(12) STANDARD PATENT (11) Application No. **AU 2015252403 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Ophthalmic surgical instrument with internal frame and external coating

(51) International Patent Classification(s)
A61F 9/007 (2006.01)

(21) Application No: **2015252403** (22) Date of Filing: **2015.03.26**

(87) WIPO No: **WO15/165666**

(30) Priority Data

(31) Number	(32) Date	(33) Country
14/268,321	**2014.05.02**	**US**

(43) Publication Date: **2015.11.05**
(44) Accepted Journal Date: **2019.07.18**

(71) Applicant(s)
Novartis AG

(72) Inventor(s)
Schaller, Philipp

(74) Agent / Attorney
Phillips Ormonde Fitzpatrick, PO Box 323, Collins Street West, VIC, 8007, AU

(56) Related Art
US 3656481 A
US 2005/0234473 A1
US 2005/0090849 A1
WO 2007/047030 A2

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

(19) **World Intellectual Property Organization**
International Bureau

(43) **International Publication Date**
5 November 2015 (05.11.2015)

(10) **International Publication Number**
WO 2015/165666 A1

(51) **International Patent Classification**:
A61F 9/007 (2006.01)

(21) **International Application Number**:
PCT/EP2015/056641

(22) **International Filing Date**:
26 March 2015 (26.03.2015)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
14/268,321 2 May 2014 (02.05.2014) US

(71) **Applicant**: **NOVARTIS AG** [CH/CH]; Lichtstrasse 35, CH-4056 Basel (CH).

(72) **Inventor**: **SCHALLER, Philipp**; Winkelriedstrasse 52, CH-8203 Schaffhausen (CH).

(74) **Agent**: **HANRATTY, Catherine**; Hanna Moore & Curley, 13 Lower Lad Lane, Dublin D2 (IE).

(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, 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, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:

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

WO 2015/165666 A1

(54) **Title**: OPHTHALMIC SURGICAL INSTRUMENT WITH INTERNAL FRAME AND EXTERNAL COATING

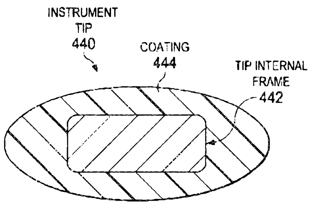

Fig.6

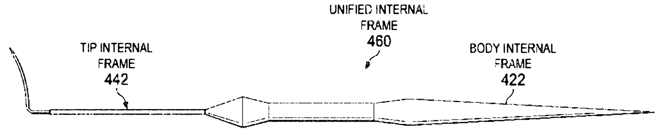

Fig.8

(57) **Abstract**: A method of manufacturing a surgical device can include generating a first internal frame (442) defining an internal structure of an instrument tip (440); covering at least a portion of the first internal frame with a first coating (444) to define an exterior surface of the instrument tip; and generating an instrument body such that a proximal end of the instrument tip is positioned at a distal end of the instrument body. An ophthalmic surgical instrument can include an instrument body; and an instrument tip disposed at a distal end of the instrument body, the instrument tip including a first section linearly extending along a longitudinal axis of the instrument body and a second section extending obliquely from the first section, the second section being arcuately shaped; and wherein the instrument tip comprises a first internal frame and a first coating covering the first internal frame.

OPHTHALMIC SURGICAL INSTRUMENT WITH INTERNAL FRAME AND EXTERNAL COATING

TECHNICAL FIELD

[0001] Embodiments disclosed herein are related to ophthalmic surgical instruments. More specifically, embodiments described herein relate to an instrument tip with an internal frame defining an interior structure and an external coating defining an exterior surface.

BACKGROUND

[0002] Ophthalmic surgical instruments can include complex distal tips that are used by a surgeon to manipulate a patient's anatomy (e.g., one or more layers of the patient's eye). The designs of these instrument tips can be a combination of free formed surfaces, defined by small edge radii and other demanding design features. Conventionally, the instrument tips are manufactured by hand, using manual processes. For example, the instrument tips can be hand-rolled, bent, grinded, polished, etc., to finish and ensure the surface is smooth and free of edges or burrs. Manufacturing can thus be highly laborious and time-consuming.

[0003] The instrument tips are conventionally manufactured using entirely metal (e.g., stainless steel) to ensure an appropriate bending stiffness for the component. Further, the metallic instrument tip can directly contact the patient's anatomy. The materials used can thus have demanding technical requirements (e.g., flexibility, stiffness, porosity, hardness, density, etc.), resulting in high monetary expense. Because of the high material and manufacturing costs in money and time, it is not economically feasible to make the instrument tips disposable or single-use.

[0004] Microsurgical instruments are additionally difficult to manufacture by hand, while satisfying the necessary technical requirements, because they are extremely small. For example, in flapless refractive surgery, an ophthalmic surgical instrument, the lenticule manipulator, can be used to delaminate the lenticule after treatment of the cornea by UV Femtolaser. This surgical instrument can be characterized by the complex shape of its tip, which is used to manipulate individual layers of the eye. Other ophthalmic surgical instruments can similarly include complex tip designs with high technical requirements.

[0004a] A reference herein to a patent document or other matter which is given as prior art is not to be taken as an admission that that document or matter was known or that the information it contains was part of the common general knowledge as at the priority date of any of the claims.

[0004b] Throughout the description and claims of the specification, the word "comprise" and variations of the word, such as "comprising" and "comprises", is not intended to exclude other additives, components, integers or steps.

SUMMARY

[0005] The presented solution fills an unmet medical need with a unique solution to provide ophthalmic surgical instrument tips with an internal frame and an external coating that can be manufactured faster and more cost-effectively while providing the ability to generate complex shapes and meet necessary technical requirements.

[0005a] According to a first aspect the invention provides a method of manufacturing an ophthalmic surgical device, comprising: generating a first internal frame defining an internal structure of an instrument tip; covering at least a portion of the first internal frame with a first coating to define an exterior surface of the instrument tip; and generating an instrument body having a proximal end and a distal end such that a proximal end of the instrument tip is positioned at the distal end of the instrument body, wherein the instrument body comprises: a second internal frame separate from and not unitary with the first internal frame; and a second coating covering the second internal frame, wherein the instrument body and the instrument tip are separate components.

[0005b] According to a further aspect, the invention provides an ophthalmic surgical instrument, comprising: an instrument body having a proximal end, a distal end, and a longitudinal axis; and an instrument tip disposed at the distal end of the

2015252403 24 Jun 2019

instrument body, the instrument tip comprising: a first internal frame comprising a first section linearly extending along a longitudinal axis of the instrument body and a second section extending obliquely from the first section, the second section being arcuately shaped; and a first coating covering the first internal frame to define an exterior surface of the instrument tip, wherein the instrument body comprises: a second internal frame separate from and not unitary with the first internal frame; and a second coating covering the second internal frame, wherein the instrument body and the instrument tip are separate components.

[0005c] According to a further aspect, the invention provides a method of manufacturing an ophthalmic surgical device, comprising: generating an internal frame defining an internal structure of an instrument tip, the instrument tip having a distal end, a linear first section, an arcuate second section extending obliquely from the first section, and a flattened portion at the distal end; generating an instrument body using a coating, the instrument body having a longitudinal axis and an external surface comprising surface features to enhance a user's grip of the instrument body; and covering the internal frame with the coating simultaneously as generating the instrument body to define a shape of an exterior surface of the instrument tip for manipulating one or more layers of a patient's eye, wherein the cross-sectional profiles of the internal frame and coating in a plane perpendicular to the longitudinal axis of the instrument body define different shapes along at least a portion of the longitudinal axis.

[0006] Consistent with some embodiments, a method of manufacturing an ophthalmic surgical instrument comprises: generating a first internal frame defining an internal structure of an instrument tip; covering at least a portion of the first internal frame with a first coating to define an exterior surface of the instrument tip; and generating an instrument body having proximal end and a distal end such that a proximal end of the instrument tip is positioned at the distal end of the instrument body.

[0007] Consistent with some embodiments, an ophthalmic surgical instrument comprises: an instrument body having a proximal end, a distal end, and a longitudinal axis; and an instrument tip disposed at the distal end of the instrument body, the instrument tip including a first section linearly extending along a longitudinal axis of

2015252403 24 Jun 2019

the instrument body and a second section extending obliquely from the first section, the second section being arcuately shaped; and wherein the instrument tip comprises a first internal frame and a first coating covering the first internal frame.

[0008] Consistent with some embodiments, a method of manufacturing an ophthalmic surgical instrument comprises: generating an internal frame defining an internal structure of an instrument tip, the instrument tip having a distal end, a linear first section, an arcuate second section extending obliquely from the first section, and a flattened portion at the distal end; generating an instrument body using a coating, the instrument body having a longitudinal axis and an external surface of the instrument body including surface features; and covering the internal frame with the coating to define an exterior surface of the instrument tip simultaneously as generating the instrument body, wherein the cross-sectional profiles of the internal frame and coating in a plane perpendicular to the longitudinal axis of the instrument body define different shapes along at least a portion of the longitudinal axis.

[0009] Additional aspects, features, and advantages of the present disclosure will become apparent from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] **FIG. 1** is a flow diagram illustrating a method of manufacturing an ophthalmic surgical instrument.

[0011] **FIG. 2** is a flow diagram illustrating a method of manufacturing an ophthalmic surgical instrument.

[0012] **FIG. 3** is a flow diagram illustrating a method of manufacturing an ophthalmic surgical instrument.

[0013] **FIG. 4** is a diagram illustrating an internal frame of an instrument tip of an ophthalmic surgical instrument.

[0014] **FIG. 5a** is a diagram illustrating an instrument tip of an ophthalmic surgical instrument.

[0015] **FIG. 5b** is a diagram illustrating an instrument tip of an ophthalmic surgical instrument.

[0016] **FIG. 6** is a diagram illustrating a cross-sectional view of an instrument tip of an ophthalmic surgical instrument.

[0017] **FIG. 7a** is a diagram illustrating an instrument body of an ophthalmic surgical instrument.

[0018] **FIG. 7b** is a diagram illustrating an internal frame of an instrument body of an ophthalmic surgical instrument.

[0019] **FIG. 7c** is a diagram illustrating an instrument body of an ophthalmic surgical instrument.

[0020] **FIG. 8** is a diagram illustrating a unified internal frame of an instrument tip and an instrument body of an ophthalmic surgical instrument.

[0021] **FIG. 9a** is a diagram illustrating an ophthalmic surgical instrument.

[0022] **FIG. 9b** is a diagram illustrating an ophthalmic surgical instrument.

[0023] In the drawings, elements having the same designation have the same or similar functions.

DETAILED DESCRIPTION

[0024] In the following description specific details are set forth describing certain embodiments. It will be apparent, however, to one skilled in the art that the disclosed embodiments may be practiced without some or all of these specific details. The specific embodiments presented are meant to be illustrative, but not limiting. One skilled in the art may realize other material that, although not specifically described herein, is within the scope and spirit of this disclosure.

[0025] The present disclosure describes an ophthalmic surgical instrument tip with a metal skeleton or an internal frame that is sheathed with plastic or a coating. The internal frame can ensure the technical requirements for flexibility and/or stiffness are satisfied, while the complex outer profile of the instrument tip can be defined by the coating. Instruments manufactured according to the present disclosure can be used for refractive surgery, cataract surgery, vitreoretinal surgery, and/or other ophthalmic surgical procedures.

[0026] The internal frame can be manufactured using a relatively inexpensive component, such as a blanked, wire eroded, or metal injection molded (MIM) metal part. The internal frame can be used as an insert in an injection molding process, which covers the internal frame with the coating to define the outer profile. This present disclosure describes the manufacture of instruments with comparable technical properties as hand-made instruments but with lower materials and manufacturing costs. Thus, disposable or single-use instruments are more feasible to manufacture.

[0027] The devices, systems, and methods of the present disclosure provide numerous advantages, including: (1) faster, less laborious, and more cost-effective manufacturing based on relatively simple materials/industrial processing compared to manual processing; (2) more cost-effective materials such as lower cost bulk goods with less stringent technical requirements; (3) unlimited design complexity using injection molding; (4) high process stability using established materials/industrial processing (die-cutting, bending, injection molding, etc.); (6) flexibility in manufacturing multiple components of the instrument, such as the body and the tip, using the same processing steps; (7) automation of manufacturing using established materials/industrial processing; and (8) flexibility in choosing internal frame and external coating materials based on surgical objectives.

[0028] **FIGS. 1-3** provide flow diagrams of methods 100, 200, and 300, respectively, of manufacturing an ophthalmic surgical instrument 400 (**FIGS. 9a** and **9b**). The methods 100, 200, and 300, can be further understood with reference to **FIGS. 4-9b**, which illustrate the instrument 400 in various stages of the methods 100, 200, and 300. **FIGS. 9a** and **9b** can illustrate the fully-assembled instrument 400. The instrument 400 includes an instrument body 420 and an instrument tip 440. The method 100 can describe the manufacture of an instrument 400 in which the instrument tip 440, and not the instrument body 420, includes an internal frame and an external coating. The methods 100 and 200 can describe the manufacture of an instrument 400 in which the instrument body 420 and the instrument tip 440 each include an internal frame and an external coating. In the method 100, the instrument body 420 and the instrument tip 440 are separate components, while in the method 200, the instrument body and the instrument tip are a single component.

[0029] Referring to **FIG. 1**, the method 100 includes, at step 110, generating an internal frame of an instrument tip. The method 100 further includes, at step 120, covering the tip internal frame with a first coating to define an exterior surface of the instrument tip. As shown in **FIGS. 4-6** and **8-**

9b, the instrument tip 440 is sized and shaped to contact one or more layers of the patient's eye during a surgical procedure. The tip internal frame 442 can define an interior structure of the instrument tip 440. The coating 444 can define the exterior surface of the instrument tip 440. Using the coating to define the exterior surface can allow for a complex tip shape to be generated in a faster and more cost efficient manner (compared to, e.g., rolling, bending, filing and polishing a wholly metallic instrument tip 440). At the same time, the tip internal frame 442 can provide necessary flexibility and/or stiffness for the instrument tip 440 as the coating 444 is in contact with the patient's anatomy during a surgical procedure. Providing the necessary flexibility and/or stiffness can allow movements of a surgeon's hand to be translated to the instrument tip. Additional flexibility and/or stiffness are provided by the coating 444. The coating 444 can also be selected to satisfy various technical requirements including, for example, surface roughness, surface structure, porosity, hardness, density, etc.

[0030] The tip internal frame 442 can be made of or include a first material, such as a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, an elastomer, and/or any other suitable material. The first material can be selected such that the instrument tip 440 has sufficient flexibility and/or stiffness for the surgical procedure. Because the coating 444, and not the tip internal frame 442, directly contacts the patient's anatomy and because the coating 444 additionally satisfies technical requirements for the instrument tip 440, a cost-effective material can be a chosen for the tip internal frame 442 (e.g., lower cost bulk goods with less stringent technical requirements).

[0031] Covering the tip internal frame 442 (step 120) can include injection molding with a first coating 444, such as a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, an elastomer, and/or any other suitable material. The coating 444 can be chosen based on surgical objectives. For example, using a non-metallic coating 444 can provide lower friction between the instrument tip 440 and the patient's anatomy (e.g., the stroma of the cornea). The tip internal frame 442 can be used as an insert in the injection molding process. In other embodiments, other materials/industrial processing can be utilized to cover the tip internal frame 442 with the coating 444.

[0032] In some embodiments, the tip internal frame 442 can be solid. Thus, covering the tip internal frame 442 with the coating 444 (step 120) includes surrounding the tip internal frame 442 with the coating 444. In some embodiments, the tip internal frame 442 can include spaces that are permeable to the coating 444. Thus, covering the tip internal frame 442 with the coating 444 (step 120) can include both filling the spaces and surrounding the tip internal frame 442 with the coating 444.

[0033] The instrument tip 440 can be variously shaped in different embodiments, depending on, e.g., the instrument needs for different surgical procedures. For example, one or more sections of the instrument tip 440 can be straight, angular, curved, arcuate, etc.; include a hook, etc.; and/or define forceps, blades, scissors, etc. The tip internal frame 442 can define an internal structure of any shape needed for the instrument tip 440. The coating 444 can define the external surface of any shape needed for the instrument tip 440. An exemplary embodiment of an instrument tip 440 used in flapless refractive surgery is described herein. It is understood that the teachings of the present disclosure can be applied to various instruments used in different ophthalmic surgical procedures and other medical procedures.

[0034] As shown in **FIGS. 4**, **5a**, and **5b**, the tip internal frame 442 can include a first section 446 and a second section 450. The second section 450 can be used by a surgeon to manipulate the patient's anatomy during the surgical procedure. The first section 446 can be generally linear and extend along a longitudinal axis 430 of the instrument body 420 (**FIGS. 9a** and **9b**). The second section 450 can extend obliquely from the first section 446. The second section 450 can be arcuately shaped. In some embodiments, the second section 450 of the tip internal frame 442 can be linearly shaped, and the coating 444 can cover the second section 450 of the tip internal frame 442 such that exterior profile of the second section 450 is arcuately shaped. In some embodiments, only the second section 450 is covered with the coating 444. In some embodiments, both the first and second sections 446 and 450 are covered with the coating 444. For different surgical instruments, the first and second sections 446 and 450 can be variously shaped. For example, the second section 450 can be angled, include a hook, etc.

[0035] The shape of the tip internal frame 442 can be similar to the desired exterior profile of the instrument tip 440. However, the shape of the tip internal frame 442 can be simpler than the final exterior profile. For example, one or more surfaces features (e.g., constant small edge radius at the distal end 454) of the exterior surface can be defined by the coating 444 without being replicated in the tip internal frame 442. In some embodiments, the coating 444 defines a smooth exterior profile of the instrument tip 400. In some embodiments, the coating 444 can define one or more surface features at the distal end 454. The surface features can include projections, recesses, grooves, ridges, striations, bumps, and/or other textural features. The surface features can modify the friction and/or contact feel between the instrument tip 440 and the patient's anatomy compared when the coating 444 defines a smooth exterior profile.

[0036] The tip internal frame 442 can include a proximal end 456 and a distal end 454. The distal end 454 of the tip internal frame 442 can include a flattened portion 452. The flattened portion 452 can be variously shaped in different embodiments, for example, as substantially circular, rectangular, elliptical, hexagonal, polygonal, a combination thereof, or any other profile. The flattened portion 452, covered with the coating 444, can have additional surface area for contact with the patient's anatomy compared to other portions of the instrument tip 440. The additional surface area can facilitate manipulation of, e.g., one or more layers of the patient's eye during the surgical procedure. A magnitude of a dimension (e.g., a radius or a width) of the flattened portion 452 in a direction perpendicular to the longitudinal axis 430 (**FIGS. 9a** and **9b**) can be greater than the magnitude of the dimension (e.g., the radius or the width) of the first and/or second sections 446 and 450. The coating 444 can define the flattened portion 452. For example, as shown in **FIG. 5a**, in some embodiments, the coating 444 defines the interior and the exterior of the flattened portion 452 such that the tip internal frame 442 does not extend through the flattened portion 452. As shown in **FIG. 5b**, in some embodiments, the tip internal frame 442 (e.g., the second section 450) extends through the flattened portion 452. The instrument tip 440 can have a length between approximately 1 mm and 50 mm, 10 mm and 40 mm, 20 mm and 40 mm, and 30 mm and 40 mm, in various embodiments. The instrument tip 440 can have a diameter between approximately 0.1 mm and 2 mm, 0.1 mm and 1 mm, 0.1 mm and 0.5 mm, and 0.1 mm and 0.3 mm, in various embodiments. The coating 444 can have a thickness at the distal end 454 of the instrument tip 440 between approximately 0.01 mm and 1 mm, 0.01 mm and 0.5 mm, 0.01 mm and 0.25 mm, and 0.01 mm and 0.15 mm, in various embodiments.

[0037] The tip internal frame 442 can have a cross-section in a plane perpendicular to the longitudinal axis 430 (**FIGS. 9a** and **9b**) that is shaped as a circle, rectangle, ellipse, polygon, a combination thereof, or any other profile. For example, as shown in **FIG. 6**, which is a cross-sectional view along line A-A of **FIGS. 5a** and **5b**, the tip internal frame 442 has a cross-section that is rectangular with rounded corners. Similarly, the coating 444 can have a cross-section in the plane perpendicular to the longitudinal axis 430 (**FIGS. 9a** and **9b**) that is shaped as a circle, rectangle, ellipse, polygon, a combination thereof, or any other profile. For example, as shown in **FIG. 6**, the coating 444 has a cross-section that is elliptical. Thus, in some embodiments, as shown in **FIG. 6**, the cross-sectional profiles of the tip internal frame 442 and the coating 444 define different shapes. In some embodiments, the cross-sectional profiles of the tip internal frame 442 and the coating 444 define the same or similar shapes (e.g., both are elliptical, both are rectangular, etc.).

[0038] Referring again to **FIG. 1**, the method 100, at step 130, can include generating an instrument body. As shown in **FIGS. 7a, 7b**, **9a**, and **9b**, the instrument body 420 is sized and shaped for grasping by a user (e.g., a surgeon) during a surgical procedure. The instrument body 420 can be a single component. For example, as shown in **FIG. 7a**, an instrument body 420 without a distinct internal frame or external coating can be utilized. The instrument body 420 of **FIG. 7a** can be hand formed or machine manufactured. For example, manufacturing the instrument body 320 can include turning (e.g., on a lathe), injection molding, milling, 3D printing, or any other suitable manufacturing method. In some embodiments, the instrument 420 can be a metallic component. In some embodiments, the instrument body 420 can be defined using the first coating 444. The coating 424 and/or coating 444 can be described as a molding material, such as the molding material used in an injection molding process. For example, the interior structure and the exterior surface of the instrument body 420 can be defined by the first coating 444. The instrument body 420 can be solid or hollow. In some embodiments, the instrument body 420 is generated using an injection molding process or other suitable materials/industrial process. Covering the tip internal frame 442 with the first coating 444 (step 120) can occur substantially simultaneously (e.g., during the same processing step) as generating the instrument body 420 (step 130). The tip internal frame 442 can be used an insert mold for injection molding. A thin layer of the first coating 444 can cover the tip internal frame 442 with the first coating 444 to define the exterior surface of the distal end 454, and the instrument body 420 can be molded as one piece with the first coating 444. The instrument 400 (**FIG. 9a**) can be formed thus formed in one embodiment. The method 100 can additionally include one or more finishing steps (e.g., polishing, laser marking, sterilizing, packaging, etc.).

[0039] **FIG. 2** illustrates a method 200 for manufacturing an ophthalmic surgical instrument with an instrument body and instrument tip each including an internal frame and an external coating. The method 200, at step 210, can include generating an internal frame of the instrument tip. The method 200, at step 220, can further include covering the tip internal frame with an external coating to define an exterior surface. The tip internal frame 442 can be generated in a similar manner as described with respect to step 110 of method 100 (**FIG. 1**). For example, the tip internal frame 442 can be made of or include a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, an elastomer, and/or any other suitable material. The tip internal frame 442 can be covered with the external coating in a similar manner as described with respect to step 120 of method 100 (**FIG. 1**). For example, covering the tip internal frame 442 (step 220) can include injection molding with the coating, such as a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, an elastomer, and/or any other suitable material.

[0040] The method 200, at step 230, can include generating an internal frame for an instrument body. **FIGS. 7b**, **7c**, and **9b** can illustrate the body internal frame 422. The body internal frame 422 can define an internal structure of the instrument body 420. The method 200 can further include, at step 240 (**FIG. 2**), covering the body internal frame with a second coating to define an exterior surface of the instrument body. Steps 230 and 240, which are related to the body internal frame 422 and corresponding coating 424 of the instrument body, can be similar to steps 210 and 220 for the tip internal frame 442 and corresponding coating 444. For example, the body internal frame 422 can be made of or include a second material, such as a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, an elastomer, and/or any other suitable material. The same material or different materials can be used for the body internal frame 422 and the tip internal frame 442. Covering the body internal frame 422 (step 240) can include injection molding with a second coating 424 (**FIGS. 7c** and **9b**), such as a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, an elastomer, and/or any other suitable material. The first coating 444 and the second coating 424 can be the same or different.

[0041] As shown in **FIGS. 7b**, **7c**, and **9b**, the shape of the body internal frame 422 can be similar to the desired exterior profile of the instrument body 420. However, the shape of the body internal frame 422 can be simpler than the final exterior profile. For example, one or more surface features defined by the coating 424 to enhance the user's grip of the instrument body 420 can be omitted from the body internal frame 422. The coating 424 can define a textured surface (*e.g.*, roughened, knurled, projections/recesses, tapers, other surface features, and/or combinations thereof) on the instrument body 420.

[0042] Referring again to **FIG. 2**, the method 200, at step 250, can include bringing the instrument tip and the instrument body into engagement. In some embodiments, the tip internal frame 442 can be engaged with the body internal frame 422. For example, the proximal end 448 of the tip internal frame 442 can be mechanically coupled to the distal end 426 of the body internal frame 422 via an attachment mechanism 448 (**FIG. 4**). The attachment mechanism 448 can be disposed at the proximal end 456 of the tip internal frame 442. The attachment mechanism 448 can include any suitable mechanical configuration to allow for the instrument tip 440 to be joined to the instrument body 420. The attachment mechanism 448 can be omitted in embodiments in which the tip internal frame 442 and body internal frame 422 are not separate components. In **FIG. 4**, the attachment mechanism 448 can have a radius less than the first and/or sections 446 and 450. For example, the attachment mechanism 148 can include external threads that are configured to mate with corresponding internal threads at the distal end 426 of the instrument body 420. In some embodiments, the tip internal frame 442 is configured to be press fit, slip fit, compression fit, interference fit, or otherwise engagingly fit with the instrument body 420. In some embodiments, the connection between instrument tip 440 and the instrument body 420 is form- and/or force-closed. For example, in an injection molding processing, tip internal frame 442 can be inserted into an injection molding machine, and the proximal end 456 of the tip internal frame 442 can be over molded. In some embodiments, the tip internal frame 442 can be engaged with the coating 424 of the instrument body 420 or the body internal frame 422 can be engaged with the coating 444 of the instrument tip 440. In some embodiments, an adhesive can be used to engage the instrument body 420 and the instrument tip 440. The instrument 400 (**FIG. 9b**) is formed when the instrument body 420 and the instrument tip 440 are brought into engagement.

[0043] **FIG. 3** illustrates a method 300 for manufacturing an ophthalmic surgical instrument with a unified internal frame. The method 300, at step 310, can include generating a unified internal frame of the instrument tip and the instrument body. The method 300, at step 320, can further include covering the unified internal frame with an external coating to define an exterior surface. As shown in **FIG. 8**, the tip internal frame 442 and the body internal frame 422 can comprise a unitary component. The unified internal frame 460 can be generated in a similar manner as described with respect to step 110 of method 100 (**FIG. 1**). For example, the unified internal frame 460 can be made of or include a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, an elastomer, and/or any other suitable material. The unified internal frame 460 can be covered with the external coating in a similar manner as described with respect to step 120 of method 100 (**FIG. 1**). For example, covering the unified internal frame 460 (step 320) can include injection molding with the coating, such as a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, an elastomer, and/or any other suitable material. As shown in **FIGS. 8** and **9b**, the shape of the unified internal frame 460 can be similar to the desired exterior profile of the instrument body 420 and the instrument tip 440. However, the shape of the body internal frame 422 can be simpler than the final exterior profile. For example, one or more features defined by the coating (such as complex shapes of the instrument tip 440, surface features of the instrument body 420, etc.) can be omitted from the unified internal frame 460. The instrument 400 (**FIG. 9b**) is formed when the unified internal frame 460 is covered by the external coating. The method 300 can additionally include one or more finishing steps (e.g., polishing, laser marking, sterilizing, packaging, etc.).

[0044] Suitable materials/industrial processing, including blanking, molding, casting, machining, cutting, etc., can be used to generate the tip internal frame 442, the body internal frame 422, and/or the unified internal frame 460, and/or covering an internal frame with an external coating. For example, blow molding, injection molding, thermoforming, centrifugal casting, investment casting, permanent mold casting, sand casting, shell mold casting, milling, turning, forming, shearing, punching, laser beam cutting, plasma cutting, water jet cutting, stereolithography, fused deposition modeling, selective laser sintering, direct metal laser sintering, 3D printing, extrusion, electric discharge machining, electrochemical machining, electroforming, bending, roll forming, spinning, deep drawing, stretch forming, among others, can be utilized.

[0045] Embodiments as described herein can provide devices, systems, and methods that facilitate the manufacture of ophthalmic surgical instruments with complex shapes while satisfying necessary technical requirements for flexibility and/or stiffness. The devices, systems, and methods described herein can be used with any surgical instrument. The examples provided above are exemplary only and are not intended to be limiting. One skilled in the art may readily devise other systems consistent with the disclosed embodiments which are intended to be within the scope of this disclosure. As such, the application is limited only by the following claims.

2015252403 24 Jun 2019

The claims defining the invention are as follows:

1. A method of manufacturing an ophthalmic surgical device, comprising:

generating a first internal frame defining an internal structure of an instrument tip;

covering at least a portion of the first internal frame with a first coating to define an exterior surface of the instrument tip; and

generating an instrument body having a proximal end and a distal end such that a proximal end of the instrument tip is positioned at the distal end of the instrument body,

wherein the instrument body comprises:

a second internal frame separate from and not unitary with the first internal frame; and

a second coating covering the second internal frame,

wherein the instrument body and the instrument tip are separate components.

2. The method of claim 1, wherein:
generating the first internal frame comprises at least one of molding, casting, machining, and cutting of a first material.

3. The method of claim 2, wherein:

the first material is at least one of a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, and an elastomer.

4. The method of any one of claims 1 to 3, wherein:

covering the first internal frame with a first coating comprises injection molding to cover the first internal frame with at least one of a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, and an elastomer.

5. The method of any one of claims 1 to 4, wherein generating an instrument body further comprises defining an exterior surface of the instrument body using the second coating.

6. The method of any one of claims 1 to 5, further comprising:

engaging the proximal end of the instrument tip and the distal end of the instrument body.

7. The method of any one of claims 1 to 6, wherein:

generating the first internal frame comprises generating the first internal frame having a proximal end, a distal end, a linear first section, and an arcuate second section extending obliquely from the first section.

8. The method of claim 7, wherein:

covering at least a portion of the first internal frame with a first coating comprises covering the distal end and the arcuate second section with the first coating.

9. The method of claim 7 or claim 8, wherein:

covering the first internal frame with a first coating comprises defining a flattened portion at a distal end of the instrument tip.

10. The method of any one of claims 1 to 9, wherein:

covering the first internal frame with a first coating comprises defining different shapes for the cross-sectional profiles of the first internal frame and the first coating in a plane perpendicular to a longitudinal axis of the instrument body.

11. An ophthalmic surgical instrument, comprising:

an instrument body having a proximal end, a distal end, and a longitudinal axis; and

an instrument tip disposed at the distal end of the instrument body, the instrument tip comprising:

a first internal frame comprising a first section linearly extending along a longitudinal axis of the instrument body and a second section extending obliquely from the first section, the second section being arcuately shaped; and

a first coating covering the first internal frame to define an exterior surface of the instrument tip,

wherein the instrument body comprises:

a second internal frame separate from and not unitary with the first internal frame; and a second coating covering the second internal frame,

wherein the instrument body and the instrument tip are separate components.

12. The ophthalmic surgical instrument of claim 11, wherein cross-sectional profiles of the first internal frame and the first coating in a plane perpendicular to the longitudinal axis of the instrument body define different shapes.

13. The ophthalmic surgical instrument of claim 11 or claim 12, wherein the instrument tip comprises a flattened portion at a distal end.

14. The ophthalmic surgical instrument of any one of claims 11 to 13, wherein the first and second internal frames, and the first and second coatings comprise at least one of a metal, a metal alloy, a ceramic, a composite, a polymer, a plastic, and an elastomer.

15. The ophthalmic surgical instrument of any one of claims 11 to 14, wherein the first internal frame comprises spaces that are permeable to the first coating.

16. A method of manufacturing an ophthalmic surgical device, comprising:

generating an internal frame defining an internal structure of an instrument tip, the instrument tip having a distal end, a linear first section, an arcuate second section extending obliquely from the first section, and a flattened portion at the distal end;

generating an instrument body using a coating, the instrument body having a longitudinal axis and an external surface comprising surface features to enhance a user's grip of the instrument body; and

covering the internal frame with the coating simultaneously as generating the instrument body to define a shape of an exterior surface of the instrument tip for manipulating one or more layers of a patient's eye, wherein the cross-sectional profiles of the internal frame and coating in a plane perpendicular to the longitudinal axis of the instrument body define different shapes along at least a portion of the longitudinal axis.

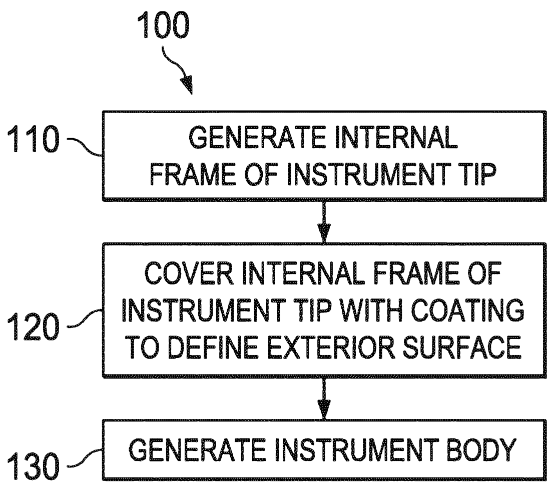

Fig. 1

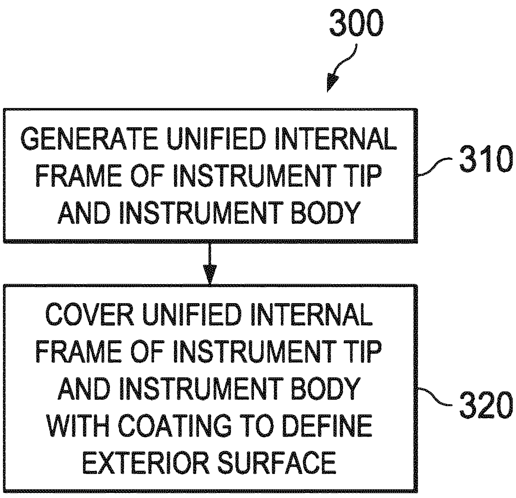

Fig. 3

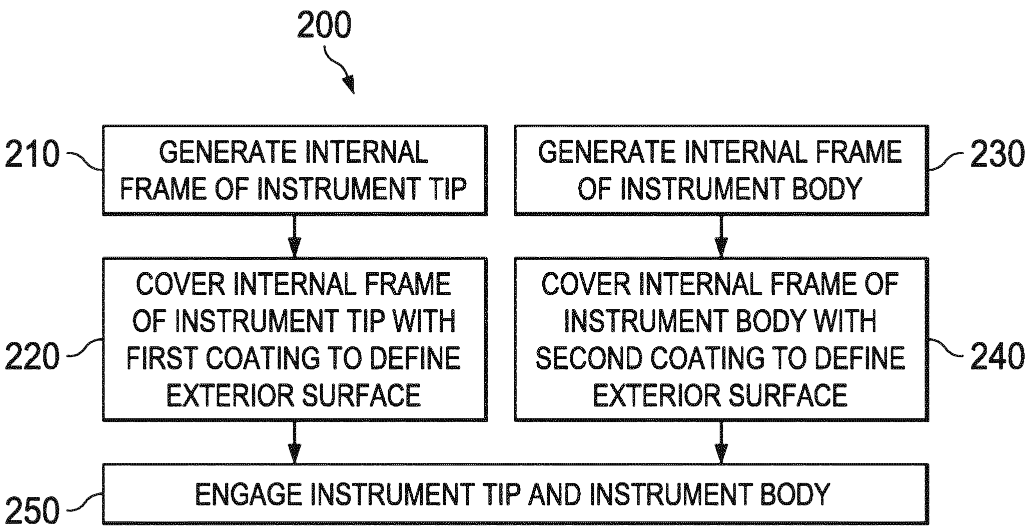

Fig. 2

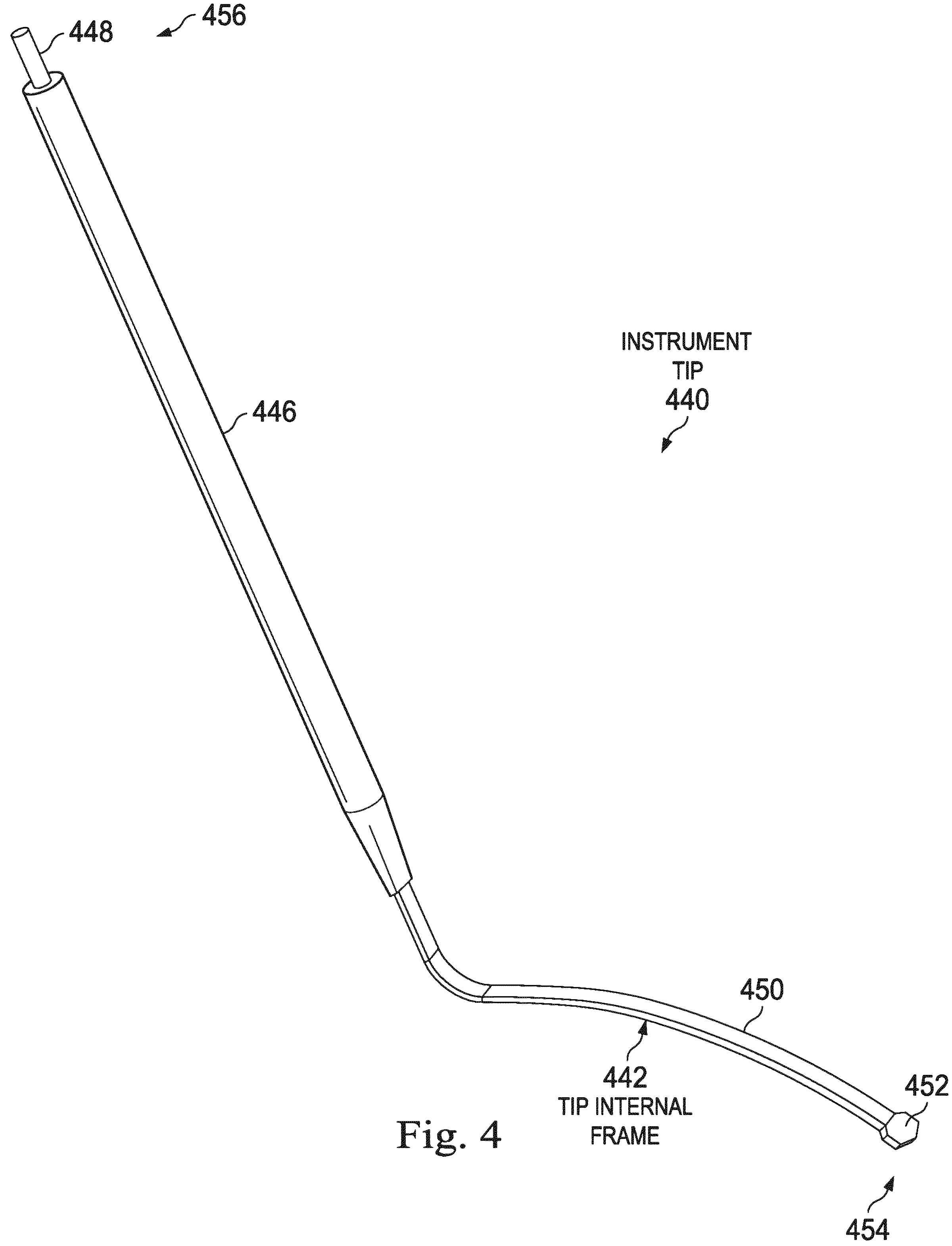
448
456
446
INSTRUMENT
TIP
440
450
442
TIP INTERNAL
FRAME
452
454

Fig. 4

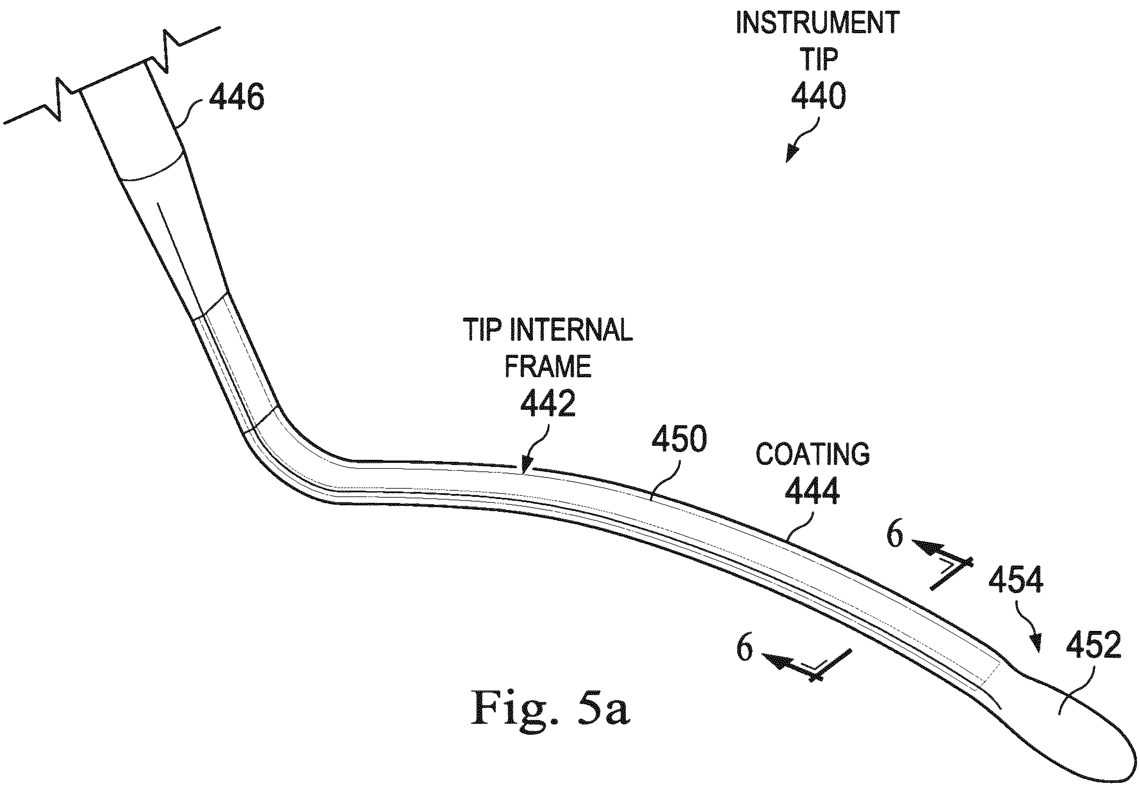
INSTRUMENT
TIP
440
446
TIP INTERNAL
FRAME
442
450
COATING
444
6
454
452
6

Fig. 5a

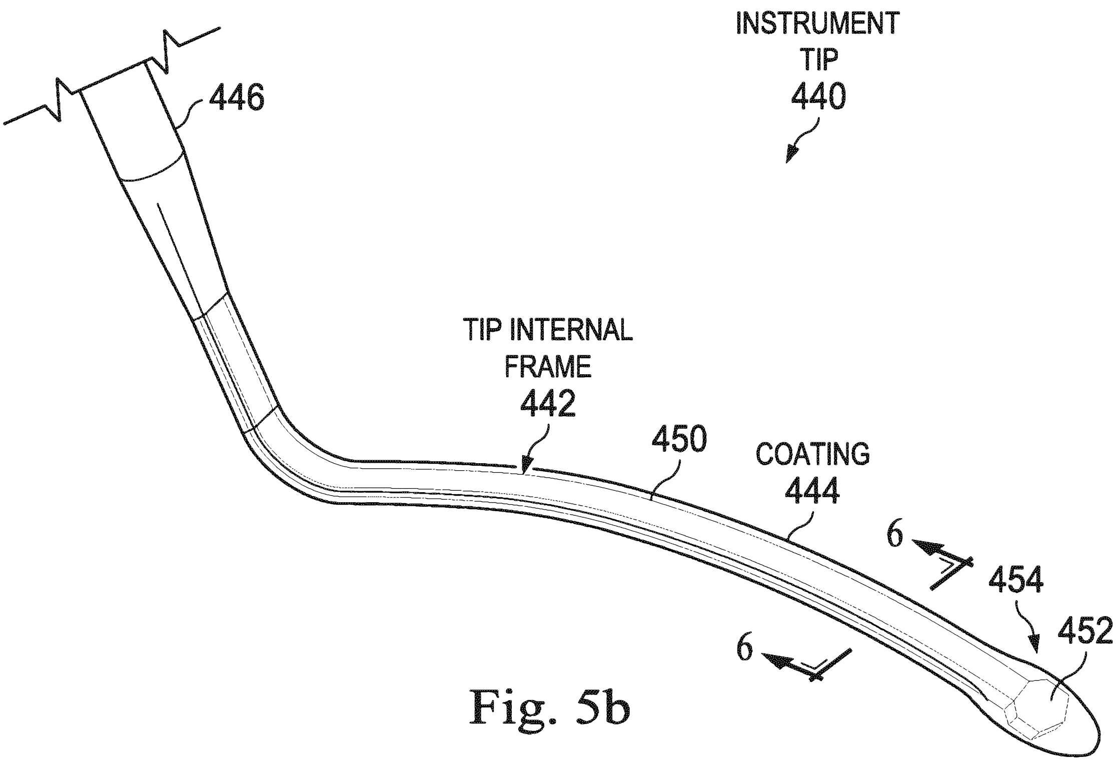
INSTRUMENT
TIP
440
446
TIP INTERNAL
FRAME
442
450
COATING
444
6
454
452
6

Fig. 5b

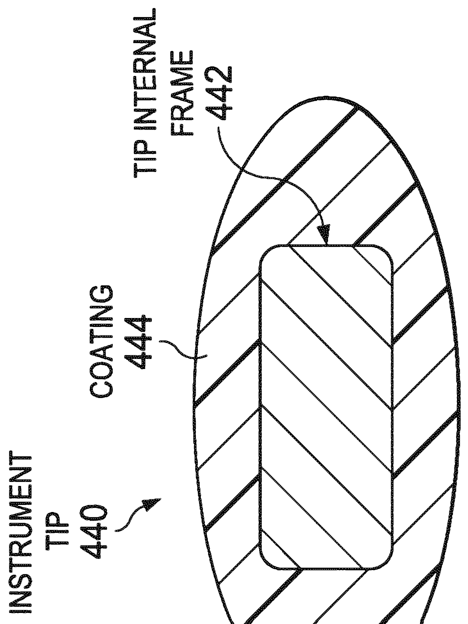
INSTRUMENT
TIP
440
COATING
444
TIP INTERNAL
FRAME
442

Fig.6

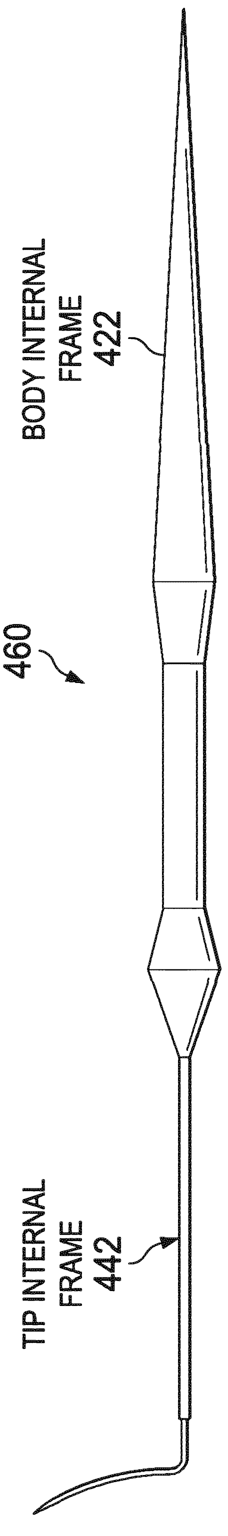
TIP INTERNAL
FRAME
442
UNIFIED INTERNAL
FRAME
460
BODY INTERNAL
FRAME
422

Fig.8

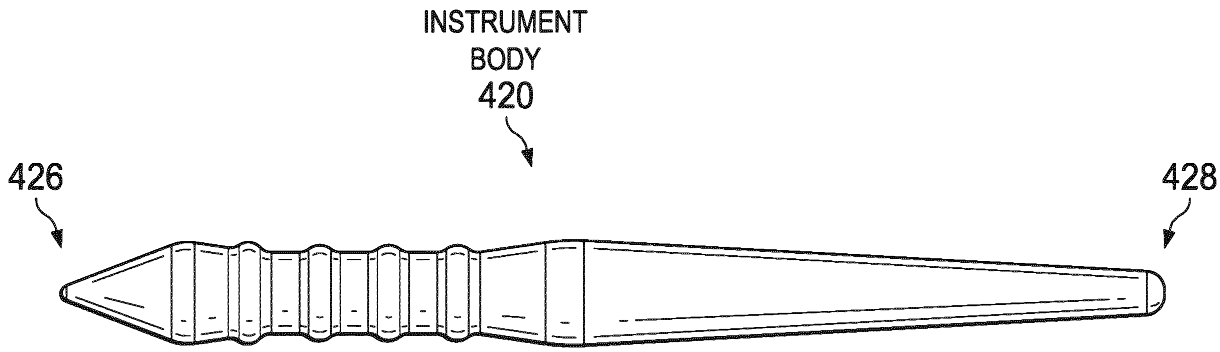

Fig. 7a

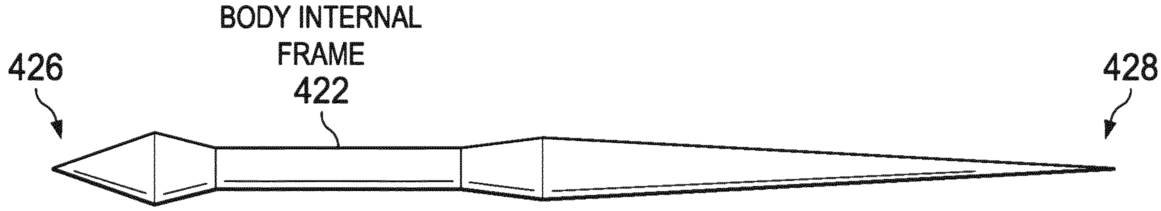

Fig. 7b

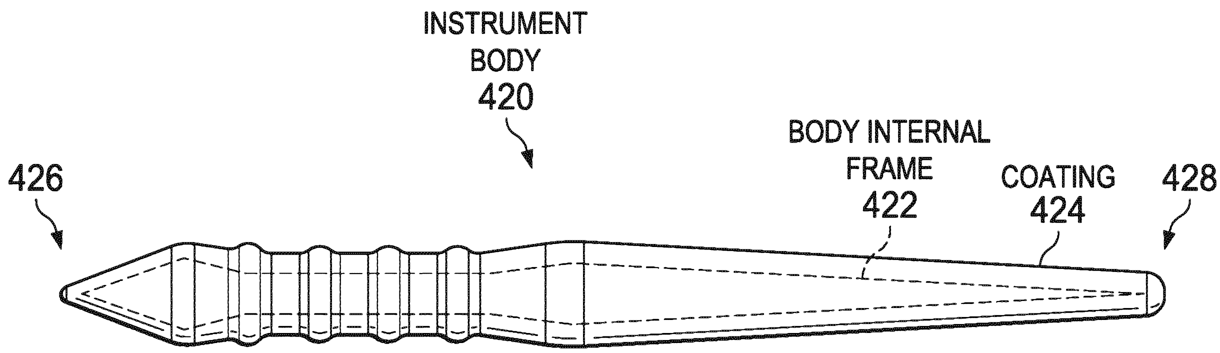

Fig. 7c

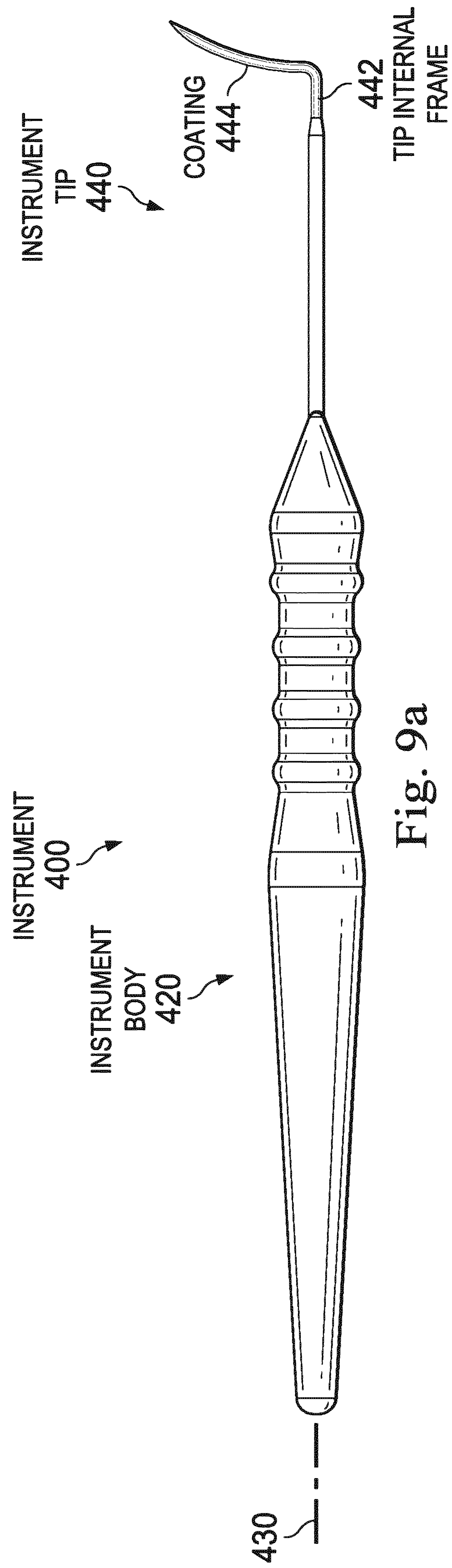
INSTRUMENT TIP 440
COATING 444
442 TIP INTERNAL FRAME
INSTRUMENT 400
INSTRUMENT BODY 420
430

Fig. 9a

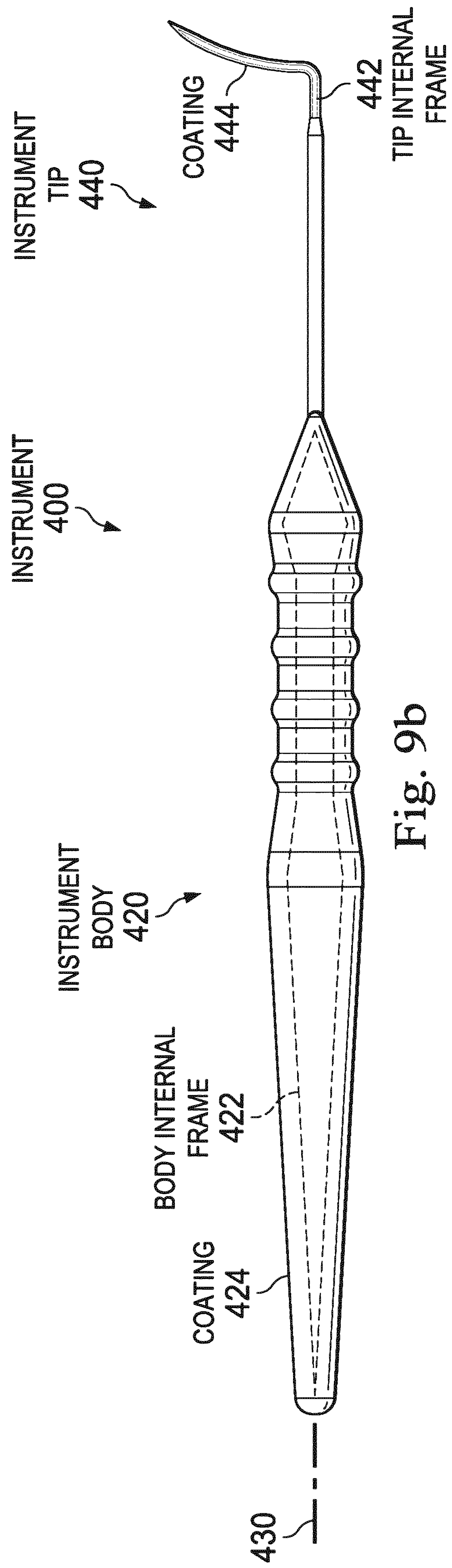
INSTRUMENT TIP 440
COATING 444
442 TIP INTERNAL FRAME
INSTRUMENT 400
INSTRUMENT BODY 420
BODY INTERNAL FRAME 422
COATING 424
430

Fig. 9b