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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
02 June 2022 (02.06.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/113111 A1

(51) International Patent Classification:
A61B 10/02 (2006.01) *B01L 3/00* (2006.01)

(21) International Application Number:
PCT/IN2021/051104

(22) International Filing Date:
26 November 2021 (26.11.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
202021051839 27 November 2020 (27.11.2020) IN

(71) Applicant: **RELIANCE INDUSTRIES LIMITED** [IN/IN]; Maker Chambers - IV, Nariman Point, Mumbai 400 021 (IN).

(72) Inventors: **ELANGOVAN, Ravikrishnan**; Department of Biochemical Engineering and Biotechnology, Indian Institute of Technology, Delhi, Hauz Khas, New Delhi 110016 (IN). **KALYANASUNDARAM, Dinesh**; Centre for Biomedical Engineering Indian, Institute of Technology Delhi Hauz Khas, New Delhi 110016 (IN). **MENON, Manoj Balakrishna**; Kusuma School of Biological Science, Indian Institute of Technology Delhi Hauz Khas, New Delhi 110016 (IN). **PERUMAL, Vivekanandan**; Kusuma School of Biological Science, Indian Institute of Technology Delhi Hauz Khas, New Delhi 110016 (IN). **ZWETLANA, Ada**; Department of Biochemical Engineering and, Biotechnology, Indian Institute of Technology, Delhi, Hauz Khas, New Delhi 110016 (IN). **GROVER, Kanishka**; Department of Biochemical Engineering and, Biotechnology, Indian Institute of Technology, Delhi, Hauz Khas, New Delhi 110016 (IN). **SHARMA, Kabir**; Department of Biochemical Engineering and, Biotechnology, Indian Institute of Technology, Delhi, Hauz Khas, New Delhi 110016 (IN). **PENUMARTHY, Vineet**; Department of Biochemical Engineering and, Biotechnology, Indian Institute of Technology, Delhi, Hauz Khas, New Delhi 110016 (IN). **PARMAR, Vinod**; Centre for Biomedical Engineering Indian Institute, of Technology Delhi Hauz Khas, New Delhi 110016 (IN). **SWAROOP, Allanki Sai**; Department of Biochemical Engineering and, Biotechnology, Indian Institute of Technology, Delhi, Hauz Khas, New Delhi 110016 (IN). **DHAIYA, Ujjwal**; Centre for Biomedical Engineering Indian, Institute of Technology Delhi Hauz Khas, New Delhi 110016 (IN). **RAWAT, Chitra**; Kusuma School of Biological Science, Indian Institute of Technology Delhi Hauz Khas, New Delhi 110016 (IN). **CHOWDHARI, Shruti**; Kusuma School of Biological Science, Indian Institute of Technology Delhi Hauz Khas, New Delhi 110016 (IN). **JEET, Tushar**; Department of Biochemical Engineering and, Biotechnology, Indian Institute of Technology, Delhi, Hauz Khas, New Delhi 110016 (IN). **BALASUBRAMANIAN, Prabhu**; Department of Biochemical Engineering and, Biotechnology, Indian Institute of Technology, Delhi, Hauz Khas, New Delhi 110016 (IN).

(74) Agent: **LAKSHMIKUMARAN, Malathi** et al.; B6/10, Safdarjung Enclave, New Delhi 110029 (IN).

(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,

(54) Title: COLLECTION DEVICE FOR SAMPLE COLLECTION

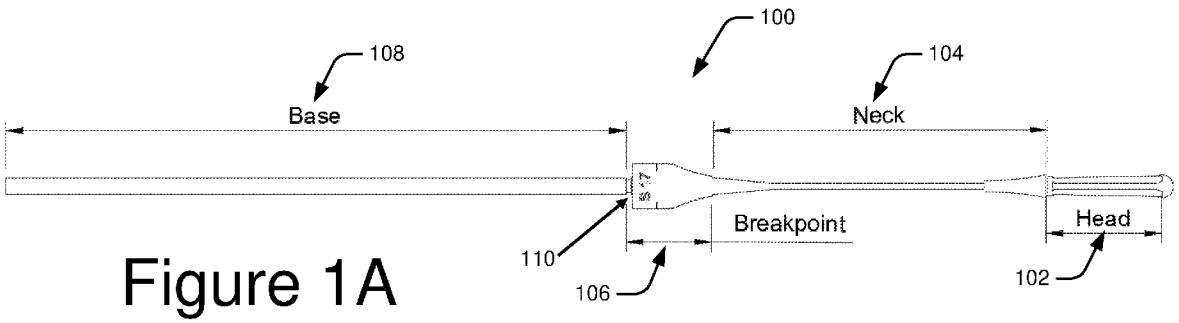


Figure 1A

(57) Abstract: A collection device (100), for sample collection, includes a holding portion (108), a neck (104), and a head (102). The holding portion (108) is used to hold the collection device (100) for sample collection. The neck (104) is flexibly coupled to the holding portion (108). The neck (104) includes a locking mechanism (106) to detachably couple the holding portion (108) to the neck (104). Further, the head (102) is coupled to the neck (104) opposite to the holding portion (108). The head (102) includes a plurality of grooves adapted to perform capillary action when the head (102) is inserted in a pool of liquid mixture. The collection device (100) is made of a single material.

WO 2022/113111 A1

[Continued on next page]

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).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

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

— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

COLLECTION DEVICE FOR SAMPLE COLLECTION

BACKGROUND

[0001] Generally, for non-invasive collection of respiratory pathogens, including respiratory bacteria and viruses, from patients for clinical detection, use of collection devices, such as swabs, is preferred over aspirates and washes, especially in crowded healthcare settings. This is owing to the ease and speed of sampling via swabs, although at the expense of sensitivity. The swabs to be used as collection devices for pathogens must be able to remove sufficient sample, including cells and bodily fluids within the sampled orifice, retain that sample throughout transport, and release the samples into the testing and/or transport media upon agitation or exposure.

BRIEF DESCRIPTION OF DRAWINGS

[0002] The detailed description is described with reference to the accompanying figures. In the figures, the left-most digit(s) of a reference number identifies the figure in which the reference number first appears. The same numbers are used throughout the drawings to reference like features and components.

[0003] Figure 1A, Figure 1B, and Figure 2 illustrate a collection device for sample collection, according to examples of the present subject matter.

[0004] Figure 3 illustrates an example embodiment of a collection device to be used in nasopharyngeal region, according to an example of the present subject matter.

[0005] Figure 4 illustrates an example embodiment of a collection device to be used in the throat region, according to an example of the present subject matter.

[0006] Figure 5A and Figure 5B illustrate a locking mechanism of the collection device, in accordance with an example of the present subject matter.

[0007] Figure 6A and Figure 6B illustrate the locking mechanism of the collection device, in accordance with another example of the present subject matter.

[0008] Figure 7A illustrates a container for storing the collection device, in accordance with an example of the present subject matter.

[0009] Figure 7B illustrates the collection device being accommodated inside the container, in accordance with an example of the present subject matter.

[0010] Figure 8A and Figure 8B illustrate the various designs of a head of the collection device, as examples of the present subject matter.

[0011] Throughout the drawings, identical reference numbers designate similar elements, but may not designate identical elements. The figures are not necessarily to scale, and the size of some parts may be exaggerated to more clearly illustrate the example shown. Moreover, the drawings provide examples and/or examples consistent with the description; however, the description is not limited to the examples and/or examples provided in the drawings.

DETAILED DESCRIPTION

[0012] Swabs are widely used as collection devices for non-invasive collection of samples. Various different types of swabs are currently used clinically, with the most common being either swabs with a nylon flocked-fibre tip (hereafter referred to as flocked swabs) or swabs with tightly-wound fibres made of a polyester, a cellulose fibre, or cotton, at the tips (hereinafter referred to as bud swabs). While bud swabs can absorb a greater amount of fluids and are generally cheaper, flocked swabs have been shown to provide greater

sensitivity, especially, when used for nucleic acid detection-based diagnostic procedures for bacterial and viral pathogens and cancer cytology. The reasons for this advantage of the flocked swabs have been hypothesized to be the greater cell sampling capabilities and enhanced surface area of the flocked swabs. The flocked swabs also generally retain a lower amount of sample than bud swabs after agitation, which means that the flocked swabs have an improved sample release upon agitation. In addition, the inherent abrasiveness of flocked swabs may assist in releasing cells from the epithelia, i.e., the sampled cells, thereby improving epithelial cell yields. Therefore, the flocked swabs have a higher sensitivity as compared to rayon bud swabs for respiratory pathogens, such as the Respiratory Syncytial Virus and Influenza.

[0013] In addition, the flocked swabs may have an appreciably high diagnostic sensitivity for intracellular pathogens. For example, the disease mechanism of intracellular pathogens, such as coronaviruses, is such that they rely on viral entry through endocytosis upon interaction with ACE2 receptors. Accordingly, pathogens, such as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), has been found to be detectable at rather low levels in the epithelial cells of the upper respiratory tract. Furthermore, patients infected by such pathogens have typically presented dry cough and produce relatively little mucus. Thus, it can be argued that the enhanced cell sampling capabilities of flocked swabs, rather than the increased fluid retention of bud swabs, is beneficial in maintaining diagnostic sensitivity.

[0014] The production of flocked swabs, however, involves complex processes, for example, including shooting of nylon fibres out of a thin tube and pasting the nylon fibres on the surface of the swab using glue at a high pressure. Therefore, the manufacturing may be time-consuming. In few other cases, swabs have been manufactured by 3D printing to emulate the performance of the flocked swabs. However, the manufacturing of such 3D printed swabs may

be time-intensive and costly as it requires specialized resources including raw materials (such as biocompatible resins) and specialized 3D printing hardware. This not only increases the cost and time of manufacturing but also reduces the availability of such products in low-resource environments, especially when the demand is high. For instance, owing to the declaration of COVID-19 as a pandemic by the World Health Organization, international supply chains have been disrupted, leading to a shortage of flocked swabs worldwide. In such circumstances, swabs, such as bud swabs or polyester swabs, which have a notably inferior performance may have to be adopted.

[0015] Examples of a collection device for collecting samples are described. The design of the collection device is based on two core principles – the collection device is easy and cheap to manufacture while allowing for having cell sampling performance comparable to flocked swabs. Accordingly, the collection device described herein can be mass-produced using widely used manufacturing techniques and readily available raw material. For example, the collection device may be manufactured using available thermoplastics or any other polymer by injection moulding. Therefore, the collection device can be mass-produced at short notice and is formed such that it can be easily sterilized to address any surges in demand and meaningfully aid in enhancing diagnostic capabilities and speed. Furthermore, owing to the material choice and the design, the collection device can be effectively used for cell and liquid sampling with capability aimed to match the performance of flocked swabs or other similar existing swabs in sampling intracellular pathogens. The collection device of the present subject matter has the following aspects – (1) provide scalable manufacturing of collection devices, (2) provide easy and reliable collection of pathogen samples from patients, (3) provide comfort for the user while sample collection, (4) provide the collection device to be compatible with a sample collection and processing container, such as a cartridge. In an example, the

cartridge may be similar to a test tube and can provide for holding the pathogen sample before it is processed.

[0016] According to an example, the collection device has different sub-parts along its length, namely, a head, a neck, and a base or a holding portion. A user can use the holding portion to hold the collection device while collecting a sample or otherwise. The neck is flexibly and detachably coupled to the holding portion. Further, the neck includes a locking mechanism adjacent to a point of connection of the neck to the holding portion. The locking mechanism is to detachably couple the neck to the holding portion. The term "detachably" means that the neck is not fixedly attached to the holding portion, and can be detached from the holding portion. The term "flexibly" means that the neck is not rigid with respect to the holding portion, rather can flex or bend with respect to the holding portion. The head is coupled to the neck opposite to the holding portion and may include a plurality of grooves. The grooves provided on the head are capable of performing a capillary action when the head is inserted in a pool of liquid mixture. For instance, when the collection device is inserted in nasal region of a patient, the grooves of the head are capable of collecting a sample from the nasal region.

[0017] The collection device may include a breaking portion to detach the holding portion from the remaining of the collection device. The breaking portion serves as a point which allows for easy breakage of the collection device to separate the holding portion from the rest once the sample has been collected and allows for easily accommodating the broken collection device, for instance, in a container, such as a cartridge for transportation. Further, the neck is designed to be a balanced combination of flexibility and strength so that the collection device can be manoeuvred into the nasal passage or the throat. In an example, the neck of the collection device for nasopharyngeal cavity or canal can have a greater flexibility than the neck of the collection device for the throat,

since the manoeuvrability required for accessing the nasal passage is greater than that required for accessing the throat. Further, the head can be designed to be able to perform two functions – (1) scrape the tissue to collect the sample, and (2) retain the sample, thereby emulating the performance of the flocked swab.

[0018] The entire collection device, including the holding portion, the neck and the head, is formed of a single material. In other words, the collection device is monolithic. As a result, it is possible to mass produce the collection device using a forming process. In one example, the design of the collection device has been optimized to allow manufacturing using thermoplastics, such as medical grade polypropylene (PP), by injection moulding. The material for manufacturing is also selected in a way to allow for ease of sterilization via autoclaving or steam or other sterilization methods for allowing use with human patients.

[0019] These and other advantages of the present subject matter would be described in greater detail in conjunction with the following figures. While aspects of the fastener assembly can be implemented in any number of different configurations, the embodiments are described in the context of the following device(s).

[0020] Figure 1A, Figure 1B, and Figure 2 illustrate a collection device 100, according to examples of the present subject matter. In the example shown in Figure 1A and Figure 1B, the collection device 100 is for use as a nasopharyngeal collection device, i.e., for collection of samples from the nasopharyngeal canal. In the example shown in Figure 2, the collection device 100 is for use as a throat collection device, i.e., for collection of samples from the throat of the patient. In either of the two examples, the construction of the collection device 100 is such that it does not have any sharp edges so as to avoid injuries to the patient.

[0021] In both the examples, the collection device has different sub- parts along its length, namely, a head 102, a neck 104, and a base or a holding portion 108. A user can use the holding portion 108 to hold the collection device 100 while collecting a sample or otherwise. The neck 104 is flexibly and detachably coupled to the holding portion 108. Further, the neck 104 includes a locking mechanism 106 adjacent to a point of connection of the neck 104 to the holding portion 108. The locking mechanism 106 is to detachably couple the neck 104 to the holding portion 108. The term "detachably" means that the neck 104 is not fixedly attached to the holding portion 108, and can be detached from the holding portion 108 if required. The term "flexibly" means that the neck 104 is not rigid with respect to the holding portion 108, rather can flex or bend with respect to the holding portion 108.

[0022] The head 102 is coupled to the neck 104 opposite to the holding portion 108, and may include a plurality of grooves. The grooves provided on the head 102 are capable of performing a capillary action when the head 102 is inserted in a pool of liquid mixture such that the portion of the liquid mixture can stagnate in the head 102. For instance, when the collection device 100 is inserted in nasal region of a patient, the grooves of the head 102 are capable of collecting a sample from the nasal region.

[0023] The collection device 100 may include a breaking portion 110 to detach the holding portion 108 from remaining of the collection device 100. In an example, where the neck 104 includes the locking mechanism 106, the breaking portion 110 is provided such that it is positioned between the locking mechanism 106 and holding portion 108. In other words, the breaking portion 110 is provided adjacent to the locking mechanism 106 as well as the holding potion 108. The breaking portion 110 serves as a point which allows for easy breakage of the collection device 100 to separate the holding portion 108 from the rest of the collection device 100 once the sample has been collected and

allows for easily accommodating the broken collection device, for instance, in a cartridge for transportation. The breaking portion 110 may comprise a notch to detach the holding portion 108 from the neck 104. The provision of the notch in the breaking portion 110 creates a region of stress concentration which allows for easy breakage.

[0024] In addition, as an example, Figure 1B and Figure 2 illustrate the dimensions of the respective collection devices 100. The holding portion 108 has a length ranging from 95 to 110 millimetre (mm) and a diameter of approximately 3 mm. The holding portion 108 is followed by the locking mechanism 106. The locking mechanism 106 may have a length ranging from 10 mm to 20 mm. The holding portion 108 can be separated from the rest of the collection device 100, after sample collection is completed, by a twisting action provided to the locking mechanism 106. In other words, the holding portion 108 can be separated from the rest of the collection device by twisting the locking mechanism 106. In other examples, the holding portion 108 can be separated from the rest of the collection device by providing a pulling or pushing force to the locking mechanism 106.

[0025] The neck 104 may be coupled to the locking mechanism 106 by a tapered portion. Further, the neck 104 may be coupled to the head 102 by a tapered portion. For example, as shown in Figure 1B, the neck 104 may include two tapered portions, a first tapered portion to couple the neck 104 to the locking mechanism 106, and a second tapered portion to couple the neck 104 to the head 102. In another example, as shown in Figure 2, the neck 104 is coupled to the locking mechanism 106 by a tapered portion.

[0026] The profile of the locking mechanism 106 is designed such that the profile itself locks with the holding portion 108 without requiring any external element, such as fasteners. In other words, the profile may itself acts as a locking mechanism and can engage with the holding portion 108 to couple the

neck 104 to the holding portion 108 such that an air-tight seal is provided between the holding portion 108 and the neck 104. In an example, the locking mechanism 106 may have different geometrical profiles, such as a cubical profile, a spherical profile, a conical profile, a trapezoidal profile, etc. According to an example, the profile of the locking mechanism 106, irrespective of shape, may include a tapered portion which locks with the holding portion 108.

[0027] The neck 104 may have a length varying from 50 mm to 55 mm. Further, the neck 104 may have a non-uniform cross-sectional area between the head 102 and the locking mechanism 106. In other words, the diameter of the neck 104 may vary over the length of the neck 104. In an example, cross-sectional area of the neck 104 in proximity of the locking mechanism 106 may be greater than cross-sectional area of the neck 104 in proximity of the head 102. For instance, as show in Figure 1B, the neck 104 may have a diameter of approximately 1.5 mm in proximity of the locking mechanism 106 and a diameter of approximately 3.0 mm in proximity of the head 102. The neck 104 is designed such that it can flex with respect to the holding portion 108 such that the collection device 100 can be used in regions which are difficult to access.

[0028] The neck 104 is followed by the head 102, which has an approximate dimeter of 3 mm to 4 mm and a length of 15 to 20 mm and is responsible for sampling. To facilitate sampling, in an example, the head 102 may have various designs of multiple grooves which may be either vertical or circular, for instance, of about 0.5 to 1 mm. As explained above, the grooves are capable of capillary action when inserted inside a pool of liquid mixture. Further, all the edges in the head 102 are rounded or chamfered to reduce the number of sharp edges in an attempt to reduce the risk of epistaxis or any damage to the tissue of the patient while sampling.

[0029] The entire collection device 100, including the holding portion 108, the neck 104 and the head 102, is formed of a single material. In other words,

the collection device 100 is monolithic. As a result, it is possible to mass produce the collection device 100 using a forming process. In one example, the design of the collection device 100 has been optimized to allow manufacturing using thermoplastics, such as medical grade polypropylene (PP). In other words, the collection device 100 may be made of different types of thermoplastic materials. In an example, the collection device 100 is manufactured by injection moulding process. The material for manufacturing is also selected in a way to allow for ease of sterilization via autoclaving or steam for allowing use with human patients.

[0030] Further, the neck 104 may have a thinner profile in case the collection device 100 is used for sample collection in region which is difficult to access, for example, buccal cavity region or cheek region of the body. The thinner profile allows for enhanced flexibility of the neck 104 to easily access the desired region for efficient sample collection. Figure 3 illustrates an example embodiment of a collection device 100 for collecting sample from a nasopharyngeal region. In another example, the neck may have a thicker profile in case the collection device 100 requires strength for collection sample, for example, throat region of the body. Figure 4 illustrates an example embodiment of a collection device 100 for collecting sample from a buccal cavity or throat region.

[0031] As illustrated in Figure 3, the collection device 100 for the nasopharyngeal region includes the neck 104 having an approximate length of 65.6 mm, an approximate diameter of 4mm in proximity of a point where the neck 104 is coupled with the holding portion 108, and an approximate diameter of 1.5 mm at a centre point between the holding portion 108 and the head 102. The head 102 has an approximate diameter of 3 mm. On the other hand, as illustrated in Figure 4, the collection device 100 for the throat region includes the neck 104 having an approximate length of 65mm, an approximate diameter

of 2.3 mm in proximity of a point where the neck 104 is coupled with the holding portion 108, and an approximate diameter of 3.4 mm at a centre point between the holding portion 108 and the head 102. The head 102 has an approximate diameter of 4 mm and an approximate length of 17 mm.

[0032] Accordingly, the neck 104 can be designed such that it can allow the collection device 100 to be used in different regions. For instance, the neck 104, in view of the material of the collection device 100, is designed such that it is substantially flexible with respect to the holding portion 108 for collecting sample from nasopharyngeal region. Since, the neck 104 must be flexible to access the nasopharyngeal region due to curvature of the region, the neck 104 has a thinner profile. Even though high flexibility is desirable for neck 104 when the collection device 100 is used in the nasopharyngeal region, the neck 104 can also have a certain amount of strength such that the neck 104 does not break off while collecting sample. In another scenario, the neck 104, in view of the material of the collection device 100, is designed such that that it is substantially inflexible with respect to the holding portion 108 for collecting sample from throat or buccal cavity region. Since, it is easy to access the throat region, the neck 104 is designed such that it has high structural strength for collection sample from the said region. Even though high strength is desirable for neck 104 when the collection device 100 is used in the throat region, the neck 104 can also have a certain amount of flexibility.

[0033] Figure 5A and Figure 5B illustrate the region of the locking mechanism 106, according to an example, of the present subject matter. While Figure 5A illustrates a side view thereof, Figure 5B illustrates a cross-sectional view of the locking mechanism 106, as an example, also illustrating the dimensions thereof as an example. In said example, the locking mechanism 106 has a cube extrusion (side length 4 to 7 mm and thickness of 6 mm) and a taper of 10-11mm, which tapers to form the neck 104. Accordingly, the locking

mechanism 106 has a substantially rectangular cross-section in said example. The locking mechanism 106 is designed such that all edges of the locking mechanism 106 are smooth, such that, no injury occurs in a case where the locking mechanism 106 of the collection device 100 comes in contact with skin of the patient's body.

[0034] Figure 6A and Figure 6B illustrate the region of the locking mechanism 106, according to another example, of the present subject matter. While Figure 6A illustrates a cross-sectional view of the locking mechanism 106, Figure 6B illustrates a side view thereof. In said example, the locking mechanism 106 has a spherical extrusion (having an approximate diameter of 6.8 mm). Accordingly, the locking mechanism 106 has a substantially circular cross-section in said example. The locking mechanism 106, in said example, includes a circular ring between the neck 104 and the holding portion 108. An O-Ring fastener can be used in the circular ring to couple the neck 104 to the holding portion 108. The circular ring has a thickness of approximately 1.5 mm.

[0035] In an example, the locking mechanism 106 can have other type of cross-sections, such as an oval shaped cross-section, an elliptical shaped cross-section, etc. The profile of the locking mechanism 106 is designed such that the profile itself locks with the holding portion 108 without requiring any external element, such as fasteners. In other words, the profile may itself acts as a locking mechanism and can engage with the holding portion 108 to couple the neck 104 to the holding portion 108 such that an air-tight seal is provided between the holding portion 108 and the neck 104. In an example, the locking mechanism 106 may have different geometrical profiles, such as a cubical profile, a spherical profile, a conical profile, a trapezoidal profile, etc. According to an example, the profile of the locking mechanism 106, irrespective of shape, may include a tapered portion which locks with the holding portion 108. In an example, the locking mechanism 106 may include different fasteners to couple

the neck 104 to the holding portion 108. For example, the locking mechanism may include one of of a snap-fit lock, an O-Ring lock, a screw, a bolt and a grommet.

[0036] After disengaging the holding portion 108 from rest of the collection device 100, the remaining portion of the collection device 100 can be accommodated inside a container, such as a cartridge, as shown in Figure 7A and 7B. Figure 7A illustrates a container 200 for storing the collection device 100 after the holding portion 108 is disengaged. The locking mechanism 106 of the neck 104 can interact with the container 200 such that an air-tight lock is provided between the collection device 100 and the container 200. In other words, the locking mechanism 106 is adapted to form an air-tight seal or lock with the container 200, when the collection device 100 is disposed in the container 200. Figure 7B illustrates the collection device 100 being accommodated inside the container 200. The collection device 100, after sample collection is done, is stored and transported inside the container 200 so that the collected sample is not transmitted in atmosphere. As mentioned previously, the locking mechanism 106 of the neck 104 is provided adjacent to the holding portion 108, such that, in one example, the breaking portion 110 is between the locking mechanism 106 and the holding portion 108. Accordingly, when the collection device 100 is inserted in the container 200 and after the locking mechanism 106 locks, i.e., forms an air-tight seal, with the container 200, the holding portion 108 can be separated from rest of the collection device 100 by detaching at the breaking portion 110, for instance, by twisting, bending, or pulling. The air-tight sealing or locking of the collection device 100 with the container 200 before detaching the holding portion 108 ensures that when the holding portion 108 is detached, the seal does not break or unlock and there is no contamination of the collected sample.

[0037] The profile of the locking mechanism 106 may itself lock with the container 200 without requiring any external element, such as fasteners. In other words, the profile may itself acts as a locking mechanism and can engage with the container 200 to secure the collection device 100 inside the container 200. The profile provides an air-tight seal between the collection device 100 and the container 200. In an example, the locking mechanism 106 may have different geometrical profiles, such as a cubical profile, a spherical profile, a conical profile, a trapezoidal profile, etc. According to an example, the profile of the locking mechanism 106, irrespective of shape, may include a tapered portion which locks with the container 200. In an example, the locking mechanism 106 may include different fasteners to couple the neck 104 to the holding portion 108. For example, the locking mechanism may include one of of a snap-fit lock, an O-Ring lock, a screw, a bolt and a grommet.

[0038] Further, the neck 104 is designed to be a balanced combination of flexibility and strength so that the collection device 100 can be manoeuvred into the buccal cavity or the throat. Accordingly, in an example, the neck 104 of the collection device 100, such as the nasopharyngeal collection device, can have a stepped construction forming a first neck portion 104-1 and a second neck portion 104-2 having a step therebetween. The neck 104 can have the first neck portion 104-1 which has a greater thickness than the second neck portion 104-2. The provision of the greater thickness of the first neck portion 104-1 helps maintain structural integrity of the neck 104 whereas the second neck portion 104-2 helps maximize structural flexibility of the neck 104. In an example, the first neck portion 104-1 can be connected to the second neck portion 104-2 by a taper or by a step. As an example, in the former case, the taper between the first neck portion 104-1 and the second neck portion 104- 2 can have a length of around 3 to 3.4 mm to provide a smooth transition between the two.

[0039] Figure 8A and Figure 8B illustrate the various designs of the head 102 of the collection device 100, as examples of the present subject matter. In said examples, the illustrations of Figure 8B show the various designs of the head 102 rotated by 45 degrees from the illustrations of the respective designs of the head 102 shown in Figure 8A.

[0040] As mentioned above, the head 102 is designed for sampling the throat or oropharyngeal region as well as the nasopharyngeal region or the nasal canal. The head 102 is designed to have a certain amount of abrasiveness required to allow for cell sampling without damaging the tissue. In addition, channels formed in the head allow for liquid sample capture via capillary action.

[0041] Further, as mentioned above, the collection device 100 is designed so that it can be easily mass-produced using simple techniques, such as injection moulding. In the present example, the head 102 can also have such a design that it facilitates that the collection device 100 is injection moulded. Accordingly, the head 102 is formed such that there are no in-cuts in the head 102. In other words, the design of the head 102 is such that during injection moulding, the plastic can flow in one direction to form the entire collection device 100 including the head 102. If the head 102 has in-cuts, i.e., portions having a through-and-through or hollow design, the plastic is unable to flow out during injection moulding and, therefore, the head 102 is not formable by injection moulding.

[0042] Although examples for the collection device 100 have been described in language specific to structural features and/or methods, it is to be understood that the appended claims are not limited to the specific features described. Rather, the specific features are disclosed as examples of the collection device 100.

I/We Claim:

1. A collection device (100) for sample collection, the collection device (100) comprising:

a holding portion (108) to hold the collection device (100) for sample collection;

a neck (104) flexibly coupled to the holding portion (108), wherein the neck (104) is detachable from the holding portion (108);

a head (102) coupled to the neck (104) opposite to the holding portion (108), wherein the head (102) includes a plurality of grooves adapted to perform capillary action when the head (102) is inserted in a pool of liquid mixture; and

wherein the collection device (100) is made of a single material.

2. The collection device (100) as claimed in claim 1, wherein the collection device (100) is manufactured by injection moulding.

3. The collection device (100) as claimed in claim 1, wherein the collection device (100) is made of a thermoplastic material.

4. The collection device (100) as claimed in claim 1, comprising a breaking portion (110) to detach the holding portion (108) from the neck (104)

5. The collection device (100) as claimed in claim 4, wherein the breaking portion (110) comprises a notch to detach the holding portion (108) from the neck (104).

6. The collection device (100) as claimed in claim 1, wherein the neck comprises a locking mechanism (106) adjacent to a point of connection to the holding portion (108), wherein the locking mechanism (106) is adapted to form

an air-tight seal with a container, when the collection device (100) is disposed in the container.

7. The collection device (100) as claimed in claim 6, wherein the locking mechanism is one of a snap-fit lock, an O-Ring lock, a screw, a bolt and a grommet.

8. The collection device (100) as claimed in claim 1, wherein the neck (104) has a non-uniform cross-sectional area between the head (102) and the locking mechanism (106).

9. The collection device (100) as claimed in claim 1, wherein the neck (104) is coupled to the head (102) by a tapered portion.

10. The collection device (100) as claimed in claim 1, wherein the neck (104) is coupled to the locking mechanism (106) by a tapered portion.

11. The collection device (100) as claimed in claim 1, wherein the collection device (100) is for collecting sample from a nasopharyngeal region, the neck (104) being designed to be substantially flexible with respect to the holding portion (108).

12. The collection device (100) as claimed in claim 1, wherein the collection device (100) is for collecting sample from buccal cavity or throat region, the neck (104) being designed to be substantially inflexible with respect to the holding portion (108).

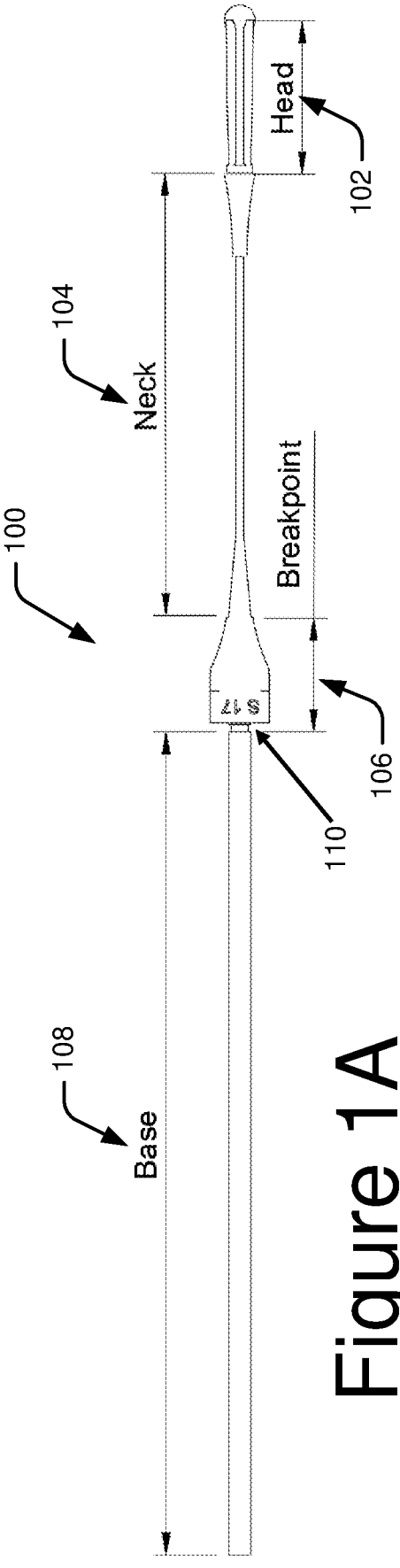


Figure 1A

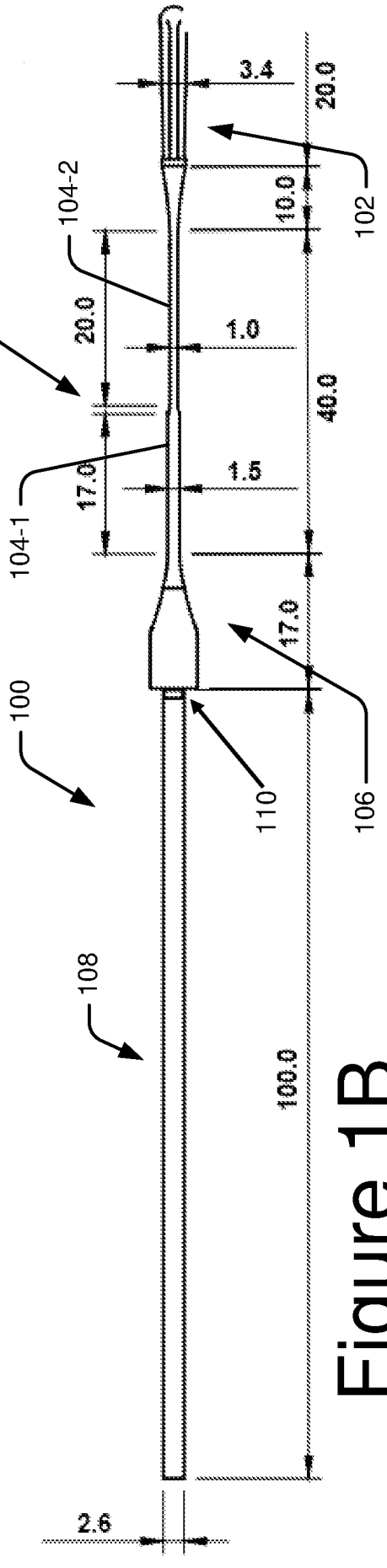


Figure 1B

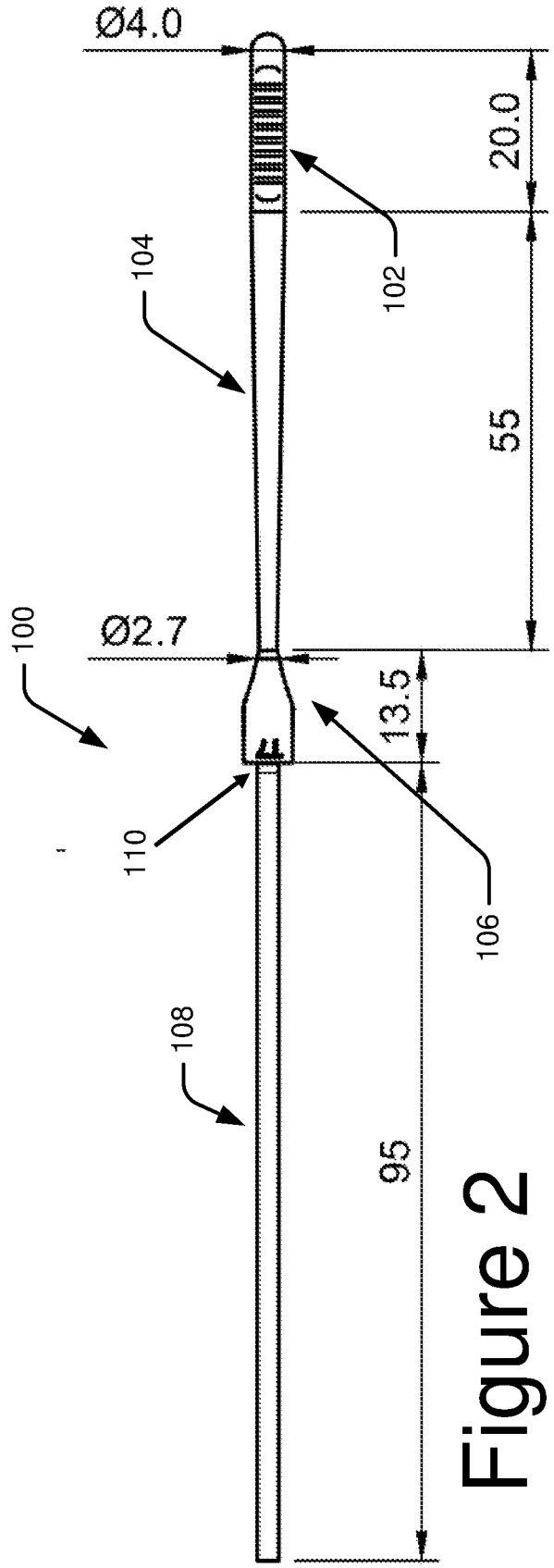


Figure 2

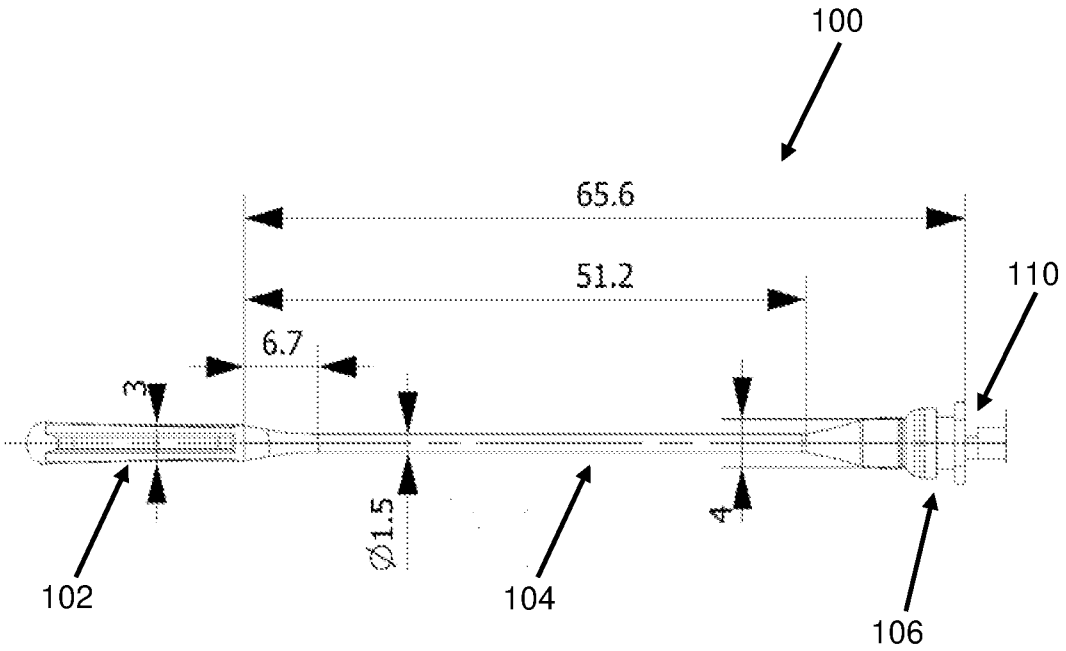


Figure 3

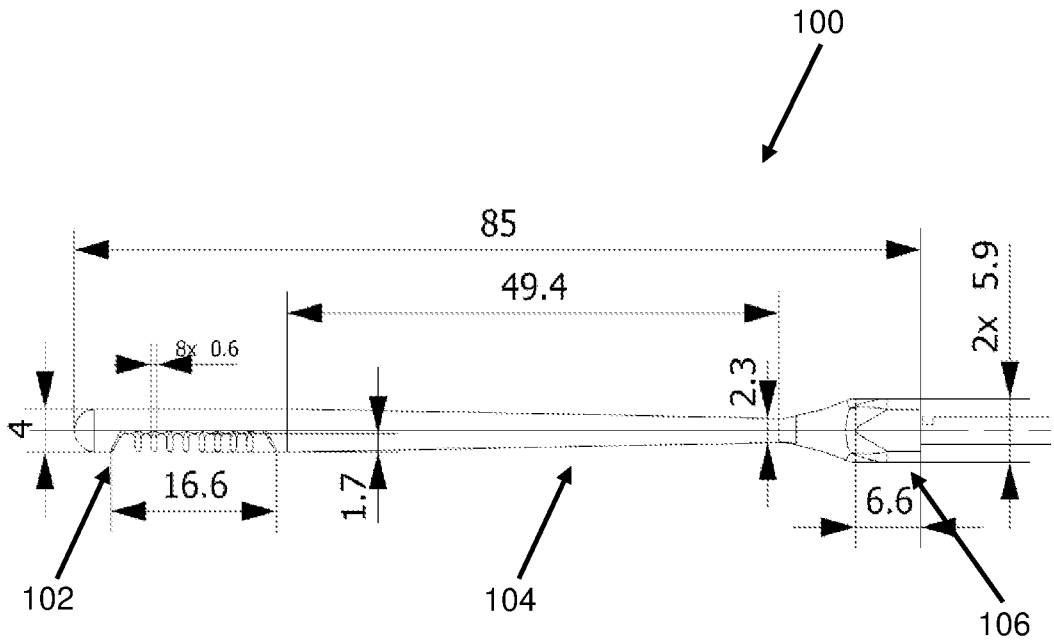


Figure 4

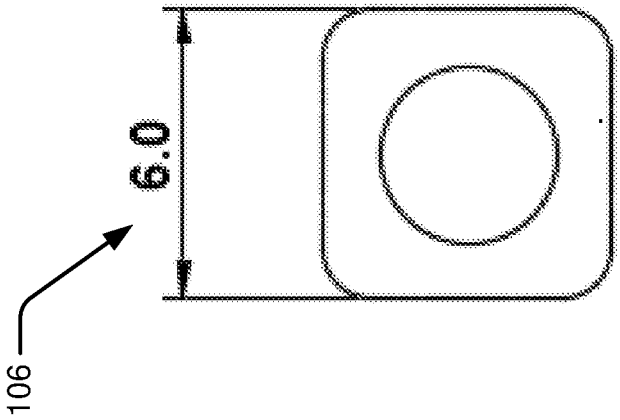


Figure 5B

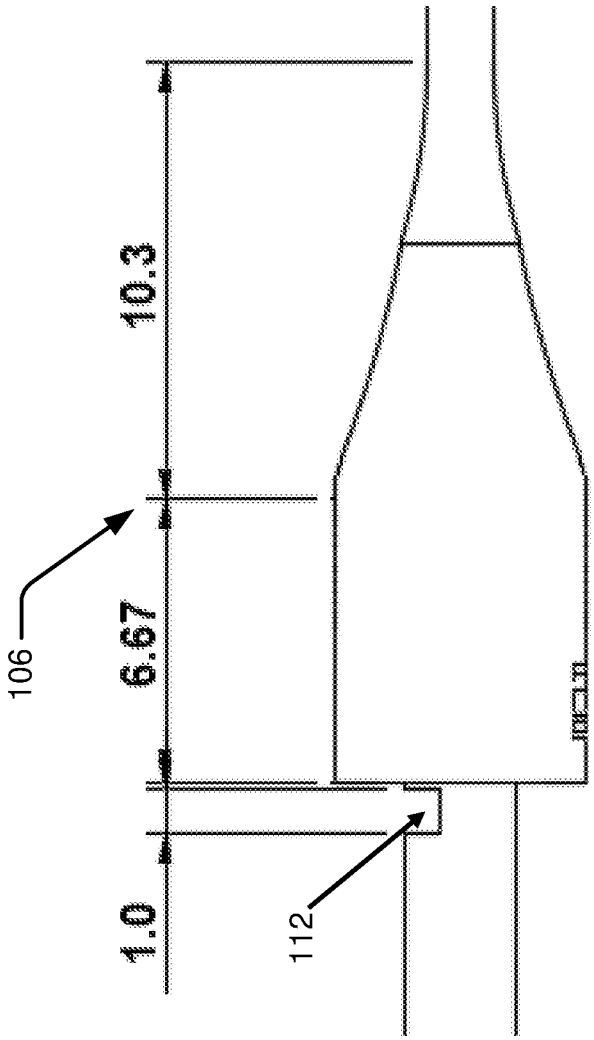


Figure 5A

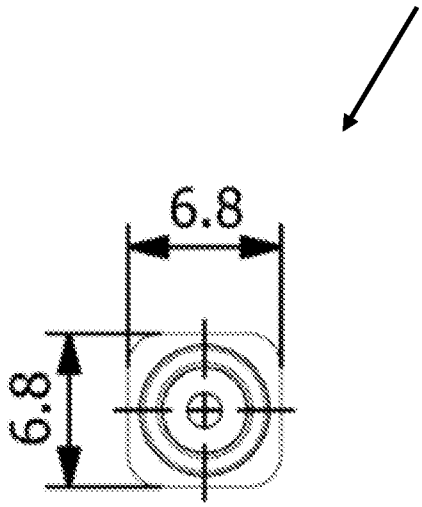


Figure 6A

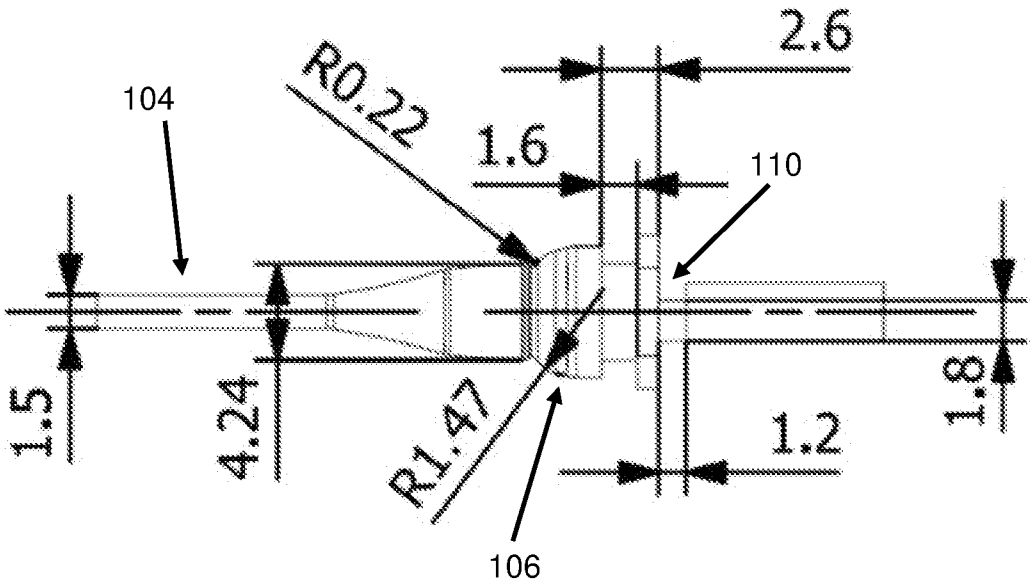


Figure 6B

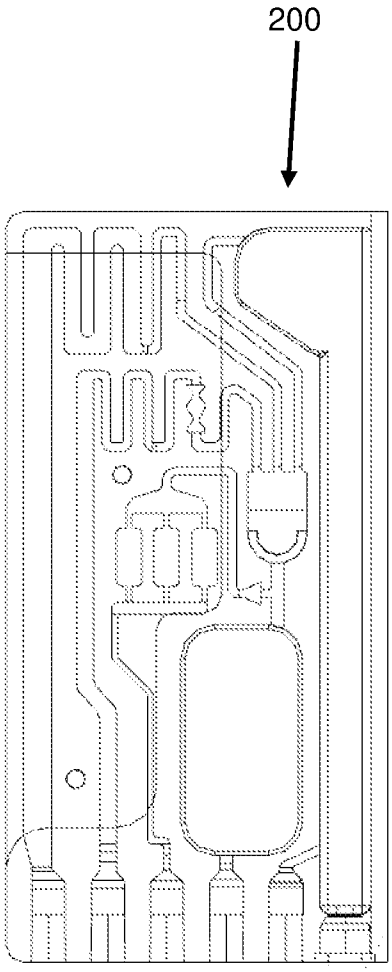


Figure 7A

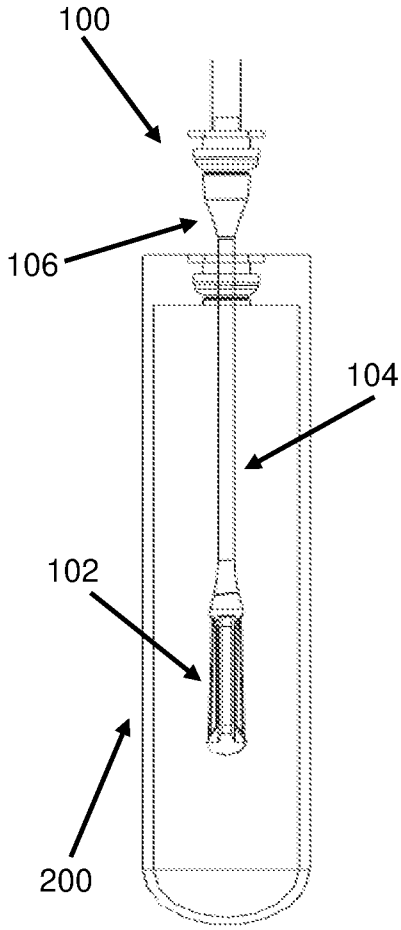


Figure 7B

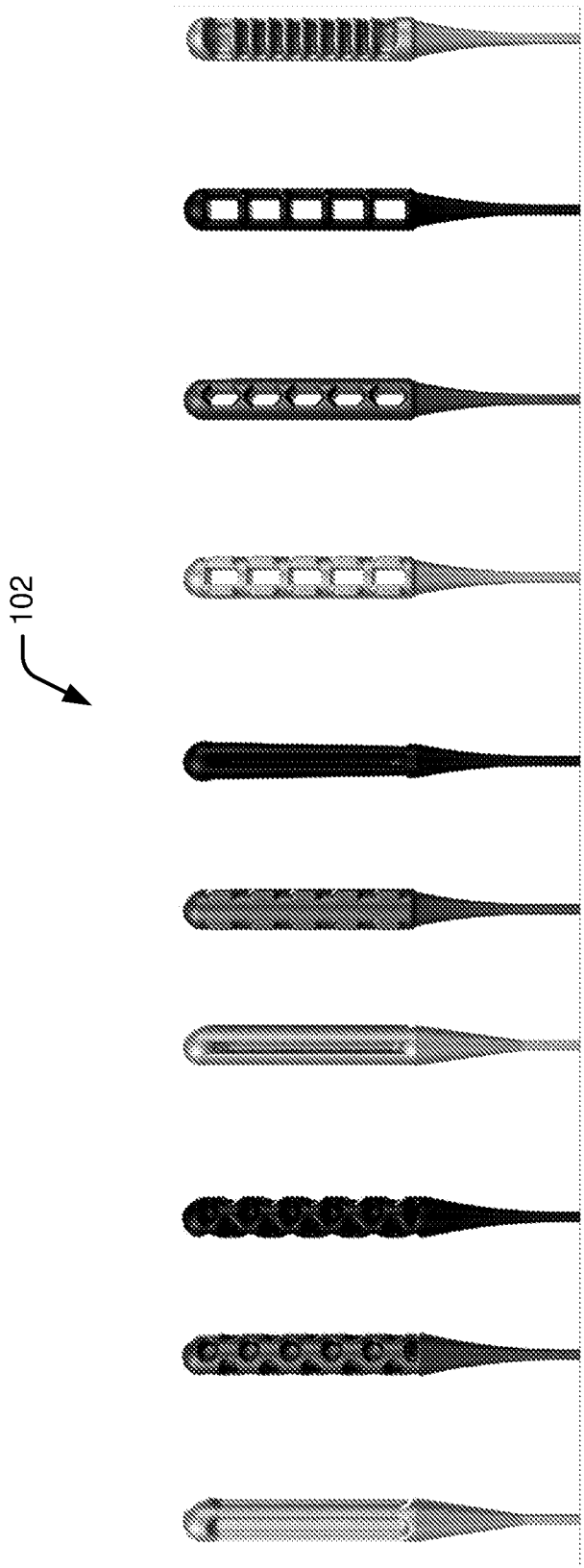


Figure 8A

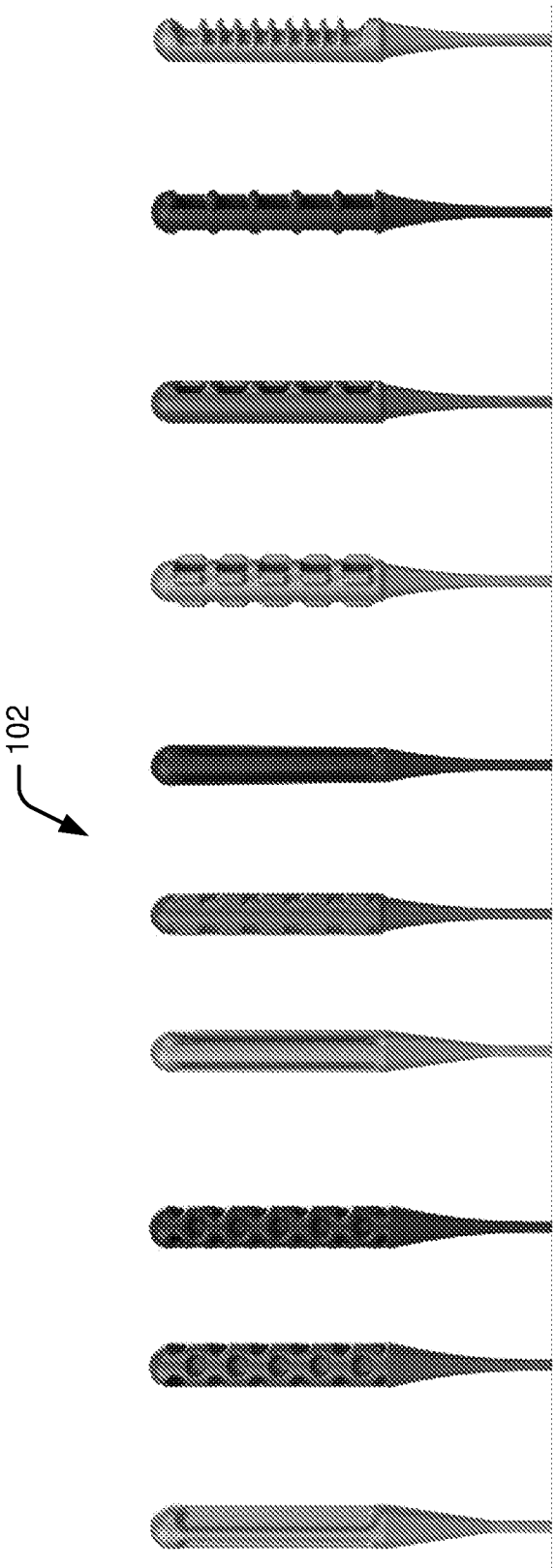


Figure 8B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2021/051104

A. CLASSIFICATION OF SUBJECT MATTER
A61B10/02,B01L3/00 Version=2022.01

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B; B01L

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)

PatSeer, IPO Internal Database

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US10517575B2 (COPAN ITALIA S.P.A) December 31, 2019 Abstract; Figures 1-7; Column 3, Line 22- 67; Column 5, Line 1-15	1-12
A	US5266266A (FREDERIC L. NASON) November 30, 1993 Abstract; Figure 1-3; Column 2, Line 49-60; Column 3, Line 57-68;	1-12

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04-03-2022	04-03-2022
Name and mailing address of the ISA/ Indian Patent Office Plot No.32, Sector 14,Dwarka,New Delhi-110075 Facsimile No.	Authorized officer Aniruddh Garg Telephone No. +91-1125300200

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IN2021/051104

Citation	Pub.Date	Family	Pub.Date
US 10517575 B2	31-12-2019	DK 3014240 T3	08-04-2019
		EP 3014240 A1	04-05-2016
		ES 2714712 T3	29-05-2019
		IT MI20131088 A1	29-12-2014
		WO 2014207598 A1	31-12-2014