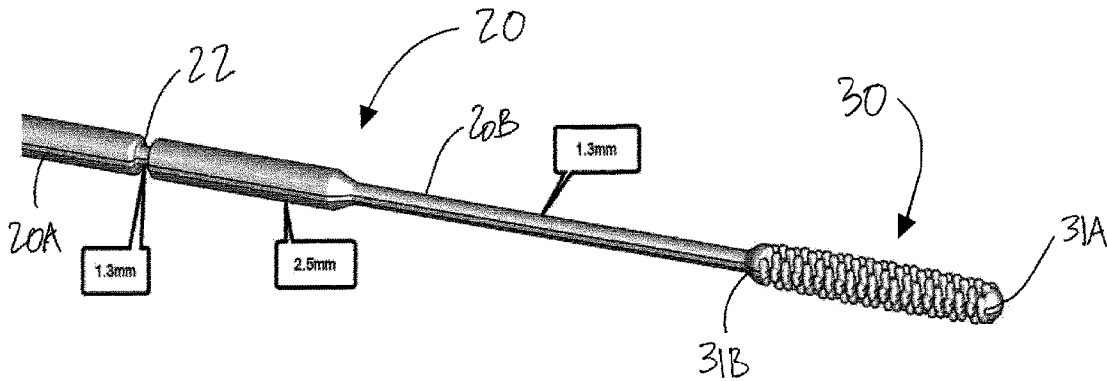




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(54) Titre : ECOUVILLON DE DIAGNOSTIC
(54) Title: DIAGNOSTIC SWAB



(57) Abrégé/Abstract:

A diagnostic swab comprises a monolithic molded body defining an elongated handle, and an adsorbing member at an end of the elongated handle, the adsorbing member having a plurality of lobes projecting from a shaft. A contour envelope of the adsorbing member defines a truncated prolate spheroid. The adsorbing member may have a junction plane. Halves of the adsorbing member separated by the junction plane each define a single-mold-cavity imprint surface.

ABSTRACT

A diagnostic swab comprises a monolithic molded body defining an elongated handle, and an adsorbing member at an end of the elongated handle, the adsorbing member having a plurality of lobes projecting from a shaft. A contour envelope of the adsorbing member defines a truncated prolate spheroid. The adsorbing member may have a junction plane. Halves of the adsorbing member separated by the junction plane each define a single-mold-cavity imprint surface.

DIAGNOSTIC SWAB

TECHNICAL FIELD

[0001] The application relates to diagnostic swabs used in sample collection in the nose or throat, the diagnostic swab also known as sample or specimen collection swabs, nasopharyngeal swab, oropharyngeal swab, nasal swab, among other names.

BACKGROUND

[0002] A diagnostic swab is a medical device used for collecting samples of human secretions, such as nasal secretions, for subsequent analysis of the secretions to detect the presence of organisms or markers for a disease, for example. The diagnostic swabs may have other names, including among others sample or specimen collection swabs, nasopharyngeal swab, oropharyngeal swab, nasal swab. The diagnostic swabs conventionally have an elongated handle or stick at the end of which is an adsorbing material, the adsorbing material for collecting the sample.

[0003] In typical use, the diagnostic swab is entered into a human cavity, such as a nostril. The diagnostic swab, with the adsorbing material leading, may then be moved to a sampling region, such as the nasopharynx. The adsorbing material is then rubbed against the soft tissue of the target region for the secretions to be adsorbed onto the adsorbing material. The use of the diagnostic swab may be uncomfortable for people being tested, notably by the larger dimensions of the adsorbing material, the rigidity of the diagnostic swab. Moreover, to ensure that a suitable sample is obtained, people being tested may have to endure a sample collection that lasts several seconds.

SUMMARY

[0004] In one aspect, there is provided a diagnostic swab comprising: a monolithic molded body defining an elongated handle, and an adsorbing member at an end of the elongated handle, the adsorbing member having a plurality of lobes projecting from a

shaft, wherein a contour envelope of the adsorbing member defines a truncated prolate spheroid.

[0005] In another aspect, there is provided a diagnostic swab comprising: a monolithic molded body defining an elongated handle, and an adsorbing member at an end of the elongated handle, the adsorbing member having a plurality of lobes projecting from a shaft, wherein the adsorbing member has a junction plane, and wherein halves of the adsorbing member separated by the junction plane each define a single-mold-cavity imprint surface.

DESCRIPTION OF THE DRAWINGS

[0006] Reference is now made to the accompanying figures in which:

[0007] Fig. 1 is a perspective view of a diagnostic swab in accordance with the present disclosure;

[0008] Fig. 2 is an elevation view of the diagnostic swab of Fig. 1;

[0009] Fig. 3 is an enlarged view of a sampling half of the diagnostic swab of Fig. 1;

[0010] Fig. 4 is a first perspective view of an adsorbing member of the diagnostic swab of Fig. 1;

[0011] Fig. 5 is a second perspective view of the adsorbing member of the diagnostic swab of Fig. 1;

[0012] Fig. 6A is an elevation view of the adsorbing member of Fig. 4;

[0013] Fig. 6B is a longitudinal section view of the adsorbing member of Fig. 6A;

[0014] Fig. 6C is another longitudinal section view of the adsorbing member of Fig. 6A;

[0015] Fig. 7A is a first cross-section view of the adsorbing member of Fig. 6A taken along line 7A-7A;

[0016] Fig. 7B is a first cross-section view of the adsorbing member of Fig. 6A taken along line 7B-7B;

[0017] Fig. 7C is a first cross-section view of the adsorbing member of Fig. 6A taken along line 7C-7C; and

[0018] Fig. 8 is an elevation view of the adsorbing member of Fig. 4, with exemplary ejection surfaces.

DETAILED DESCRIPTION

[0019] Referring to the drawings and more particularly to Figs. 1 and 2, a diagnostic swab in accordance with an embodiment of the present disclosure is generally shown at 10. The diagnostic swab 10 may also be known as sample or specimen collection swabs, nasopharyngeal swab, oropharyngeal swab, nasal swab, among other possible names. For simplicity and consistency, the expression “diagnostic swab” will be used, although other names could apply. The diagnostic swab 10 is particularly well suited for use as a nasopharyngeal swab, oropharyngeal swab, mid-turbinate swab, i.e., to collect secretions in the nasopharynx or in the pharynx or throat, etc, due to the features described hereinbelow. However, other uses are contemplated as well.

[0020] The diagnostic swab 10 may be generally described as having an elongated stick or handle 20, and an adsorbing member 30 at the sampling end of the handle 20. The handle 20 is the part of the diagnostic swab 10 that is manipulated by a tester, and that provides the reach for the adsorbing member 30 to collect a sample by contact, by adsorption. In an embodiment, the diagnostic swab 10 is a monoblock component, i.e., fabricated from a single material. The diagnostic swab 10 may be molded from a polymer, though it is considered to use other fabrication processes, such as 3D printing, material deposition, etc. In an embodiment, the diagnostic swab 10 is molded using acetal (i.e., acetal polymer), such as Delrin SC655 NC010 as one particular example.

Other materials could be used, for instance polyamide (nylon), as an example among numerous others. Medical grade polymers with low coefficients of friction are well suited to be used for the diagnostic swab 10, though not necessary. The plastic density of the body of the diagnostic swab 10 is from 0.8-1.5 g/cm³.

[0021] The handle 20 may have a uniform cross-section as a possibility, but is shown as having two different sections, i.e., a section 20A and a section 20B. In an embodiment, the section 20A may be the portion of the diagnostic swab 10 that is manipulated by a tester's fingers. As shown, the section 20A may have a circular cross-section, for instance with a 2.5 mm ± 0.5 mm diameter. As another possibility, the section 20A may have generally flat surface(s), or otherwise a non-round sectional shape, so as not to have the section 20A rotate in the tester's fingers. Exemplary cross-section shapes include obround, oblong, oval, rectangular, polygonal and even round, though other shapes are considered as well. Section 20B may have a smaller cross-section. For example, section 20B has a circular cross-section with a diameter of 1.3 mm + 0.1 mm – 0.4 mm, i.e., with a maximum diameter or cross-sectional dimension of 1.4 mm in an embodiment. The diameter could be even lower for child configurations (1.0-1.2 mm). Other shapes are contemplated, including polygonal, squircle, square, etc. As seen in Fig. 3, a frusto-conical portion may be at the junction between the section 20A and the section 20B.

[0022] Therefore, with the greater diameter of section 20A, the handle 20 may exhibit greater stiffness in the manipulated part of the handle 20. On the other hand, with the smaller diameter of section 20B, the handle 20 may exhibit greater flexibility in the penetrating part of the handle 20. This may allow the handle 20 to flex in proximity to the adsorbing member 30, as the adsorbing member 30 contacts surrounding soft tissue in being moved to the target location. The flexibility may reduce a patient's discomfort.

[0023] The handle 20 may have other various features, including an end flange 21 at the trailing end of the diagnostic swab 10. The end flange 21 may define a stop assisting in the manipulation of the diagnostic swab 10. In another embodiment, the handle 20 has a break-out segment 22 in the section 20B. The break-out segment 22 is

a local reduction in cross-sectional dimensions to form a point of weakness in the handle 20. Therefore, by applying forces on opposite sides of the segment 22, the handle 20 with snap broken. Consequently, the dimension of the diagnostic swab 10 may be reduced, to facilitate its storage, its manipulation, its sampling, once a sample has been collected with the adsorbing member 30. In an embodiment, the segment 22 is generally halfway in the diagnostic swab 10. For example, the diagnostic swab 10 may have a length of 150 mm +50 mm -25 mm, and the segment may be at 70 mm ± 20 mm from the leading end of the diagnostic swab 10 (i.e., at the adsorbing member 10). The dimensions can vary based on the age group of the tested. For example, the segment 22 may be at 40-65 mm from the leading end for child swab 10. The end flange 21 and/or the break-out segment 22 may be optional.

[0024] Referring now to Figs. 3 to 5, the adsorbing member 30 is shown in greater detail. Though the expression “adsorbing member” is used, other expressions may be used to describe the leading end member of the diagnostic swab 10, such as swab tip, collecting member, sampling member, etc. The adsorbing member 30 is tasked with collecting sample secretions or liquid bodily fluids, as per the intended use of the diagnostic swab 10. The adsorbing member 30 may be part of the monoblock construction of the diagnostic swab 10. In another embodiment, the adsorbing member 30 is monoblock in and of itself, and is connected to a separate stick or handle.

[0025] As shown in Figs. 6B and 6C, the adsorbing member 30 has a shaft 31. The shaft 31 is a longitudinal continuation of the handle 20. In an embodiment, the shaft 31 is coaxial with the handle 20. The shaft 31 may have a circular cross-section, for instance with the same diameter or cross-sectional dimensions as the section 20B of the handle 20, though other dimensions are possible. A nose 31A may be at the leading end of the shaft 31. In an embodiment, the nose 31A is a truncated sphere portion. Other shapes are possible, but the nose 31A may advantageously be without sharp edges. A frustoconical segment 31B may optionally be at the junction between the adsorbing member 30 and the handle 20. Other tapering features may be present from the adsorbing member 30 to the handle 20. Such tapering features, including the frustoconical segment 31B may be said to be part of the handle 20 as well.

[0026] Rows of lobes projecting generally radially from the shaft 31, i.e., in a plane to which the longitudinal axis of the shaft 31 is normal according to an embodiment. The lobes are shown as A1 and B1, and form the contact portions of the adsorbing member 30, in that the lobes come into rubbing contact with the soft tissue in the target region. The lobes A1 and B1 may have other names, such as bristles, fibers, spokes, rays, fingers, etc. As best observed from Figs. 5 and 6A, the rows of lobes may exhibit a variation in dimensions, so as to give the adsorbing member 30 an oval outline or envelope E (Fig. 6A). In terms of three-dimensional shape, the outline of the adsorbing member 30 may resemble a central portion of a football ball, or a rugby ball, and may be regarded as a prolate spheroid, or a truncated prolate spheroid, if looking at an envelope E passing through the tips of the lobes. Such a shape may reduce the invasiveness of the diagnostic swab 10, by having a smaller dimension at the nose 31A, and then increasing in diameter toward a central portion of the adsorbing member 30, to optimize contact with surrounding soft tissue and to increase adsorption volume capacity. The subsequent tapering in the trailing direction may ease the removal of the diagnostic swab 10 from the nasal cavity. In an embodiment, the smallest diameter of the envelope E is 2.7 mm +0.2 mm -0.4 mm, at the leading end and the trailing end of the envelope E. The largest diameter may be 3.0 mm +0.1 mm -0.5 mm. Other dimensions are considered, notably as a function of the contemplated. For example, if the diagnostic swab 10 is used as an oropharyngeal swab, its dimensions may be greater. Other shapes are contemplated for the envelope E, such as a frusto-cone, a cylinder, etc.

[0027] In an embodiment, with reference to Figs. 6A-6C and 7A-7C, the lobes are arranged in two types of rows, rows 32A (Fig. 7B) and rows 32B (Fig. 7C). The rows 32A and 32B are shown in the figures as being in an alternating sequence, 32A, 32B, 32A, 32B, etc, and spaced apart by segments of the shaft 31 without lobes, as shown in Fig. 7A. The rows 32A and 32B give the prolate spheroid shape to the adsorbing member 30.

[0028] With reference to the X-Y referential shared by Figs. 7A-7C, in the row 32A (Fig. 7B), there are six lobes A1, i.e., three extending in the Y direction, and three extending in the negative Y direction. Two lobes A2 extend in the X direction and

negative X direction. Therefore, row 32A has eight lobes. The row 32A may have a symmetry line SX passing through a center of the row 32A and parallel to the X direction. The row 32A may also have a symmetry line SY passing through a center of the row 32A and parallel to the Y direction. When split along the symmetry line SX parallel to the X direction, the row 32A forms two symmetrical halves that may be formed by a two-cavity mold, shown as M1 and M2. The halves may also be asymmetrical. In the molding process, a relative translation occurs between cavities M1 and M2, along direction Y. Consequently, from the symmetry line SX, and toward direction Y or negative Y, the upper and lower halves of the row 32A taper, respectively. Stated differently, the upper half of the row 32A has a demoldable surface, demoldable in a mold translation direction parallel to direction Y. The mold translation direction may be said to be parallel to a normal of a plane separating the upper half from the lower half. Even though the expression "half" is used, the upper half may define more or less than half of the volume of the row 32A, with the lower half of the row 32A forming the other part of the volume of the row 32A. Likewise, the lower half of the row 32A also has a demoldable surface, demoldable in a mold translation direction parallel to direction negative Y. The mold translation direction may be said to be parallel to a normal of a plane separating the lower half from the upper half.

[0029] Still with reference to the X-Y referential shared by Figs. 7A-7C, in the row 32B (Fig. 7C), there are four lobes B1, i.e., two extending in the Y direction, and two extending in the negative Y direction. Two lobes B2 extend in the X direction and in the negative X direction. Hence row 32B has six lobes. The row 32B may also have a symmetry line SX passing through a center of the row 32B and parallel to the X direction. The row 32B may also have a symmetry line SY passing through a center of the row 32B and parallel to the Y direction. When split along the symmetry line SX parallel to the X direction, the row 32B forms two symmetrical halves that may be formed by the same two-cavity mold with cavities M1 and M2. The halves of the row 32B may also be asymmetrical. The relative translation occurs between cavities M1 and M2, along direction Y. Consequently, from the symmetry line SX, and toward direction Y or negative Y, the upper and lower halves of the row 32B taper, respectively. Stated differently, the upper half of the row 32B has a demoldable surface, demoldable in a mold translation direction parallel to direction Y. The mold translation direction may

be said to be parallel to a normal of a junction plane separating the upper half from the lower half. Even though the expression “half” is used, the upper half may define more or less than half of the volume of the row 32B, with the lower half of the row 32B forming the other part of the volume of the row 32B. Likewise, the lower half of the row 32B also has a demoldable surface, demoldable in a mold translation direction parallel to direction negative Y. The mold translation direction may be said to be parallel to a normal of the junction plane separating the lower half from the upper half. The junction plane may be the mold line. The lower half and the upper half may each be said to be a mold cavity imprint or have a single-mold-cavity imprint surface, i.e., a negative of the mold cavity surface.

[0030] In order to increase a peripheral contact coverage, the lobes of the rows 32A and 32B overlap one another, as best observed from Fig. 5. More specifically, by the rows 32A and 32B having a different number of lobes, an outer periphery of the adsorbing member 30 may display a sequence of lobes A1-B1-A1-B1-A1, from a POV on the longitudinal axis of the diagnostic swab 10 – parallel to axis Z in Fig. 6A, for pairs of adjacent rows 32A and 32B. The flanks of pairs of adjacent rows 32A and 32B may display a sequence of A2-B2-A2. The sequences A1-B1-A1-B1-A1 and A2-B2-A2 may be referred to as a circumferential offset of tips of the lobes.

[0031] In an embodiment, as shown in the figures, none of the lobes of the adsorbing member 30 has sharp exposed edges. The lobes have rounded geometries, at least at their free ends coming into contact with the soft tissue. A thickness of the lobes A1, B1, A2, B2 is 0.6 [µm] mm or less (though a thickness of 0.7 mm is contemplated), the thickness being in a longitudinal direction of the diagnostic swab 10. If the adsorbing member 30 has a spheroid shape as shown in the figures, the rows 32A may have different sizes. In an embodiment, all rows 32A are geometrically similar, though the rows 32A may also be geometrically different. Likewise, in an embodiment, all rows 32B are geometrically similar, though the rows 32B may also be geometrically different. It is also contemplated to have a third row different than the two others, a fourth row, etc.

[0032] In order to preserve some flexibility yet ensure suitable sample collection, the rows 32A and 32B are spaced apart, so as to create voids or empty volumes between them, in which the shaft 31 is without lobes, as in Figs. 6B, 6C and 7A. In an embodiment, the proportion of such void or empty volume is 44% \pm 20%. The proportion of void can be defined as the percentage of free space relative to the total volume of envelope E, from the leading row to the trailing row, in the adsorbing member 30.

[0033] Referring to Fig. 8, to facilitate the demolding, also known as the ejection, abutment zones 35 may be present. The abutment zones 35 may be generally flat, and may be directly on the shaft 31, for ejectors in the mold to apply an ejection force on the adsorbing member 30. The abutment zones 35 are optional. Three of the abutment zones 35 are shown, but there may be fewer or more depending on the length of the shaft 31.

[0034] In an embodiment, the diagnostic swab 10 may be described as being a monoblock, single-shot molding swab (i.e., a single mold cavity translates) of complete nasal swabs with minimum feature size, high quality and repeatability combined with high flexibility. If the diagnostic swab 10 is molded, the molding manufacturing allows repeatability and thinner elements with no potential sharp edges in comparison to other manufacturing techniques.

[0035] The above description is meant to be exemplary only, and one skilled in the art will recognize that changes may be made to the embodiments described without departing from the scope of the invention disclosed. Still other modifications which fall within the scope of the present invention will be apparent to those skilled in the art, in light of a review of this disclosure, and such modifications are intended to fall within the appended claims.

CLAIMS

1. A diagnostic swab comprising:
a monolithic molded body defining
an elongated handle, and
an adsorbing member at an end of the elongated handle, the adsorbing member having a plurality of lobes projecting from a shaft,
wherein the adsorbing member has a junction plane, and wherein halves of the adsorbing member separated by the junction plane each define a single-mold-cavity imprint surface.
2. The diagnostic swab according to claim 1, wherein the elongated handle has at least a first section and a second section, the first section being a trailing section having a first diameter, the second section being between the first section and the adsorbing member and having a second diameter, and wherein the first diameter is greater than the second diameter.
3. The diagnostic swab according to claim 2, wherein the first section has a circular cross-section and the first diameter has a dimension of $2.5 \text{ mm} \pm 0.5 \text{ mm}$.
4. The diagnostic swab according to any one of claims 2 and 3, wherein the second section has a circular cross-section and the second diameter has a dimension of $1.3 \text{ mm} + 0.1 \text{ mm} - 0.4 \text{ mm}$.
5. The diagnostic swab according to any one of claims 1 to 4, wherein a break-out segment is defined in the handle.
6. The diagnostic swab according to any one of claims 1 to 5, wherein the adsorbing member has a nose at a leading end, the nose having a truncated sphere shape.
7. The diagnostic swab according to any one of claims 1 to 6, wherein a frusto-cone is at a junction between the adsorbing member and the handle.

8. The diagnostic swab according to any one of claims 1 to 7, wherein the plurality of lobes are arranged in at least a first row and a second row spaced apart by voids around the shaft.
9. The diagnostic swab according to claim 8, wherein the adsorbing member has an alternating sequence of the first row and of the second row.
10. The diagnostic swab according to any one of claims 8 and 9, wherein the first row has eight of the lobes, and the second row has six lobes.
11. The diagnostic swab according to any one of claims 8 to 10, wherein tips of at least some of the lobes of the first row are circumferentially offset from tips of the at least some of the lobes of the second row.
12. The diagnostic swab according to any one of claims 1 to 11, wherein the adsorbing member has a proportion of void of $44\% \pm 20\%$.
13. The diagnostic swab according to any one of claims 1 to 12, wherein the lobes have a thickness of at most 0.7 mm in a longitudinal direction of the handle.
14. The diagnostic swab according to any one of claims 1 to 13, wherein the contour envelope has a smallest diameter of 2.7 mm +0.2 mm -0.4 mm.
15. The diagnostic swab according to any one of claims 1 to 14, wherein the contour envelope has a biggest diameter of 3.0 mm +0.1 mm -0.5 mm.
16. The diagnostic swab according to any one of claims 1 to 15, wherein the monolithic molded body is an acetal polymer or polyamide body.

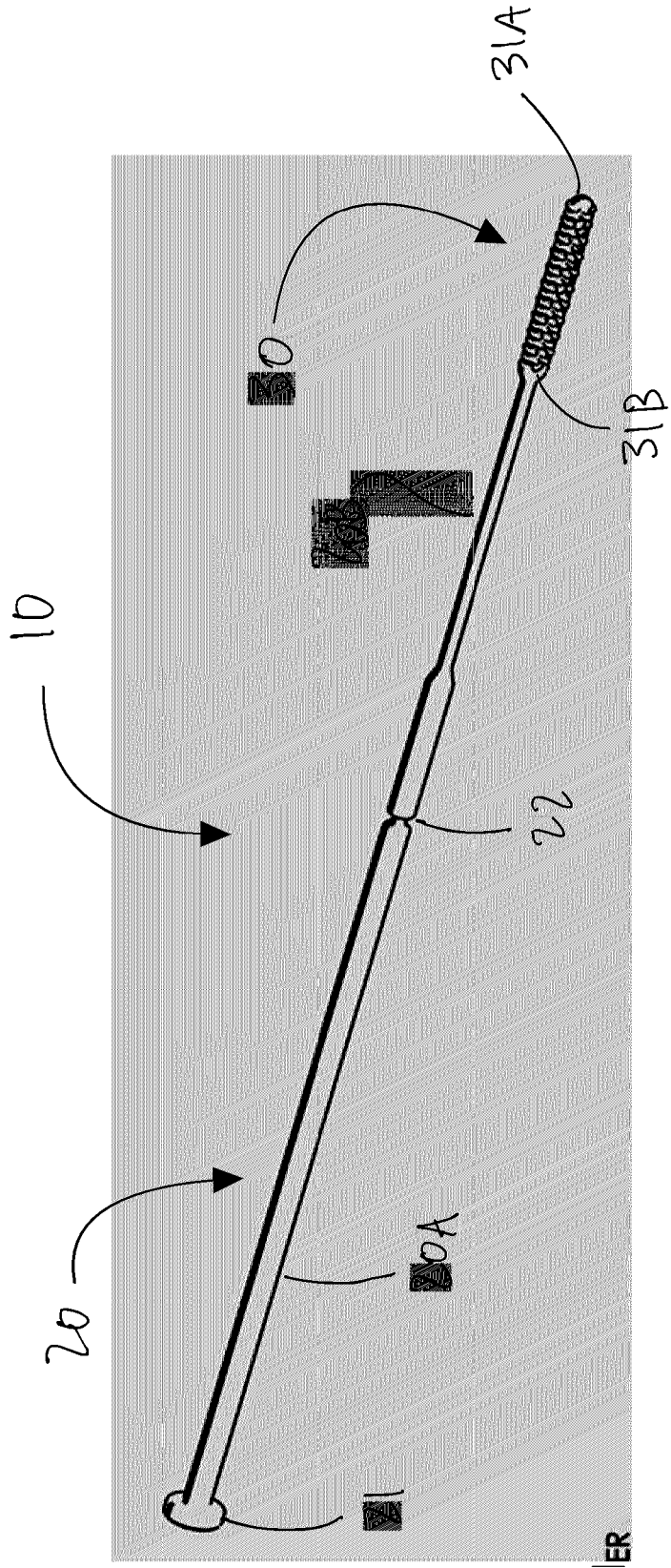


FIG. 1

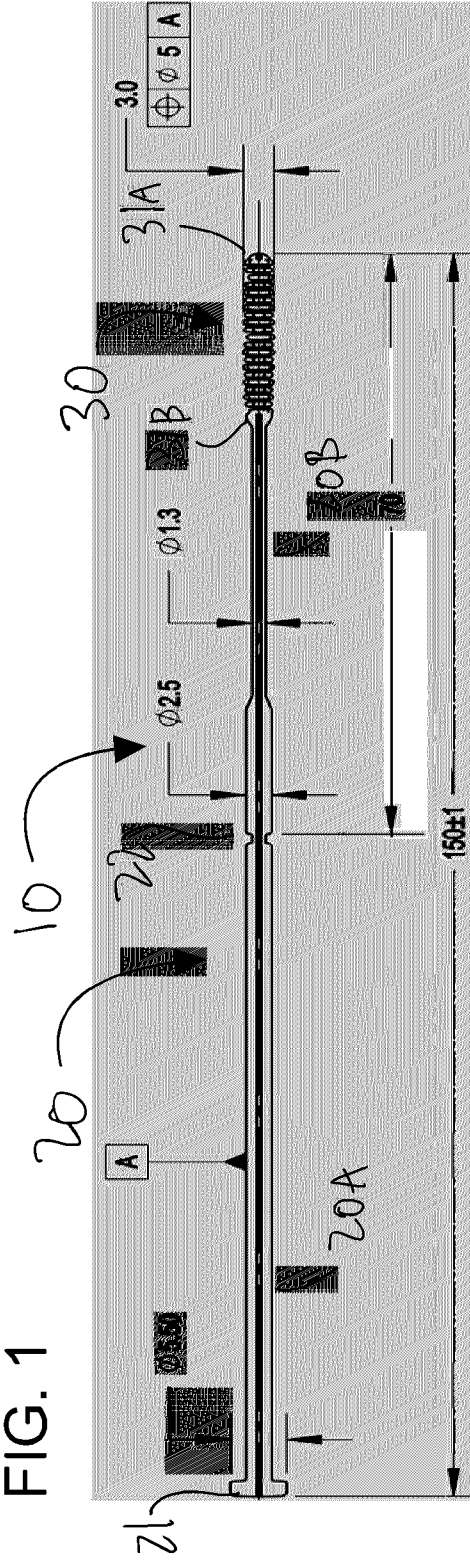


FIG. 2

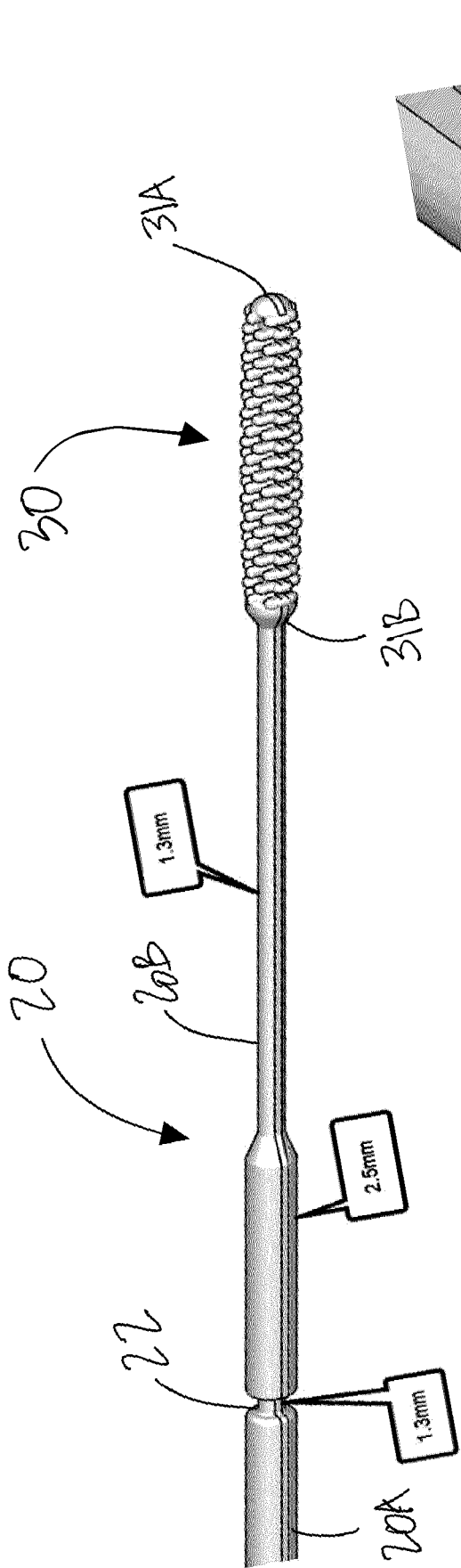


FIG. 3

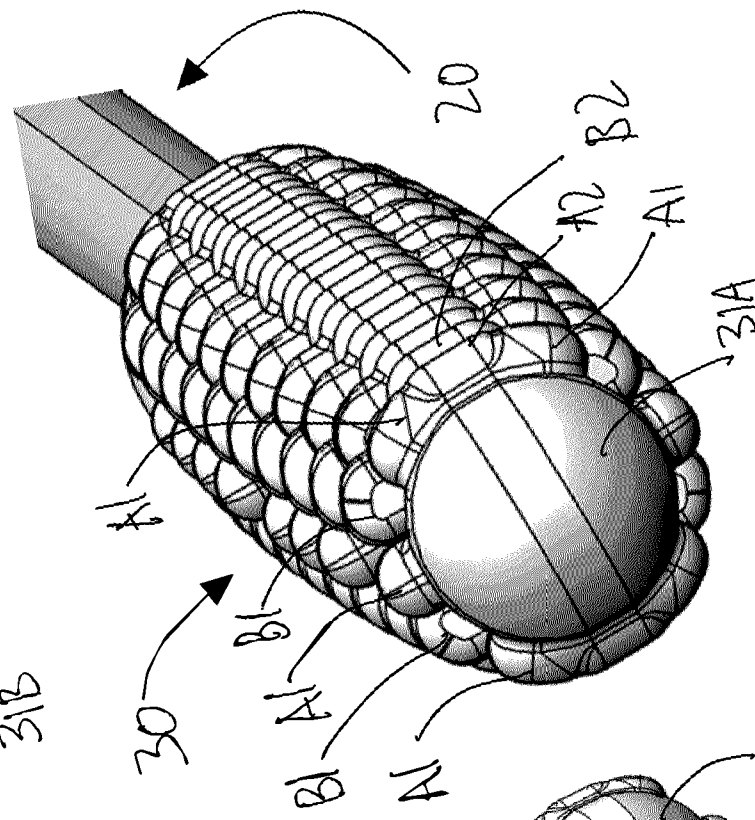


FIG. 5

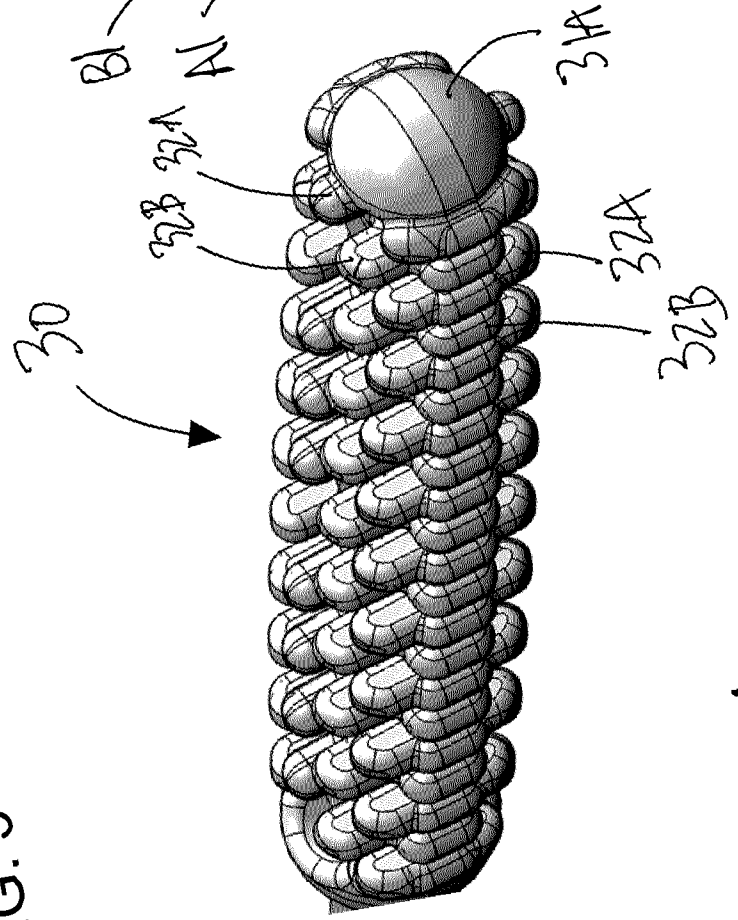


FIG. 4

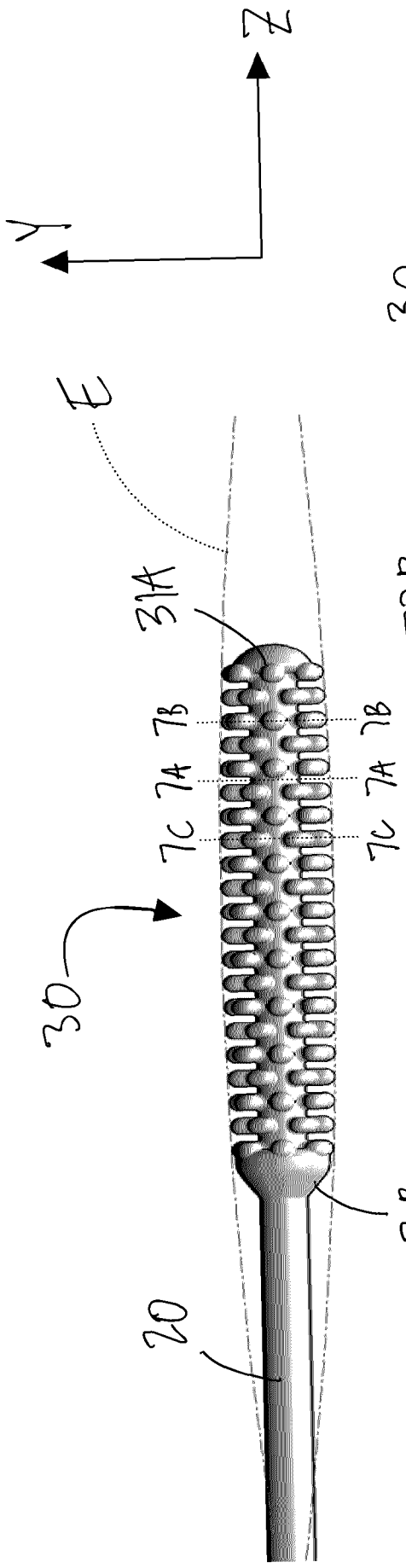


FIG. 6A

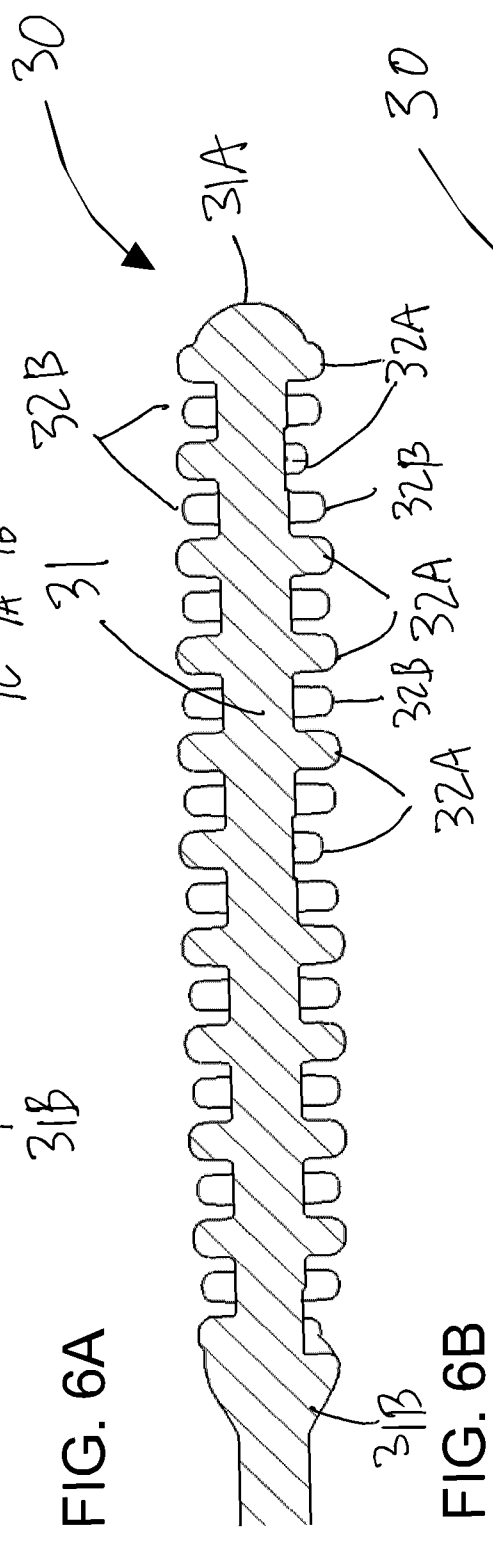


FIG. 6B

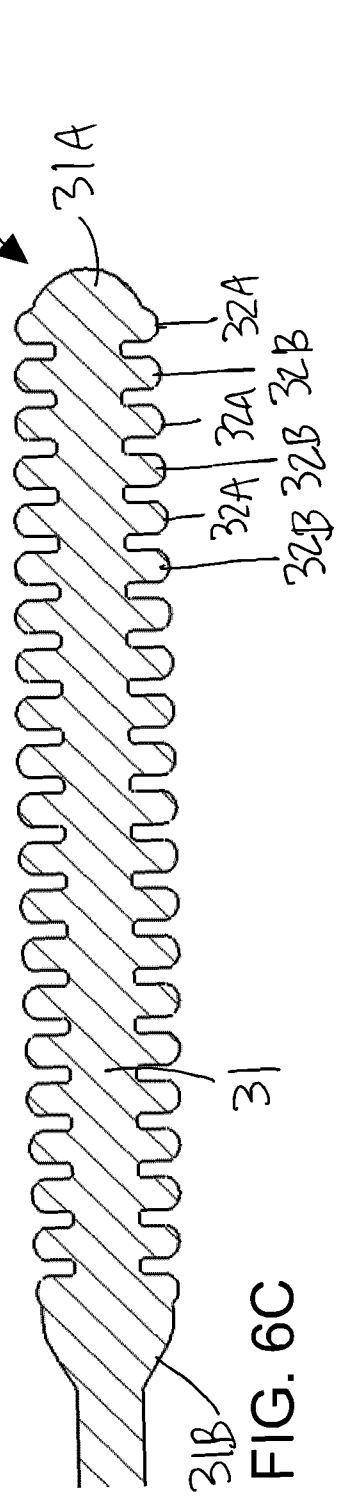


FIG. 6C

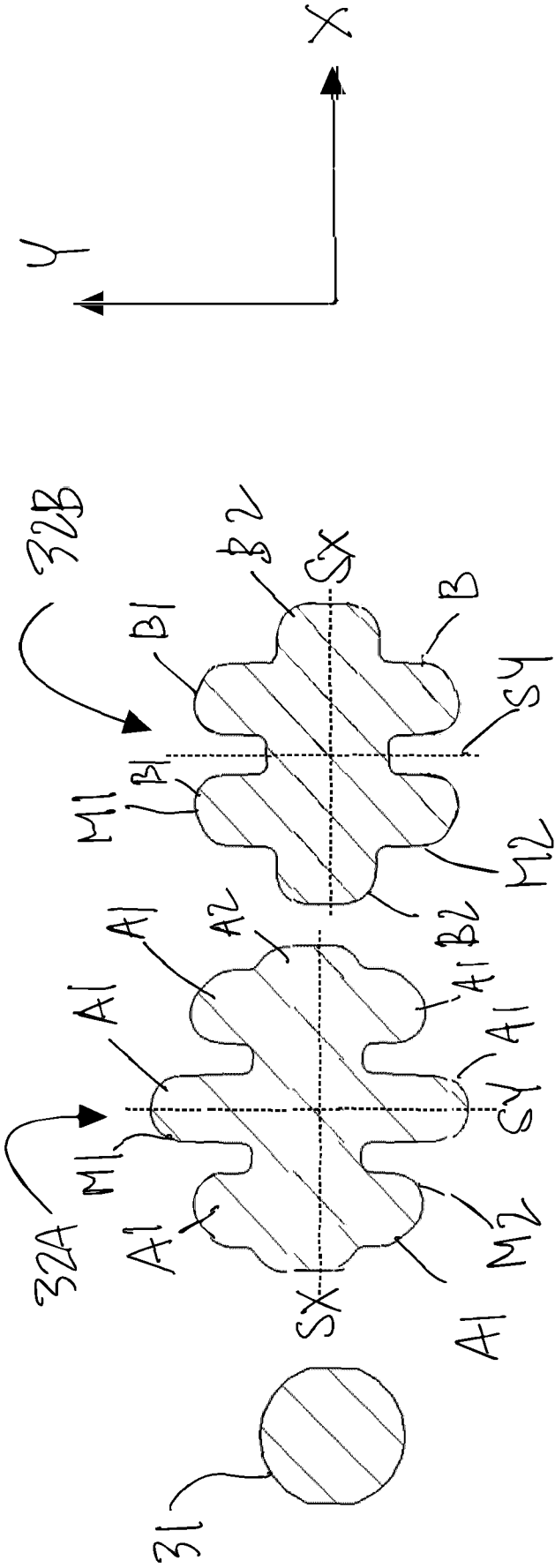


FIG. 7A

FIG. 7B

FIG. 7C

30

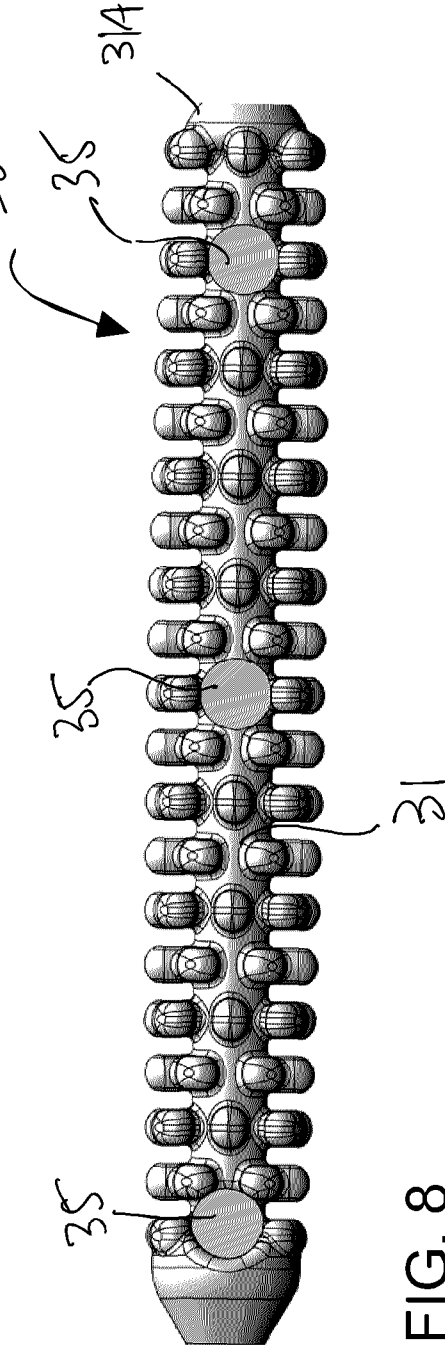


FIG. 8

