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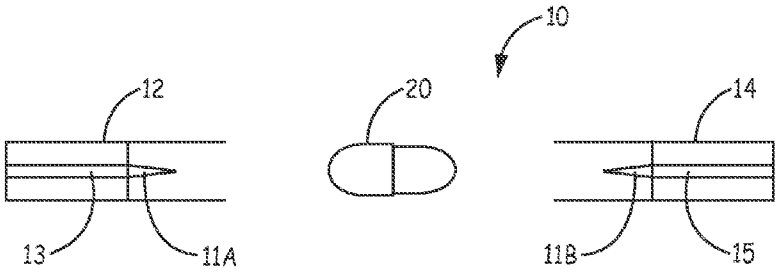

FIG. 1

(57) Abstract: This disclosure relates to nicotine powder inhalers where the nicotine powder is delivered at air flow rates that mimic a smoking regime.

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NICOTINE POWDER INHALER

This disclosure relates to nicotine powder inhalers, where the nicotine powder is delivered at low air flow rates.

Dry powder inhalers (DPI) are known and are used to treat respiratory diseases by delivering a dry powder comprising a pharmaceutical, in aerosol form through inhalation to the patients' airways. For delivery deep into the lungs, particles in the range of 1 to 5 micrometers are required. In pharmaceutical dry powders, the active pharmaceutical ingredient (API) is agglomerated on the surface of larger carrier particles, e.g. lactose, and DPI's therefore operate complex mechanisms to ensure such agglomerates disperse, break up or disaggregate before the API can be inhaled deep into the lungs. Pharmaceutical dry powders containing lactose as a carrier are typically in the range of 20 to 100 micrometers. Existing DPI's for example first "grind" or de-agglomerate the dry powder or impact the larger particles of the dry powder to result in the aforementioned particle size range.

DPI's rely on the force of the patients' inhalation to entrain the powder from the device to subsequently break-up the powder into particles that are small enough to enter the lungs. Sufficiently high inhalation rates are required to ascertain correct dosing and complete disaggregation of the powder. Typically a large amount of API remains attached on the surface of the carrier and is deposited in the upper airways due to incomplete de-aggregation of the powder. Inhalation rates of existing DPI's are usually in the range of 40-120 liters/min (L/min). Existing DPI's are therefore only suitable for delivering dry powders to users in a manner that is different from the inhalation rate associated with smoking articles.

It would be desirable to provide a nicotine powder inhaler that can deliver nicotine powder to a user at inhalation or air flow rates that are close to or within conventional smoking regime inhalation or air flow rates. It would be desirable to provide a nicotine powder inhaler that is a similar size and configuration as a conventional cigarette. It would be desirable to provide a nicotine powder inhaler that can provide a metered dose of nicotine and an optional simultaneous delivery of a second active ingredient.

Nicotine powder inhalers of the invention described herein can be utilized to deliver nicotine to a user at inhalation or air flow rates that are within conventional smoking regime inhalation or air flow rates. The nicotine powder inhalers can provide a predictable and metered

dose of nicotine or other optional active ingredients. Nicotine powder inhalers of the invention described herein have a similar size and configuration as a conventional cigarette and have a simple configuration.

As described herein, a nicotine powder inhaler includes a body extending between a mouthpiece and a distal end portion and an airflow channel extends along the body of the inhaler. A nicotine powder receptacle along the airflow channel holds a dose of nicotine powder. The dose of nicotine powder can be inhaled into lungs of a user at an inhalation rate of less than about 5 L/min or preferable less than about 2 L/min. Preferably the dose of nicotine powder can be contained in a capsule that can be pierced by the inhaler. Preferably the dose of nicotine is a nicotine salt.

Various aspects of the nicotine powder inhalers described herein may have one or more advantages relative to standard dry powder inhalers. For example, the nicotine powder inhalers deliver the dry powder nicotine at inhalation or air flow rates that are within conventional smoking regime inhalation or air flow rates and inhalation manner. This allows users with even compromised or impaired breathing conditions to successfully deliver the dry powder nicotine and optional second active ingredients. The nicotine powder inhalers described herein have a simplified configuration that allows the user to predetermine the metered dose of dry powder nicotine and optional second active ingredients. The dry powder nicotine utilized with this inhaler, and described herein, is carrier-free and has a constant size from storage to inhalation. Additional advantages of one or more aspects flavour delivery system described herein will be evident to those of skill in the art upon reading and understanding the present disclosure.

The term “nicotine” refers to nicotine and nicotine derivatives such as nicotine salts.

The present disclosure provides nicotine powder inhalers for inhaling dry powder nicotine. The nicotine powder inhalers include a body extending between a mouthpiece portion and a distal end portion. An airflow channel extends between the mouthpiece portion and a distal end portion and a nicotine powder receptacle. The nicotine powder receptacle is disposed along the airflow channel and is configured to receive a dose of nicotine powder. Surprisingly, the dose of nicotine powder can be inhaled into lungs of a user at an inhalation rate of less than about 5 L/min or less than about 2 L/min which mimics the inhalation flow rate utilized for a conventional smoking regime. The nicotine powder inhalers described herein are

"passive" devices that utilize only the inhalation air flow created by the lungs of a user to create air flow though the body of the nicotine powder inhaler.

The airflow path or airflow channel through the body of the inhaler is a simple path or channel. In many embodiments the airflow path or airflow channel through the body of the inhaler is parallel to a longitudinal axis of the inhaler and is linearly extending along an entire length of the inhaler body. In some embodiments the inhaler includes two or three co-extensive airflow channels. One, two or all three of the airflow channels can include a capsule receptacle. In some embodiments the one or more airflow paths or airflow channels includes a swirl generator element that is configured to induce a rotational movement of the airflow moving through the body of the inhaler. The swirl generator element can discharge into an outlet channel that can be a larger volume than the one or more individual airflow paths or airflow channels.

The nicotine powder receptacle can receive a capsule of nicotine powder. The capsule can contain a predetermined amount or dose of nicotine powder. In many embodiments the capsule can contain enough nicotine powder to provide at least 2 inhalations or "puffs" of nicotine powder, or at least about 5 inhalations or "puffs" of nicotine powder, or at least about 10 inhalations or "puffs" of nicotine powder. In many embodiments the capsule can contain enough nicotine powder to provide from about 5 to 50 inhalations or "puffs" of nicotine powder, or from about 10 to 30 inhalations or "puffs" of nicotine powder. Each inhalation or "puff" of nicotine powder can deliver from about 0.5 mg to about 3 mg of nicotine powder to the lungs of the user or from about 1 mg to about 2 mg of nicotine powder to the lungs of the user or about 1 mg of nicotine powder to the lungs of the user.

In many embodiments the capsule holds or contains at least about 5 mg of nicotine powder or at least about 10 mg of nicotine powder. In many embodiments the capsule holds or contains less than about 30 mg of nicotine powder or less than about 25 mg of nicotine powder, or less than 20 mg of nicotine powder. In many embodiments the capsule holds or contains from about 5 mg to about 30 mg of nicotine powder or from about 10 mg to about 20 mg of nicotine powder.

The capsule can be formed of an airtight material that can be pierced or punctured by the inhaler. The capsule can formed of a metallic or polymeric material that serves to keep contaminates out of the capsule but can be pierced or punctured by the inhaler during use.

The inhaler can include a piercing element or pair of opposing piercing elements that are configured to pierce the capsule of nicotine powder. The piercing element or pair of opposing piercing elements fluidly connect the airflow channel with the dose of nicotine powder. The piercing element or pair of opposing piercing elements can engage with the capsule of nicotine powder upon loading the capsule of nicotine powder into the nicotine powder receptacle or upon demand by an actuator on the body of the inhaler.

In many embodiments the nicotine powder is a pharmaceutically acceptable nicotine salt or nicotine salt hydrate. Useful nicotine salts or nicotine salt hydrates include nicotine bitartrate, nicotine salicylate, nicotine fumarate, nicotine mono-pyruvate, nicotine glutamate or nicotine hydrochloride, for example. The compound combining with nicotine to from the salt or salt hydrate can be chosen based on its pharmacological effect. For example: nicotine salicylate can be administered for fever relief, as an anti-inflammatory or painkiller; nicotine fumarate can be administered to treat multiple sclerosis; and nicotine mono-pyruvate can be administered for treating chronic obstructive pulmonary disease (COPD) or for weight loss.

The nicotine powder can have any useful size distribution for inhalation delivery into the lungs of a user. In many embodiments at least about 90 wt% of the nicotine powder has a particle size of about 10 micrometers or less, preferably about 7 micrometers or less. The nicotine powder preferably has a mean average diameter size range from about 0.1 to about 10 micrometers, more preferably from about 1 to about 7 micrometers, even more preferably from about 2 to 6 about micrometers.

Conventional formulations for dry powder inhalation typically contain carrier particles that serve to increase the fluidization of the active particles since the active particles are typically too small to be influenced by the airflow though the inhaler. The carrier particles thus were utilized to improve the dose uniformity by acting as a diluent or bulking agent in a formulation. However, the nicotine powder described herein is carrier-free. Being carrier-free allows the nicotine powder to be inhaled and delivered to the user's lungs at inhalation or airflow rates that are similar to typical smoking regime inhalation or airflow rates. In addition, since the nicotine

powder is carrier-free, the airflow path of the inhaler can have simple geometry or a simple configuration.

The carrier-free nicotine powder described herein can be a surface modified nicotine salt where the nicotine salt particle is a coated particle. One preferred coating material is L-leucine. These carrier-free nicotine powders are described and are available from Teicos Pharma Inc., Espoo, Finland. One particularly useful nicotine powder is an L-luecine coated nicotine bitartrate.

A second active agent or ingredient can be delivered along with the nicotine powder. The second active agent or ingredient can be mixed with the nicotine in the capsule or separate from the nicotine in its own capsule. The second active agent or ingredient can be fluidized with the nicotine powder and inhaled by a user.

This second active agent or ingredient can be any active pharmaceutical material. In many embodiments the second active agent or ingredient can be combined with the nicotine powder described herein by blending the two materials during inhalation. The nicotine powder and the second active agent or ingredient can be blended in the same capsule or provided in series in a single air flow channel in the DPI or provided in parallel in separate flow channels of the DPI. The second active agent or ingredient can have a similar mean average diameter size range as the nicotine powder described above.

The nicotine powder inhaler is less complex and has a simplified powder storage and airflow path as compared to existing DPIs, and does not need a carrier ingredient, such as lactose, as described above. Therefore the complex mechanisms to dissociate/disaggregate a pharmaceutical dry powder is not required in the described nicotine inhaler and therefore the described nicotine inhaler operates under low airflow. The inhaler does not require the typical high inhalation rates of conventional DPIs to deliver the dry nicotine powders described above deep into the lungs.

The nicotine inhaler according to this invention operates using a flow rate of less than about 5 L/min or less than about 3 L/min or less than about 2 L/min or about 1.6 L/min. In many embodiments the flow rate is in a range from about 1 L/min to about 3 L/min or from about 1.5 L/min to about 2.5 L/min. In preferred embodiments the inhalation rate or flow rate is similar to that of Health Canada smoking regime, that is about 1.6 L/min. In contrast, a conventional DPI

operates at a flow rate of about 40-120 L/min and often requires an energy source or propellant to promote air flow to achieve this air flow rate.

The nicotine inhaler described herein can be used by a consumer like smoking a conventional cigarette or vaping an electronic cigarette. Such smoking or vaping is characterized by two steps: a first step during which a small volume containing the full amount of nicotine desired by the consumer is drawn into the mouth cavity, followed by a second step during which this small volume comprising the aerosol comprising the desired amount of nicotine is further diluted by fresh air and drawn deeper into the lungs. Both steps are controlled by the consumer. During the first inhalation step the consumer can determine the amount of nicotine to be inhaled. During the second step, the consumer can determine the volume for diluting the first volume to be drawn deeper into the lungs, maximizing the concentration of active agent delivered to the airway epithelial surface. This smoking mechanism is sometimes called “puff-inhale-exhale”.

All scientific and technical terms used herein have meanings commonly used in the art unless otherwise specified. The definitions provided herein are to facilitate understanding of certain terms used frequently herein.

The terms “upstream” and “downstream” refer to relative positions of elements of the inhaler described in relation to the direction of inhalation air flow as it is drawn through the body of the inhaler from a distal end portion to the mouthpiece portion.

As used herein, the singular forms “a”, “an”, and “the” encompass embodiments having plural referents, unless the content clearly dictates otherwise.

As used herein, “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise. The term “and/or” means one or all of the listed elements or a combination of any two or more of the listed elements.

As used herein, “have”, “having”, “include”, “including”, “comprise”, “comprising” or the like are used in their open ended sense, and generally mean “including, but not limited to”. It will be understood that “consisting essentially of”, “consisting of”, and the like are subsumed in “comprising,” and the like.

The words "preferred" and "preferably" refer to embodiments of the invention that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred, under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the disclosure, including the claims.

FIG.s 1-7 are schematic diagrams of illustrative nicotine powder inhalers **10**. **FIG.s 3-7** are shown with transparent bodies for ease of illustration of the flow channels and internal elements. The schematic drawings are not necessarily to scale and are presented for purposes of illustration and not limitation. The drawings depict one or more aspects described in this disclosure. However, it will be understood that other aspects not depicted in the drawing fall within the scope and spirit of this disclosure.

Referring now to **FIG. 1** and **FIG. 2**, the nicotine powder inhalers **10** include a mouthpiece portion **12** and a distal end portion **14** and a nicotine capsule **20** disposed between them. Piercing elements **11A** and **11B** are configured to pierce the capsule **20** and fluidly connect the airflow channel **13** of the mouthpiece portion **12** with the airflow channel **15** of the distal end portion **14**. The airflow channel extends linearly along a length of the nicotine powder inhaler **10**. **FIG. 2** further illustrates the capsule **20** within a receptacle **25** that can be re-usable.

FIG. 3 and **FIG. 4** illustrate nicotine powder inhalers **10** having a single linear airflow channel **13**, **15**. Piercing elements **11A** and **11B** extend into a nicotine powder receptacle **30** and are configured to pierce the nicotine powder capsule and fluidly connect the airflow channel **13** of the mouthpiece portion **12** with the airflow channel **15** of the distal end portion **14**. The airflow channel extends linearly along a length of the nicotine powder inhaler **10** from a proximal mouthpiece end **18** to a distal end **19**. The mouthpiece portion **12** can connect with the distal end portion **14** via a bayonet-type connection. In **FIG. 3** the mouthpiece portion **12** is not symmetrical with the distal end portion **14**. In In **FIG. 4** the mouthpiece portion **12** is symmetrical with the distal end portion **14**.

FIG. 5 and **FIG. 6** is a further illustrative nicotine powder inhaler **10**. **FIG. 6** is a view of **FIG. 5** taken along lines **6-6**. This embodiment includes three airflow channels **15** and a first, second and third powder receptacles **30, 32** and **33** respectively. A nicotine powder capsule can be received in at least one of the powder receptacles **30, 32** and **33**. In some embodiments, a second active agent can be received in at least one of the powder receptacles

30, 32 and **33**. The three flow channels **15** fluidly connect to an outlet channel **40** via a swirl generator **50** configured to induce rotation movement in the airflow. The airflow channels **15** extend linearly along a length of the nicotine powder inhaler **10** from a proximal mouthpiece end **18** to a distal end **19**. A ventilation element **70** can be disposed along an airflow channels **15** to provide dilution air, as desired.

FIG. 7 is a further illustrative nicotine powder inhaler **10**. This embodiment includes three airflow channels **15A, 15B** and **15C** and first, second and third powder receptacles **30, 32** and **33** respectively. A nicotine powder capsule can be received in at least one of the powder receptacles **30, 32** and **33**. In some embodiments, a second active agent can be received in at least one of the powder receptacles **30, 32** and **33**. The three flow channels **15** fluidly connect to an outlet channel **40** via a swirl generator **50** configured to induce rotation movement in the airflow. The airflow channels **15A, 15B** extend linearly along a length of the nicotine powder inhaler **10** from a proximal mouthpiece end **18** to a distal end **19**. In some embodiments an airflow loop element **60** is disposed along an airflow channels **15C**.

CLAIMS:

1. A nicotine powder inhaler comprising:
a body extending between a mouthpiece portion and a distal end portion;
an airflow channel extending between the mouthpiece portion and a distal end portion;
a nicotine powder receptacle comprising a dose of nicotine powder and disposed along the airflow channel;
wherein the dose of nicotine powder can be inhaled into lungs of a user at an inhalation rate of less than about 5 L/min.

2. A nicotine powder inhaler according to claim 1, wherein the nicotine powder receptacle is configured to receive a capsule containing nicotine powder.

3. A nicotine powder inhaler according to claim 2, further comprising opposing piercing elements configured to pierce the received capsule and fluidly connect the nicotine powder with the airflow channel.

4. A nicotine powder inhaler according to any of the preceding claims, wherein the airflow channel extends linearly along the body from the distal end portion to the mouthpiece portion.

5. A nicotine powder inhaler according to any of the preceding claims, wherein the nicotine powder is a nicotine salt.

6. A nicotine powder inhaler according to any of the preceding claims, wherein the nicotine powder is nicotine bitartrate, nicotine salicylate, nicotine fumarate, nicotine mono-pyruvate, or nicotine hydrochloride.

7. A nicotine powder inhaler according to any of the preceding claims, wherein at least about 90 wt% of the nicotine powder has a particle size of about 10 micrometers or less.

8. A nicotine powder inhaler according to any of the preceding claims, further comprising a swirl generator element configured to induce rotational movement in the airflow from the airflow channel.

9. A nicotine powder inhaler according to any of the preceding claims, further comprising a second airflow channel extending between the mouthpiece portion and a distal end portion and a second powder receptacle and disposed along the second airflow channel.

10. A nicotine powder inhaler according to any of the preceding claims, further comprising a third airflow channel extending between the mouthpiece portion and a distal end portion and a third powder receptacle disposed along the third airflow channel.

11. A nicotine powder inhaler according to any of the preceding claims, further comprising dose of a second active agent.

12. A nicotine powder inhaler according to claims 9 to 11, further comprising an outlet channel in fluid connection and combing the airflow channel, the second airflow channel and the third airflow channel.

13. A nicotine powder inhaler according to claim 12, further comprising a swirl generator element configured to induce rotational movement in the airflow from the airflow channel, the second airflow channel and the third airflow channel.

14. A nicotine powder inhaler according to claim 13, wherein the swirl generator is in fluid connection between the airflow, second, and third channels and the outlet channel and the outlet channel mixes the airflow from the airflow, second, and third channels.

15. A method of inhaling nicotine into lungs of a user:
inhaling air through the nicotine power inhaler according to any one of claims 1 to 14 at a flow rate of less than about 2 L/min to deliver powder nicotine into lungs of a user.

16. A method according to claim 15, further comprises inhaling a second active agent with the nicotine powder through the nicotine power inhaler according to any one of claims 1

to 14 at a flow rate of less than about 2 L/min to deliver the powder nicotine and second active agent into lungs of a user.

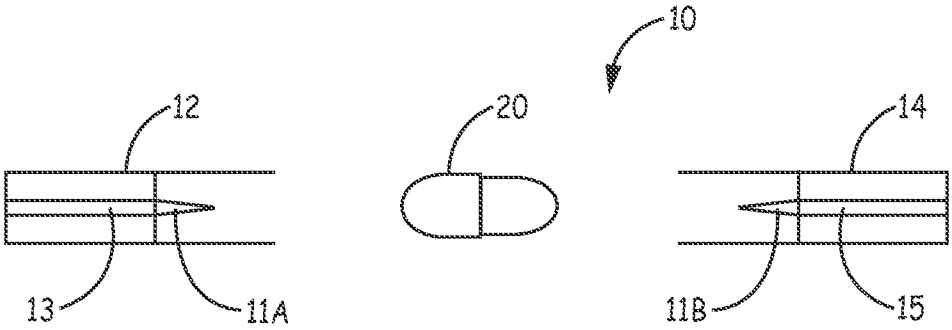

FIG. 1

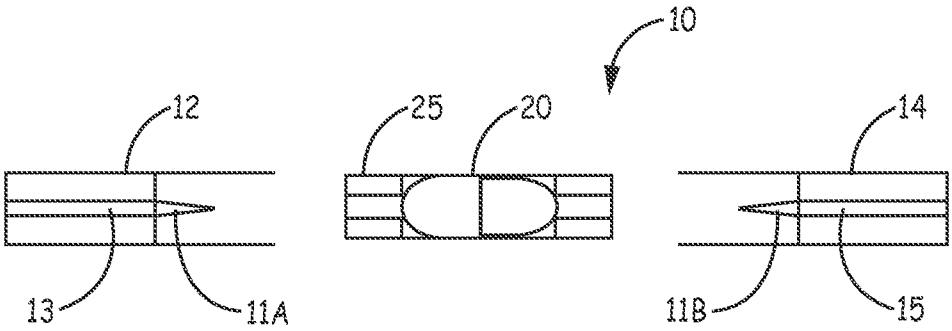

FIG. 2

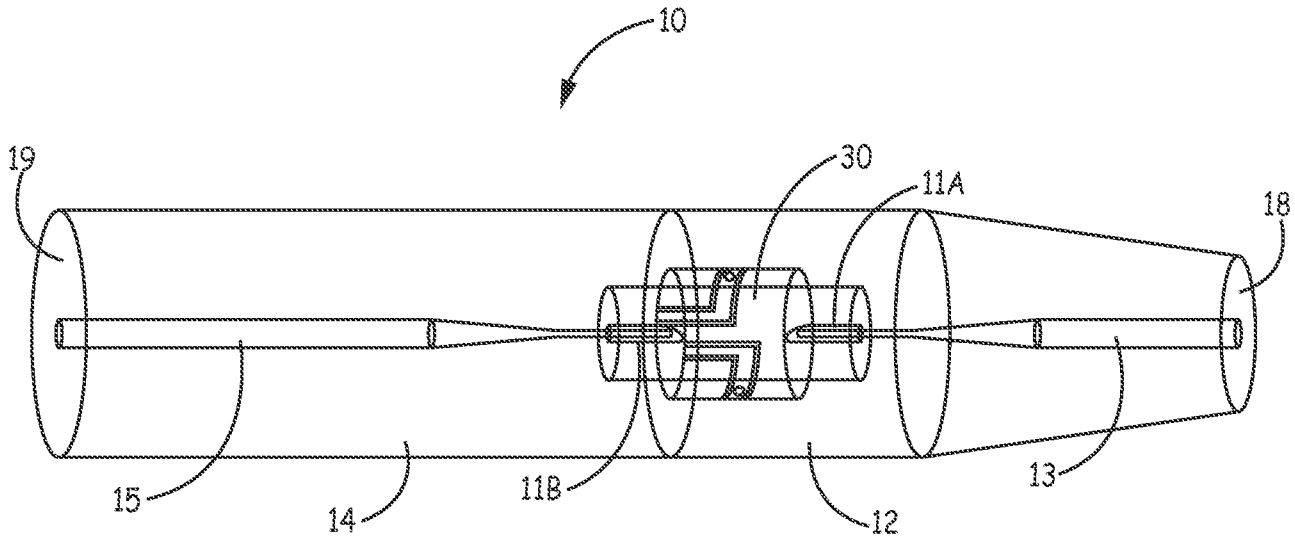

FIG. 3

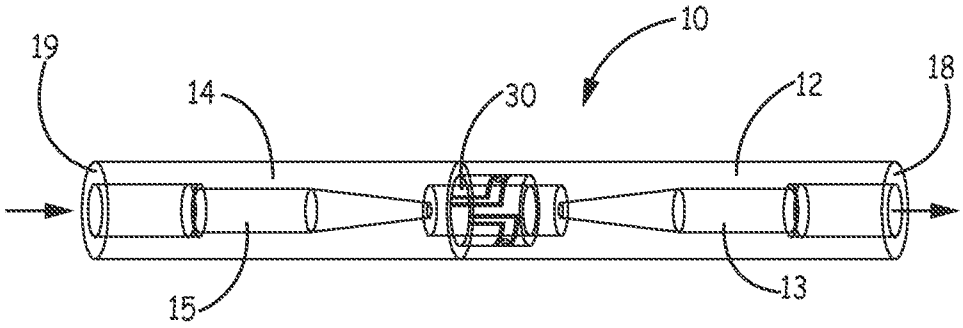

FIG. 4

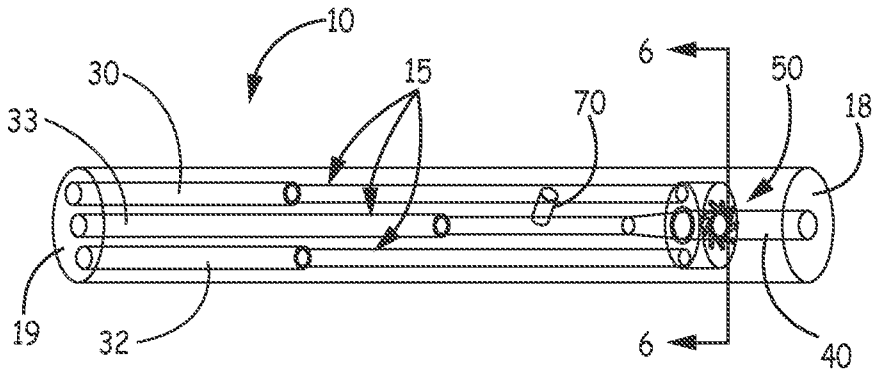

FIG. 5

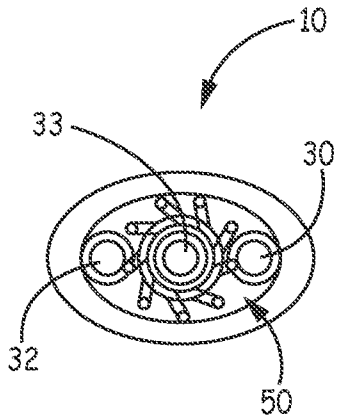

FIG. 6

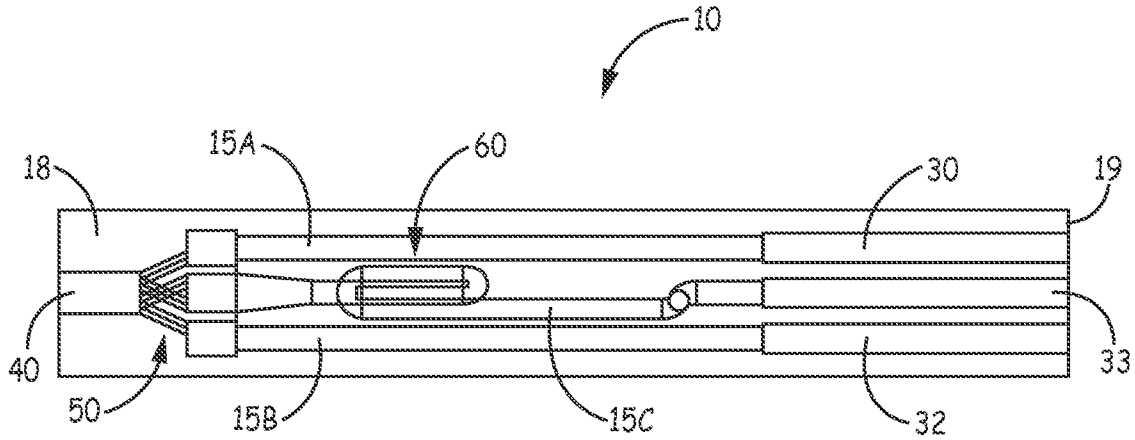

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2015/000924

A. CLASSIFICATION OF SUBJECT MATTER
INV. A24F47/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A24F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 461 008 A (EXCHANGE SUPPLIES LTD [GB]) 23 December 2009 (2009-12-23) the whole document	1,2,15, 16
X	US 2008/241255 A1 (ROSE JED E [US] ET AL) 2 October 2008 (2008-10-02) the whole document	1,2,15, 16
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A	US 4 735 217 A (GERTH DONALD L [US] ET AL) 5 April 1988 (1988-04-05) the whole document	1-16

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

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 September 2015	07/10/2015

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

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2015/000924

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2014/088044 A1 (RIGAS BASIL [US] ET AL) 27 March 2014 (2014-03-27) the whole document -----	1-16
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1

INTERNATIONAL SEARCH REPORT

Information on patent family members

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