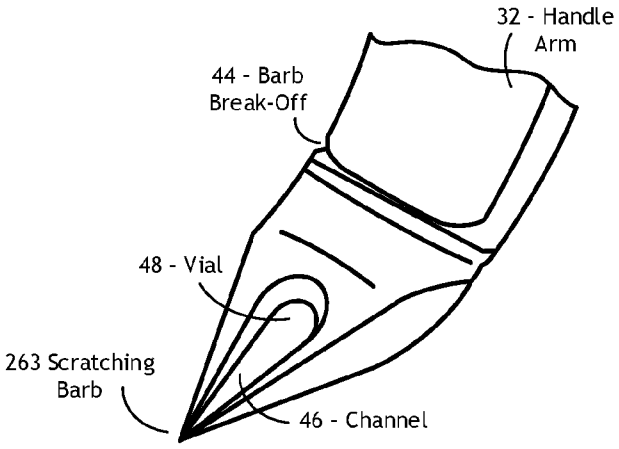
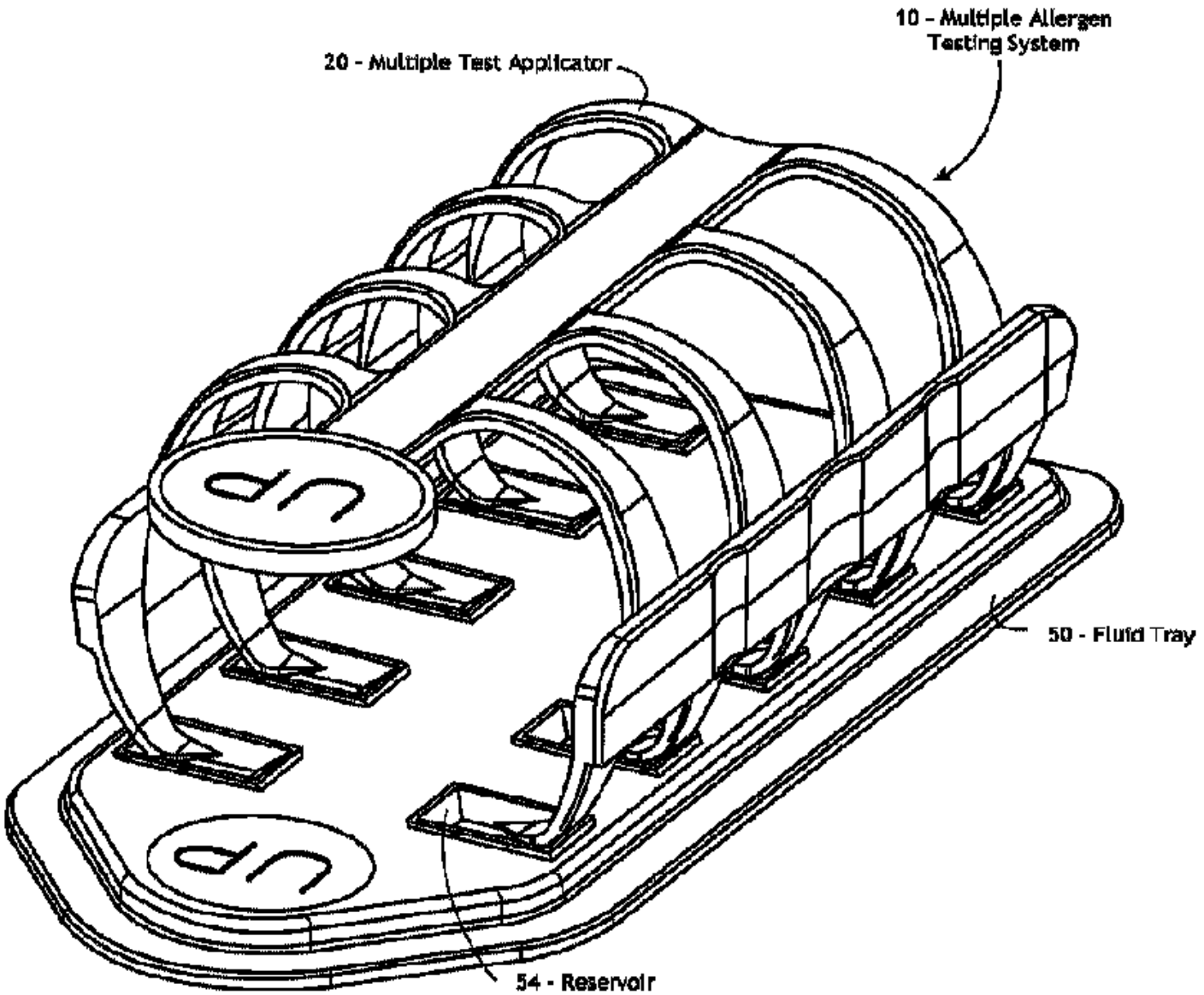
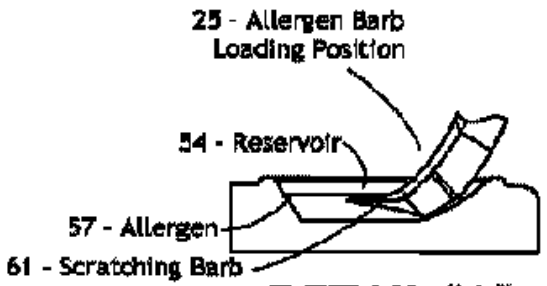


FIGURE 14C
BARB TILTED DOWN





DETAIL "A"
ALLERGEN LOADING