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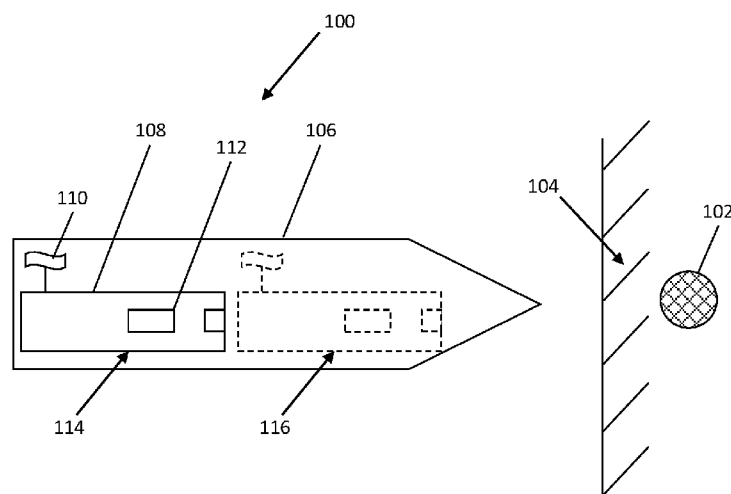


FIG. 1

(57) Abstract: A device and method for extracting a sample from a site of interest, the device comprising a needle assembly configurable to be in at least a loaded configuration or a default configuration, said needle assembly comprising a guide member for accessing the site, a retention member coupled to the guide member, and a drug storage unit; and a biasing member coupled to the needle assembly, said biasing member for biasing the needle assembly in the default configuration; wherein the guide member and retention member are capable of moving relative to each other between the loaded and the default configurations, wherein moving from the loaded configuration to the default configuration causes the sample to be extracted and retained in the retention member; and the default configuration allows the drug to be delivered to the site of interest. Preferably, the device is for kidney biopsy and the drug is a water insoluble haemostatic agent in the form of a sponge.

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BIOPSY DEVICE WITH HAEMOSTATIC FUNCTION

5 TECHNICAL FIELD

The present disclosure relates broadly to a device and a method for extracting a sample from a site of interest.

10

BACKGROUND

Kidney biopsy is the current gold standard in diagnosing kidney diseases, especially glomerulonephritis. Kidney biopsy is a procedure which involves extraction of kidney tissue for
15 laboratory analysis to diagnose and to prognosticate kidney diseases. Kidney biopsy can be performed in a native kidney and a transplanted kidney. Percutaneous kidney biopsy using a needle and an ultrasound probe to extract a tissue sample is one of the commonly practised clinical procedures.

20 However, kidney biopsy is associated with a significant risk of clinically significant bleeding. This is partly due to the relatively deep seated and mobile appendage of the kidney's anatomical lie, as well as its highly vascular nature. Bleeding may be defined as clinically significant if it requires blood transfusion, or admission to the hospital for more than 24 hours e.g. intensive care unit (ICU) care, or surgery e.g. embolization and partial nephrectomy under open
25 surgery to stop the bleeding, or results in death. Patients with relatively high bleeding risks are hence excluded from the kidney biopsy procedure.

The inventors have recognized that existing biopsy devices are unable to adequately address or mitigate significant post-biopsy bleeding. Thus, there is a need for a device and a
30 method for extracting a sample from a site of interest, which seek to address at least one of the above problems.

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SUMMARY

According to one aspect, there is provided a device for extracting a sample from a site of interest, the device comprising, a needle assembly configurable to be in at least a loaded configuration or a default configuration, said needle assembly comprising a guide member for
5 accessing the site of interest, a retention member coupled to the guide member, and a drug storage unit for storing a drug; and a biasing member coupled to the needle assembly, said biasing member for biasing the needle assembly in the default configuration; wherein the guide member and retention member are capable of moving relative to each other between the loaded
10 configuration and the default configuration, wherein moving from the loaded configuration to the default configuration causes the sample to be extracted from the site of interest and retained in the retention member; and the default configuration allows the drug to be delivered to the site of interest.

The device may further comprise an actuator coupled to the biasing member, the actuator comprising one or more catch members for retaining the biasing member in a loaded position such that the needle assembly is in the loaded configuration; and a trigger member for triggering a movement of the guide member or retention member from a loaded position to a default position such that the needle assembly moves from the loaded configuration to the default configuration.
20

The guide member may comprise a tube, said tube comprising, a lumen extending between a proximal and a distal portion of the tube, and an access window defined on the distal portion of the tube; the retention member may comprise a rod, said rod coaxially positioned within the lumen of the tube and comprising a sample receptacle defined on a distal portion of the rod;
25 and the drug storage unit may comprise a drug storage receptacle defined on the distal portion of the rod.

The actuator may comprise a rotator assembly coupled to the proximal portion of the tube, said rotator assembly configured for axially rotating the tube relative to the rod, wherein the
30 loaded position comprises the sample receptacle on the rod being substantially aligned with the access window on the tube, and wherein the default position comprises the drug storage receptacle on the rod being substantially aligned with the access window on the tube.

The sample receptacle may comprise a first groove on the rod, said first groove
35 comprising cutting edges for removing the sample from the site of interest into the sample receptacle, when the tube is rotated from the loaded position to the default position.

The drug storage receptacle may comprise a second groove on the rod, said second groove exposed to the site of interest via the access window on the tube when the tube is in the default position.

5 The first and second groove may be radially spaced apart on the lateral surface of the rod.

 The actuator may comprise a slider member coupled to the proximal end of the rod, said slider member configured for translating the rod relative to the tube along the lumen, wherein the
10 rod is not accessible from the access window on the tube when the rod is in the loaded position; and wherein the drug storage unit is accessible from the access window on the tube when the rod is in the default position.

 The sample receptacle may comprise a groove on the rod, said groove comprising a
15 cutting edge on the distal end of the rod; said cutting edge capable of cutting the sample from the site of interest and depositing the sample on the groove, in a space defined by the first groove and the tube, as the rod moves from the loaded position to the default position.

 The actuator may further comprise a rotator assembly coupled to the proximal portion of
20 the rod, said rotator assembly configured for axially rotating the rod relative to the tube such the sample can be retrieved.

 The drug storage receptacle may be disposed within the rod; said drug storage receptacle further comprising a drug delivery outlet disposed on the outer surface of the rod and exposed to
25 the site of interest via the access window on the tube when the rod is in the default position.

 The drug delivery outlet may be disposed along the length of the rod, apart from the groove.

30 The drug delivery outlet may further be disposed on an opposite surface of the rod.

 The device may further comprise an ejection member coupled to the drug storage unit, wherein actuation of the ejection member delivers the drug from the drug storage unit to the site of interest.

35 The ejection member may be configured to be actuated in stages, such that each stage of actuation delivers one unit of the drug.

The guide member may comprise, a semi-cylindrical tube having a semi-annular groove defined on an inner surface; the retention member may comprise, a rod comprising a collection member defined on a distal portion of the rod, said rod slidably received on the semi-annular groove of the semi-cylindrical tube; and the drug storage unit may comprise a drug storage receptacle defined on the distal portion of the rod.

The actuator may comprise a first slider member coupled to the proximal end of the rod, said first slider member configured for translating the rod along the semi-annular groove of the tube, wherein the collection member is held within the distal and proximal ends of the guide member when the rod is in the loaded position; and wherein the collection member extends beyond the distal end of the guide member when the rod is in the default position.

The device may further comprise, a cutter slidably coupled to the guide member; a cutter biasing member for biasing the cutter in a cutter default position; a cutting edge defined on a distal portion of the cutter; a cutter actuator comprising a second slider member coupled to the proximal end of the cutter, said second slider member configured for translating the cutter along the guide member of the tube, one or more catch members for retaining the cutter biasing member in a cutting position; and a cutter trigger member for triggering a movement of the cutter from the cutting position to the default position; wherein the cutting edge is held within the distal and proximal ends of the guide member when the cutter is in the cutting position; and wherein the cutting edge extends beyond the distal end of the guide member when the cutter is in the cutter default position.

The drug storage unit may be configured to provide a greater volume of the drug as compared to the volume of sample extracted.

The drug may comprise a haemostatic agent, said haemostatic agent configured to be water insoluble and in the form of a sponge, fibre, matrix, sheet, granule, bead, liquid or powder.

According to another aspect, there is provided a method for extracting a sample from a site of interest using a device as described herein, the method comprising, accessing the site of interest with the needle assembly; triggering relative movement between the retention member and the guide member such that the needle assembly is moved from the loaded configuration to the default configuration, causing the sample to be extracted from the site of interest and retained in the retention member; and delivering a drug stored in a drug storage unit to the site of interest when the needle assembly is in the default configuration.

According to another aspect, there is provided a method for fabricating a device for extracting a sample from a site of interest, the method comprising, providing a needle assembly configurable to be in at least a loaded configuration or a default configuration, said needle assembly comprising a guide member for accessing the site of interest, a retention member coupled to the guide member, and a drug storage unit for storing a drug; and providing a biasing member coupled to the needle assembly, said biasing member for biasing the needle assembly in the default configuration; wherein the guide member and retention member are capable of moving relative to each other between the loaded configuration and the default configuration, wherein moving from the loaded configuration to the default configuration causes the sample to be extracted from the site of interest and retained in the retention member; and the default configuration allows the drug to be delivered to the site of interest.

BRIEF DESCRIPTION OF THE DRAWINGS

Exemplary embodiments of the invention will be better understood and readily apparent to one of ordinary skill in the art from the following written description, by way of example only, and in conjunction with the drawings, in which:

FIG. 1 is a schematic diagram of a device for extracting a sample from a site of interest in an exemplary embodiment.

FIG. 2 is a perspective view drawing of a device for extracting a sample from a site of interest in an exemplary embodiment.

FIG. 3 is an enlarged perspective view drawing of the outer tube in the exemplary embodiment.

FIG. 4A is a perspective view drawing of the inner rod in the exemplary embodiment.

FIG. 4B is a first cross-sectional view drawing of the inner rod taken along line A-A' of FIG. 2.

FIG. 4C is a second cross-sectional view drawing of the inner rod taken along line A-A' of FIG. 2.

FIG. 5 is an enlarged perspective view drawing of the rotator assembly in the exemplary embodiment.

FIG. 6A is a photograph showing a biopsy device for extracting a sample from a site of interest in an exemplary embodiment.

FIG. 6B is a photograph of the biopsy device in a default configuration.

FIG. 6C is a photograph of the biopsy device in a loaded configuration

FIG. 7 is a perspective view drawing of a device for extracting a sample from a site of interest in an exemplary embodiment.

FIG. 8 is an enlarged perspective view drawing of the outer tube in the exemplary embodiment.

FIG. 9A is an enlarged perspective view drawing of the inner rod in the exemplary embodiment.

FIG. 9B is a first side view drawing of the inner rod in the exemplary embodiment.

FIG. 9C is a second side view drawing of the inner rod in the exemplary embodiment.

FIG. 10 is an enlarged perspective view drawing of the base member in the exemplary embodiment.

FIG. 11 is an enlarged perspective view drawing of the slider member in the exemplary embodiment.

FIG. 12 is a photograph showing a biopsy device for extracting a sample from a site of interest in an exemplary embodiment.

FIG. 13 is a perspective view drawing of a device for extracting a sample from a site of interest in an exemplary embodiment.

FIG. 14 is an enlarged perspective view drawing of a distal end of a needle assembly of the device in the exemplary embodiment.

FIG. 15 is an enlarged perspective viewing drawing of the guide member/ delivery sheath in the exemplary embodiment.

5 FIG. 16 is an enlarged perspective view drawing of the retention member in the exemplary embodiment.

FIG. 17 is an enlarged perspective view drawing of the cutter/ cutting sheath in the exemplary embodiment.

10 FIG. 18A is a first side view drawing of the distal end of the needle assembly of the device in the exemplary embodiment.

FIG. 18B is a second side view drawing of the distal end of the needle assembly of the device in the exemplary embodiment.

15 FIG. 18C is a third side view drawing of the distal end of the needle assembly of the device in the exemplary embodiment.

20 FIG. 18D is a fourth side view drawing of the distal end of the needle assembly of the device in the exemplary embodiment.

FIG. 19 is a schematic flowchart for illustrating a method for extracting a sample from a site of interest in an exemplary embodiment.

25 FIG. 20 is a schematic flowchart for illustrating a method for fabricating a device for extracting a sample from a site of interest in an exemplary embodiment.

30 **DETAILED DESCRIPTION**

Exemplary, non-limiting embodiments may provide a device and a method for extracting a sample from a site of interest.

35 In various exemplary embodiments, the sample may comprise tissue and the site of interest may be located within a body. The body may refer to a bodily organ or anatomical

structure which include but is not limited to a kidney, breast, lung, liver, pancreas, spleen, stomach, prostate, brain and the like. The body may be located within a human or an animal.

In various exemplary embodiments, the terms distal and proximal ends of various features of the device are used with reference to a handle portion of the device, away from the site of interest. For example, the distal end refers to the end nearer the site of interest where the sample is to be obtained, when the device is in use, while the proximal end refers to the end further away from the site of interest. Distal and proximal portions of a feature refer to portions of the feature which are in the area near respective distal and proximal ends.

FIG. 1 is a schematic diagram of a device 100 for extracting a sample 102 from a site of interest 104 in an exemplary embodiment. The device 100 comprises a needle assembly having a guide member 106 for accessing the site of interest 104, a retention member 108 coupled to the guide member 106, and a drug storage unit 112 for storing a drug. The needle assembly is configurable to be in at least a loaded configuration or a default configuration. The device 100 further comprises a biasing member 110 coupled to the needle assembly and is capable of biasing the needle assembly in the default configuration.

The guide member 106 and the retention member 108 are capable of moving relative to each other between the loaded configuration and the default configuration. For example, the retention member 108 may be configured to move from a loaded position 114 to a default position 116 (shown in dotted outline). It will be appreciated that the loaded and default positions as shown in FIG. 1 are for illustration only. In other words, movement of the retention member 108 from the loaded position 114 to a default position 116 is not limited to a translational/sliding movement. The retention member 108 may be configured to rotate and/or translate relative to the guide member 106. The guide member 106 may be stationary/moving when the retention member 108 rotates and/or slides with respect to the guide member 106. Alternatively, the device 100 may be configured such that the guide member 106 rotates and/or translates relative to the retention member 108. The retention member 108 may be stationary/moving when the guide member 106 rotates and/or slides with respect to the retention member 108. The relative movement from the loaded configuration to the default configuration e.g. movement from the loaded position 114 to the default position 116 is driven by the biasing member 110 which is biased to move the needle assembly to the default configuration.

In the exemplary embodiment, the relative movement from the loaded configuration to the default configuration e.g. translation of the retention member 108 from the loaded position 114 to the default position 116 causes the sample 102 to be cut/excised/removed/extracted from the

site of interest 104 and to be held/retained/stored in the retention member 108. The drug storage unit 112 is configured for storing a drug and allowing the drug to be delivered e.g. dispensed/released to the site of interest 104 when the needle assembly is in the default configuration e.g. when the retention member 108 is in the default position 116.

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In various exemplary embodiments, the biasing member 110 may be coupled to an actuator. The actuator may comprise one or more catch members e.g. releasable latch, hook and the like, for maintaining/retaining the biasing member 110 in a loaded position such that the needle assembly is in the loaded configuration, and a trigger member for triggering a movement of the guide member 106 or retention member 108 from the loaded position 114 to the default position 116 such that the needle assembly moves from the loaded configuration to the default configuration. It will be appreciated that the biasing member 110 may include but is not limited to spring members e.g. compression spring, torsion spring, elastic members in other shapes/designs which are capable of biasing/urging the needle assembly in the default configuration.

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In various exemplary embodiments, the drug may comprise one or more types of haemostatic agents. A haemostatic agent comprises materials that are suitable for use in sealing, stopping or controlling active bleeding from blood vessel (e.g. artery and vein) lacerations and punctures, and for controlling oozing of blood from tissue. A haemostatic agent may have one or more, but not limited to, the following properties, water insoluble, hydrophilic, bioabsorbable, biocompatible, superior haemostasis, adherence to wound. A haemostatic agent may be fabricated into different forms which include but are not limited to a sponge, fibre, matrix, sheet, granule, bead, liquid or powder.

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In some exemplary embodiments, the drug may be dislodged and deposited at the site of interest 104 as the device 100 is being removed from the site of interest 104. In other exemplary embodiments, the drug may be actively delivered/dispensed at the site of interest 104 via an ejection mechanism/means.

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FIG. 2 is a perspective view drawing of a device 200 for extracting a sample from a site of interest in an exemplary embodiment. The device 200 comprises a needle assembly, said needle assembly comprising a guide member e.g. outer tube 202 for accessing the site of interest, a retention member e.g. inner rod coupled to the outer tube 202, and a drug storage unit defined on the inner rod. The device 200 further comprises a biasing member (not shown) coupled to the outer tube 202 such that the needle assembly is capable of being biased in a default configuration.

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FIG. 3 is an enlarged perspective view drawing of the outer tube 202 in the exemplary embodiment. The outer tube 202 comprises a lumen/hollow space extending between a proximal end 204 and a distal end 206 of the outer tube 202. The lumen of the outer tube 202 comprises a substantially circular cross section and is capable of receiving a retention member in the form of an inner rod. In the exemplary embodiment, the inner rod is encased within the tube 202. An access window 208 is defined on the distal portion of the outer tube 202, such that the access window allows the interior of the outer tube 202 to be exposed or accessible from outside the outer tube.

In the exemplary embodiment, the access window 208 is in the form of an elongated opening on a lateral/circumferential surface of the outer tube 202. The length and size of the elongated opening are at least equal to, or more than the length and size of a drug storage receptacle/cavity (compare 218 of FIG. 4), e.g. haemostatic agent cavity defined on the inner rod, when the haemostatic agent cavity is positioned to be substantially aligned with the access window 208. This allows the drug e.g. haemostatic agent to be released smoothly and completely for effective blood stemming with substantially full coverage of a lesion/wound created at the site of interest e.g. kidney/breast/liver.

FIG. 4A is a perspective view drawing of the inner rod 210 in the exemplary embodiment. FIG. 4B is a first cross-sectional view drawing of the inner rod 210 taken along line A-A' of FIG. 2. FIG. 4C is a second cross-sectional view drawing of the inner rod 210 taken along line A-A' of FIG. 2. For ease of illustration, the outer tube 202 is shown together with the inner rod 210 in FIGS. 4B and 4C.

Referring to FIG. 4A, the inner rod 210 comprises a tubular structure extending between a proximal end 212 and a distal end 214 of the inner rod 210. The inner rod 210 further comprises a first groove/cavity 216 and a second groove/cavity 218 defined on a circumferential surface at a distal portion of the inner rod 210. The first groove 216 functions as a sample receptacle for receiving and holding/retaining a sample e.g. extracted tissue sample removed from the site of interest, e.g. kidney/breast/liver. The second groove 218 functions as a drug storage receptacle for holding and delivering a drug stored therein, e.g. haemostatic agent such as ARISTA™ microporous polysaccharide hemospheres.

Referring to FIGS. 4B and 4C, the first groove 216 and the second groove 218 are positioned on the circumferential surface of the rod 210 and are radially spaced from each other by an angle 242 of separation e.g. 120° of separation. It will be appreciated that other angles of

separation apart from 120° may be used. In use, the inner rod 210 is coaxially positioned within the hollow outer tube 202, said outer tube 202 having the access window 208 for exposing the grooves 216, 218. FIG. 4B shows the outer tube 202 and inner rod 210 in a default configuration/position such that the second groove 218 is exposed to the site of interest via the access window 208 on the outer tube 202. FIG. 4C shows the outer tube 202 and inner rod 210 in a loaded configuration/position. The outer tube 202 is configured to axially rotate e.g. in a clockwise manner with respect to the inner rod 210 to the loaded position such that the first groove 216 is exposed to the site of interest via the access window 208 on the outer tube 202.

The first groove 216 comprises cutting edges 244 provided along the length of the first groove 216, for removing the sample from the site of interest into the first groove 216, when the rod 210 is rotated from the loaded position to the default position. During cutting, the yet uncut tissue protrudes into and is wedged within the first groove 216 via the window 208. The rotation e.g. anticlockwise rotation of the outer tube 202 causes the cutting edges 244 to cut/slice the tissue sample off the site of interest, the sample of which is of a substantially uniform thickness given the rotational slicing action. Upon cutting, the tissue sample is collected within the first groove 216, between the cutting surface of the rod 210 and an inner surface of the outer tube 202.

The second groove 218 for storing the haemostatic agent therein is configured to be longer in length than the first groove 216 for containing the extracted tissue sample, such that the entire wound created at the site of interest is substantially covered. (See FIG. 4A). In the exemplary embodiment, a sharp/tapered tip 220 may be formed at the distal end 214 of the rod 210 for facilitating access to the site of interest.

It will be appreciated that there may be more than one sample receptacle/groove e.g. 216 on the inner rod 210 for containing the extracted tissue sample and more than one drug storage receptacle/groove e.g. 218 on the inner rod 210 for storing the drug e.g. haemostatic agent. It will also be appreciated that there may be more than one access window e.g. 208 on the outer tube 202 for providing access/exposure of the grooves e.g. 216, 218 to the site of interest.

In the exemplary embodiment, the outer tube 202 and the inner rod 210 form a needle assembly wherein the distal ends 206, 214 of the outer tube 202 and inner rod 210 penetrate a surface e.g. skin surface, organ surface, before the proximal ends 204, 212, to access the site of interest. The needle assembly is configurable to be in (i) at least a loaded configuration where the inner rod 210 is positioned with respect to the outer tube 202 such that the sample receptacle 216 is aligned/accessible or exposed to the site of interest via the access window 208 on the

outer tube 202, or (ii) a default configuration where the drug storage receptacle 218 is aligned/accessible to the site of interest via the access window 208.

Returning to FIG. 2, the device 200 further comprises a handle 222 coupled to the proximal portion of the inner rod 210. The handle 222 comprises a pair of handle halves e.g. 224, a hand grip 226 provided on the pair of handle halves e.g. 224, said hand grip 226 attached/fixed to the proximal portion of the inner rod 210, and an actuator e.g. rotator assembly 228 coupled to the proximal portion of the outer tube 202 and the biasing member e.g. torsion spring. In FIG. 2, one of the handle half 224 has been removed to allow the components e.g. rotator assembly 228 held within the handle 222, to be viewed.

FIG. 5 is an enlarged perspective view drawing of the rotator assembly 228 in the exemplary embodiment. The rotator assembly 228 is configured for axially rotating the outer tube 202 relative to the inner rod 210. The rotator assembly 228 is designed to incorporate a spring e.g. torsion spring mechanism with a catch-and-release system. The rotator assembly 228 comprises an outer rotating disc 230 coupled to an inner disc 232 via ball bearings 234 (see FIG. 2), and a spring cavity 236 coupled to the inner disc 232. The rotator assembly 228 further comprises a trigger member e.g. spring-loaded plunger 238 disposed on a circumferential surface of the inner disc 232. The spring-loaded plunger 238 is configured to be accessible to a user via an opening on the handle 222.

In the exemplary embodiment, the biasing member e.g. torsion spring is installed within the inner disc 232 and outer rotating disc 230 which is rotatable about an axis 246. The spring cavity 236 comprises a slot 240 for allowing an end portion of the torsion spring to pass through to access/couple to components outside the spring cavity 236. For example, the slot 240 may allow an end portion of the torsion spring to abut/couple/anchor to a surface, e.g. handle half 224. The rotator assembly 228 may further comprise one or more catch members e.g. latches disposed within the discs 230, 232 (not shown). The one or more catch members function to retain/maintain the torsion spring in a loaded position. The spring-loaded plunger 238 is configured to trigger rotation of the outer rotating disc 230, and inner disc 232 relative to each other.

The rotator assembly 228 is configured to be held in a loaded position where the torsion spring is twisted/wound and maintained in a twisted state by means of one or more catches interior to the discs 230, 232. When the trigger member 238 is actuated, i.e., the spring-loaded plunger is activated, the catch releases the spring from its twisted state/loaded position, and the spring returns the rotator assembly 228 into a default position. It will be appreciated that in the

default state, the torsion spring is in an untwisted or relatively less twisted state as compared to the loaded position. Further one or more catch members e.g. latches may be comprised within the rotator assembly to allow the rotator assembly 228 to be maintained in the default position.

5 It will be appreciated that because the outer tube 202 is coupled to one of the discs 230, 232 and the inner rod 210 is coupled to the hand grip 226 of the handle 222, rotation of the outer tube 202 relative to the inner rod 210 is effectively controlled by the discs of the rotator assembly 228. In other words, the outer tube 202 rotates with respect to a substantially stationary inner rod 210.

10 In use, the device 200 utilizing the catch-and-release system undergoes up to four different stages to perform a complete biopsy with extraction of the sample e.g. tissue from the site of interest within a subject e.g. patient's body/organ. The four stages are drug loading stage, pre-incision/pre-insertion stage, cutting stage, and tissue retrieval stage.

15 During the drug loading stage, the outer tube 202 and inner rod 210 are in the default configuration (i.e. start state, compare FIG. 4B) where the drug storage receptacle 218 on the inner rod 210 is substantially aligned with the access window 208 on the outer tube 202. This allows for loading of the drug e.g. haemostatic agent into the drug storage receptacle 218.

20 After the haemostatic agent is loaded into the drug storage receptacle 218, the outer rotating disc/dial 230 at the end of the handle 222 is manually axially rotated/turned 120° in a clockwise manner by a user, causing the torsion spring within the handle 222 to be twisted/compressed. The 120° clockwise rotation sets the outer tube 202 in the pre-incision stage (i.e. loaded position, compare FIG. 4C). In the exemplary embodiment, the device is configured such that a user can hear a click sound as the inner mechanism of the rotator assembly 228 passes a catch member e.g. a latch and engages the latch to maintain the outer tube in the loaded position. That is, for each latch it passes through, a click can be heard or felt.

30 During the pre-incision stage, the outer tube 202 is in the loaded position such that the sample receptacle 216 (for collecting tissue sample) is exposed prior to insertion of the needle assembly and during placement of the needle assembly at the site of interest/incision. See FIG. 4C. The position of the needle assembly within the body may be obtained through an imaging device e.g. ultrasound. Once in position at the site of incision i.e. when the distal portion of the outer tube 202 and inner rod 210 are at the site of interest, the biopsy procedure proceeds to the cutting stage.

During the cutting stage, the spring-loaded plunger 238 is depressed or actuated by the user to release the torsion spring, causing the outer tube 202 to axially rotate 120° in an anticlockwise manner, said rotation causing the inner mechanism of the rotator assembly 228 to move from the latched position (i.e. loaded position, compare FIG. 4C) to the “start state” (i.e. default position, compare FIG. 4B). During the rotation, the interface between the outer tube 202 and the inner rod 210 interact to produce a cutting action. In this case, the length of the first groove 216 (i.e. sample receptacle) is defined with relatively sharp edges 244, and is capable of cutting the desired sample from the site of interest such that it is then deposited within the sample receptacle 216. For the extraction of the tissue sample, the tissue is wedged between the cutting edge on the inner rod/needle 210 and the outer tube/needle 202 while the outer tube is rotated. The rotation of the outer tube in relation to the stationary inner rod results in a pinching force which causes cutting of a substantially uniform tissue sample. The tissue is collected between the cutting surface of the inner rod/needle 210 and the inner surface of the outer tube/needle 202.

After the 120° rotation of the outer tube 202 to the default position, the drug storage receptacle 218 is exposed via the access window 208, while the sample is held within the sample receptacle 216 and is no longer exposed via the access window 208. With the drug storage receptacle 218 exposed to the site of interest via the access window 208, the haemostatic agent stored therein is in contact with fluid e.g. blood at the site of interest. The haemostatic agent expands in size after absorbing fluid e.g. blood, causing the expanded haemostatic agent to be gradually expelled from the drug storage receptacle as the device 200 is removed from the site of interest out of the patient's body.

After the device 200 is removed from the site of interest, the tissue is ready to be removed from the device. During this tissue retrieval stage, the outer rotating disc/dial 230 at the end of the handle 222 is turned 120° in a clockwise manner such that it is held at the latch position (i.e., the loaded position), which exposes the sample receptacle 216 such that the cut tissue sample contained therein can be retrieved, via the access window 208.

It will be appreciated that the dimensions of the device 100 depend on the specific desired usage requirements. In the exemplary embodiment, the outer diameter of the outer tube is 2 mm, the outer diameter of the inner rod is 1.8 mm. The length of the outer tube is 160 mm. The sample storage receptacle (i.e. first groove 216 for storing a sample) measures 0.7 mm in width by 20 mm in length. The drug storage receptacle (i.e. second groove 218 for storing a haemostatic agent measures 0.7 mm in width by 25 mm in length. The access window 208 has a length of 25 mm and a width greater than 0.7 mm.

It will also be appreciated that the device is not limited to the configuration as described with respect to FIGS. 2 to 5. For example, in an alternative exemplary embodiment, the outer tube 202 may be configured to be fixed/stationary and the inner rod 210 may be configured to axially rotate with respect to the outer tube 202. In other words, the rotator assembly 228 may be coupled to the inner rod 210 such that the inner rod 210 is configurable to rotate between a loaded configuration where the first groove 216 is aligned/exposed via the access window 208 and a default configuration where the second groove 218 is aligned/exposed via the access window 208. With the outer tube 202 being stationary while the inner rod 210 rotates, the access window 208 on the outer tube 202 may advantageously allow the drug e.g. haemostatic agent to be precisely released at the lesion/wound created at the site of interest.

In another alternative exemplary embodiment, the device 100 may be configured to include more than one loaded position. For example, after the haemostatic agent is loaded into the drug storage receptacle 218, the outer rotating disc/dial 230 at the end of the handle 222 may be manually axially over-rotated/over-turned by e.g. 210° (instead of 120°) in a clockwise manner by a user, causing the torsion spring within the handle 222 to be twisted/compressed. The 210° clockwise rotation sets the outer tube 202 such that none of the drug storage receptacle 218 or sample receptacle 216 are accessible via the access window 208. This can advantageously ensure that when the needle assembly is inserted into the body, the cavity does not inadvertently cut and retain other surrounding tissue other than at the site of interest.

The device 100 may be configured such that a user can hear e.g. 2 clicks (instead of one) as the inner mechanism of the rotator assembly 228 passes e.g. two catch members (instead of one catch member). In other words, at the pre-incision stage, none of the drug storage receptacle 218 or sample receptacle 216 are accessible via the access window 208. During the cutting stage, the needle assembly is inserted to access the site of interest. Once the needle assembly is determined to be in position at the site of incision, the spring-loaded plunger 238 (i.e. release catch) is depressed by the user. This releases the torsion spring, causing the outer tube 202 to axially rotate 90° in an anticlockwise manner, said rotation causing the inner mechanism of the rotator assembly 228 to move from a second latch to a first latch (i.e. loaded position). The 90° anticlockwise rotation exposes the sample receptacle 216 for the third (cutting) stage such that the sample receptacle is exposed via the access window 208. The spring-loaded plunger 238 is then depressed or actuated again by the user to release the torsion spring, causing the outer tube 202 to axially rotate a further 120° in an anticlockwise manner. During the rotation, the interface between the outer tube 202 and the inner rod 210 interact to produce a cutting action. At the same time, the haemostatic agent is exposed to the site of interest as the drug storage

receptacle 218 is aligned/exposed via the access window 208. After the needle assembly is removed/retracted from the site of interest, the outer rotating disc/dial 230 at the end of the handle 222 is turned 120° in a clockwise manner such that it is held at the first latch (i.e., loaded position), which exposes the sample receptacle 216 such that the cut tissue sample contained therein can be retrieved, via the access window 208.

In the exemplary embodiment, the device 200 may be applied to pre-surgery minimally invasive renal biopsy, e.g. kidney biopsy device. The device 200 utilises a rotating mechanism via torsion spring and provides a haemostatic function. The needle design enhances efficiency of tissue extraction and deployment of haemostatic measures, and the handle design emphasises on user-friendliness through easy-to-use rotating and clicking mechanism.

The device 200 advantageously requires only the use of one hand to initiate when inserted into a body e.g. kidney. Sample extraction may advantageously be performed with a single actuation of the trigger i.e. spring-loaded plunger 238. Actuating the trigger member with the e.g. push of a button triggers the rotating mechanism of the inner rod, by releasing the charged torsion spring, relative to a stationary outer tube. This, in turn, causes a shearing force which cuts and collects the tissue sample. Simultaneous drug delivery (e.g., haemostatic agent) to the entire kidney lesion site is provided. It will be appreciated that prior to insertion of the device 200 into the kidney, two hands may be required to rotate the torsion spring and load the haemostatic agent e.g. ARISTA™ into the drug storage receptacle of the inner rod.

FIG. 6A is a photograph showing a biopsy device 600 for extracting a sample from a site of interest in an exemplary embodiment. The biopsy device 600 is substantially similar to the device 200 of FIG. 2 and comprises substantially similar components. For example, the biopsy device 600 comprises a needle assembly 602 for accessing the site of interest e.g. suspected diseased tissue within an organ. The needle assembly may be formed by an outer tube acting as a guide member (compare 202 of FIG. 3) and an inner rod acting as a retention member (compare 210 of FIG. 4A). The inner rod may comprise a sample receptacle (compare 216 of FIG. 4A) and a drug storage receptacle (compare 218 of FIG. 4A). The outer tube may comprise an access window (compare 208 of FIG. 3), said access window configured to align/expose the sample receptacle or drug storage receptacle from outside the outer tube. The biopsy device 600 further comprises a rotator assembly 604 coupled to the needle 602, said rotator assembly 604 further coupled to a handle 606 for allowing a user to hold the biopsy device 600. In FIG. 6A, the handle 606 of the device 600 is taken apart to show the portion of the rotator assembly 604 that is held within the handle 606. The rotator assembly 604 comprises an outer rotating disc 608 disposed adjacent to the handle 606 and an inner disc 610 disposed within the handle 606. The outer

rotating disc 608 is configured to rotate the outer tube of the needle assembly 602 with respect to the inner rod which is fixed to the handle 606.

FIG. 6B is a photograph of the biopsy device 600 in a default configuration. In the default configuration, the outer tube is rotated such that the access window is aligned to expose the drug storage receptacle (compare FIG. 4B). FIG. 6C is a photograph of the biopsy device 600 in a loaded configuration. In the default configuration, the outer tube is rotated such that the access window is aligned to expose the sample receptacle (compare FIG. 4C). As shown in FIGS. 6B and 6C, a marking 612 is indicated on the outer rotating disc 608 to show the relative positions of the outer rotating disc in the default and loaded configurations. To set the biopsy device 600 in the loaded configuration, the outer rotating disc 608 is rotated 120° in a clockwise manner, when viewed from the handle end of the biopsy device 600. As shown in FIG. 6B and FIG. 6C, the position of the marking 612 changes as the outer rotating disc 608 is rotated to set the biopsy device 600 from the default configuration to the loaded configuration.

FIG. 7 is a perspective view drawing of a device 700 for extracting a sample from a site of interest in an exemplary embodiment. The device 700 comprises a guide member e.g. outer tube 702 for accessing the site of interest, a retention member e.g. inner rod 704 coupled to the outer tube 702, a biasing member e.g. spring 706 coupled to the inner rod 704, and a drug storage unit defined on the inner rod 704.

FIG. 8 is an enlarged perspective view drawing of the outer tube 702 in the exemplary embodiment. The outer tube 702 comprises a lumen/hollow space extending between a proximal end 708 and a distal portion 710 of the outer tube 702. The lumen of the tube 702 comprises a substantially circular cross section and is capable of receiving a rod i.e. inner rod 704 and allowing the rod to be encased therein e.g. coaxially encased. The proximal end 708 of the outer tube 702 is open and the distal end 710 of the outer tube 702 is closed. In this respect, a rod may be inserted into the outer tube 702, through the opening at the proximal end 708. The closed distal end 710 of the outer tube 702 is bevelled to form a tip 712 for facilitating penetration and reducing friction when inserting the outer tube 702 into a body to access a site of interest within the body e.g. kidney.

In the exemplary embodiment, an access window 714 is defined on a circumferential surface at the distal portion of the outer tube 702. The access window 714 is configured to allow the interior of the outer tube 702 to be exposed or accessible from outside the outer tube. The access window 714 comprises a longitudinal opening having a substantially semi-cylindrical shape and is configured to receive a sample extracted from the site of interest. A bottom groove

716 is defined at the portion of the tube 702 diametrically opposite the access window 714. In the exemplary embodiment, the bottom groove 716 has a substantially semi-cylindrical shape and allows a sample to be stored/retained therein. The access window 714 is further configured to provide access to a drug storage unit e.g. drug delivery outlet, when the drug delivery outlet is positioned to be substantially aligned with the access window 714 or exposed via the access window 714. This allows the drug e.g. haemostatic agent to be released smoothly and completely for effective blood stemming with substantially full coverage of a wound created at a site of interest.

FIG. 9A is an enlarged perspective view drawing of the inner rod 704 in the exemplary embodiment. FIG. 9B is a first side view drawing of the inner rod 704 in the exemplary embodiment. FIG. 9C is a second side view drawing of the inner rod 704 in the exemplary embodiment. For the purpose of illustration, the outer tube 702 is shown together with the inner rod 704 in FIGS. 9B and 9C.

Referring to FIG. 9A, the inner rod 704 comprises a substantially tubular structure extending between a proximal end 718 and a distal end 720. The inner rod 704 further comprises a sample receptacle in the form of a substantially semi-cylindrical groove 722 on the distal portion of the inner rod 704. The groove 722 comprises a cutting edge 724 formed on the distal end 720 of the inner rod 704, said cutting edge 724 capable of cutting the sample from the site of interest and retaining the sample on the groove 722 as the inner rod 704 translates along its longitudinal axis in the direction of the cutting edge 724. The cut sample is retained in a space defined by a concave inner surface of the groove 722 and an inner concave surface of the bottom groove 716 of the outer tube 702. In this respect, the semi-cylindrical groove 722 functions as a cover for covering the access window 714 to prevent the cut sample from falling out from the access window 714. For example, the groove 722 may be a substantially semi-cylindrical thin wall cutter.

In the exemplary embodiment, the inner rod 704 further comprise a drug storage receptacle formed at a hollow space disposed within a proximal portion 726 of the inner rod 704 and a drug delivery outlet/port 728 disposed on the outer surface of the inner rod and which is coupled to the interior hollow space, for allowing a drug e.g. haemostatic agent stored therein to be exposed to the site of interest. The drug delivery outlet 728 is disposed along the length of the inner rod 704, spaced apart from the groove 722 along the longitudinal axis of the rod 704, and on an opposite circumferential surface of the inner rod 704. The inner rod 704 may be coupled to an ejection member e.g. push rod 730 (see FIG. 7), disposed partially within the hollow space of the drug storage receptacle, such that actuation of the ejection member 730 delivers/pushes

the drug from within the drug storage receptacle, out of rod 704 via the drug delivery outlet 728 to the site of interest.

With reference to FIG. 9B and 9C, in use, the rod 704 is coaxially positioned within the lumen of the outer tube 702. The access window 714 is configured to provide access to the inner rod 704 and the drug delivery outlet 728. The inner rod 704 is configured to translate with respect to the outer tube 702 to a loaded position such that the inner rod 704 is not accessible or exposed to the site of interest via the access window 714 on the outer tube 702. FIG. 9B shows the inner rod 704 (with dotted line representing the portion of the inner rod 704 within the outer tube 702) in the loaded position. The inner rod 704 is further configured to translate with respect to the outer tube 702 to a default position such that the drug delivery outlet 728 is accessible or exposed to the site of interest via the access window 714 on the outer tube. FIG. 9C shows the inner rod 704 (with dotted line representing the portion of the inner rod 704 within the outer tube 702, and solid line representing the portion of the inner rod 704 exposed via the access window 714) in the default position.

Prior to cutting, the inner rod 704 is in the loaded position (see FIG. 9B). The yet uncut tissue protrudes into the access window 714. To extract a sample from the site of interest, the inner rod 704 is translated with respect to the outer tube 702 from the loaded position to the default position (see FIG. 9C). In other words, the distal end 720 of the inner rod 704 translates along the lumen towards the distal end 710 of the outer tube 702. While translating from the loaded position to the default position, the cutting edge 724 on the distal end 720 of the inner rod 704 cuts the sample from the site of interest. As the inner rod 704 moves from the loaded position to the default position, the cut sample is retained on the groove 722 such that the sample is deposited and held in a space defined by the inner concave surface of the groove 722 and the inner concave surface of the bottom groove 716 of the outer tube 702. In the default position, the drug delivery outlet 728 is also exposed to the site of interest via the access window 714 (see FIG. 9C). The ejection member 730 is then actuated/pushed to deliver the drug from the drug storage receptacle to the site of interest via the access window 714.

In the exemplary embodiment, the outer tube 702 and inner rod 704 form a needle assembly wherein the distal ends 710, 720 of the outer tube and inner rod 702, 704 penetrate a surface e.g. skin surface, organ surface, before the proximal ends 708, 718, to access the site of interest. The needle assembly is configurable to be in (i) at least a loaded configuration where the inner rod 704 is in the loaded position with respect to the outer tube 702 such that the inner rod 704 is not accessible or exposed to the site of interest via the access window 714 on the outer tube 702, or (ii) a default configuration where the inner rod 704 is in the default position with

respect to the outer tube 702 such that the drug delivery outlet 728 is accessible or exposed to the site of interest via the access window 714 on the outer tube.

The device 700 further comprises a base or handle e.g. hand-held base member 732 coupled to the proximal portion of the outer tube 702.

FIG. 10 is an enlarged perspective view drawing of the base member 732 in the exemplary embodiment. The base member 732 is defined by a top surface 734, a needle connection port 736 formed on/ coupled to the top surface 734 on one end of the base member 732, and a trigger/ejector port 738 formed on/ coupled to the top surface 734 on another end of the base member 732 opposite the needle connection port 736. The base member 732 further comprises a first substantially linear track/groove 740 and a second substantially linear track/groove 742 formed on the top surface 734, between the needle connection port 736 and the trigger/ejector port 738.

The needle connection port 736 is configured to couple the proximal portion of the outer tube 702 to the base member 732. The trigger/ejector port 738 is configured to be coupled to a trigger member 744 (see FIG. 7) for providing a triggering mechanism and is further configured to receive an ejection member e.g. push rod 730 (see FIG. 7). The first track 740 is configured for allowing an actuator e.g. slider member 746 to be mounted thereon, said slider member 746 capable of translating along the first track 740. The second track 742 is configured for receiving/coupling to the biasing member e.g. spring 706. One end of the spring 706 may be coupled to the slider member 746 and the other end of the spring may be coupled to the trigger/ejector port 738.

FIG. 11 is an enlarged perspective view drawing of the slider member 746 in the exemplary embodiment. The slider member 746 comprises grooves 748, 750 for allowing the slider member 746 to be mounted onto the first track 740 of the base member 732. The slider member 746 further comprises ports e.g. 752, 754 for allowing the slider member 746 to connect to other components of the device 700. The slider member 746 further comprises a pair of handles e.g. finger grips 756, 758 for allowing a user to place two fingers thereon to move/slide the slider member 746.

Returning to FIG. 7, the device 700 further comprises the trigger member 744 disposed on the top surface 734 of the base member 732. The trigger member 744 comprises a catch 760 for latching to a depression 762 disposed on the slider member 746. The trigger member 744 functions to retain/maintain the spring 706 in the loaded position. Actuation of the trigger member

744 triggers a translation of the inner rod 704 from the loaded position to the default position. The loaded position comprises the rod 704 being positioned relative to the outer tube 702 such that the rod is not accessible or visible from the access window 714 on the outer tube 702.

5 In the loaded position, the spring 706 is in a compressed state. The catch 760 of the trigger member 744 latches onto the depression 762 such that it is retained in the loaded position. Actuating the trigger member 744 causes the catch 760 to disengage from the depression 762, and triggers the release of the spring 706 which pushes or translates the inner rod 704 within the outer tube 702, into its default position. The default position comprises the inner rod 704 being
10 positioned relative to the outer tube 702 such that the drug storage receptacle or drug delivery outlet 728 is accessible or visible from the access window 714 on the outer tube 702. In the default position, the spring 706 is in an uncompressed state, or a relatively less compressed state as compared to the loaded position.

15 The device 700 further comprises a rotator assembly 764 coupled to the proximal portion of the rod 704. The rotator assembly 764 is configured for rotating the inner rod 704 about its longitudinal axis (e.g. about 180°), relative to the outer tube 702 such that the sample stored in the space defined by the concave inner surface of the groove 722 and the inner concave surface of the bottom groove 716, is exposed or accessible via the access window 714, such the sample
20 can be retrieved from the sample receptacle 722. In other words, the rotator assembly 764 rotates the inner rod 704 such that the groove 722 does not block the access window 714. The rotator assembly 764 is further coupled to the slider member 746 via a locking screw mechanism 766. It will be appreciated that this is performed after the device 700 has been removed from the body.

25 The device 700 further comprises the ejection member e.g. push rod 730 coupled to the drug storage unit within the rod 704. Actuation of the ejection member 730 delivers the drug stored within the drug storage unit, from/out of the drug storage unit to the site of interest. In other words, the push rod 730 acts to flush out the drug contained within the drug storage receptacle. Controlling the degree of actuation of the push rod 730 advantageously provides control over the
30 amount of drug e.g. haemostatic agent dispensed via the drug delivery outlet 728 to the site of interest.

In use, the device 700 undergoes up to four different stages to perform a complete biopsy with extraction of the sample from the site of interest within a subject e.g. patient's body/organ.
35 The four stages are drug loading stage, pre-incision/pre-insertion stage, cutting stage, and tissue retrieval stage.

During the drug loading stage, the inner rod 704 is in the default position with the slider 746 translated along the first track 740 towards the needle connection port 736 such that the spring 706 is in an uncompressed or relatively less compressed state. The rotator assembly 764 is rotated such that the drug delivery outlet/port 728 is exposed/accessible via the access window 714 on the outer tube 702. In the default position, the drug may be loaded into the drug storage receptacle via the drug delivery outlet/port 728. Alternatively, the drug may be already pre-loaded in the drug storage receptacle and in this respect, there is no need for the drug loading stage.

During the pre-incision stage, the slider member 746 is pulled by a user to the loaded position along the first track 740 towards the trigger member 744 to compress the spring 706. The slider member 746 is held in the loaded position as the catch 760 on the trigger member 744 engages the depression 762 on the slider member 746 in the loaded position.

During the cutting stage, the tip 712 at the distal end 710 of the outer tube 702 pierces a surface e.g. skin to reach the site of interest (i.e. target position) under guidance of an imaging device e.g. ultrasound. Once the distal end 710 of the outer tube 702 is determined to be at the target position, the trigger member 744 is actuated by the user, releasing the spring 706 from its compressed state and hence, causing the slider member 746 carrying the rotator assembly 764 and the inner rod 704 to translate along the outer tube 702 to the default position. The translation of the inner rod 704 from the loaded to the default position causes sample tissue which protrudes into the outer tube 702 via the access window 714 to be sliced/cut. It should be appreciated that the translation should be of a relatively high speed in order for the cut/slice to occur. When the inner rod 704 is in the default position, the push rod 730 is pushed at its proximal end towards the site of interest. This causes the drug e.g. haemostatic agent previously stored within the drug storage unit (i.e., the hollow chamber within the inner rod 704) to be pushed out of the inner rod 704 via the drug delivery outlet 728 and out of the outer tube 702 via the access window 714 to the lesion site/ injured area. Thereafter, the device 700 is then removed from the lesion site after the haemostatic agent is delivered.

After the device 700 is removed from the site of interest, the tissue is ready to be removed from the device. During this tissue retrieval stage, the rotator assembly 764 is turned to rotate the inner rod 704 about its longitudinal axis (e.g. about 180°) with respect to the outer tube 702 such that the cut sample which was previously held in the space between the sample receptacle 722 and the outer tube 702 is exposed via the access window 714.

FIG. 12 is a photograph showing a biopsy device 1200 for extracting a sample from a site of interest in an exemplary embodiment. The biopsy device 1200 is substantially similar to the

device 700 of FIG. 7 and comprises substantially similar components. For example, the biopsy device 1200 comprises a needle assembly 1202 for accessing the site of interest e.g. suspected diseased tissue within an organ, a slider member 1204 coupled to the needle assembly 1202, said slider member 1204 further coupled to a base member 1206. The biopsy device 1200 further comprises a trigger 1208 coupled to the base member 1206 and a push rod 1210 coupled to the base member 1206. The trigger 1208 is configured for releasably coupling to the slider member 1204 and the push rod 1210 is configured for ejecting a drug e.g. haemostatic agent stored within a drug storage unit.

FIG. 13 is a perspective view drawing of a device 1300 for extracting a sample from a site of interest in an exemplary embodiment. FIG. 14 is an enlarged perspective view drawing of a distal end of a needle assembly of the device 1300 in the exemplary embodiment. The device 1300 comprises a guide member 1302 for accessing the site of interest, a retention member 1304 coupled to the guide member 1302, a biasing member e.g. spring 1306 coupled to the retention member 1304, and a drug storage unit 1308 defined in the retention member 1304.

FIG. 15 is an enlarged perspective viewing drawing of the guide member/ delivery sheath 1302 in the exemplary embodiment. The guide member 1302 comprises a semi-cylindrical tube 1310 having a semi-annular groove 1312 defined along an inner concave surface of the semi-cylindrical tube 1310, between a proximal end 1314 and a distal end 1316 of the semi-cylindrical tube 1310. The semi-annular groove 1312 is arranged to receive the retention member 1304 such that the retention member 1304 is allowed to translate relative to the semi-cylindrical tube 1310 along the semi-annular groove 1312. The distal end 1316 of the semi-cylindrical tube 1310 is substantially flat/blunt to reduce the chances of bleeding due to puncture e.g. of the kidney by the semi-cylindrical tube 1310 during incision/drug delivery. The guide member 1302 comprises an engager e.g. drug engager 1318 at the distal portion of the semi-cylindrical tube 1310, said drug engager 1318 configured to be in contact with a drug e.g. haemostatic agent and to facilitate forward push movement of the haemostatic agent beyond the distal end 1316 of the guide member 1302 into a site of interest e.g. biopsy tract. The guide member 1302 further comprises an adjustment/controller member 1320 configured for controlling a sliding movement of the guide member 1302.

FIG. 16 is an enlarged perspective view drawing of the retention member 1304 in the exemplary embodiment. The retention member 1304 comprises a rod 1322 having a substantially cylindrical shape between a proximal end 1324 and a distal end 1326 of the rod 1322. The rod 1322 comprises a collection member 1328 defined on a distal portion of the rod 1322. The collection member 1328 comprises a collection site e.g. recess in the rod 1322 for storing the

extracted/cut sample e.g. anatomical renal tissue sample so that subsequently, a medical professional can retrieve the e.g., anatomical renal tissue from the collection site and perform appropriate analytical tests on the tissue. The distal end 1326 of the rod 1304 is shaped to form a tapered surface 1332 to facilitate penetration/insertion of the distal end of the rod to access a site of interest. The rod 1304 further comprises a connector 1334 defined at the proximal end 1324 of the rod 1304, said connector 1334 configured for coupling other components of the device 1300.

Returning to FIG. 13, the device 1300 further comprises a handle 1336 coupled to the proximal portion of the semi-cylindrical tube 1310. A cut-open view of the handle 1336 is shown in FIG. 13 for illustration of the interior features of the handle. The handle 1336 comprises a housing, said housing comprising a substantially semi-cylindrical upper casing 1338 and a substantially semi-cylindrical lower casing 1340 that are joined together to define a cavity e.g. substantially elongated space therein. A portion (e.g., proximal portions) of the semi-cylindrical tube 1310 and inner rod 1322 are housed in the cavity of the lower casing 1340.

In the exemplary embodiment, the connector 1334 at the proximal end 1324 of the rod 1322 (see FIG. 16) is coupled to a first slider member 1342 disposed within the handle 1336. The first slider member 1342 is further coupled to one end of the spring 1306. The other end of the spring 1306 is coupled to a first partition wall 1372 formed within the upper casing 1338. A trigger member 1344 is disposed at one end of the handle 1336 opposite to the semi-cylindrical tube 1310. The trigger member 1344 comprises a plurality of catches e.g. 1346 for releasably coupling to the first slider member 1342 and a deployment spring 1366 for returning the trigger member 1344 to its default position after being actuated/depressed. One end of the deployment spring 1366 is coupled to the trigger member 1344 and the other end of the deployment spring 1366 is coupled to a second partition wall 1374 formed within the upper casing 1338.

The first slider member 1342 is configured for translating the inner rod 1322 along the semi-annular groove 1312 of the semi-cylindrical tube 1310. To this end, one or more handles may be provided on the first slider member 1342, the one or more handles may protrude outside the casings 1338, 1340 to allow a user to grip and move/translate the first slider member 1342 along the semi-annular groove 1312 of the semi-cylindrical tube 1310. The first slider member 1342 is configured to be held in a loaded position where the first slider member 1342 is translated towards the first partition wall 1372, and where the spring 1306 is compressed and maintained in a compressed state by means of the plurality of catches e.g. 1346 coupled to the trigger 1344. In the loaded position, the retention member 1304 is positioned relative to the guide member 1302 such that the collection member 1328 on the retention member 1304 is held between/within the

proximal and distal ends 1314, 1316 of the guide member 1302. When the trigger member 1344 is actuated/depressed by a user, the plurality of catches e.g. 1346 releases the spring 1306 from its compressed state, and the spring returns the first slider member 1342 into a default position where the first slider member 1342 is translated away from the first partition wall 1372. In the default position, the retention member 1304 is positioned relative to the guide member 1302 such that the collection member 1328 on the retention member 1304 extends beyond the distal end 1316 of the guide member 1302. In the default position, the spring 1306 is in an uncompressed state, or a relatively less compressed state as compared to the loaded position.

In the exemplary embodiment, the device 1300 further comprises a cutter 1348 slidably coupled to the guide member 1302 and retention member 1304.

FIG. 17 is an enlarged perspective view drawing of the cutter/ cutting sheath 1348 in the exemplary embodiment. The cutter 1348 comprises a semi-cylindrical tube 1350 having a semi-annular groove defined along an inner concave surface of the semi-cylindrical tube 1350, between a proximal end 1352 and a distal end 1354 of the semi-cylindrical tube 1350. The cutter 1348 has a substantially similar shape and structure as the guide member 1302 and is configured to couple to the guide member to form a substantially cylindrical structure. The distal end 1354 of the semi-cylindrical tube 1350 is shaped to form a tapered cutting surface 1356 to facilitate penetration/ insertion and for reducing friction during penetration/insertion of the distal end 1354 to access a site of interest within a body e.g. kidney. The semi-cylindrical tube 1350 further comprises a connector 1358 defined at the proximal end 1352 of the semi-cylindrical tube 1350, said connector 1358 configured for coupling other components of the device 1300.

With reference to FIG. 13, the cutter 1348 is coupled to a cutter biasing member 1360 for biasing the cutter 1348 in a cutter default position. One end of the cutter biasing member 1360 is coupled to a second slider member 1362 disposed within the handle 1336. The other end of the cutter biasing member 1360 is coupled to a third partition wall 1376 formed within the upper casing 1338. The second slider member 1362 is coupled to the connector 1358 of the cutter 1348 and is configured for translating the cutter 1348 along the longitudinal axis of the guide member 1302 and relative to the guide member 1302. The second slider member 1362 further comprises a plurality of catches e.g. 1364 for retaining the cutter biasing member 1360 in a cutting position, and a cutter trigger member, e.g. trigger 1344 coupled to the deployment spring 1366 for triggering a movement of the cutter 1348 from the cutting position to a default position. One or more handles may be provided on the second slider member 1362, the one or more handles may be arranged to protrude outside the casings 1338, 1340 to allow a user to grip and move/translate

the second slider member 1362 with respect to the guide member 1302 and retention member 1304.

The second slider member 1362 is configured to be held in a cutting position where the
5 second slider member 1362 is translated towards the third partition wall 1376, and where the
cutter biasing member 1360 is compressed and maintained in a compressed state by means of
the plurality of catches e.g. 1364 coupled to the trigger 1344 via the plurality of catches e.g. 1346.
In the cutting position, the cutter 1348 is held within the distal end 1316 and proximal end 1314
of the guide member 1302. When the trigger member 1344 is actuated/depressed by the user,
10 the plurality of catches e.g. 1346 releases the first slider member 1342 from the loaded position
into the default position, which in turn causes the plurality of catches e.g. 1364 to release the
cutter biasing member 1360 from its compressed state, and the cutter biasing member 1360
returns the second slider member 1362 into the cutter default position as the second slider
member 1362 translates away from the third partition wall 1376. In the cutter default position, the
15 cutting surface/edge 1356 extends beyond the distal end 1316 of the guide member 1302. In the
cutter default position, the cutter biasing member 1360 is in an uncompressed state, or a relatively
less compressed state as compared to the cutting position. The cutter 1348 is configured to cut
the sample e.g. anatomical renal tissue from the site of interest e.g. within kidney of a patient to
obtain the sample when the cutter translates from the cutting position to the cutter default position.

Both the guide member 1302 and the cutter 1348 comprise extrusions defined along the
length on respective inner concave surfaces of semi-cylindrical tubes which cooperate with
respective channels defined along the length of the rod 1322 of the retention member 1304. The
channels on the rod 1322 act as grooves which slidably couple to the extrusions on the semi-
25 cylindrical tubes 1310 and 1350 such that both the guide member 1302 and the cutter 1348
adhere better to the retention member 1304.

In the exemplary embodiment, the guide member 1302, the retention member 1304, and
the cutter 1348 form the needle assembly wherein the distal ends 1316, 1326, 1354 of the guide
30 member, retention member and cutter penetrate a surface e.g. skin surface, organ surface,
before the proximal ends 1314, 1324, 1352, to access the site of interest. The needle assembly
is configurable to be in (i) at least a loaded configuration where the retention member 1304 is in
the loaded position and is positioned relative to the guide member 1302 such that the collection
member 1328 on the retention member 1304 is held between/within the proximal and distal ends
35 1314, 1316 of the guide member 1302, or (ii) a default configuration where the retention member
1304 is in the default position and is positioned relative to the guide member 1302 such that the
collection member 1328 on the retention member 1304 extends beyond the distal end 1316 of

the guide member 1302. The device 1300 utilizes a spring assembly housed in the cavity of the lower casing 1340 and comprises the cutter retract-and-trigger mechanism, the inner rod/collection member retract-and-trigger mechanism, trigger member e.g. button 1344 coupled to a deployment spring 1366.

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The cutter retract mechanism allows the cutter 1348 to be retracted into the housing to harness the stored/recoil energy in the spring 1360 that is required to extend the cutter 1348. The cutter trigger mechanism allows the cutter 1348 to be extended out of the housing to cut a tissue e.g. anatomical renal tissue.

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The inner rod retract mechanism allows the retention member 1304 to be retracted into the housing to harness the stored/recoil energy in the spring 1306 that is required to extend the retention member 1304. The inner rod trigger mechanism allows the retention member 1304 to be extended out of the housing to collect the tissue e.g. anatomical renal tissue.

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The trigger button 1344 facilitates the deployment of both the cutter trigger mechanism as well as the inner rod trigger mechanism. The deployment spring 1366 harnesses the stored/recoil energy that is required to deploy the trigger button when the trigger button is in a locked position.

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In the exemplary embodiment, the drug storage unit 1308 (see FIG. 14) comprises a drug storage receptacle/cannula having a hollow space defined at the distal portion 1330 of the rod 1322 of the retention member 1304 and a delivery port 1368 defined on the distal end 1326 of the rod 1322. The drug storage receptacle/cannula is capable of storing one or more, e.g. two dosages of drug e.g. haemostatic agent dosages (assuming each dosage to be 2 cm in length) that are removably housed in the drug storage receptacle. For example, the haemostatic agent used may be GELFOAM Sterile Sponge, which is a medical device that may be applied to bleeding surfaces as a haemostatic agent. Other haemostatic agents e.g. any appropriate water-insoluble or sponge form haemostatic agent may be used to reduce or stop bleeding caused by the biopsy procedure.

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In the exemplary embodiment, the guide member 1302 also functions as a drug delivery sheath (i.e. ejection device). The drug engager 1318 at the distal end 1316 of the semi-cylindrical tube 1310 is configured to contact the haemostatic agent and facilitate forward push movement of the haemostatic agent, which is stored in the drug storage receptacle stored at the distal portion 1330 of the rod 1322 of the retention member 1304, into the site of interest e.g. biopsy tract, when the retention member 1304 is in the default position. The semi-cylindrical tube 1310 of the guide

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member 1302 also comprises the controller member 1320 in a form of an abutment member. The abutment member 1320 is configured to interact with the lower casing 1340 to control the amount of haemostatic agent delivered within the site of interest e.g. within a kidney. The lower casing 1340 comprises a plurality of catches e.g. 1370 which interact with the abutment member 1320 to indicate the delivery of individual haemostatic agent dosage. This allows a user e.g. physician to estimate the amount of drug delivered to the site of interest e.g. within the kidney, in case a computerized tomography (CT) scan is unable to detect the drug delivered due to bleeding at the site of interest.

For example, from a default position where the abutment member 1320 is substantially aligned with the trigger member 1344, when the abutment member 1320 moves two catches forward, toward the collection site 1328 on the retention member 1304, it indicates that a first haemostatic agent dosage has been delivered via the delivery port 1368. When the abutment member 1320 moves three catches forward, toward the collection site 1328 found on the retention member 1304, it indicates that a second haemostatic agent dosage has been delivered via the delivery port 1368. In other words, the abutment/ejection member 1320 is configured to be actuated in stages, and each stage of actuation of the abutment member delivers one unit of the drug. Such an ejection mechanism advantageously does not require additional components. Indication of the delivery of the haemostatic agent is done manually through a manual forward push movement of the semi-cylindrical tube 1310 serving as the drug delivery sheath.

FIG. 18A is a first side view drawing of the distal end of the needle assembly of the device 1300 in the exemplary embodiment. FIG. 18B is a second side view drawing of the distal end of the needle assembly of the device 1300 in the exemplary embodiment. FIG. 18C is a third side view drawing of the distal end of the needle assembly of the device 1300 in the exemplary embodiment. FIG. 18D is a fourth side view drawing of the distal end of the needle assembly of the device 1300 in the exemplary embodiment. FIG. 18A to FIG. 18D are sequential schematic illustrations of the device 1300 at various stages of performing sample extraction, i.e. biopsy.

In use, the device 1300 undergoes up to four different stages to perform a complete biopsy with extraction of the sample from the site of interest within a subject e.g. patient's body/organ. The four stages are drug loading stage, pre-incision/pre-insertion stage, cutting stage, and tissue retrieval stage.

During the drug loading stage, two dosages of drug e.g. haemostatic agent dosages are inserted into the drug storage receptacle via the delivery port 1368. Alternatively, the drug may

be already pre-loaded in the drug storage receptacle and in this respect, there is no need for the drug loading stage.

FIG. 18A shows the relative positions of the guide member 1302, retention member 1304 and cutter 1348 prior to insertion, i.e. pre-incision stage. During the pre-incision stage, the first slider member 1342 is translated by a user towards the first partition wall 1372 to the loaded position where the spring 1306 is compressed. The first slider member 1342 is held in the loaded position as the trigger member 1344 engages the first slider member 1342 via the plurality of catches e.g. 1346 in the loaded position. In addition, the second slider member 1362 is translated towards the third partition wall 1376 to the cutting position where the cutter biasing member 1360 is compressed. The second slider member 1362 is held in the cutting position by means of the plurality of catches e.g. 1364 coupled to the trigger 1344. As shown in FIG. 18A, during the pre-incision stage, the guide member 1302, retention member 1304, and the cutter 1348 are arranged such that the respective distal ends 1316, 1326, 1354 are substantially aligned together, and the collection member 1328 is not exposed to the site of interest.

FIG. 18B shows the relative positions of the guide member 1302, retention member 1304 and cutter 1348 at the end of a first phase of the cutting stage. During the first phase of the cutting stage, the cutting surface 1356 at the distal end 1354 of the cutter 1348 pierces a surface e.g. skin to reach the site of interest (i.e. target position) under guidance of an imaging device e.g. ultrasound. Once the distal end 1354 of the cutter 1348 is determined to be at the target position, the trigger member 1344 is actuated by the user, releasing the spring 1306 from its compressed state. The release of the spring 1306 causes the first slider member 1342 carrying the rod 1322 to translate along the semi annular groove 1312 of the guide member 1302 to the default position. As shown in FIG. 18B, the rod 1322 is translated from the loaded to the default position and as a result, the collection member 1328 is exposed to the site of interest.

FIG. 18C shows the relative positions of the guide member 1302, retention member 1304 and cutter 1348 at the end of a second phase of the cutting stage. As a result of the translation of the rod 1322 from the loaded to the default position in FIG. 18B, the cutter biasing member 1360 is being released from its compressed state, causing the second slider member 1362 carrying the cutter 1348 to translate away from the third partition wall 1376 into the cutter default position, as shown in FIG. 18C. In other words, the translation of the rod 1322 from the loaded to the default position automatically triggers the sequential release of the cutter biasing member 1360. This causes sample tissue which protrudes into the collection member 1328 to be sliced/cut. It should be appreciated that the translation should be of a relatively high speed in

order for the cut/slice to occur. The cut sample tissue is stored in a space defined by the collection member 1328 and the inner concave surface of the cutter 1348.

When both the rod 1322 and the cutter 1348 are in the default position (i.e. the sample is retained in the collection member 1328), the abutment member 1320 is pushed at its proximal end towards the collection member 1328 and the site of interest, as shown in FIG. 18D. The drug e.g. haemostatic agent previously stored within the drug storage receptacle (i.e., the hollow chamber within the rod 1322), is pushed out of the rod 1322 via the drug delivery outlet 1368 to the lesion site/ injured area. The device 1300 is then removed from the lesion site after the haemostatic agent is delivered.

After the device 1300 is removed from the site of interest, the tissue is ready to be removed from the device. During this tissue retrieval stage, the cutter 1348 is translated with respect to the rod 1322 towards the third partition wall 1376 into the cutting position, such that the cut sample which was previously held in the space between the collection member 1328 and the inner concave surface of the cutter 1348 is exposed for retrieval.

In the exemplary embodiment, the needle assembly of the device 1300 may be fabricated via 3D printing using metal, specifically stainless steel, to confer superior mechanical properties and to allow the needle assembly to be sterilized through autoclave method. 3D printing advantageously enables fabrication of fine structural features in the device 1300 which may be difficult to achieve through milling or drilling techniques due to the relatively small scale of the device 1300.

In some exemplary embodiments, the upper casing 1338 and lower casing 1340 of the housing may be made via 3D printing using acrylonitrile butadiene styrene (ABS), as ABS is a relatively strong and sturdy material. In other exemplary embodiments, the housing is made of polypropylene (PP) which possesses relatively superior fatigue resistance and integral hinge property. Polypropylene also allows the housing to be sterilized through autoclave method.

In addition, the components for actuating the retention member 1304 and the cutter 1334 may be made via 3D printing using PLA or PP which possesses good fatigue resistance, integral hinge property and allow the components to be sterilized through autoclave method. In addition, the deployment spring 1366 of the trigger 1344 is made of stainless steel which conforms to DIN 17224 No. 1 and the springs 1306, 1360 employed in the retention member 1304 and cutter 1348 are made of steel alloy. All the springs' dimensions and forces conform to DIN 2095 (grade 2). The springs required to extend the cutter 1348 and retention member 1304 out of the housing.

FIG. 19 is a schematic flowchart 1900 for illustrating a method for extracting a sample from a site of interest in an exemplary embodiment. At step 1902, the site of interest is accessed with the needle assembly. At step 1904, relative movement between the retention member and the guide member is triggered such that the needle assembly is moved from the loaded configuration to the default configuration, causing the sample to be extracted from the site of interest and retained in the retention member. At step 1906, a drug stored in a drug storage unit is delivered to the site of interest when the needle assembly is in the default configuration.

FIG. 20 is a schematic flowchart 2000 for illustrating a method for fabricating a device for extracting a sample from a site of interest in an exemplary embodiment. At step 2002, a needle assembly configurable to be in at least a loaded configuration or a default configuration is provided, said needle assembly comprising a guide member for accessing the site of interest, a retention member coupled to the guide member, and a drug storage unit for storing a drug. At step 2004, a biasing member coupled to the needle assembly is provided, said biasing member for biasing the needle assembly in the default configuration; wherein the guide member and retention member are capable of moving relative to each other between the loaded configuration and the default configuration, wherein moving from the loaded configuration to the default configuration causes the sample to be extracted from the site of interest and retained in the retention member; and the default configuration allows the drug to be delivered to the site of interest.

In the described exemplary embodiments, the biopsy device/tool utilises a spring actuated mechanism and additionally provides delivery of haemostatic agents. The inventors have recognised that there are currently no biopsy tools with haemostatic properties on the international market which are able to effectively stop/control bleeding at the site of interest in organs such as kidneys. The delivery of haemostatic agents by the biopsy device of the described exemplary embodiments may advantageously stop/control bleeding in a biopsy procedure. The biopsy device may reduce the occurrence of clinically significant bleeding during biopsy and may significantly improve safety in biopsy procedures.

The terms "coupled" or "connected" as used in this description are intended to cover both directly connected or connected through one or more intermediate means, unless otherwise stated.

The description herein may be, in certain portions, explicitly or implicitly described as algorithms and/or functional operations that operate on data within a computer memory or an

electronic circuit. These algorithmic descriptions and/or functional operations are usually used by those skilled in the information/data processing arts for efficient description. An algorithm is generally relating to a self-consistent sequence of steps leading to a desired result. The algorithmic steps can include physical manipulations of physical quantities, such as electrical, magnetic or optical signals capable of being stored, transmitted, transferred, combined, compared, and otherwise manipulated.

Further, unless specifically stated otherwise, and would ordinarily be apparent from the following, a person skilled in the art will appreciate that throughout the present specification, discussions utilizing terms such as “scanning”, “calculating”, “determining”, “replacing”, “generating”, “initializing”, “outputting”, and the like, refer to action and processes of an instructing processor/computer system, or similar electronic circuit/device/component, that manipulates/processes and transforms data represented as physical quantities within the described system into other data similarly represented as physical quantities within the system or other information storage, transmission or display devices etc.

The description also discloses relevant device/apparatus for performing the steps of the described methods. Such apparatus may be specifically constructed for the purposes of the methods, or may comprise a general purpose computer/processor or other device selectively activated or reconfigured by a computer program stored in a storage member. The algorithms and displays described herein are not inherently related to any particular computer or other apparatus. It is understood that general purpose devices/machines may be used in accordance with the teachings herein. Alternatively, the construction of a specialized device/apparatus to perform the method steps may be desired.

In addition, it is submitted that the description also implicitly covers a computer program, in that it would be clear that the steps of the methods described herein may be put into effect by computer code. It will be appreciated that a large variety of programming languages and coding can be used to implement the teachings of the description herein. Moreover, the computer program if applicable is not limited to any particular control flow and can use different control flows without departing from the scope of the invention.

Furthermore, one or more of the steps of the computer program if applicable may be performed in parallel and/or sequentially. Such a computer program if applicable may be stored on any computer readable medium. The computer readable medium may include storage devices such as magnetic or optical disks, memory chips, or other storage devices suitable for interfacing with a suitable reader/general purpose computer. In such instances, the computer readable

storage medium is non-transitory. Such storage medium also covers all computer-readable media e.g. medium that stores data only for short periods of time and/or only in the presence of power, such as register memory, processor cache and Random Access Memory (RAM) and the like. The computer readable medium may even include a wired medium such as exemplified in the Internet system, or wireless medium such as exemplified in bluetooth technology. The computer program when loaded and executed on a suitable reader effectively results in an apparatus that can implement the steps of the described methods.

The exemplary embodiments may also be implemented as hardware modules. A module is a functional hardware unit designed for use with other components or modules. For example, a module may be implemented using digital or discrete electronic components, or it can form a portion of an entire electronic circuit such as an Application Specific Integrated Circuit (ASIC). A person skilled in the art will understand that the exemplary embodiments can also be implemented as a combination of hardware and software modules.

Additionally, when describing some embodiments, the disclosure may have disclosed a method and/or process as a particular sequence of steps. However, unless otherwise required, it will be appreciated the method or process should not be limited to the particular sequence of steps disclosed. Other sequences of steps may be possible. The particular order of the steps disclosed herein should not be construed as undue limitations. Unless otherwise required, a method and/or process disclosed herein should not be limited to the steps being carried out in the order written. The sequence of steps may be varied and still remain within the scope of the disclosure.

Further, in the description herein, the word "substantially" whenever used is understood to include, but not restricted to, "entirely" or "completely" and the like. In addition, terms such as "comprising", "comprise", and the like whenever used, are intended to be non-restricting descriptive language in that they broadly include elements/components recited after such terms, in addition to other components not explicitly recited. For an example, when "comprising" is used, reference to a "one" feature is also intended to be a reference to "at least one" of that feature. Terms such as "consisting", "consist", and the like, may, in the appropriate context, be considered as a subset of terms such as "comprising", "comprise", and the like. Therefore, in embodiments disclosed herein using the terms such as "comprising", "comprise", and the like, it will be appreciated that these embodiments provide teaching for corresponding embodiments using terms such as "consisting", "consist", and the like. Further, terms such as "about", "approximately" and the like whenever used, typically means a reasonable variation, for example a variation of +/- 5% of the disclosed value, or a variance of 4% of the disclosed value, or a variance of 3% of

the disclosed value, a variance of 2% of the disclosed value or a variance of 1% of the disclosed value.

Furthermore, in the description herein, certain values may be disclosed in a range. The values showing the end points of a range are intended to illustrate a preferred range. Whenever a range has been described, it is intended that the range covers and teaches all possible sub-ranges as well as individual numerical values within that range. That is, the end points of a range should not be interpreted as inflexible limitations. For example, a description of a range of 1% to 5% is intended to have specifically disclosed sub-ranges 1% to 2%, 1% to 3%, 1% to 4%, 2% to 3% etc., as well as individually, values within that range such as 1%, 2%, 3%, 4% and 5%. The intention of the above specific disclosure is applicable to any depth/breadth of a range.

It will be appreciated by a person skilled in the art that other variations and/or modifications may be made to the specific embodiments without departing from the scope of the invention as broadly described. For example, in the description herein, features of different exemplary embodiments may be mixed, combined, interchanged, incorporated, adopted, modified, included etc. or the like across different exemplary embodiments. The present embodiments are, therefore, to be considered in all respects to be illustrative and not restrictive.

It will also be appreciated that the specific rotations described herein are illustrative and not restrictive. Other rotational combinations and directions may be implemented without deviating from the spirit of the invention.

CLAIMS

1. A device for extracting a sample from a site of interest, the device comprising,
a needle assembly configurable to be in at least a loaded configuration or a default
5 configuration, said needle assembly comprising
a guide member for accessing the site of interest,
a retention member coupled to the guide member, and
a drug storage unit for storing a drug; and
a biasing member coupled to the needle assembly, said biasing member for biasing the
10 needle assembly in the default configuration;
wherein
the guide member and retention member are capable of moving relative to each
other between the loaded configuration and the default configuration, wherein moving
from the loaded configuration to the default configuration causes the sample to be
15 extracted from the site of interest and retained in the retention member; and
the default configuration allows the drug to be delivered to the site of interest.
2. The device of claim 1 further comprising an actuator coupled to the biasing member, the
actuator comprising
20 one or more catch members for retaining the biasing member in a loaded position such
that the needle assembly is in the loaded configuration; and
a trigger member for triggering a movement of the guide member or retention member
from a loaded position to a default position such that the needle assembly moves from the loaded
configuration to the default configuration.
- 25 3. The device of claim 2, wherein
the guide member comprises a tube, said tube comprising,
a lumen extending between a proximal and a distal portion of the tube, and
an access window defined on the distal portion of the tube;
30 the retention member comprises a rod, said rod coaxially positioned within the lumen of
the tube and comprising a sample receptacle defined on a distal portion of the rod; and
the drug storage unit comprises a drug storage receptacle defined on the distal portion of
the rod.
- 35 4. The device of claim 3, wherein the actuator comprises a rotator assembly coupled to the
proximal portion of the tube, said rotator assembly configured for axially rotating the tube relative
to the rod,

wherein the loaded position comprises the sample receptacle on the rod being substantially aligned with the access window on the tube, and

wherein the default position comprises the drug storage receptacle on the rod being substantially aligned with the access window on the tube.

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5. The device of claim 4,

wherein the sample receptacle comprises a first groove on the rod, said first groove comprising cutting edges for removing the sample from the site of interest into the sample receptacle, when the tube is rotated from the loaded position to the default position.

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6. The device of claim 5, wherein the drug storage receptacle comprises a second groove on the rod, said second groove exposed to the site of interest via the access window on the tube when the tube is in the default position.

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7. The device of claim 6, wherein the first and second groove are radially spaced apart on the lateral surface of the rod.

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8. The device of claim 3, wherein the actuator comprises a slider member coupled to the proximal end of the rod, said slider member configured for translating the rod relative to the tube along the lumen,

wherein the rod is not accessible from the access window on the tube when the rod is in the loaded position; and

wherein the drug storage unit is accessible from the access window on the tube when the rod is in the default position.

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9. The device of claim 8,

wherein the sample receptacle comprises a groove on the rod, said groove comprising a cutting edge on the distal end of the rod; said cutting edge capable of cutting the sample from the site of interest and depositing the sample on the groove, in a space defined by the first groove and the tube, as the rod moves from the loaded position to the default position.

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10. The device of claim 9, wherein the actuator further comprises a rotator assembly coupled to the proximal portion of the rod, said rotator assembly configured for axially rotating the rod relative to the tube such the sample can be retrieved.

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11. The device of claim 9 or 10, wherein the drug storage receptacle is disposed within the rod; said drug storage receptacle further comprising a drug delivery outlet disposed on the outer

surface of the rod and exposed to the site of interest via the access window on the tube when the rod is in the default position.

12. The device of claim 11, wherein the drug delivery outlet is disposed along the length of the rod, apart from the groove.

13. The device of claim 12, wherein the drug delivery outlet is disposed on an opposite surface of the rod.

14. The device of any of claims 11 to 13, further comprising an ejection member coupled to the drug storage unit, wherein actuation of the ejection member delivers the drug from the drug storage unit to the site of interest.

15. The device of claim 14, wherein the ejection member is configured to be actuated in stages, such that each stage of actuation delivers one unit of the drug.

16. The device of claim 2, wherein the guide member comprises,

a semi-cylindrical tube having a semi-annular groove defined on an inner surface;

the retention member comprises,

a rod comprising a collection member defined on a distal portion of the rod, said rod slidably received on the semi-annular groove of the semi-cylindrical tube; and

the drug storage unit comprises a drug storage receptacle defined on the distal portion of the rod.

17. The device of claim 16, wherein the actuator comprises a first slider member coupled to the proximal end of the rod, said first slider member configured for translating the rod along the semi-annular groove of the tube,

wherein the collection member is held within the distal and proximal ends of the guide member when the rod is in the loaded position; and

wherein the collection member extends beyond the distal end of the guide member when the rod is in the default position.

18. The device of claim 17, further comprising,

a cutter slidably coupled to the guide member;

a cutter biasing member for biasing the cutter in a cutter default position;

a cutting edge defined on a distal portion of the cutter;

a cutter actuator comprising

a second slider member coupled to the proximal end of the cutter, said second slider member configured for translating the cutter along the guide member of the tube,

one or more catch members for retaining the cutter biasing member in a cutting position; and

a cutter trigger member for triggering a movement of the cutter from the cutting position to the default position;

wherein the cutting edge is held within the distal and proximal ends of the guide member when the cutter is in the cutting position; and

wherein the cutting edge extends beyond the distal end of the guide member when the cutter is in the cutter default position.

19. The device of any one of the preceding claims,

wherein the drug storage unit is configured to provide a greater volume of the drug as compared to the volume of sample extracted.

20. The device of any one of the preceding claims, wherein the drug comprises a haemostatic agent, said haemostatic agent configured to be water insoluble and in the form of a sponge, fibre, matrix, sheet, granule, bead, liquid or powder.

21. A method for extracting a sample from a site of interest using a device of any one of claims 1 to 20, the method comprising,

accessing the site of interest with the needle assembly;

triggering relative movement between the retention member and the guide member such that the needle assembly is moved from the loaded configuration to the default configuration, causing the sample to be extracted from the site of interest and retained in the retention member; and

delivering a drug stored in a drug storage unit to the site of interest when the needle assembly is in the default configuration.

22. A method for fabricating a device for extracting a sample from a site of interest, the method comprising,

providing a needle assembly configurable to be in at least a loaded configuration or a default configuration, said needle assembly comprising a guide member for accessing the site of interest, a retention member coupled to the guide member, and a drug storage unit for storing a drug; and

providing a biasing member coupled to the needle assembly, said biasing member for biasing the needle assembly in the default configuration;

wherein

the guide member and retention member are capable of moving relative to each other between the loaded configuration and the default configuration, wherein moving from the loaded configuration to the default configuration causes the sample to be extracted from the site of interest and retained in the retention member; and

the default configuration allows the drug to be delivered to the site of interest.

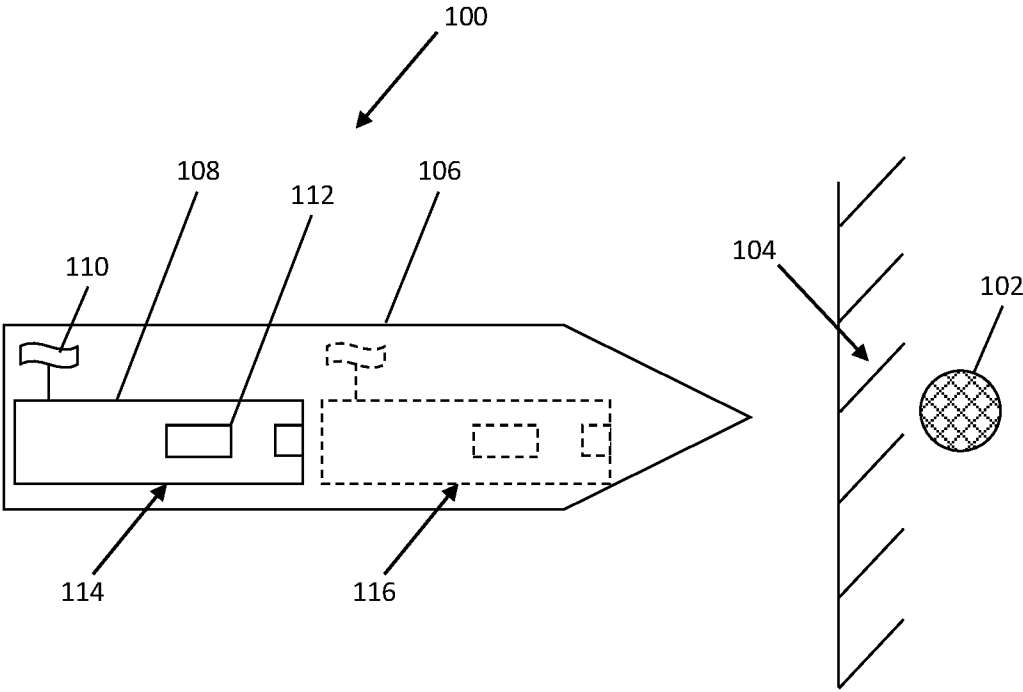


FIG. 1

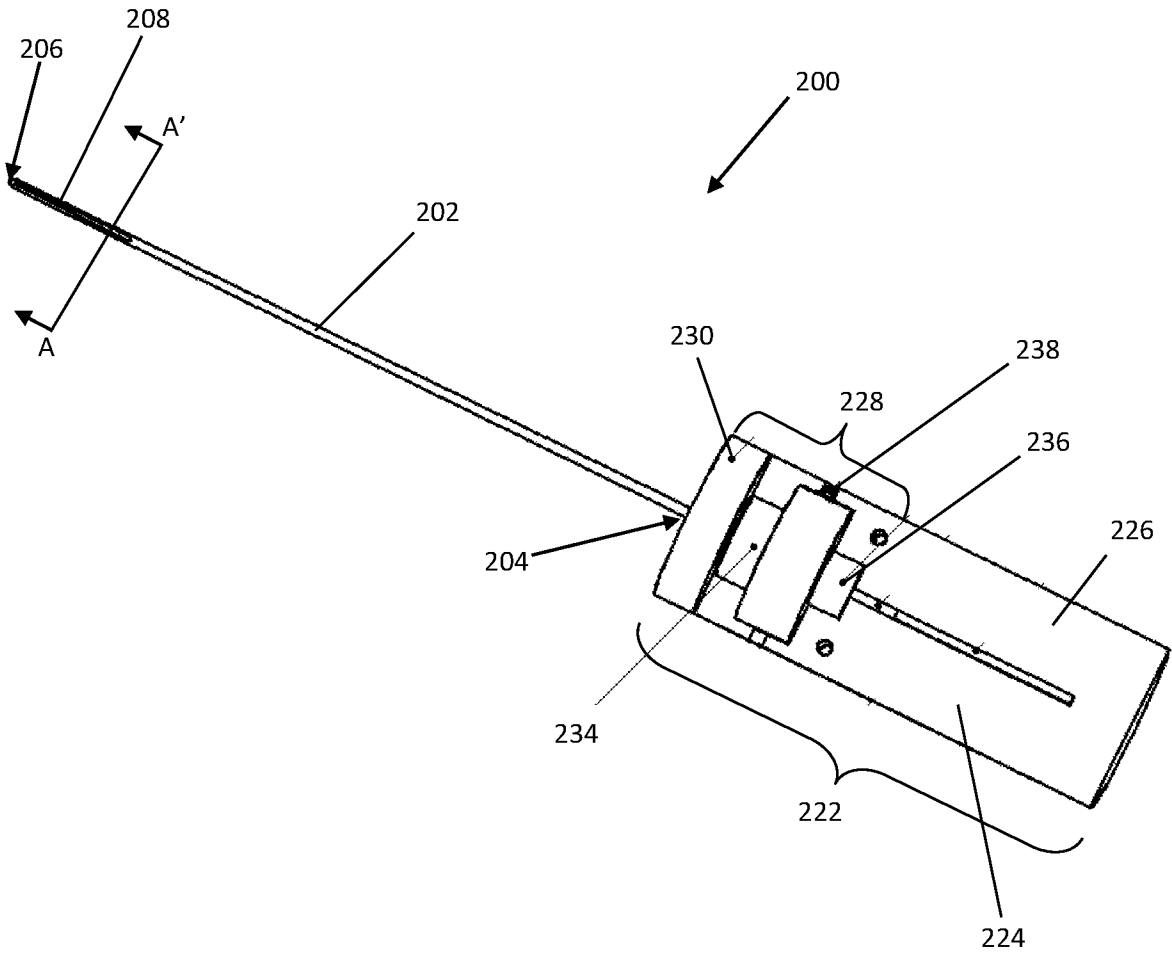


FIG. 2

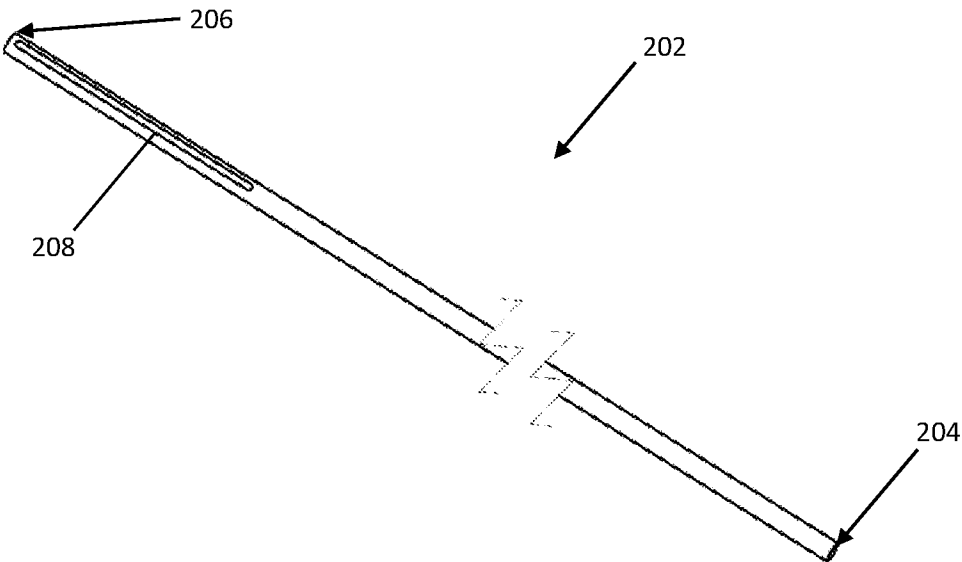


FIG. 3

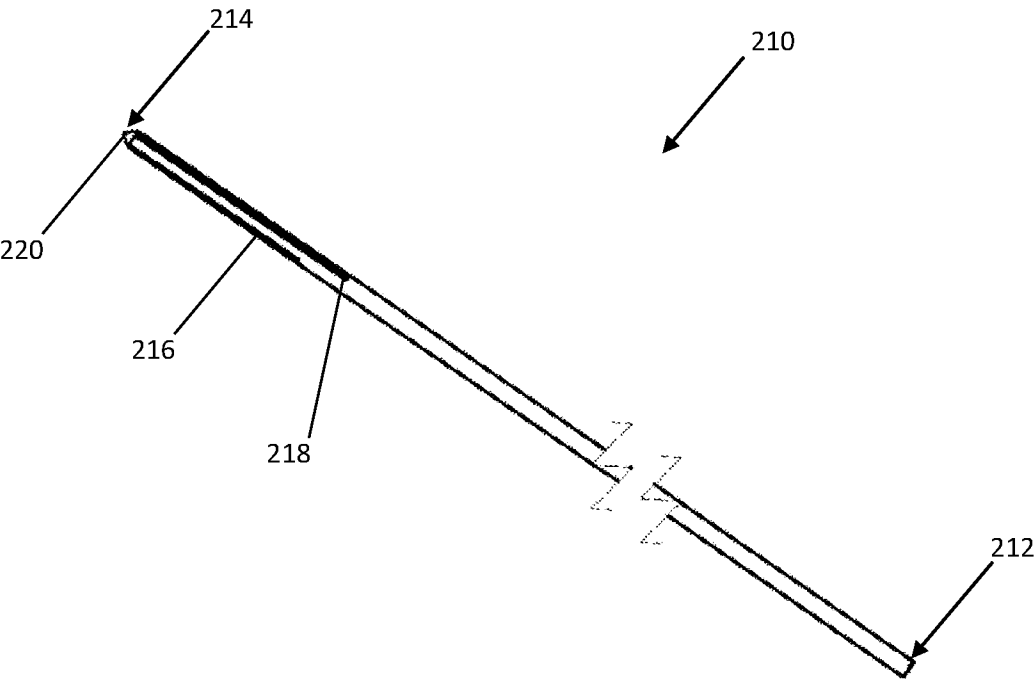


FIG. 4A

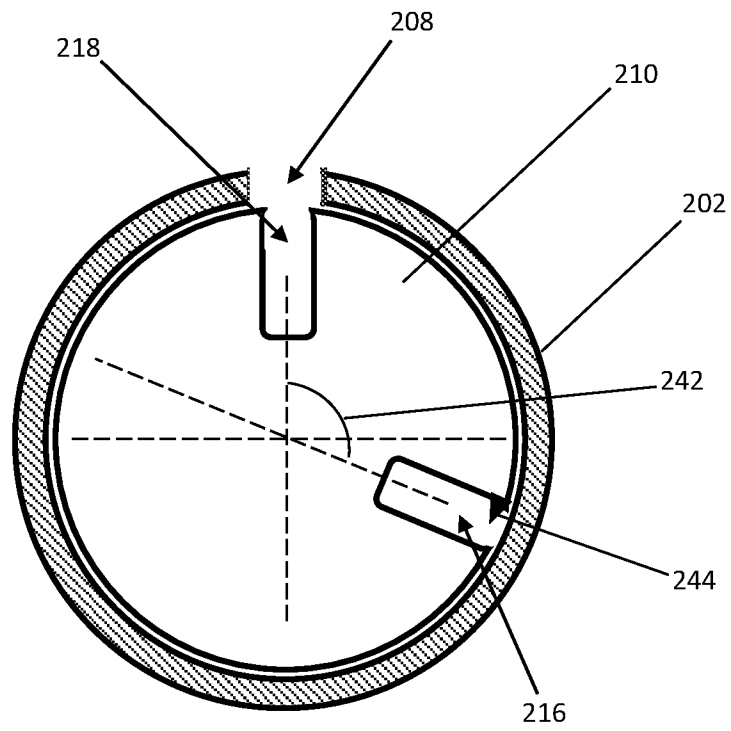


FIG. 4B

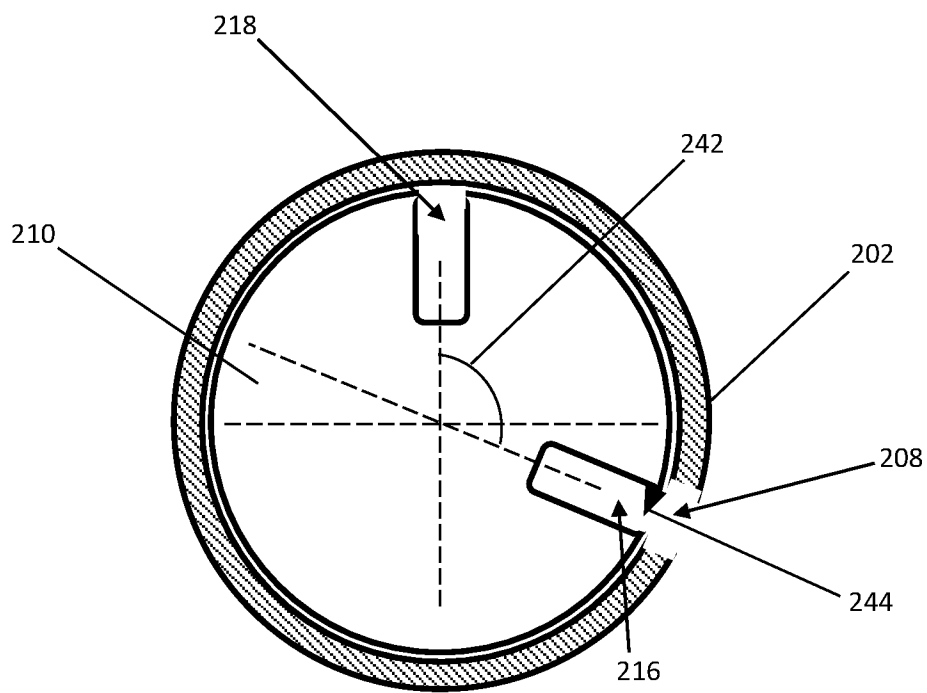


FIG. 4C

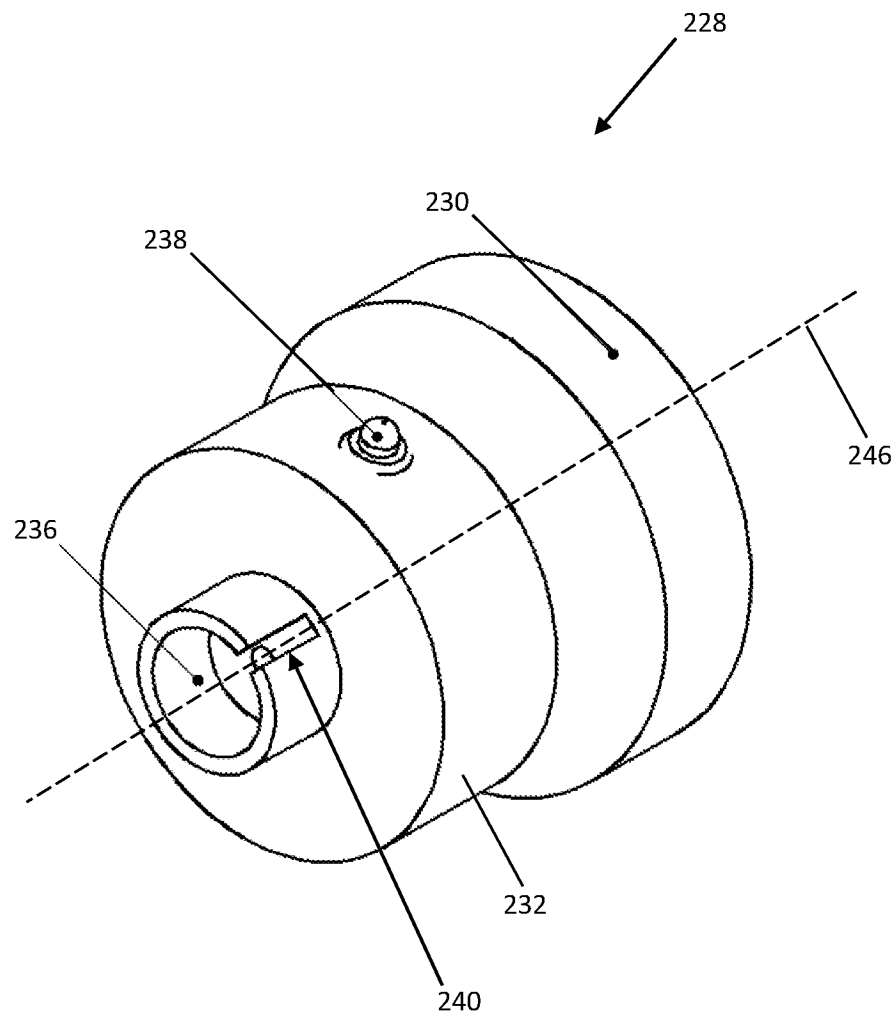


FIG. 5

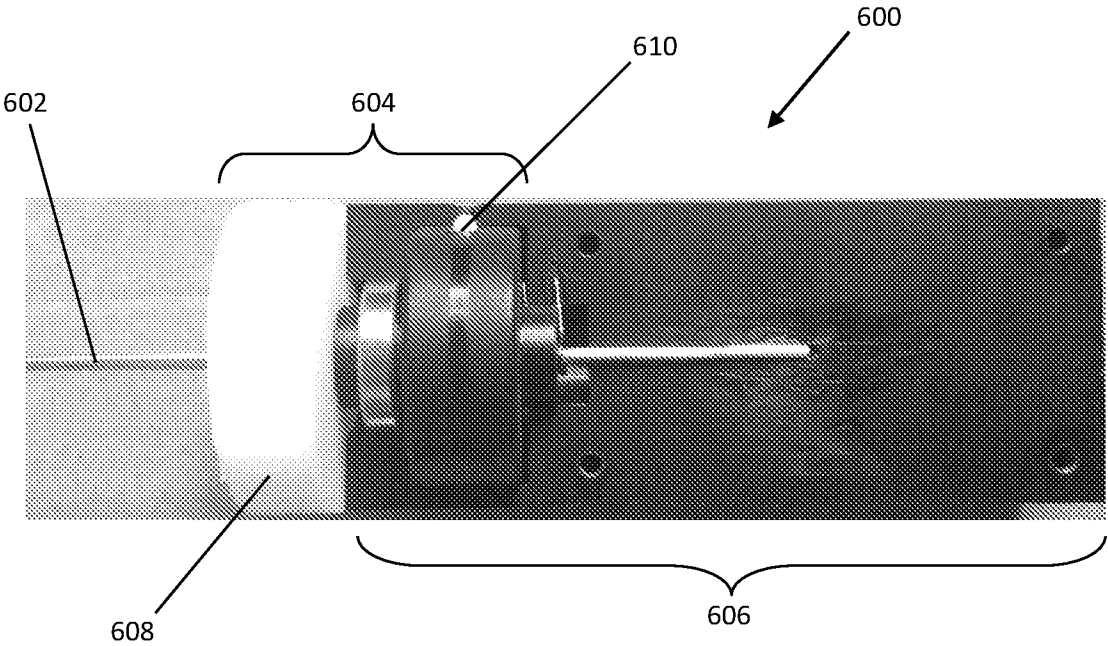


FIG. 6A

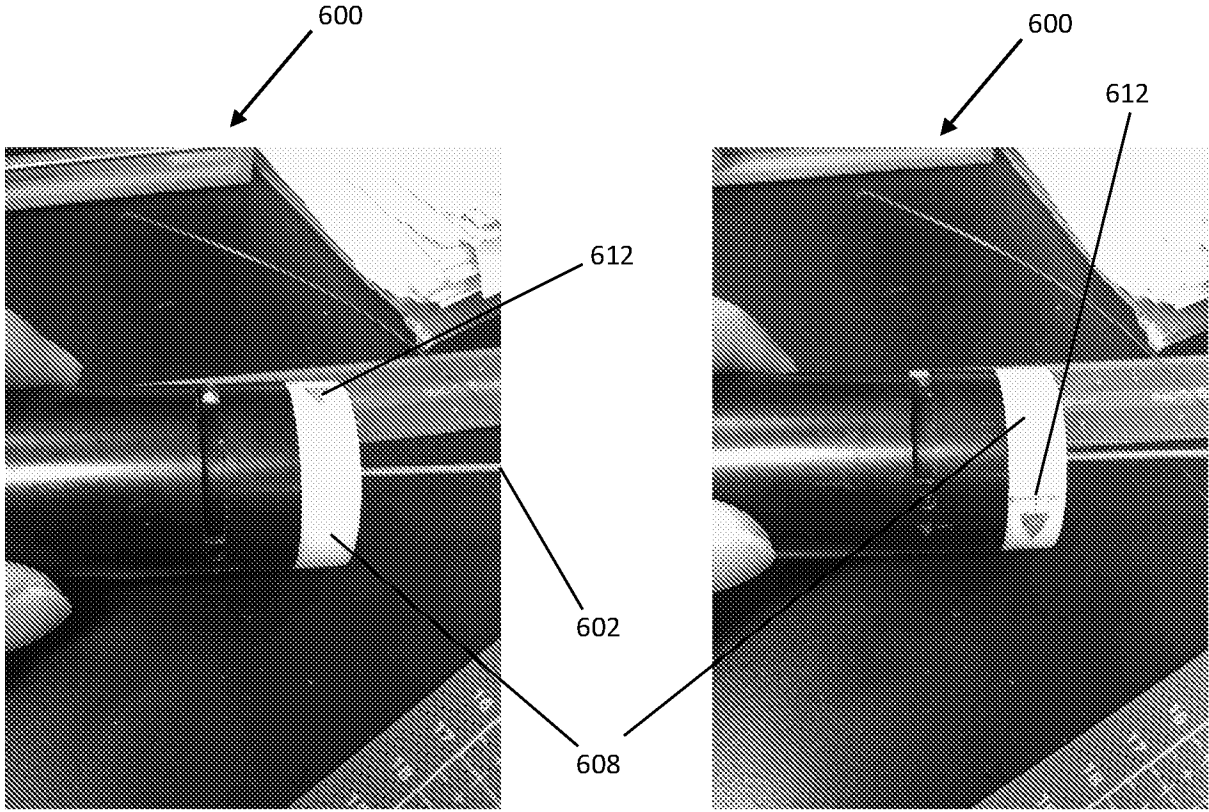


FIG. 6B

FIG. 6C

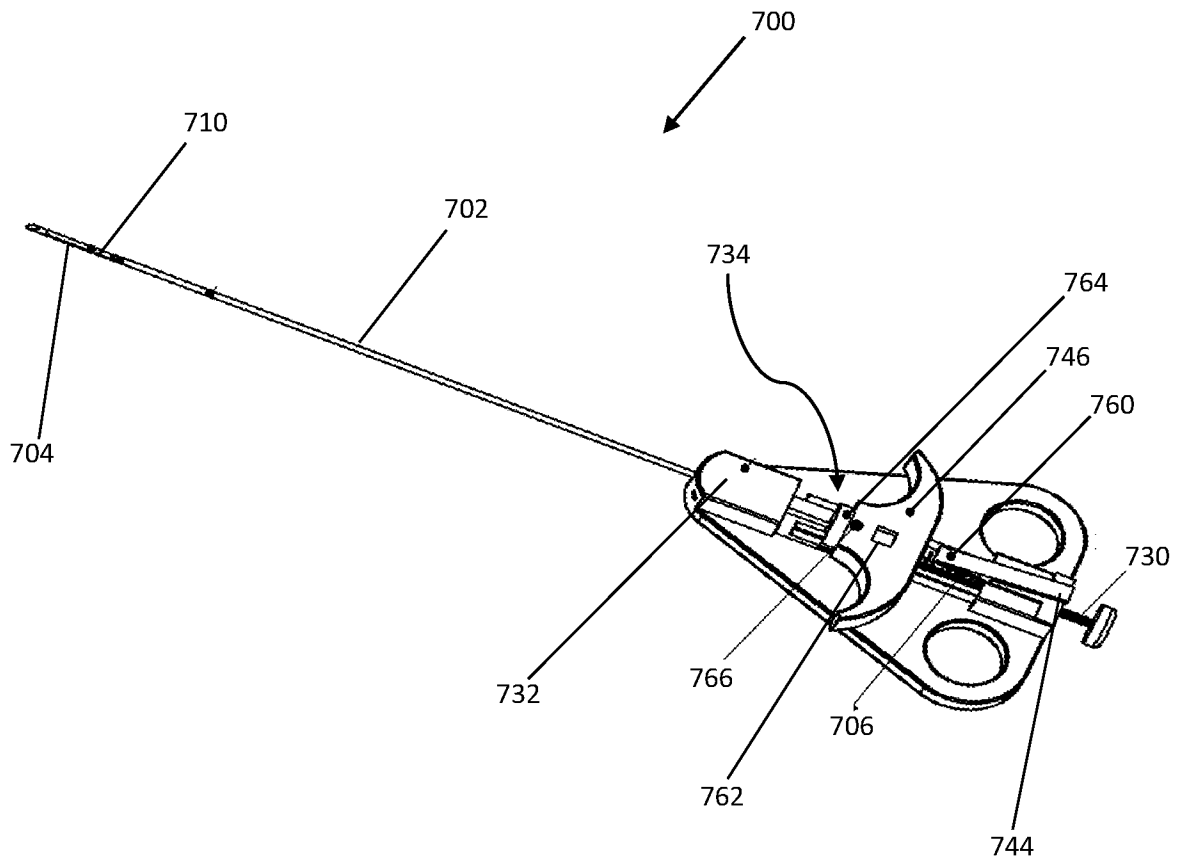


FIG. 7

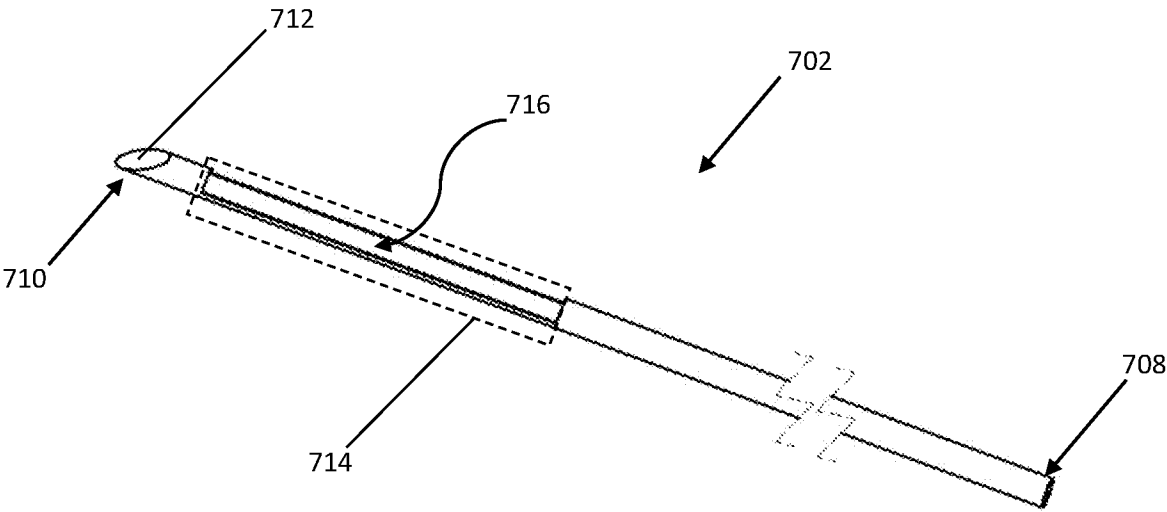


FIG. 8

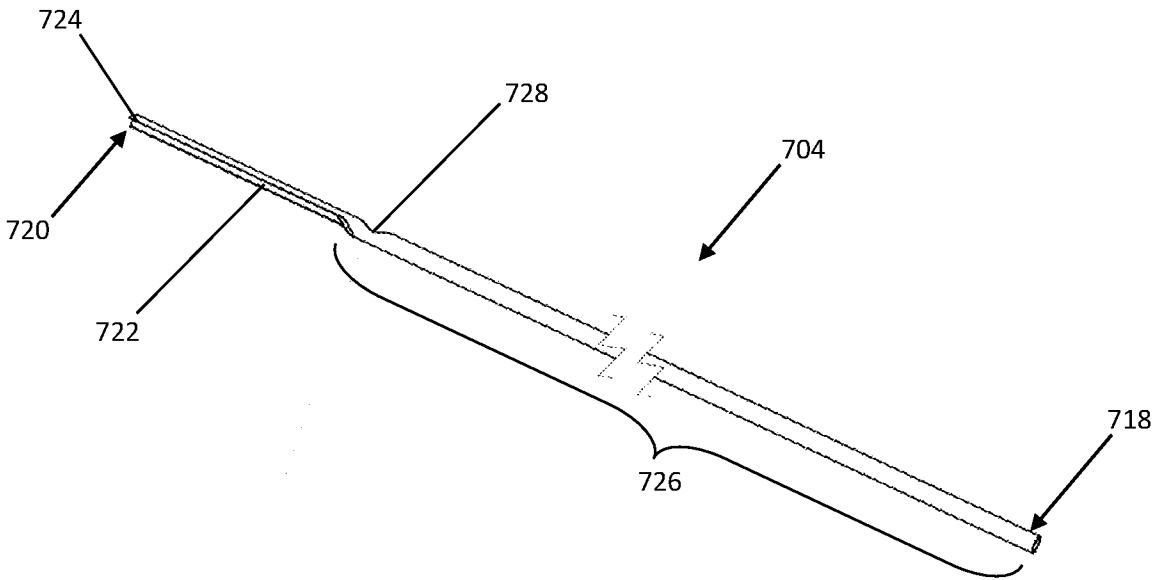


FIG. 9A

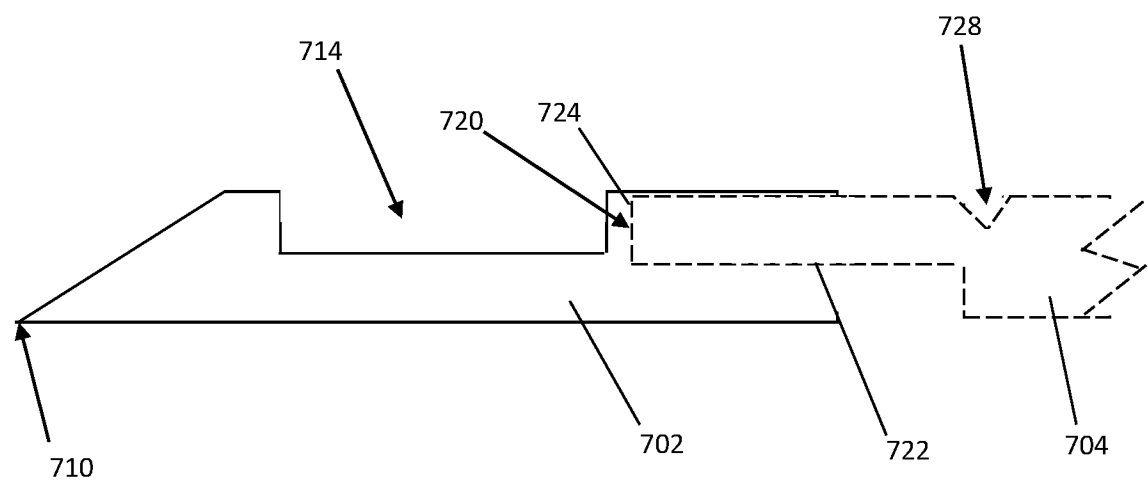


FIG. 9B

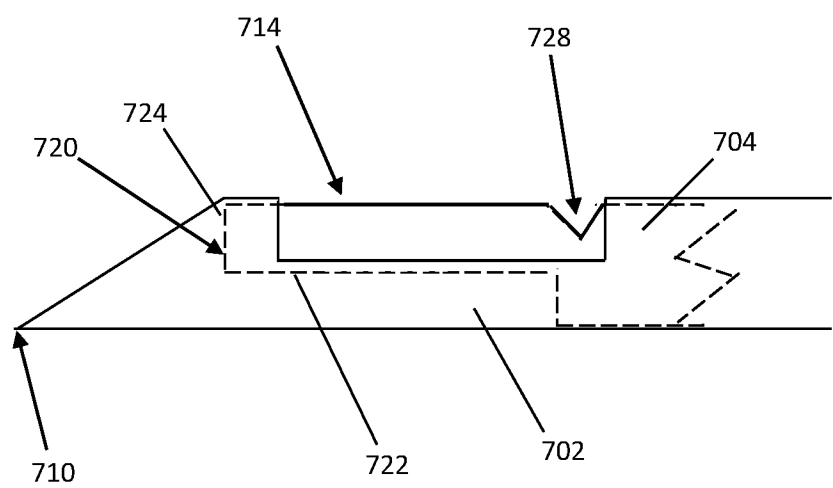


FIG. 9C

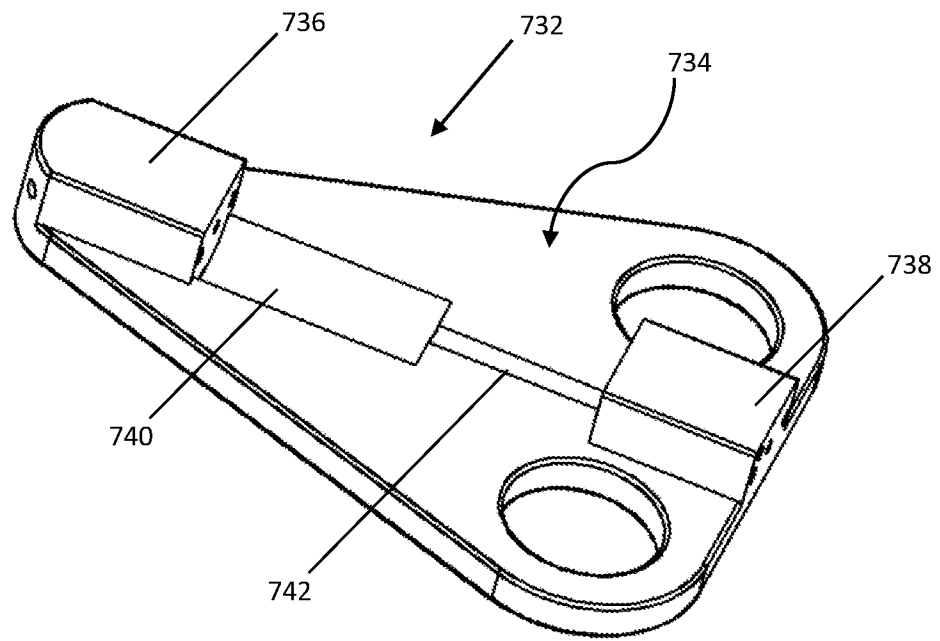


FIG. 10

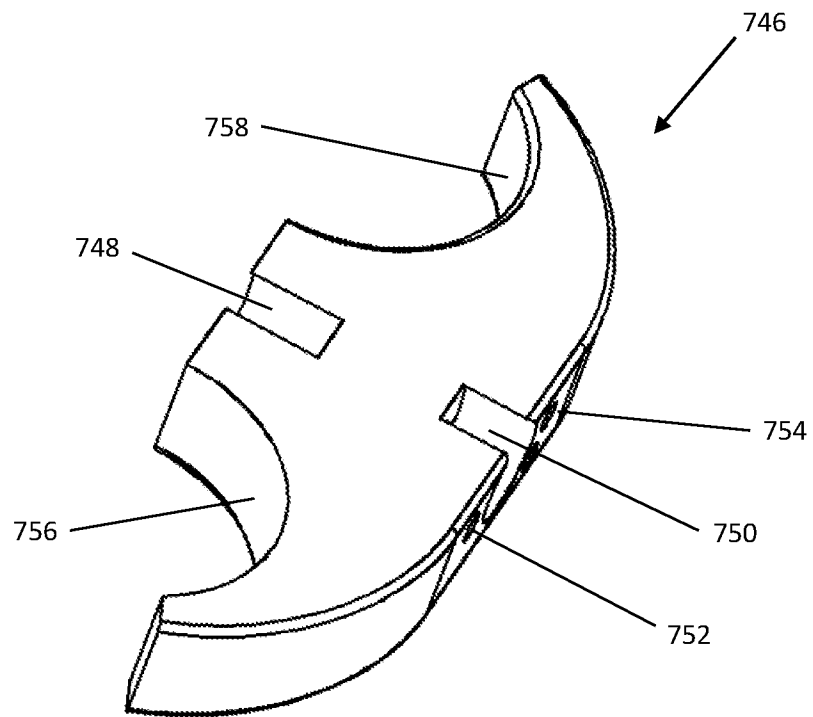


FIG. 11

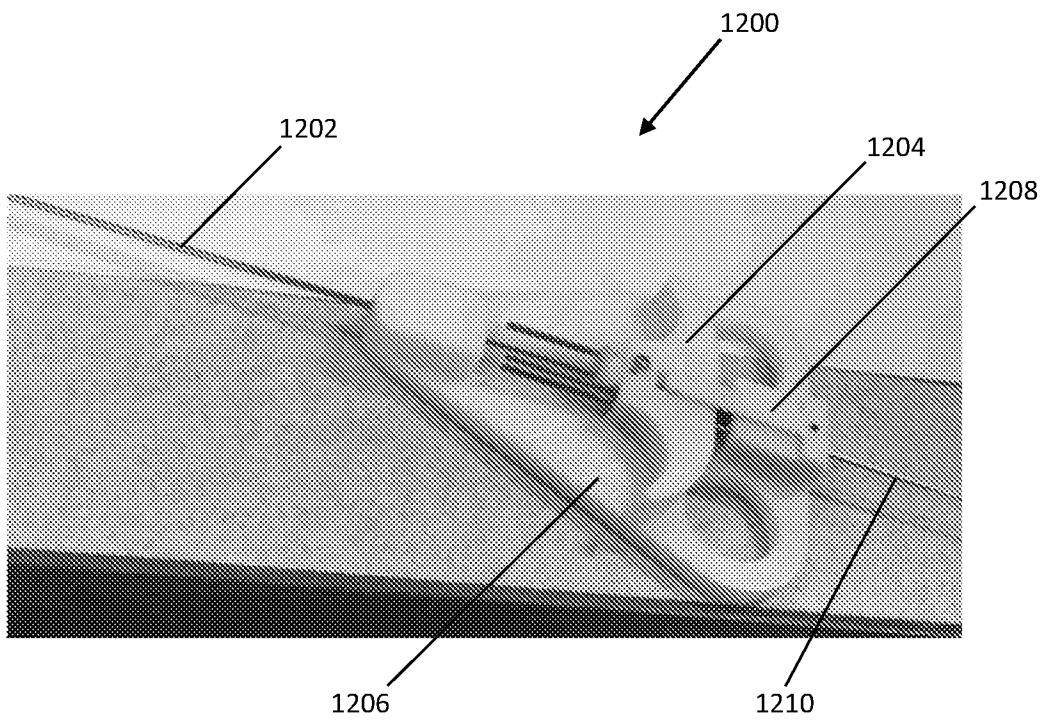


FIG. 12

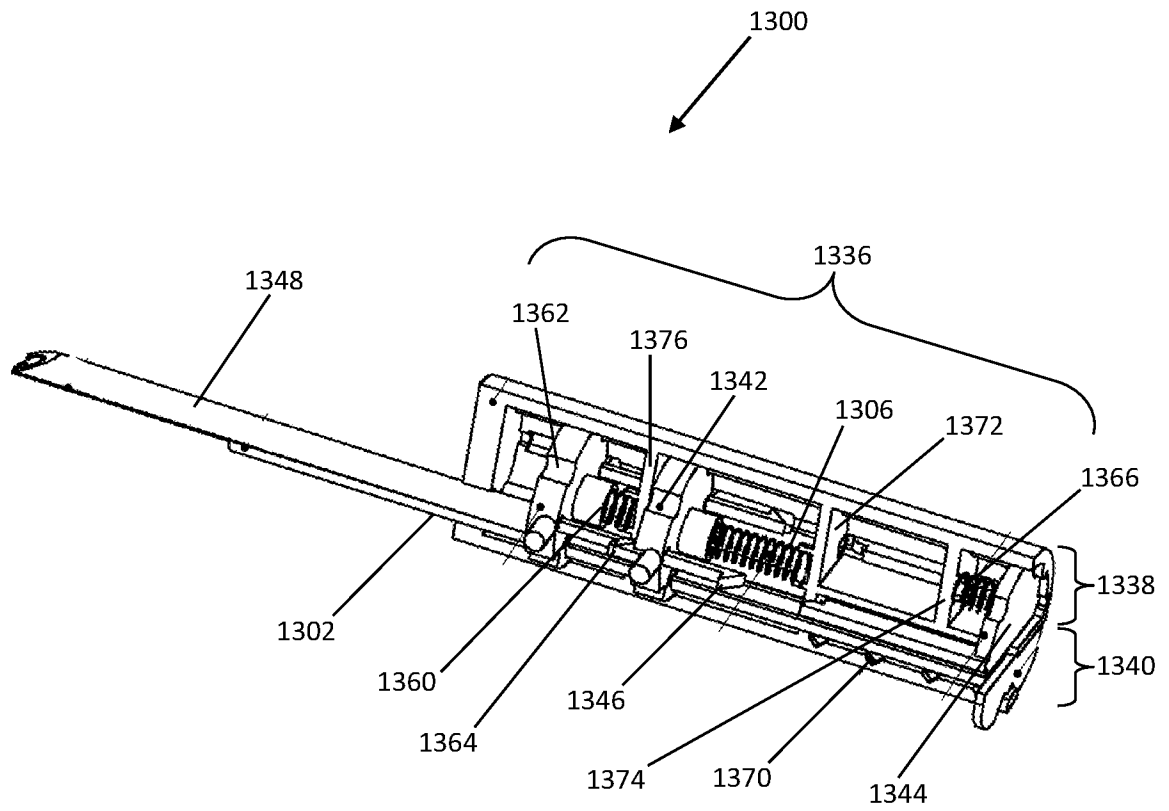


FIG. 13

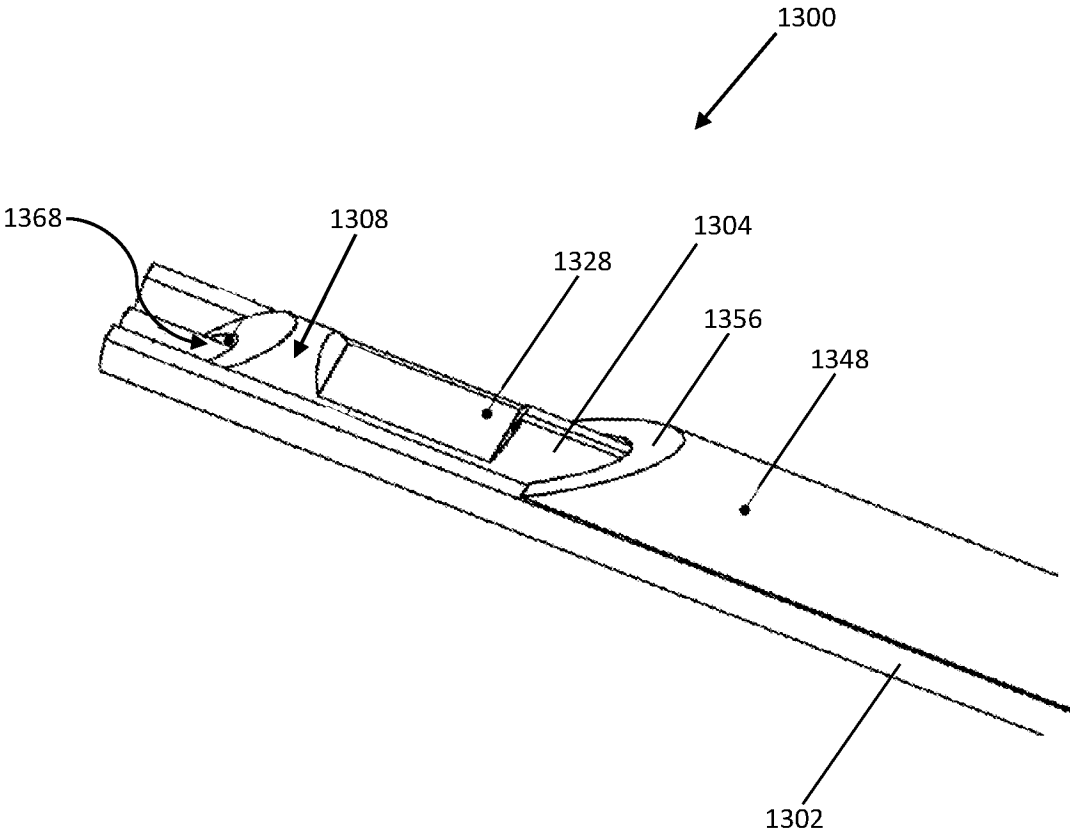


FIG. 14

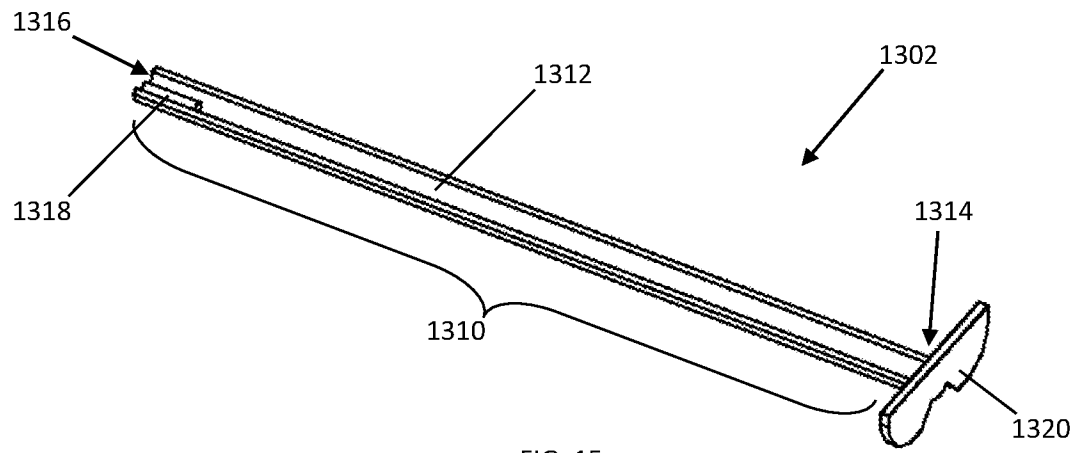


FIG. 15

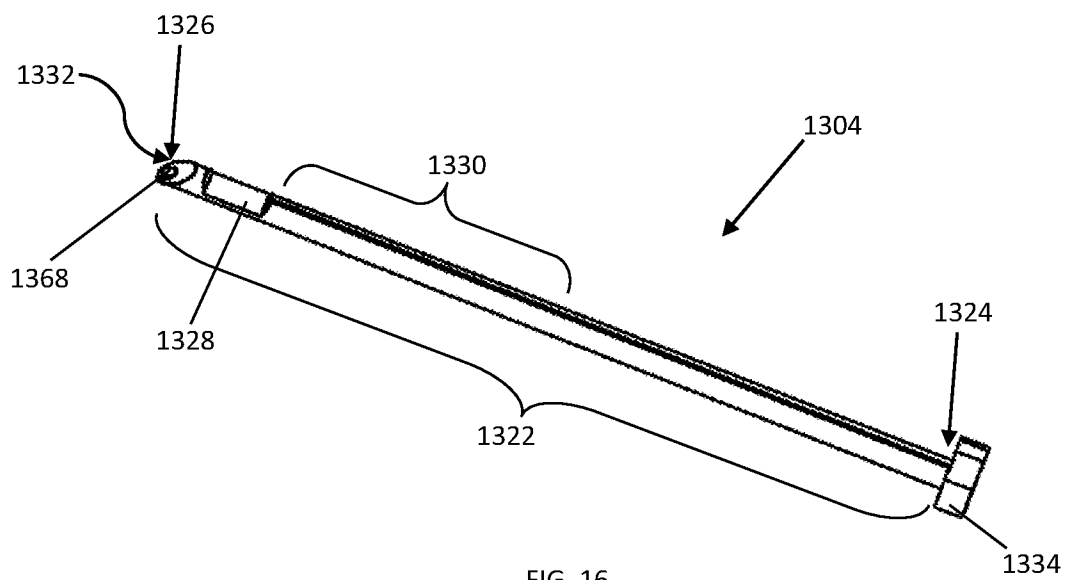


FIG. 16

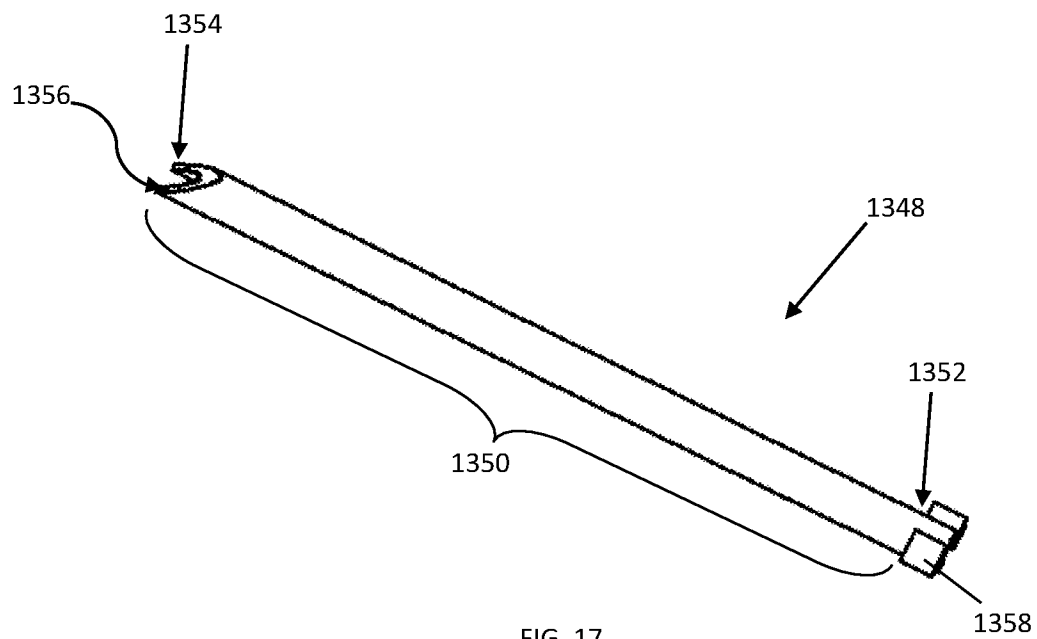


FIG. 17

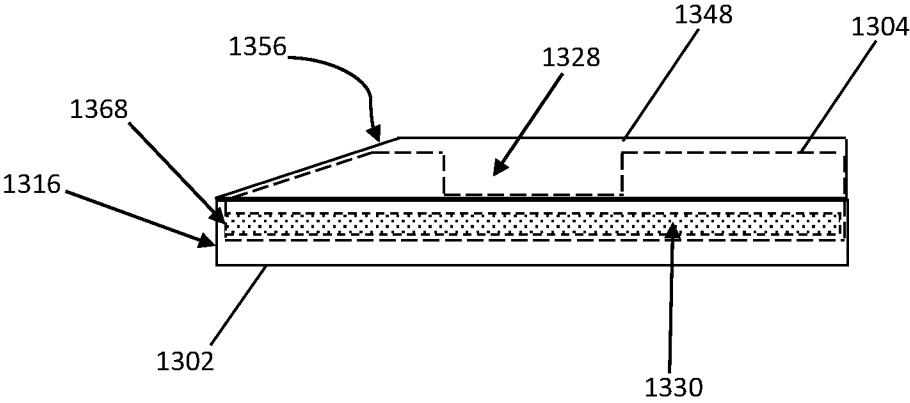


FIG. 18A

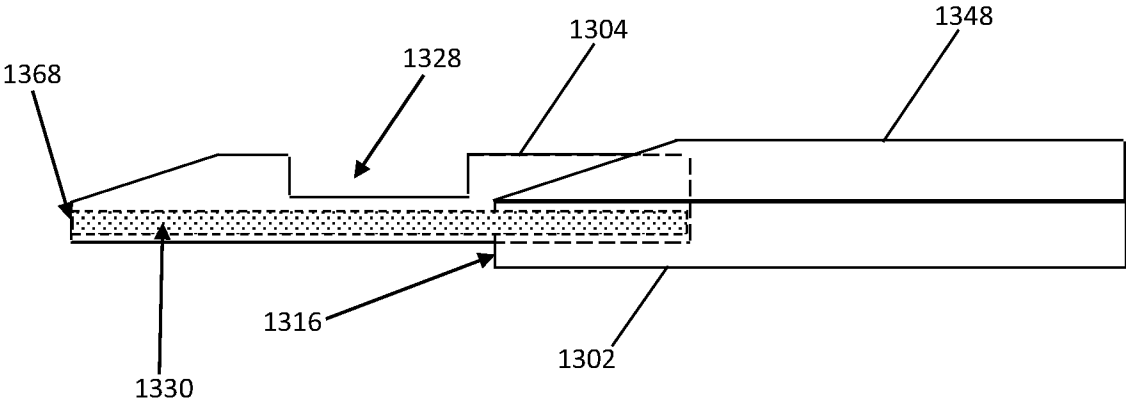


FIG. 18B

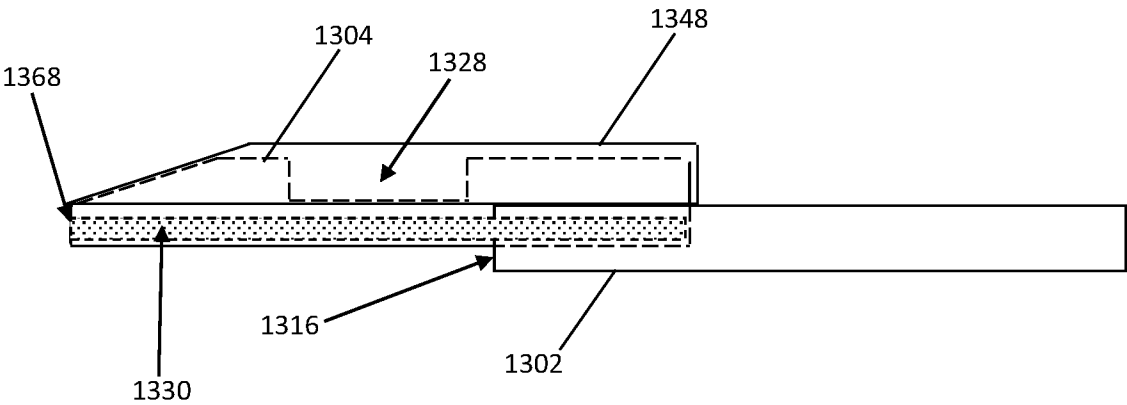


FIG. 18C

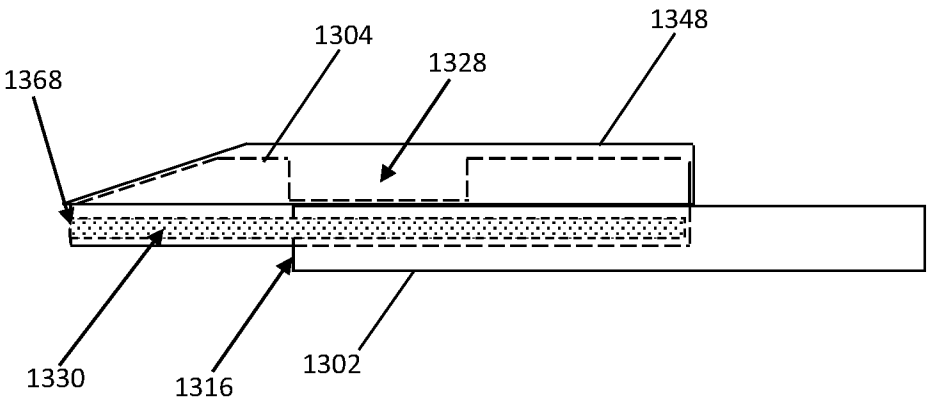


FIG. 18D

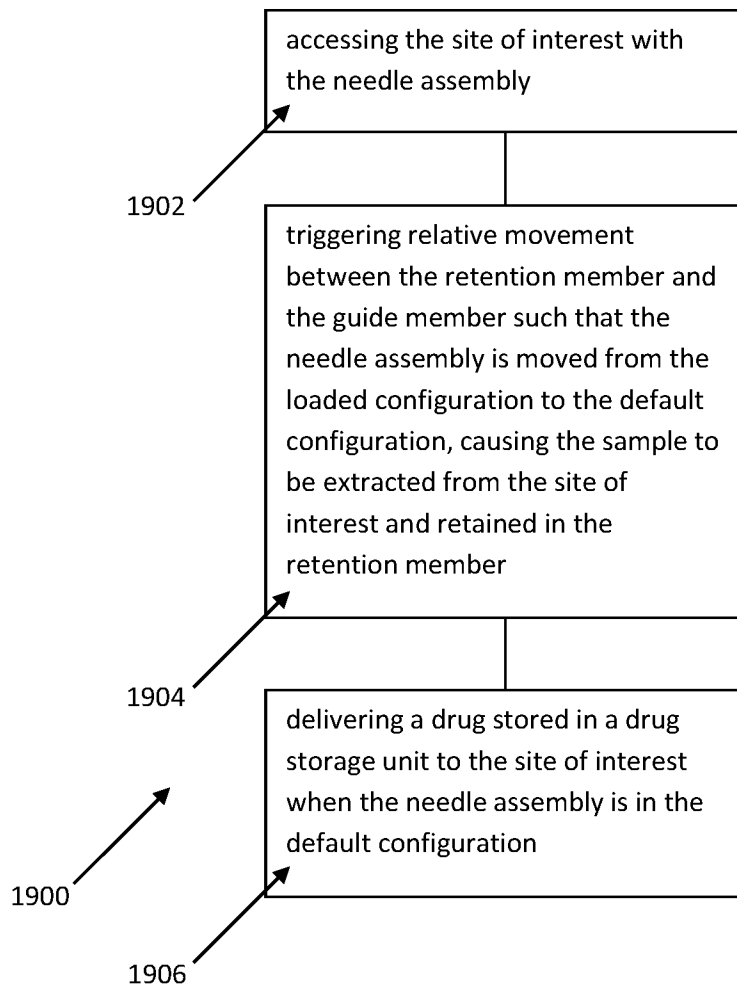


FIG. 19

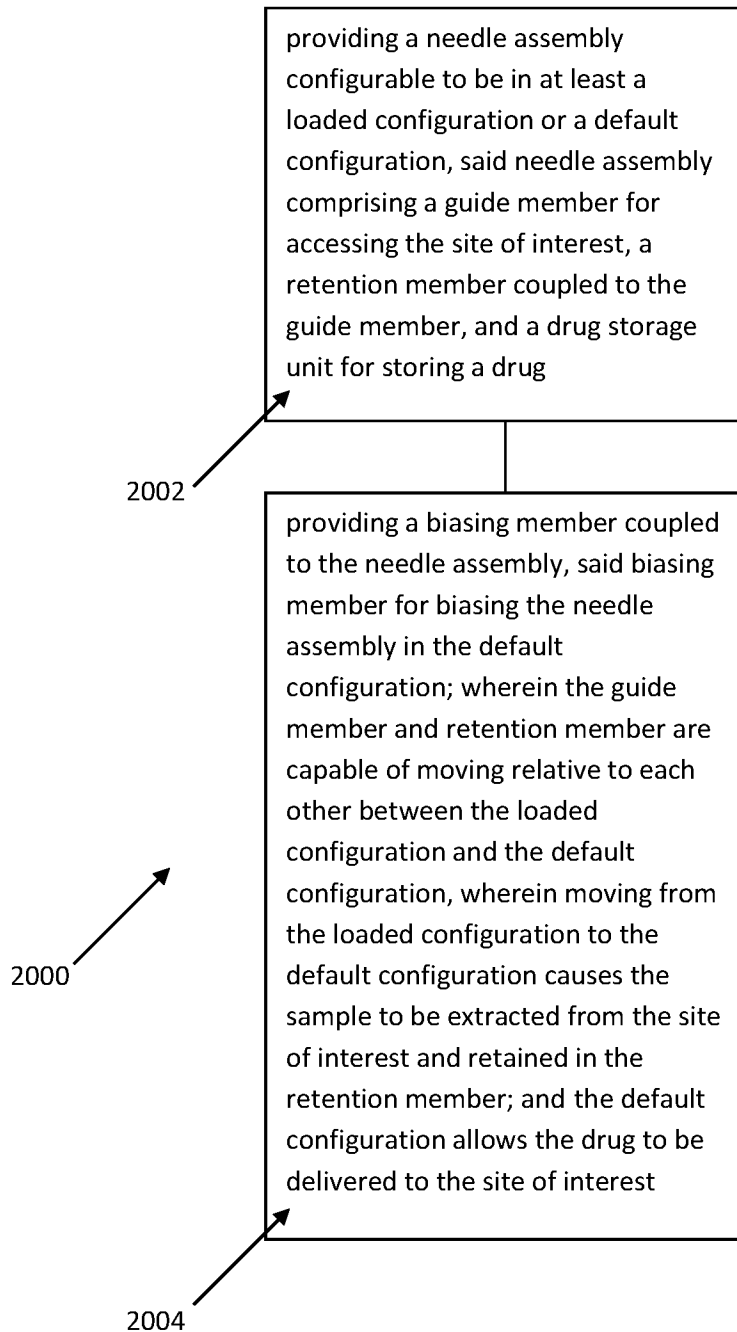


FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2019/050101

A. CLASSIFICATION OF SUBJECT MATTER

A61B 10/02 (2006.01)

According to International Patent Classification (IPC)

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC/WPI/FAMPAT: biopsy, retain, recess, receptacle, sample notch, bias, spring, drug, hemostatic, haemostatic, rotate, slide and related terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0228661 A1 (POPA-SIMIL L. AND KRAMER R.) 14 August 2014 Whole document, particularly para. [0031], [0078]-[0084], [0090]-[0092], [0096]-[0098]; Fig. 2A, 2B	1-3 AND 8-22
X	US 5718237 A (HAAGA J.R.) 17 February 1998 Whole document, particularly Fig. 2, 4, 7, 8; abstract; col. 3, lines 66-67, col. 7, lines 4-20, col. 8, lines 25-30	1-3 AND 8-22
X	US 2016/0374649 A1 (KRAMER R. ET AL) 29 December 2016 Whole document, particularly Fig. 4; para. [0003], [0005], [0025]-[0027]	1-3 AND 8-22
X	US 2016/0007975 A1 (KIM S.M. ET AL) 14 January 2016 Whole document, particularly para. [0042], [0047], [0056]-[0059]; Fig. 3, 5	1-3 AND 8-22
X	WO 2010/065736 A2 (THE REAGENTS OF THE UNIVERSITY OF MICHIGAN) 10 June 2010 Whole document, particularly Fig. 2-5, 10; para. [0029], [0032], [0034]-[0035], [0037], [0038], [0049], [0052], [0055], [0057], [0065], [0070], [0072], [0075]	1-3 AND 8-22

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search

25/04/2019

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Date of mailing of the international search report

24/05/2019

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2019/050101

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/0123797 A1 (KRAUSE W.) 31 May 2007 Whole document, particularly Fig. 8, 9, 11, 16 and 17; para. [0020], [0021], [0061], [0065], [0072]	1-3 AND 8-22
X A	US 2008/0306404 A1 (RONALD T.R.) 11 December 2008 Fig. 1, 1A; para. [0003], [0019] - [0020]	1-3 AND 8-22 4-7
X	US 2015/0305721 A1 (KANG H.G. ET AL) 29 October 2015 Fig. 7-11; para. [0007], [0010], [0023], [0063], [0074], [0093], [0105]-[0107], [0119]	1-3 AND 8-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/SG2019/050101

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2014/0228661 A1	14/08/2014	NONE	
US 5718237 A	17/02/1998	DE 69432525 T2 JP H09500565 A WO 95/13746 A1 US 5487392 A EP 0744916 A1 CA 2175831 A1	01/04/2004 21/01/1997 26/05/1995 30/01/1996 04/12/1996 26/05/1995
US 2016/0374649 A1	29/12/2016	US 2018/0055494 A1	01/03/2018
US 2016/0007975 A1	14/01/2016	KR 20140106062 A WO 2014/129743 A1	03/09/2014 28/08/2014
WO 2010/065736 A2	10/06/2010	US 2011/0237976 A1	29/09/2011
US 2007/0123797 A1	31/05/2007	WO 2007/084230 A2 EP 1968455 A2	26/07/2007 17/09/2008
US 2008/0306404 A1	11/12/2008	US 2009/0182260 A1	16/07/2009
US 2015/0305721 A1	29/10/2015	KR 20140082987 A KR 20140070333 A CN 104955403 A	03/07/2014 10/06/2014 30/09/2015