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(54) Title: COLLECTION DEVICE AND MATERIAL

(57) Abstract: Swabs, and materials of the present disclosure, and methods of making same, include randomly arranged sea-island bicomponent fibers which have randomly splayed terminal ends.

1 **COLLECTION DEVICE AND MATERIAL**

2 The present application claims benefit of U.S. Provisional Application No.
3 61/326,466, filed April 21, 2010, the entire contents of which is incorporated
4 herein by reference.

5 **Technical Field**

6 The present disclosure describes a swab, and collection material for use
7 therein, for collecting biological specimens.

8 **Background**

9 Devices, such as swabs, for collecting biological specimens of organic
10 material are known in the field of clinical and diagnostic analyses, which
11 generally include a cylindrical rod or stick containing on a collection end or tip a
12 wad of fiber material, such as rayon or a natural fiber such as cotton, with
13 hydrophilic properties to allow rapid absorption of the quantity of specimen to be
14 collected and tested. Stable adherence of the fiber wrapped around the end or tip
15 of the rod or stick is generally achieved by gluing.

16 Collection swabs containing the collected material are often immersed in a
17 culture media, such as in a test tube, vial, culture dish, or culture bottle, soon or
18 immediately after collection to preserve and conserve the collected specimen
19 during storage and/or transport to, for example, an analytical laboratory.

20 Collection swabs and devices of the prior art are described, for example, in
21 EP0643131 and WO2004/086979.

22 **Summary**

1 Devices, such as swabs, and materials of the present disclosure, and
2 methods of making same, include randomly arranged sea-island bicomponent
3 fibers which have randomly splayed terminal ends.

4

5 The present disclosure provides a swab for collecting and releasing a
6 biological sample containing an applicator and sea-island bicomponent fibers,
7 wherein at least about 85% of the fibers comprise randomly splayed terminal
8 ends of the islands of said bicomponent fibers along a length of about 50% or
9 less from the ends.

10 The swab of present disclosure contain fibers attached to an end portion
11 of the applicator, such as by adhesive.

12 The present disclosure provides a method of forming the swab of the
13 disclosure which includes adhering the bicomponent fibers to the applicator,
14 removing a portion of the sea component of the bicomponent fibers in a heated
15 alkaline solvent, and forming the randomly splayed fibers by application of
16 mechanical force to the ends of the fibers which have had the sea component
17 removed.

18 The present disclosure provides a method of collecting a biological sample
19 which includes contacting the swab of the disclosure with a source of biological
20 material such that a sample of the material is retained by the swab.

21 **Brief Description of Drawings**

22 Figure 1 provides an end view of a bicomponent fiber of PET/PET.

1 Figure 2 is an electron micrograph of randomly arranged sea-island
2 bicomponent PET/PET fibers which have randomly splayed terminal ends.

3 Figure 3 is a photograph of an experimental swab with an unsplit swab
4 stick head.

5 Figure 4 is a photograph of an experimental swab with a full split swab
6 stick head.

7 **Detailed Description**

8 Devices, such as swabs, and materials of the present disclosure, and
9 methods of making same, include randomly arranged sea-island bicomponent
10 fibers which have randomly splayed terminal ends.

11 Materials of the present disclosure may be included as a high absorbency
12 member of medical swab devices. The “splittable” flock fiber materials of the
13 present disclosure attached to the end of a thin “stick-like” polymeric shaft are
14 described and contemplated herein as swabs of the present disclosure. The flock
15 fibers of the disclosure, which are physico-chemically “split” at the end of the
16 material, provide a fibrous material with fibrous surface area which increase the
17 overall surface area of the fibrous mass. This leads to a higher degree of fluid
18 absorption by the fibrous mass.

19 The materials of the disclosure may include micro- and nano-fibers, such
20 as bicomponent sea-island materials. Segmented pie materials may also be
21 used. Bicomponent sea-island materials and segmented pie materials are
22 known and described, for example in Ndaro et al Journal of Engineered Fibers
23 and Fabrics, volume 2, Issue 4, 2007 “Splitting of Islands-in-the-Sea Fibers

1 (PA6/COPET) During Hydroentanging of Nonwovens"; and Fedorova, Nataliya
2 "Investigation of the Utility of Islands-in-the-sea Bicomponent Fiber Technology in
3 the SpunBond Process" Ph.D. Dissertation, North Carolina State University,
4 Raleigh, NC (2006); as well as in U.S. Patent Application Publication Nos.:
5 20100075143 (FIBER STRUCTURE AND METHOD FOR PRODUCTION
6 THEREOF), 20100068516 (THERMOPLASTIC FIBER WITH EXCELLENT
7 DURABILITY AND FABRIC COMPRISING THE SAME), and 20100029158
8 (ISLANDS-IN-SEA TYPE COMPOSITE FIBER AND PROCESS FOR
9 PRODUCING SAME), And WO2002042528 (A SEA-ISLAND TYPED
10 COMPOSITE FIBER USED IN WARP KNITTING, AND A PROCESS OF
11 PREPARING FOR THE SAME), WO2002042529 A SEA-ISLAND TYPE
12 COMPOSITE FIBER FOR RAISED WARP KNIT FABRIC, AND A PROCESS OF
13 PREPARING FOR THE SAME), WO2002088438 (A SEA-ISLAND TYPED
14 CONJUGATE MULTI FILAMENT COMPRISING DOPE DYEING COMPONENT,
15 AND A PROCESS OF PREPARING FOR THE SAME), and as are commercially
16 available from, for example, Kolon Industry, Kumi City, Kyungbuk, Korea and
17 generally described as ROJEL - polyester/polyester conjugated fiber yarn
18 (sea/island) or SPECIAL TYPE OF ROJEL - polyester/nylon conjugated fiber
19 yarn (sea/island); or Hyosung Corporation, Ulsan City, Kyungbuk, Korea and
20 generally described as MIPAN XF - Nylon/polyester conjugated yarn (pie-wedge
21 cross-section).

22 In the islands-in-sea type composite fiber of the presently described
23 material, an easily soluble polymer is incorporated for the sea portion and

1 preferably contains at least one polymer easily soluble in aqueous alkali
2 solutions, such as polylactic acid, super high molecular weight polyalkyleneoxide-
3 condensate polymers, polyethyleneglycol compound-copolymerized polyesters,
4 and copolymerized polyesters of polyethylene glycol (PAG) compounds with 5-
5 sodium sulfoisophthalic acid or dimethyl-5-sulfoisophthalate sodium salt (DMIS).
6 Polyester sea materials may include alkali soluble copolymer polyester materials
7 with polyester mainly containing polyethylene terephthalate of more than 90 mole
8 percent as island component (such as is described, for example, in
9 WO2002042528, the entire contents of which is incorporated herein by
10 reference).

11 The islands-in-sea type bicomponent composite fiber of the present
12 disclosure contains a sea part containing or composed of polymer of greater
13 solubility than a plurality of island parts containing or composed of a less soluble
14 polymer, in the cross-sectional profile of which the number of the island parts is
15 about 10, 24, 36, 37, 64 or 240 islands per fiber, or ranges of islands per fiber
16 between any of 10, 24, 36, 37, 64, 240 or 3000 islands per fiber.

17 The island component of the bicomponent composite fiber of the present
18 disclosure may be a polyamide, such as nylon, or a polyester. Examples of the
19 polyamide include polymers having an amide bond, such as nylon 6, nylon 66,
20 nylon 610, and nylon 12. The polyester is not particularly limited as long as it is a
21 polymer synthesized from dicarboxylic acid or an ester-forming derivative and
22 diol or an ester-forming derivative thereof and can be used as the fiber. Specific
23 examples thereof include polyethylene terephthalate, polytrimethylene

1 terephthalate, polytetramethylene terephthalate, polycyclohexylenedimethylene
2 terephthalate, polyethylene-2,6-naphthalene dicarboxylate, polyethylene-1,2-
3 bis(2-chlorophenoxy)ethane-4,4'-dicarboxylate and the like. In an embodiment of
4 the present invention, a polyethylene terephthalate or a polyester copolymer
5 containing mainly an ethylene terephthalate unit, may be used.

6 The islands-in-sea type bicomponent composite fiber of the present
7 disclosure have a linear mass density in the range of about 1-7 deniers,
8 alternatively in the range of about 2 to 6 deniers or the range of 2 to 5.8 deniers
9 (or 2.22 to 6.49 dtex) wherein a denier is the mass in grams per 9000 meters of
10 fiber and dtex is the mass in grams per 10,000 meters. The diameter (ϕ , in
11 centimeters) of a bicomponent composite fiber may be estimated from the
12 following formula, wherein ρ represents a materials density in grams per cubic
13 centimeter:

$$\phi = \sqrt{\frac{4 \times 10^{-6} \cdot \text{dtex}}{\pi \rho}}$$

15 Estimating the fiber specific gravity as being equal to 1 (specific gravity
16 values of common fiber polymers according to Gafe et al ("Polymeric Nanofibers
17 and Nanofiber Webs: A New Class of Nonwovens" INTC 2002: International
18 Nonwovens Technical Conference (Joint INDA – TAPPI Conference), Atlanta,
19 Georgia, September 24-26, 2002) are as follows: 0.92 (polypropylene or PP),
20 1.14 (polyamide 66 or nylon or PA66) and 1.38 (polyethylene terephthalate or
21 PET)), the diameter of bicomponent composite fiber of the present disclosure

1 having a linear mass density in the range of 2 to 5.8 deniers would be about
2 16.7 μ m to 28.6 μ m.

3 The islands of the bicomponent composite fibers of the present disclosure
4 have a mass linear density of about 0.01 to about 0.3 deniers, or about 0.05 to
5 about 0.2 deniers, or about 0.06 to about 0.16 deniers, depending on the linear
6 mass density of the bicomponent composite fibers of the present disclosure.

7 The islands-in-sea type bicomponent composite fibers of the material of
8 the present disclosure have a length, or cut length, of about 10 to about 100
9 thousandths of an inch (about 254 μ m to about 2,540 μ m), or about 20 to about
10 90 thousandths of an inch, or about 20 to about 80 thousandths of an inch, or
11 about 20 to about 70 thousandths of an inch, or about 20 to about 60
12 thousandths of an inch.

13 At least about 50%, 55%, 60%, 70%, 75%, 80%, 85%, 90% or 95% (by
14 number) of the islands-in-sea type bicomponent composite fibers of the material
15 of the present disclosure contain randomly splayed, or split and spread, terminal
16 ends along a length of about 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15% or
17 10% or less from one end.

18 At least about 50%, (by number) of the islands-in-sea type bicomponent
19 composite fibers of the material of the present disclosure contain randomly
20 splayed, or split and spread, terminal ends along a length of about 50% or less
21 from one end.

22 At least about 50%, (by number) of the islands-in-sea type bicomponent
23 composite fibers of the material of the present disclosure contain randomly

1 splayed, or split and spread, terminal ends along a length of about 45% or less
2 from one end.

3 At least about 50%, (by number) of the islands-in-sea type bicomponent
4 composite fibers of the material of the present disclosure contain randomly
5 splayed, or split and spread, terminal ends along a length of about 40% or less
6 from one end.

7 At least about 50%, (by number) of the islands-in-sea type bicomponent
8 composite fibers of the material of the present disclosure contain randomly
9 splayed, or split and spread, terminal ends along a length of about 35% or less
10 from one end.

11 At least about 50%, (by number) of the islands-in-sea type bicomponent
12 composite fibers of the material of the present disclosure contain randomly
13 splayed, or split and spread, terminal ends along a length of about 30% or less
14 from one end.

15 At least about 50%, (by number) of the islands-in-sea type bicomponent
16 composite fibers of the material of the present disclosure contain randomly
17 splayed, or split and spread, terminal ends along a length of about 25% or less
18 from one end.

19 At least about 50%, (by number) of the islands-in-sea type bicomponent
20 composite fibers of the material of the present disclosure contain randomly
21 splayed, or split and spread, terminal ends along a length of about 20% or less
22 from one end.

1 At least about 50%, (by number) of the islands-in-sea type bicomponent
2 composite fibers of the material of the present disclosure contain randomly
3 splayed, or split and spread, terminal ends along a length of about 15% or less
4 from one end.

5 At least about 50%, (by number) of the islands-in-sea type bicomponent
6 composite fibers of the material of the present disclosure contain randomly
7 splayed, or split and spread, terminal ends along a length of about 10% or less
8 from one end.

9 At least about 55%, (by number) of the islands-in-sea type bicomponent
10 composite fibers of the material of the present disclosure contain randomly
11 splayed, or split and spread, terminal ends along a length of about 50% or less
12 from one end.

13 At least about 55%, (by number) of the islands-in-sea type bicomponent
14 composite fibers of the material of the present disclosure contain randomly
15 splayed, or split and spread, terminal ends along a length of about 45% or less
16 from one end.

17 At least about 55%, (by number) of the islands-in-sea type bicomponent
18 composite fibers of the material of the present disclosure contain randomly
19 splayed, or split and spread, terminal ends along a length of about 40% or less
20 from one end.

21 At least about 55%, (by number) of the islands-in-sea type bicomponent
22 composite fibers of the material of the present disclosure contain randomly

1 splayed, or split and spread, terminal ends along a length of about 35% or less
2 from one end.

3 At least about 55%, (by number) of the islands-in-sea type bicomponent
4 composite fibers of the material of the present disclosure contain randomly
5 splayed, or split and spread, terminal ends along a length of about 30% or less
6 from one end.

7 At least about 55%, (by number) of the islands-in-sea type bicomponent
8 composite fibers of the material of the present disclosure contain randomly
9 splayed, or split and spread, terminal ends along a length of about 25% or less
10 from one end.

11 At least about 55%, (by number) of the islands-in-sea type bicomponent
12 composite fibers of the material of the present disclosure contain randomly
13 splayed, or split and spread, terminal ends along a length of about 20% or less
14 from one end.

15 At least about 55%, (by number) of the islands-in-sea type bicomponent
16 composite fibers of the material of the present disclosure contain randomly
17 splayed, or split and spread, terminal ends along a length of about 15% or less
18 from one end.

19 At least about 55%, (by number) of the islands-in-sea type bicomponent
20 composite fibers of the material of the present disclosure contain randomly
21 splayed, or split and spread, terminal ends along a length of about 10% or less
22 from one end.

1 At least about 60%, (by number) of the islands-in-sea type bicomponent
2 composite fibers of the material of the present disclosure contain randomly
3 splayed, or split and spread, terminal ends along a length of about 50% or less
4 from one end.

5 At least about 60%, (by number) of the islands-in-sea type bicomponent
6 composite fibers of the material of the present disclosure contain randomly
7 splayed, or split and spread, terminal ends along a length of about 45% or less
8 from one end.

9 At least about 60%, (by number) of the islands-in-sea type bicomponent
10 composite fibers of the material of the present disclosure contain randomly
11 splayed, or split and spread, terminal ends along a length of about 40% or less
12 from one end.

13 At least about 60%, (by number) of the islands-in-sea type bicomponent
14 composite fibers of the material of the present disclosure contain randomly
15 splayed, or split and spread, terminal ends along a length of about 35% or less
16 from one end.

17 At least about 60%, (by number) of the islands-in-sea type bicomponent
18 composite fibers of the material of the present disclosure contain randomly
19 splayed, or split and spread, terminal ends along a length of about 30% or less
20 from one end.

21 At least about 60%, (by number) of the islands-in-sea type bicomponent
22 composite fibers of the material of the present disclosure contain randomly

1 splayed, or split and spread, terminal ends along a length of about 25% or less
2 from one end.

3 At least about 60%, (by number) of the islands-in-sea type bicomponent
4 composite fibers of the material of the present disclosure contain randomly
5 splayed, or split and spread, terminal ends along a length of about 20% or less
6 from one end.

7 At least about 60%, (by number) of the islands-in-sea type bicomponent
8 composite fibers of the material of the present disclosure contain randomly
9 splayed, or split and spread, terminal ends along a length of about 15% or less
10 from one end.

11 At least about 60%, (by number) of the islands-in-sea type bicomponent
12 composite fibers of the material of the present disclosure contain randomly
13 splayed, or split and spread, terminal ends along a length of about 10% or less
14 from one end.

15 At least about 70%, (by number) of the islands-in-sea type bicomponent
16 composite fibers of the material of the present disclosure contain randomly
17 splayed, or split and spread, terminal ends along a length of about 50% or less
18 from one end.

19 At least about 70%, (by number) of the islands-in-sea type bicomponent
20 composite fibers of the material of the present disclosure contain randomly
21 splayed, or split and spread, terminal ends along a length of about 45% or less
22 from one end.

1 At least about 70%, (by number) of the islands-in-sea type bicomponent
2 composite fibers of the material of the present disclosure contain randomly
3 splayed, or split and spread, terminal ends along a length of about 40% or less
4 from one end.

5 At least about 70%, (by number) of the islands-in-sea type bicomponent
6 composite fibers of the material of the present disclosure contain randomly
7 splayed, or split and spread, terminal ends along a length of about 35% or less
8 from one end.

9 At least about 70%, (by number) of the islands-in-sea type bicomponent
10 composite fibers of the material of the present disclosure contain randomly
11 splayed, or split and spread, terminal ends along a length of about 30% or less
12 from one end.

13 At least about 70%, (by number) of the islands-in-sea type bicomponent
14 composite fibers of the material of the present disclosure contain randomly
15 splayed, or split and spread, terminal ends along a length of about 25% or less
16 from one end.

17 At least about 70%, (by number) of the islands-in-sea type bicomponent
18 composite fibers of the material of the present disclosure contain randomly
19 splayed, or split and spread, terminal ends along a length of about 20% or less
20 from one end.

21 At least about 70%, (by number) of the islands-in-sea type bicomponent
22 composite fibers of the material of the present disclosure contain randomly

1 splayed, or split and spread, terminal ends along a length of about 15% or less
2 from one end.

3 At least about 70%, (by number) of the islands-in-sea type bicomponent
4 composite fibers of the material of the present disclosure contain randomly
5 splayed, or split and spread, terminal ends along a length of about 10% or less
6 from one end.

7 At least about 75%, (by number) of the islands-in-sea type bicomponent
8 composite fibers of the material of the present disclosure contain randomly
9 splayed, or split and spread, terminal ends along a length of about 50% or less
10 from one end.

11 At least about 75%, (by number) of the islands-in-sea type bicomponent
12 composite fibers of the material of the present disclosure contain randomly
13 splayed, or split and spread, terminal ends along a length of about 45% or less
14 from one end.

15 At least about 75%, (by number) of the islands-in-sea type bicomponent
16 composite fibers of the material of the present disclosure contain randomly
17 splayed, or split and spread, terminal ends along a length of about 40% or less
18 from one end.

19 At least about 75%, (by number) of the islands-in-sea type bicomponent
20 composite fibers of the material of the present disclosure contain randomly
21 splayed, or split and spread, terminal ends along a length of about 35% or less
22 from one end.

1 At least about 75%, (by number) of the islands-in-sea type bicomponent
2 composite fibers of the material of the present disclosure contain randomly
3 splayed, or split and spread, terminal ends along a length of about 30% or less
4 from one end.

5 At least about 75%, (by number) of the islands-in-sea type bicomponent
6 composite fibers of the material of the present disclosure contain randomly
7 splayed, or split and spread, terminal ends along a length of about 25% or less
8 from one end.

9 At least about 75%, (by number) of the islands-in-sea type bicomponent
10 composite fibers of the material of the present disclosure contain randomly
11 splayed, or split and spread, terminal ends along a length of about 20% or less
12 from one end.

13 At least about 75%, (by number) of the islands-in-sea type bicomponent
14 composite fibers of the material of the present disclosure contain randomly
15 splayed, or split and spread, terminal ends along a length of about 15% or less
16 from one end.

17 At least about 75%, (by number) of the islands-in-sea type bicomponent
18 composite fibers of the material of the present disclosure contain randomly
19 splayed, or split and spread, terminal ends along a length of about 10% or less
20 from one end.

21 At least about 80%, (by number) of the islands-in-sea type bicomponent
22 composite fibers of the material of the present disclosure contain randomly

1 splayed, or split and spread, terminal ends along a length of about 50% or less
2 from one end.

3 At least about 80%, (by number) of the islands-in-sea type bicomponent
4 composite fibers of the material of the present disclosure contain randomly
5 splayed, or split and spread, terminal ends along a length of about 45% or less
6 from one end.

7 At least about 80%, (by number) of the islands-in-sea type bicomponent
8 composite fibers of the material of the present disclosure contain randomly
9 splayed, or split and spread, terminal ends along a length of about 40% or less
10 from one end.

11 At least about 80%, (by number) of the islands-in-sea type bicomponent
12 composite fibers of the material of the present disclosure contain randomly
13 splayed, or split and spread, terminal ends along a length of about 35% or less
14 from one end.

15 At least about 80%, (by number) of the islands-in-sea type bicomponent
16 composite fibers of the material of the present disclosure contain randomly
17 splayed, or split and spread, terminal ends along a length of about 30% or less
18 from one end.

19 At least about 80%, (by number) of the islands-in-sea type bicomponent
20 composite fibers of the material of the present disclosure contain randomly
21 splayed, or split and spread, terminal ends along a length of about 25% or less
22 from one end.

1 At least about 80%, (by number) of the islands-in-sea type bicomponent
2 composite fibers of the material of the present disclosure contain randomly
3 splayed, or split and spread, terminal ends along a length of about 20% or less
4 from one end.

5 At least about 80%, (by number) of the islands-in-sea type bicomponent
6 composite fibers of the material of the present disclosure contain randomly
7 splayed, or split and spread, terminal ends along a length of about 15% or less
8 from one end.

9 At least about 80%, (by number) of the islands-in-sea type bicomponent
10 composite fibers of the material of the present disclosure contain randomly
11 splayed, or split and spread, terminal ends along a length of about 10% or less
12 from one end.

13 At least about 85%, (by number) of the islands-in-sea type bicomponent
14 composite fibers of the material of the present disclosure contain randomly
15 splayed, or split and spread, terminal ends along a length of about 50% or less
16 from one end.

17 At least about 85%, (by number) of the islands-in-sea type bicomponent
18 composite fibers of the material of the present disclosure contain randomly
19 splayed, or split and spread, terminal ends along a length of about 45% or less
20 from one end.

21 At least about 85%, (by number) of the islands-in-sea type bicomponent
22 composite fibers of the material of the present disclosure contain randomly

1 splayed, or split and spread, terminal ends along a length of about 40% or less
2 from one end.

3 At least about 85%, (by number) of the islands-in-sea type bicomponent
4 composite fibers of the material of the present disclosure contain randomly
5 splayed, or split and spread, terminal ends along a length of about 35% or less
6 from one end.

7 At least about 85%, (by number) of the islands-in-sea type bicomponent
8 composite fibers of the material of the present disclosure contain randomly
9 splayed, or split and spread, terminal ends along a length of about 30% or less
10 from one end.

11 At least about 85%, (by number) of the islands-in-sea type bicomponent
12 composite fibers of the material of the present disclosure contain randomly
13 splayed, or split and spread, terminal ends along a length of about 25% or less
14 from one end.

15 At least about 85%, (by number) of the islands-in-sea type bicomponent
16 composite fibers of the material of the present disclosure contain randomly
17 splayed, or split and spread, terminal ends along a length of about 20% or less
18 from one end.

19 At least about 85%, (by number) of the islands-in-sea type bicomponent
20 composite fibers of the material of the present disclosure contain randomly
21 splayed, or split and spread, terminal ends along a length of about 15% or less
22 from one end.

1 At least about 85%, (by number) of the islands-in-sea type bicomponent
2 composite fibers of the material of the present disclosure contain randomly
3 splayed, or split and spread, terminal ends along a length of about 10% or less
4 from one end.

5 At least about 90%, (by number) of the islands-in-sea type bicomponent
6 composite fibers of the material of the present disclosure contain randomly
7 splayed, or split and spread, terminal ends along a length of about 50% or less
8 from one end.

9 At least about 90%, (by number) of the islands-in-sea type bicomponent
10 composite fibers of the material of the present disclosure contain randomly
11 splayed, or split and spread, terminal ends along a length of about 45% or less
12 from one end.

13 At least about 90%, (by number) of the islands-in-sea type bicomponent
14 composite fibers of the material of the present disclosure contain randomly
15 splayed, or split and spread, terminal ends along a length of about 40% or less
16 from one end.

17 At least about 90%, (by number) of the islands-in-sea type bicomponent
18 composite fibers of the material of the present disclosure contain randomly
19 splayed, or split and spread, terminal ends along a length of about 35% or less
20 from one end.

21 At least about 90%, (by number) of the islands-in-sea type bicomponent
22 composite fibers of the material of the present disclosure contain randomly

1 splayed, or split and spread, terminal ends along a length of about 30% or less
2 from one end.

3 At least about 90%, (by number) of the islands-in-sea type bicomponent
4 composite fibers of the material of the present disclosure contain randomly
5 splayed, or split and spread, terminal ends along a length of about 25% or less
6 from one end.

7 At least about 90%, (by number) of the islands-in-sea type bicomponent
8 composite fibers of the material of the present disclosure contain randomly
9 splayed, or split and spread, terminal ends along a length of about 20% or less
10 from one end.

11 At least about 90%, (by number) of the islands-in-sea type bicomponent
12 composite fibers of the material of the present disclosure contain randomly
13 splayed, or split and spread, terminal ends along a length of about 15% or less
14 from one end.

15 At least about 90%, (by number) of the islands-in-sea type bicomponent
16 composite fibers of the material of the present disclosure contain randomly
17 splayed, or split and spread, terminal ends along a length of about 10% or less
18 from one end.

19 At least about 95%, (by number) of the islands-in-sea type bicomponent
20 composite fibers of the material of the present disclosure contain randomly
21 splayed, or split and spread, terminal ends along a length of about 50% or less
22 from one end.

1 At least about 95%, (by number) of the islands-in-sea type bicomponent
2 composite fibers of the material of the present disclosure contain randomly
3 splayed, or split and spread, terminal ends along a length of about 45% or less
4 from one end.

5 At least about 95%, (by number) of the islands-in-sea type bicomponent
6 composite fibers of the material of the present disclosure contain randomly
7 splayed, or split and spread, terminal ends along a length of about 40% or less
8 from one end.

9 At least about 95%, (by number) of the islands-in-sea type bicomponent
10 composite fibers of the material of the present disclosure contain randomly
11 splayed, or split and spread, terminal ends along a length of about 35% or less
12 from one end.

13 At least about 95%, (by number) of the islands-in-sea type bicomponent
14 composite fibers of the material of the present disclosure contain randomly
15 splayed, or split and spread, terminal ends along a length of about 30% or less
16 from one end.

17 At least about 95%, (by number) of the islands-in-sea type bicomponent
18 composite fibers of the material of the present disclosure contain randomly
19 splayed, or split and spread, terminal ends along a length of about 25% or less
20 from one end.

21 At least about 95%, (by number) of the islands-in-sea type bicomponent
22 composite fibers of the material of the present disclosure contain randomly

1 splayed, or split and spread, terminal ends along a length of about 20% or less
2 from one end.

3 At least about 95%, (by number) of the islands-in-sea type bicomponent
4 composite fibers of the material of the present disclosure contain randomly
5 splayed, or split and spread, terminal ends along a length of about 15% or less
6 from one end.

7 At least about 95%, (by number) of the islands-in-sea type bicomponent
8 composite fibers of the material of the present disclosure contain randomly
9 splayed, or split and spread, terminal ends along a length of about 10% or less
10 from one end.

11 Figure 2 is a scanning photograph of an example of material of the
12 present disclosure wherein randomly splayed ends of the bicomponent
13 composite fibers is illustrated.

14 The material of the present disclosure alternatively contains islands-in-sea
15 type bicomponent composite fibers wherein at least about 85% to about 95% (by
16 number) of the bicomponent composite fibers contain randomly splayed terminal
17 ends along a length of about 40% or less from one end. The material of the
18 present disclosure alternatively contains islands-in-sea type bicomponent
19 composite fibers wherein at least about 85% to about 95% (by number) of the
20 bicomponent composite fibers contain randomly splayed terminal ends along a
21 length of about 30% or less from one end.

22 One average, a material of the present disclosure may contain islands-in-
23 sea type bicomponent composite fibers wherein about 100% (by number) of the

1 bicomponent composite fibers contain randomly splayed terminal ends along a
2 length of about 20% or less from one end.

3 The exemplary method of the present disclosure has produced a
4 distribution of fibers containing randomly splayed terminal ends along a length of
5 about 0% to about 10% from the end of the fiber in about 50% (by number) of the
6 fibers, fibers containing randomly splayed terminal ends along a length of about
7 10% to about 20% from the end of the fiber in about 40% (by number) of the
8 fibers, and fibers containing randomly splayed terminal ends along a length of
9 about 20% to about 100% from the end of the fiber in about 10% (by number) of
10 the fibers.

11 The bicomponent composite fibers of the material of the present
12 disclosure are preferably randomly arranged.

13 The percent by number of fibers of the present disclosure containing
14 randomly splayed terminal ends may be evaluated by light microscope
15 (Amscope) at 180X power with a 1 mm calibration scale (NIST) in conjunction
16 with a video camera (Amscope 3.0 megapixel) and suitable video analysis
17 software, such as for example, Version 3.0.12.498 Amscope video software
18 calibrated to 180X.

19 A swab of the present disclosure, which includes material of the present
20 disclosure, may be any shape adapted for collection, and optional retention, of
21 biological samples from a host directly or already collected biological fluid or
22 sample. Shapes and sizes of such devices are known in the art. The swab of
23 the present disclosure is constructed of materials known in the art, such as

1 acrylonitrile-butadiene-styrene (ABS). The swab of the present disclosure is
2 such that the material of the present disclosure may be attached to the applicator
3 of the swab through an adhesive during a flocking technique known in the art.

4 An applicator of the swab of the present disclosure may be a rod or rod-
5 like thermoplastic substrate wherein one end is coated, partially, substantially or
6 completely, with an adhesive to anchor or hold fibers of the present disclosure to
7 the substrate in an initial arrangement generally perpendicular to the substrate
8 and generally parallel to adjacent fibers to thereby create, for example, a bristle
9 or bristly end on the substrate.

10 In a method of making devices according to the present disclosure,
11 individual, loose or connected substrate, such as applicator shafts, sticks or rods
12 have adhesive applied by at least one adhesive applicator container, block, head,
13 nozzle, or roller by, for example, spraying, dipping, rolling, printing or a
14 combination thereof, optionally in a metered fashion, under pressure or by
15 gravity, and in a manner which may or may not include any combination of linear
16 and/or rotational, such as by axial rotation or spinning, of the adhesive applicator
17 relative to the applicator.

18 In the flocking technique of the present disclosure, an electric field of
19 alternating or direct current is applied to the fibers in a manner known in the art to
20 organize and transport charged fibers to opposite charged adhesive-covered
21 substrate such that the fibers are held in place by the tackiness or adhesive
22 strength of the adhesive, only in areas where the adhesive has been applied to
23 produce flock fiber tipped applicators, or swabs of the disclosure. The technique

1 may include movement of the substrate, linearly and/or rotationally, such as by
2 axial rotation or spinning, at any time or throughout the process of applying fibers
3 to the adhesive. Where further curing of the adhesive, such as by light or heat, is
4 required, the flock fiber tipped applicator swab may be treated with light and/or
5 heat so as to cure the adhesive.

6 Swabs of the disclosure may contain approximately 10^4 to approximately
7 10^{10} , or approximately 10^4 to approximately 10^9 , or approximately 10^4 to
8 approximately 10^8 , or approximately 10^4 to approximately 10^7 , or approximately
9 10^4 to approximately 10^6 , or approximately 10^4 to approximately 10^5 , flock fibers
10 per substrate.

11 Once applied and secured to the substrate of the disclosure by flocking,
12 the sea component of the bicomponent fibers adhered to the substrate or
13 applicator is partially extracted to the extent described herein, such as by
14 microwave radiation and sonication, to provide islands of the fibers which are
15 subsequently forced in to a random splayed formation, as described herein by
16 application of, for example, mechanical force, such as by blotting. Alternatively,
17 the sea component may be partially extracted to the extent described herein to
18 provide randomly arranged islands of the fibers by, for example, contacting,
19 applying or admixing with a heated alkali solvent or solution, which are
20 subsequently forced in to a random splayed formation, as described herein by
21 application of, for example, mechanical force, such as by blotting. A process of
22 the disclosure thereby forces substantially perpendicular flocked fibers at the tip
23 or end of the substrate or applicator device to a random arrangement with

1 randomly splayed or open islands of the original bicomponent fiber. The
2 resulting randomly splayed arrangement of the island fibers are alternatively
3 described as being in a flower arrangement as a flower flock.

4 The material of the disclosure may be made in a similar manner without
5 requiring securing of the material to the substrate wherein the sea component is
6 partially extracted and subsequent application of, for example, microwave
7 radiation and sonication, or partial extraction with heat and alkali, and
8 subsequent application of mechanical force, to produce the randomly splayed
9 fiber arrangement described herein.

10 Application of heat and alkali solutions or solvents are described herein as
11 a means of extracting the sea component of the bicomponent fiber. The choice
12 of extraction protocol is dependent of the relative solubility and properties of the
13 sea and island components such that other extraction protocols are
14 contemplated based on the bicomponent fiber materials described herein and as
15 are generally available.

16 The adhesive of the present disclosure is not particularly limited and
17 general and photo or heat cured acrylic-based, polyurethane-based, polyamide-
18 based, polyester-based, vinyl-based and/or two-part epoxy adhesives may be
19 used. Silicones, cyanoacrylates, polyurethanes and/or latex adhesives may be
20 used. Polyurethane adhesive are generally known and available, such as from
21 K&W Adhesive Products.

1 The swabs of the present disclosure are adapted or designed for
2 collection of, for example, biological samples from oral, nasal, ocular, rectal,
3 urethral, or vaginal orifices of a mammal, such as a human, or patient.

4 The swabs may be used and is designed for collection of a biological
5 specimen by contact with the fibers of the device such that the device may
6 collect, for example, about 35 to about 200 μ l, such as 40, 50, 60, 70, 80, 90,
7 100, 120, 130, 140, 150, 160, 170, 180 or 190 μ l, without causing damage or
8 substantial discomfort to the patient during specimen collection.

9 The swabs of the present disclosure is useful for and in a method of
10 collecting biological specimens. A swab of the present disclosure is of the type
11 containing a rod terminating with a tip covered in the fibers described herein to
12 allow absorption of said specimens, wherein the fibers cover or substantially
13 cover the tip in the form of a layer applied by means of flocking.

14 The present disclosure further provides a method of collecting a biological
15 sample which includes contacting a swab as described herein with a source of
16 biological material such that a sample of the material is retained by the swab.

17 The swabs of the disclosure may be provided, for example, as a
18 component part of a collection, transport, culture and/or transport kit or device
19 wherein additional specimen handling containers and/or devices are included
20 and the swab of the present disclosure is specially adapted to be integrated with
21 such other container and/or devices to assure, for example, specimen retention,
22 integrity and/or sterility.

1 The present disclosure provides a swab for collecting and releasing a
2 biological sample containing sea-island bicomponent fibers, wherein at least
3 about 85% of the fibers contain randomly splayed terminal ends of the islands of
4 said bicomponent fibers along a length of about 50% or less from said ends. The
5 swabs may further contain bicomponent fibers which are composed of a first
6 polyester sea material and a second polyester island material; the first polyester
7 may have a lower melting point than the second polyester and/or the first
8 polyester may have a greater solubility in alkaline solution than the second
9 polyester. The alkaline solution may more specifically be a sodium hydroxide
10 solution - the sodium hydroxide solution may contain about 5% to about 50% by
11 weight sodium hydroxide in water, or alternatively about 10% by weight sodium
12 hydroxide in water. The alkaline solution wherein the first polyester sea material
13 is more soluble than the second polyester sea material may be a heated alkaline
14 solution - the heated alkaline solution alternatively having a temperature of about
15 170°F to about 190°F, such as about 180°F.

16 The present disclosure provides a swab, wherein material described
17 herein is attached to an end portion of an applicator stick or rod. The material
18 may be adhered to the end of the applicator with an adhesive, and the adhesive
19 may be a photocurable acrylic adhesive or a polyurethane adhesive.

20 The bicomponent fibers of the present disclosure may be composed of a
21 polyethylene terephthalate sea material and a polyamide island material.

22 The bicomponent fibers of the present disclosure may be composed of or
23 contain 10-3000 island parts per fiber, 10-240 island parts per fiber, 10-64 island

1 parts per fiber, 10-37 island parts per fiber, 10-36 island parts per fiber, 10-24
2 island parts per fiber, and/or 24-36 island parts per fiber.

3 The present disclosure provides the fibrous material of the swab described
4 herein. The fibrous material may be incorporated separately as a part of a
5 device other than a swab, such as a filter or cleaning pad or brush.

6 The present disclosure provides a method of forming a swab of the
7 disclosure involving adhering the bicomponent fibers to an applicator, removing a
8 portion of the sea component of the bicomponent fibers in an alkaline solvent or
9 solution, and forming the randomly splayed fibers by mechanically separating the
10 fibers, such as by blotting, which have had the sea component removed.

11 A similar method is provided herein for formation of the material of the
12 disclosure involving removing a portion of the sea component of the bicomponent
13 fibers by microwaving and sonicating, or ultrasonic disruption of, said fibers.

14 The present disclosure provide a method of forming a swab of the
15 disclosure involving adhering the bicomponent fibers to an applicator rod or stick,
16 removing a portion of the sea component of the bicomponent fibers in a heated
17 alkaline solvent or solution, and forming the randomly splayed fibers by
18 mechanical action of mashing or blotting or force applied to the ends of the fibers
19 which have had the sea component removed.

20 A similar method is provided herein for formation of the material of the
21 disclosure involving removing a portion of the sea component of the bicomponent
22 fibers in a heated alkaline solvent or solution, and forming the randomly splayed

1 fibers by mechanical action of mashing or blotting or force applied to the ends of
2 the fibers which have had the sea component removed.

3 .

4

5 The following examples further illustrate the materials and methods of the
6 disclosure without limiting same.

7 EXAMPLE 1 - SWABS

8 A quantity of (about 30 or so) experimental medical swabs were prepared
9 from ABS plastic "sticks" of Puritan Medical Products (Guilford, ME) with 0.5 mm
10 long (0.020", nominal length, as determined by a Flock-In-Spect flock fiber length
11 optical measurement instrument) Nylon/PET sea/island type flock fiber. Two
12 adhesive systems were employed in these experimental fabrications; the
13 polyurethane rubber (K&W polyurethane adhesive - MECFLOCK L876/1,
14 MEDCODUR H5530 two part polyurethane adhesive, mixed 85 grams L876/1
15 resin and 15 grams H5530 hardener - product of Kissel and Wolf; cured 3 hours
16 at 110°C or else cured 16 hours at 80°C) and a UV photo-curable adhesive from
17 Puritan Medical Products.

18 The following materials and instruments were used in fabrication: ABS
19 (plastic) swab sticks (supplied by Puritan); Maag Flockmaschinen Motion (flock
20 activity) Tester SPG 1000; K & W adhesive in a shallow aluminum dish (adhesive
21 depth about 1 cm); photo-curable adhesive in light-blocked packet; flock screen
22 sifter; and a supply of Nylon/PET 0.5 mm long Flock fibers

1 The experimental swabs were fabricated as follows. The flock activity
2 tester's 4" diameter aluminum base plate is covered (by sifting) with about 2
3 grams of loose flock. This sample of loose flock was mounted on to the bottom
4 electrode pedestal of the Flock Activity Tester. The end of the swab sticks were
5 perpendicularly dipped into the fluid K & W adhesive to a depth of about 1 cm
6 and slowly removed to produce end-coated swab-sticks. Some swab samples
7 were made using photo-curable adhesive. Water-based acrylic (F1059B Lubrizol
8 Corp.) flock adhesive and other water based adhesives could be used but in
9 some applications may not be as advantageous in splitting methods under
10 investigation. A 3.5 KV/cm strength was applied to the DC electrodes of the
11 Flock Activity Tester (upflocking machine). This causes the flock fibers to align
12 themselves and actively move to the top electrode. As this flock is being
13 propelled from the bottom to the top electrode, the adhesive coated tip plastic
14 swab-stick is then placed in the "flock fiber cloud" about 1 cm from the bottom
15 electrode (source of the activated flock fibers). While in the "flock fiber cloud", the
16 swab-stick was slowly rotated by rolling the stick held in gripping fingers.

17 Flock fibers fully adhered to the saturate at the (adhesive wet) end of the
18 swab-stick after about a 2 to 5 second flock field immersion time. The swab
19 adhesive was subsequently cured.

20 Splitting studies were performed on the swab stick samples in the
21 following manner. In this procedure, the flocked end of the swab-stick was placed
22 into a 400 ml glass beaker containing 50 mls of 5% NaOH solution (enough
23 NaOH solution to cover the flocked end of the swab-stick). The beaker and swab

1 assembly was then placed in the Microwave Oven for 1 minute at high power.
2 The beaker and swab was then Sonicated for 1 minute (5 seconds on -5 seconds
3 off) at 60 power. The flocked swab-sticks were then thoroughly rinsed in tap
4 water. Photographs of the swabs unsplit and split swab-stick heads are show in
5 Figures 3 and 4. As an alternative to the use of a microwave and sonication,
6 heated alkaline solution may be used. Mechanical force is used at the ends of
7 the fibers to produce the randomly splayed ends.

8 The average amount of adhesive and the average amount of flock applied
9 to the ABS base (sticks) were determined by weight with the following results:
10 average weight of "Bare" ABS sticks: 0.5644 +/-0.00426 grams; average weight
11 of K & W Adhesive on "Sticks" before flocking: 0.0046 grams; and average
12 weight of PET/Nylon Flock on "Sticks": 0.0135 grams. With an average of 0.0135
13 grams of sea/island flock fiber on each "stick" this translates to approximately 1.2
14 X 10⁵ flock fibers per "stick".

15 The water "pick-up" capabilities of the flocked medical swabs was
16 determined by a procedure whereby a number of swab and "stick" materials were
17 first weighed (dry). Then this same series of flocked swabs and "sticks" were
18 immersed in room temperature (23°C) water (tips only) for 5 seconds and then
19 reweighed.

20 The per cent water pick-ups of the various swab configurations were then
21 compared and are presented in Table 1. The results in Table 1 demonstrate that
22 the "bare" ABS swab sticks pick-up or capture little or no water. The polyurethane
23 adhesive coated (tip only) swabs picked up or captures a little water indicating

1 that the adhesive is a more wettable surface than the "bare" ABS. The flocked
 2 fiber swab picked up or captured a measurable amount of water (8.95%) while
 3 the flocked and split fiber experimental swab picked up or captured the most
 4 water (9.25%). The flocked and split fiber swab sample will be expected to pick
 5 up or capture more water as compared with the un-split flocked swab if longer
 6 (1.0 mm) flock were used.

7 **Table 1**

Specimen Description *	Number of Replicates Tested	Average Weight -DRY- (grams)	Average Weight After Tip Water Dip (grams)	Average Water Pick-Up (grams)	Water Pick-Up (based on "dry" stick)
"Bare" Swab Sticks	12	0.5661 +/-0.0052	0.5665 +/-0.0049	0.0004	0.07 % (negligible)
Swab "Sticks" End Coated with Adhesive	13	0.5790 +/-0.0050	0.5802 +/-0.0049	0.0012	0.21 %
Experimental Swab (Not Split)	13	0.5888 +/-0.0062	0.6415 +/-0.0084	0.0527	8.95 %
Experimental Swabs (Split)	12	0.5913 +/-0.0047	0.6460 +/-0.0077	0.0547	9.25 %

8
 9 Several fiber material types (of sea/island fiber) have been evaluated. The
 10 nylon/PET (Kolon) and PET/PET (Kolon-Roje) fibers appear useful in the fiber
 11 flocked medical swab application of the present disclosure. While 0.5 mm long
 12 nylon/PET flock fiber were initially investigated, fibers of various sizes may be
 13 used and are contemplated.

14 A sea/island fiber splitting procedure has been developed involving the
 15 microwave oven processing of the flock fiber in a 5% NaOH solution followed by
 16 a sonication (ultrasonic disruption) treatment.

17 Two flock adhesives have been found to hold up to the chemical fiber
 18 splitting procedure. These were the two-package polyurethane (clear rubbery)

1 and the photo-curable (clear film plastic) systems. Other adhesives are
2 contemplated.

3 All literature and publications referred to and described herein are
4 incorporated herein in their entirety.

5

We claim:

1. A swab for collecting and releasing a biological sample comprising an applicator and sea-island bicomponent fibers, wherein at least about 85% of the fibers comprise randomly splayed terminal ends of the islands of said bicomponent fibers along a length of about 50% or less from said ends.
2. The swab of claim 1 wherein said bicomponent fibers comprise a first polyester sea material and a second polyester island material.
3. The swab of claim 2 wherein said first polyester has a lower melting point than said second polyester.
4. The swab of claim 2 wherein said first polyester has a greater solubility in alkaline solution than said second polyester.
5. The swab of claim 4 wherein the first polyester has a greater solubility in alkaline solution of sodium hydroxide, as compared to the second polyester.
6. The swab of claim 5 wherein the first polyester has greater solubility in an alkaline solution of sodium hydroxide solution containing about 5% to about 50% by weight sodium hydroxide in water, as compared to the second polyester.
7. The swab of claim 6 wherein the first polyester has greater solubility in an alkaline solution of about 10% by weight sodium hydroxide in water, as compared to the second polyester.
8. The swab of claim 4 wherein the first polyester has greater solubility in a heated alkaline solution as compared to the second polyester.

9. The swab of claim 8 wherein the first polyester has greater solubility in an alkaline solution heated to a temperature of about 170°F to about 190°F as compared to the second polyester.

10. The swab of claim 1 wherein the fibers are attached to an end portion of said applicator.

11. The swab of claim 10 wherein said fibers are adhered to said end portion with an adhesive.

12. The swab of claim 11 wherein said adhesive is selected from the group consisting of a photocurable acrylic adhesive and a polyurethane adhesive.

13. The swab of claim 1 wherein said bicomponent fibers comprise a polyethylene terephthalate sea material and a polyamide island material.

14. The swab of claim 1 wherein said bicomponent fibers comprise 10-3000 island parts per fiber.

15. The swab of claim 14 wherein said fibers comprise 10-240 island parts per fiber.

16. The swab of claim 14 wherein aid fibers comprise 10-64 island parts per fiber.

17. The swab of claim 14 wherein aid fibers comprise 10-37 island parts per fiber.

18. The swab of claim 14 wherein aid fibers comprise 10-36 island parts per fiber.

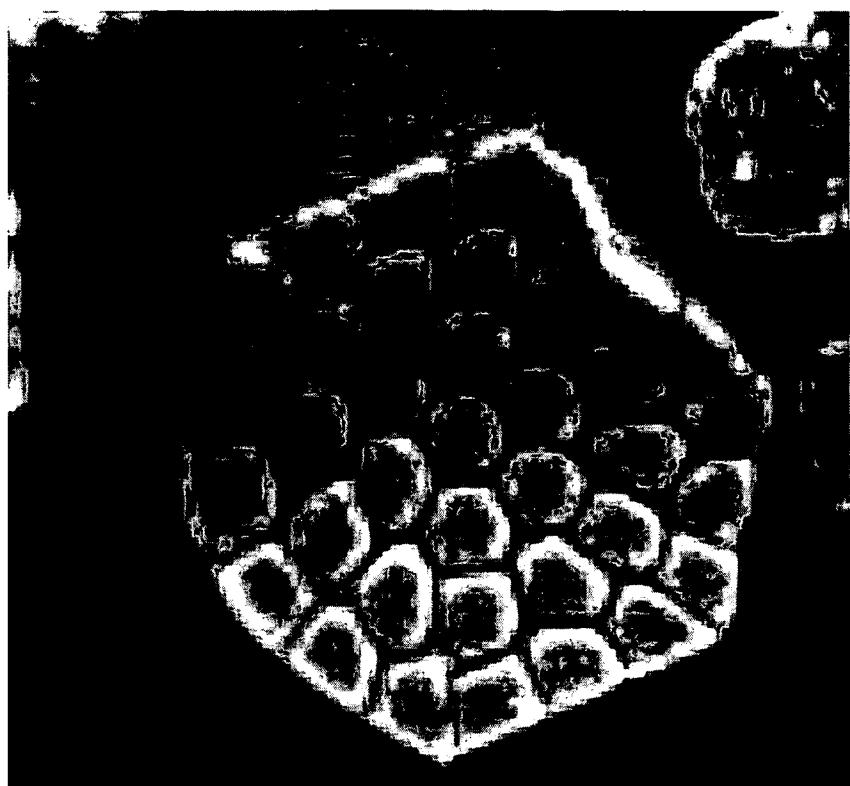
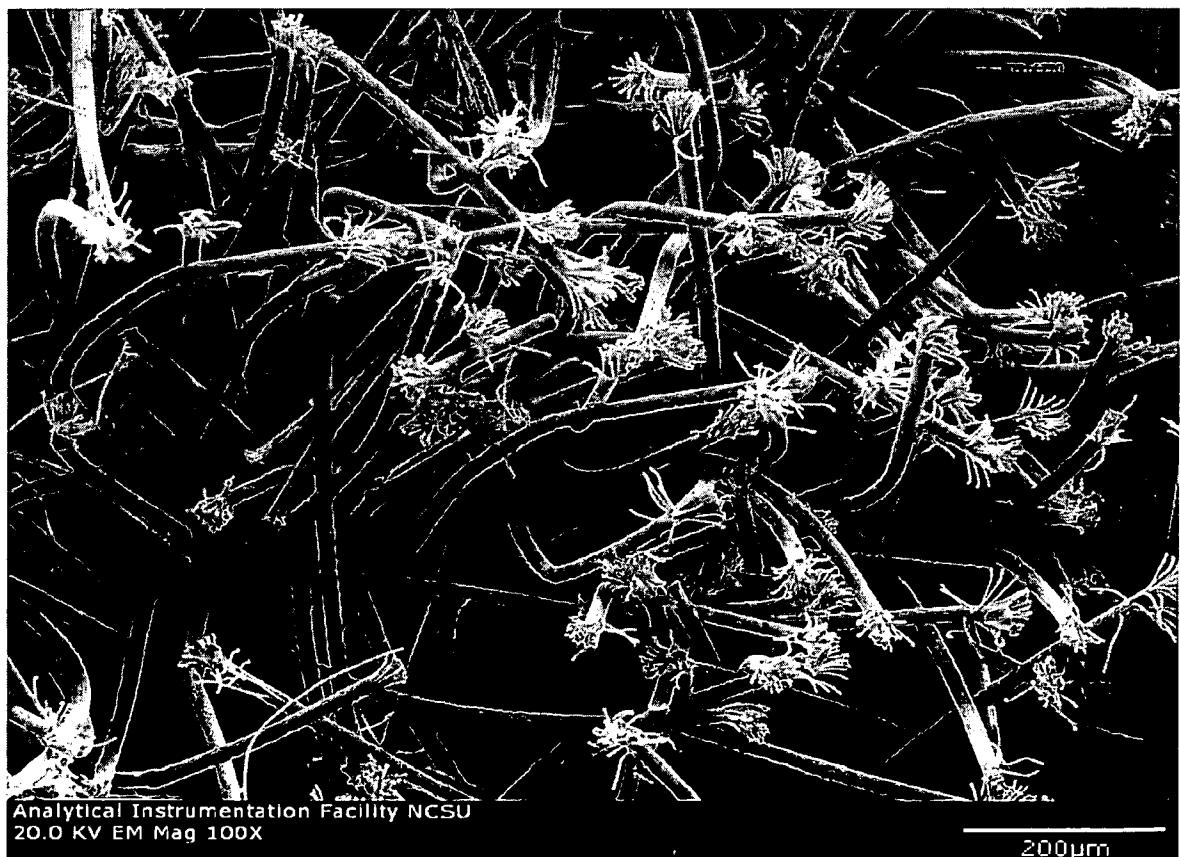
19. The swab of claim 14 wherein aid fibers comprise 10-24 island parts per fiber.

20. The swab of claim 14 wherein aid fibers comprise 24-36 island parts per fiber.

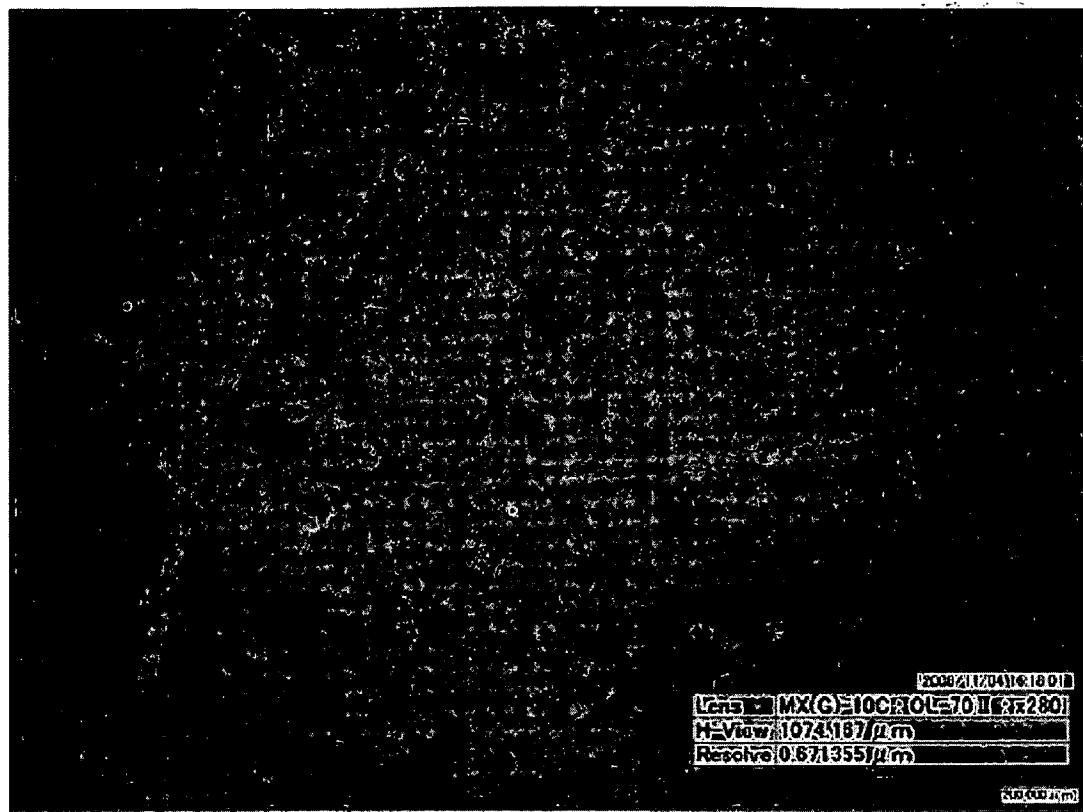
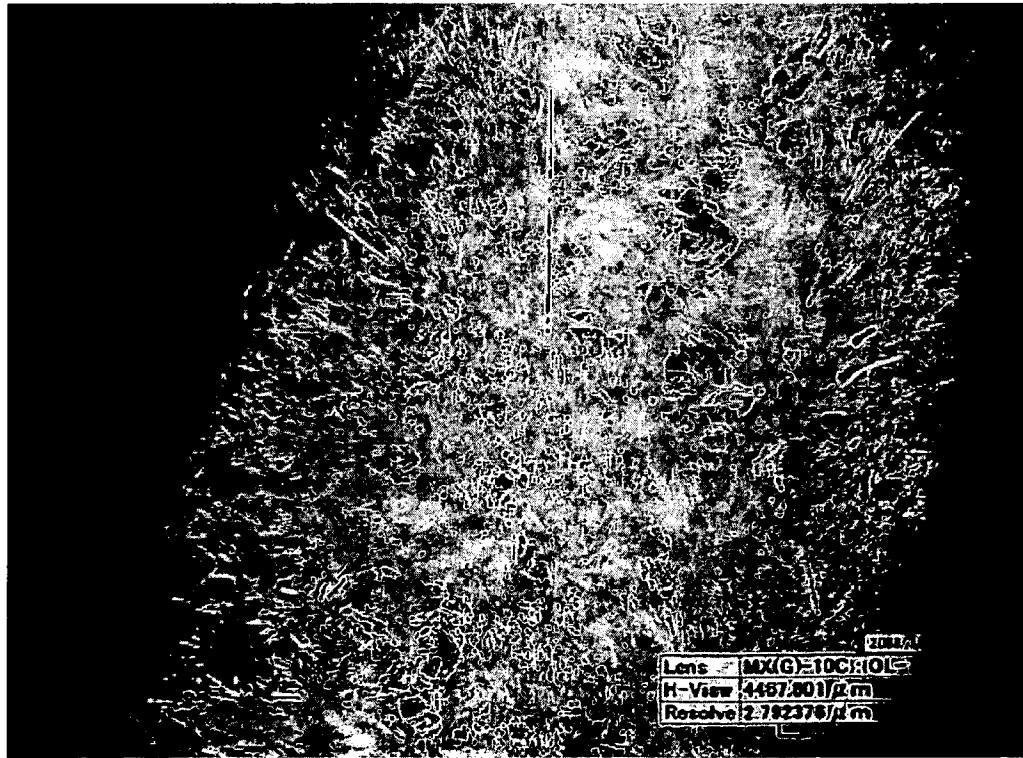
21. A method of forming the swab of claim 10 comprising adhering the bicomponent fibers to said applicator, removing a portion of the sea component of said bicomponent fibers in a heated alkaline solvent, and forming said randomly splayed fibers by application of mechanical force to the ends of said fibers which have had said sea component removed.

22. A method of collecting a biological sample comprising contacting the swab of claim 1 with a source of biological material such that a sample of the material is retained by the swab.

1/2

**FIG. 1****FIG. 2**

2/2

**FIG. 3****FIG. 4**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/002155**A. CLASSIFICATION OF SUBJECT MATTER****C12M 1/30(2006.01)i, D01F 8/14(2006.01)i, A61B 10/02(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

C12M 1/30; A61F 13/38; D01D 5/34

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility modelsElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal), Google, PubMed**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SAHBAEE BAGHERZADEH, A., Abrasion and Pilling Resistance of Nonwoven Fabrics Made from Bicomponent Fibers, Master dissertation, North Carolina State University, Raleigh, NC, USA, 2007 See abstract, pages 4, 13	1-22
A	FEDOROVA, N., Investigation of the utility of islands-in-the bicomponent fiber technology in the spunbond process, Doctoral dissertation, North Carolina State University, Raleigh, NC, USA, 2006 See abstract, pages 25, 29, 30, tables 5.10 and 5.11	1-22
A	US 2008-0208100 A1 (WOLFF, RANAN) 28 August 2008 See claims 1-46	1-22
A	WO 02-42528 A1 (KOLON INDUSTRIES, INC) 30 May 2002 See claims 1, 6-8, figures 2-4, abstract	1-22

 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
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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