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DEPLOYMENT OF MULTIPLE BILIARY STENTS

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ABSTRACT

A guide tube (220) has a guidewire-engaging portion (222) at a distal portion (260) thereof, a first stent (54) surrounding the guide tube, advanceable together with the guide tube into a subject's lumen, a guidewire (12) arranged (i) entering the guide tube from a distal-end (320) opening thereof, (ii) disposed in the guidewire-engaging portion, and (iii) passing out of the guide tube proximally to the guidewire-engaging portion, and a second stent (54), proximal to the first stent, surrounding a proximal portion (240) of the guide tube and the guidewire. The first stent is slidably deployable off the distal end of the guide tube upon the guidewire having laterally exited the guidewire-engaging portion, and the second stent is slidably deployable off the distal end of the guide tube subsequently to deployment of the first stent, without the guidewire having been moved proximally. Other applications are also described.

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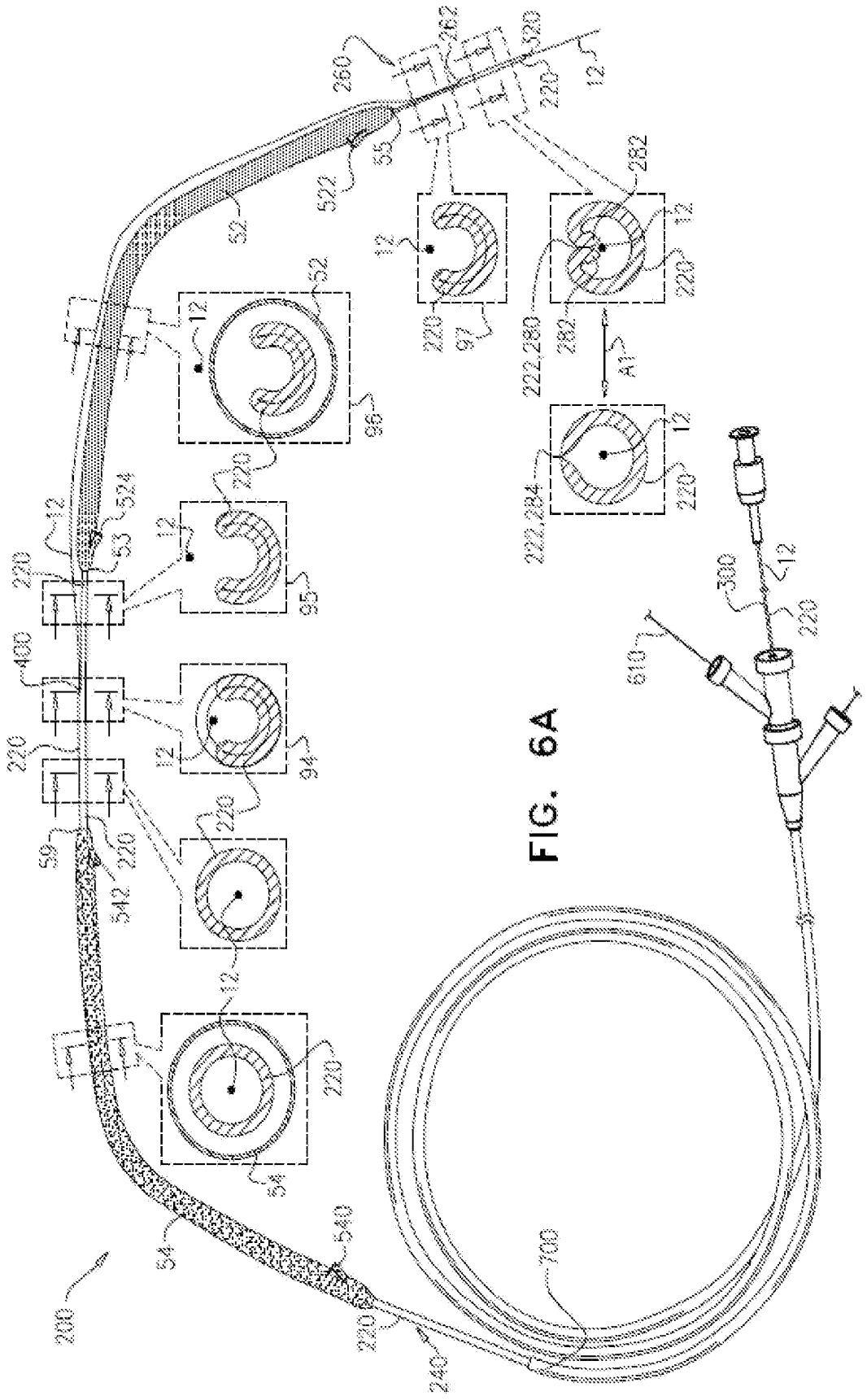

FIG. 6A

DEPLOYMENT OF MULTIPLE BILIARY STENTS

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a divisional of PCT/IL2019/050713 filed on June 27, 2019. The present application claims priority to US provisional application 62956294 filed on January 1, 2020.

FIELD OF THE INVENTION

Embodiments of the present invention relate generally to medical devices and more particularly to methods and apparatus for deploying multiple stents in a lumen of a subject.

BACKGROUND

Stents are typically deployed within a lumen of a body of a subject for various reasons. In some cases, a stent is deployed within a lumen in order to widen a narrowed section of the lumen. For example, insertion of a biliary stent into a bile duct is used to treat obstructions and strictures that occur in the bile duct. There are several conditions, malignant or benign, that can cause strictures of the bile duct. Pancreatic cancer is a common malignant cause of strictures of the bile duct. Noncancerous causes of bile duct stricture may include injury to the bile duct that occurs during surgery for gallbladder removal, and pancreatitis.

A biliary stent is typically a tube-like structure that is used to support a narrowed part of the bile duct and inhibit the reformation of the stricture.

SUMMARY OF THE INVENTION

In accordance with some applications of the present invention, apparatus and methods are provided for deployment of more than one stent (e.g., two stents) within a lumen of a subject. For example, two or more stents are deployed within a common bile duct of a subject in order to treat biliary strictures and obstructions. Typically, the two or more stents, e.g., two, three or four stents, are deployed alongside each other within the common bile duct to facilitate relieving of the biliary stricture. Typically, a guide tube is used to deploy the stents (e.g., a first and a second stent) in the lumen of the subject. In this context, in the specification and in the claims, "proximal" means closer to the orifice through which the guide tube or stent is originally placed into the body, and "distal" means further from this orifice.

For some applications, the guide tube is shaped to define a guidewire-engaging portion, e.g., a slit, extending proximally along the wall of the guide tube, from the distal end of the guide tube. A proximal end of the slit is typically located distally to the proximal end of the guide tube. Additionally, the guide tube is shaped to define a hole through a wall of the guide tube, the hole being located proximally to the proximal end of the guidewire-engaging portion and distally to the proximal end of the guide tube. Typically, a proximal end of the slit is located distally to the hole.

During delivery into the lumen of the subject, the first stent surrounds the guide tube and is advanced together with the guide tube into the lumen of the subject. Typically, the first stent is disposed along the guide tube such that, prior to insertion into the subject's body, a proximal end of the first stent is disposed distally to the hole in the wall of the guide tube while a distal end of the first stent is disposed proximally to the guidewire-engaging portion. When positioned at a desired site within the lumen of the subject, the first stent is slidably deployed from, i.e., advanced off of, the distal end of the guide tube and deployed within the lumen.

Also prior to insertion into the subject's body, the second stent is disposed proximal to the first stent, surrounding a proximal portion of the guide tube. (The proximal portion of the guide tube is called the "proximal portion" because it is proximal to the more distal portion of the guide tube, around which the first stent is disposed. The proximal portion of the guide tube, as well as the second stent surrounding the proximal

portion of the guide tube, is introduced into the subject's body, as described herein.) The second stent is shaped and sized to be advanced over the guide tube and off of the distal end of the guide tube into the lumen of the subject. The second stent is placed alongside the first stent subsequently to deployment of the first stent off of the distal end of the guide tube.

In accordance with some applications of the present invention, the first and second stents are delivered to the lumen of the subject without removing the guide tube or a guidewire used during the procedure from the body of the subject following deployment of the first stent and prior to deploying the second stent. As provided by some applications of the present invention, the first and second stents are both pre-mounted onto the guide tube and advanced into the subject's body in one advancement procedure, to be deployed subsequently within the lumen of the subject, as described herein.

There is therefore provided in accordance with some applications of the present invention, apparatus, including:

a guide tube shaped to define (a) a guidewire-engaging portion at a distal portion of the guide tube, a proximal end of the guidewire-engaging portion being located distally to a proximal end of the guide tube, (b) a hole in a wall of the guide tube, the hole being located proximally to the proximal end of the guidewire-engaging portion and distally to a proximal end of the guide tube;

a first stent surrounding the guide tube so as to be advanceable together with the guide tube into a lumen of a subject, the first stent being slidable along the guide tube such that a proximal end of the first stent is disposable distally to the hole while a distal end of the first stent is disposed proximally to the guidewire-engaging portion, the first stent being slidably deployable off of the distal end of the guide tube; and

a second stent, proximal to the first stent, surrounding a proximal portion of the guide tube, and shaped and sized to be advanceable along the guide tube and deployable off of the distal end of the guide tube into the lumen and placed alongside the first stent subsequently to deployment of the first stent off of the distal end of the guide tube.

For some applications, a distal end of the second stent is disposed proximally to the hole.

For some applications the apparatus further includes a guidewire configured to (i) enter a lumen of the guide tube from a distal-end opening of the guide tube, (ii) pass out of the lumen of the guide tube at the guidewire-engaging portion of the guide tube, and (iii) pass into the lumen of the guide tube through the hole, and the first stent is (i) constrained from distal motion past the guidewire-engaging portion when the guidewire is disposed within the guidewire-engaging portion, and (ii) constrained from proximal motion past the hole when the guidewire is disposed within the hole.

For some applications, the first stent is slidably deployable off the distal end of the guide tube when the guidewire is not disposed within the guidewire-engaging portion.

For some applications, there is no hole in the wall of the guide tube that is within 10 mm from the distal end of the guide tube.

For some applications, there is no hole having a diameter of less than 1 cm in the wall of the guide tube that is within 10 mm from the distal end of the guide tube

For some applications the apparatus further includes a guidewire that (i) enters a lumen of the guide tube from a distal-end opening of the guide tube, (ii) passes out of the lumen of the guide tube at the guidewire-engaging portion of the guide tube, and (iii) passes into the lumen of the guide tube through the hole, and

the first stent (a) has an outer surface disposed against the guidewire and (b) is configured to be advanced into the lumen of the subject while the outer surface is disposed against the guidewire,

and the second stent, surrounds the guidewire, and is configured to be advanced into the lumen of the subject over the guidewire.

For some applications, a distance between the distal end of the guide tube and the hole is 4 – 18 cm.

For some applications, the guidewire-engaging portion is shaped to define a slit extending proximally along the wall of the guide tube, from the distal end of the guide tube, the slit having a length of 1 mm – 7 cm.

For some applications, the slit has a length of 2.5 – 3 cm. For some applications, the guidewire-engaging portion is shaped to define a weak spot configured to tear in response to force applied to the weak spot by a guidewire.

There is further provided in accordance with some applications of the present invention, apparatus including:

a guide tube shaped to define a proximal end and a distal end of the guide tube;

a first stent surrounding the guide tube so as to be advanceable together with the guide tube into a lumen of a subject, and being slidably deployable off of the distal end of the guide tube;

a second stent, proximal to the first stent, surrounding a proximal portion of the guide tube, and shaped and sized to be advanceable along the guide tube into the lumen;

a first lock, which prevents proximal motion of the first stent past a location that is at least 1 mm from a distal end of the second stent; and

a second lock, which prevents distal motion of the second stent past a location that is at least 1 mm proximal of a proximal end of the first stent.

For some applications, the guide tube is shaped to define two holes in a lateral wall of the guide tube, and the first lock includes a locking wire that passes through the two holes.

For some applications:

the second stent is shaped to define a hole in a portion of the second stent,

the apparatus further includes a pushing tube, disposed proximally to the second stent and configured to push the second stent off of the guide tube,

the pushing tube is shaped to define a hole in a portion of the pushing tube, and

the second lock includes a locking wire that passes through the hole in the portion of the second stent and through the hole in the portion of the pushing tube.

For some applications, the first lock includes a first locking wire, and the second lock includes a second locking wire.

For some applications, a distance between the proximal end of the first stent and the distal end of the second stent is a fixed distance.

For some applications, a distance between the proximal end of the first stent and the distal end of the second stent is 2-80 mm.

For some applications, the distance between the proximal end of the first stent and the distal end of the second stent is at least 5 mm.

For some applications, the distance between the proximal end of the first stent and the distal end of the second stent is less than mm.

For some applications, the first lock is configured to prevent distal motion of the first stent during advancement of the first stent on the guide tube into the lumen of the subject.

For some applications the apparatus further includes a guidewire,

the guide tube is further shaped to define (a) a guidewire-engaging portion at a distal portion of the guide tube, a proximal end of the guidewire-engaging portion being located distally to a proximal end of the guide tube, and (b) a hole in a wall of the guide tube, the hole being located proximally to the proximal end of the guidewire-engaging portion and distally to a proximal end of the guide tube,

the first stent is (i) constrained from distal motion past the guidewire-engaging portion when the guidewire is disposed within the guidewire-engaging portion, and (ii) constrained from proximal motion past the hole when the guidewire is disposed within the hole, and

the first lock is not arranged to utilize the guidewire to prevent distal motion of the first stent.

There is further provided in accordance with some applications of the present invention, apparatus including:

a guide tube shaped to define a proximal end and a distal end of the guide tube;

a first stent surrounding the guide tube so as to be advanceable together with the guide tube into a lumen of a subject, and being slidably deployable off of the distal end of the guide tube;

a second stent, proximal to the first stent, surrounding a proximal portion of the guide tube, and shaped and sized to be advanceable along the guide tube into the lumen; and

a lock, which prevents distal motion of the second stent beyond a proximal end of the first stent when the first stent is being slidably deployed off of the distal end of the guide tube, and unlockable subsequently to the deployment of the first stent off of the distal end of the guide tube to allow deployment of the second stent off of the guide tube.

For some applications:

the second stent is shaped to define a hole in a portion of the second stent,

the apparatus further includes a pushing tube, disposed proximally to the second stent and configured to push the second stent off of the guide tube,

the pushing tube is shaped to define a hole in a portion of the pushing tube, and

the second lock includes a locking wire that passes through the hole in the portion of the second stent and through the hole in the portion of the pushing tube.

There is further provided in accordance with some applications of the present invention, a method including:

using apparatus including:

a guide tube shaped to define a proximal end and a distal end of the guide tube;

a first stent surrounding a distal portion of the guide tube, and

a second stent, proximal to the first stent, surrounding a proximal portion of the guide tube;

advancing the apparatus to a desired location in a lumen of a subject while: (a) the first stent is constrained from proximal motion past a location that is at least 1 mm from a distal end of the second stent, and (b) the second stent is constrained from distal motion beyond a location that is at least 1 mm proximal of a proximal end of the first stent.

For some applications: subsequently to the advancing of the apparatus, and while the second stent is constrained from distal motion, withdrawing the guide tube with respect to the first stent, until the first stent is deployed off of the distal end of the guide tube into the lumen;

subsequently to deploying the first stent off of the distal end of the guide tube, releasing the second stent such that it is not constrained from distal motion;

subsequently, advancing the second stent along the guide tube in the lumen of the subject and deploying the second stent off of the distal end of the guide tube alongside the first stent.

There is further provided in accordance with some applications of the present invention, apparatus including:

a guide tube shaped to define a guidewire-engaging portion at a distal portion of the guide tube, a proximal end of the guidewire-engaging portion being located distally to a proximal end of the guide tube;

a first stent surrounding the guide tube so as to be advanceable together with the guide tube into a lumen of a subject, the first stent being slidable along the guide tube such that a distal end of the first stent is disposed proximally to the guidewire-engaging portion of the guide tube;

a guidewire arranged (i) entering a lumen of the guide tube from a distal-end opening of the guide tube, (ii) disposed in the guidewire-engaging portion, and (iii) passing out of the lumen of the guide tube proximally to the guidewire-engaging portion of the guide tube, such that the first stent is constrained from distal motion past the

guidewire-engaging portion by the guidewire being disposed within the guidewire-engaging portion; and

a second stent, proximal to the first stent, surrounding a proximal portion of the guide tube and the guidewire, and shaped and sized to be advanceable along the guide tube, and:

(i) the guidewire is positioned to laterally exit the guidewire-engaging portion without being advanced distally or proximally,

(ii) the first stent is slidably deployable off of the distal end of the guide tube upon the guidewire having exited the guidewire-engaging portion, without the guidewire having been moved proximally subsequent to the guidewire exiting the guidewire-engaging portion, and

(iii) the second stent is slidably deployable off of the distal end of the guide tube and placeable alongside the first stent subsequently to deployment of the first stent off of the distal end of the guide tube, without the guidewire having been moved proximally subsequent to the guidewire exiting the guidewire-engaging portion.

For some applications, the first stent (a) has an outer surface disposed against the guidewire and (b) is configured to be advanced into the lumen of the subject while the outer surface is disposed against the guidewire.

For some applications, the guidewire-engaging portion is shaped to define a slit extending proximally along a wall of the guide tube, from a distal end of the guide tube, the slit having a length of 1-70 mm.

For some applications, the slit is shaped to define two slit lips that are in contact with each other to define a closed-slit configuration in the absence of any forces applied to the slit lips, and disengageable from each other, by application of a force to the lips, to define an opened-slit configuration.

For some applications, the slit is shaped to define two slit lips that are in contact with each other to define a closed-slit configuration, and disengageable from each other to define an opened slit configuration, and

further including a lock which:

presses the slit lips against each other in the closed-slit configuration when the guidewire is disposed in the guidewire-engaging portion to inhibit the lateral exiting of the guidewire from the guidewire-engaging portion, and

allows the lateral exiting of the guidewire from the guidewire-engaging portion in the opened-slit configuration when the lock does not press the slit lips against each other.

For some applications, the guidewire-engaging portion is shaped to define a weak spot configured to (i) tear in response to force applied to the weak spot by the guidewire upon the distal portion of the guide tube being withdrawn into the first stent, and (ii) shaped and sized to allow passage of the guidewire therethrough in the teared state thereof.

For some applications, the apparatus further includes:

a first lock, which prevents proximal motion of the first stent past a location that is at least 1 mm from a distal end of the second stent; and

a second lock, which prevents distal motion of the second stent past a location that is at least 1 mm proximal of a proximal end of the first stent.

For some applications, the guide tube is shaped to define two holes in a lateral wall of the guide tube, and wherein the first lock includes a locking wire that passes through the two holes.

For some applications:

the second stent is shaped to define a hole in a portion of the second stent,

the apparatus further includes a pushing tube, disposed proximally to the second stent and configured to push the second stent off of the guide tube,

the pushing tube is shaped to define a hole in a portion of the pushing tube, and

the second lock includes a locking wire that passes through the hole in the portion of the second stent and through the hole in the portion of the pushing tube.

For some applications, the first lock includes a first locking wire, and wherein the second lock includes a second locking wire.

For some applications, the first lock is configured to prevent distal motion of the first stent during advancement of the first stent on the guide tube into the lumen of the subject.

According to embodiments disclosed herein, a stent-deployment assembly for use with a guidewire comprises: (a) a biliary stent; and (b) an elongated stent-conveyance tube comprising a guidewire-retaining segment that includes (i) respective distal and proximal apertures defining a guidewire-path therethrough, and (ii) a lengthways laterally-breachable portion. The assembly is characterized as follows: (i) in a stent-advancement configuration, (A) the guidewire passes through the respective apertures so as to interiorly traverse the guidewire-retaining segment, and (B) the stent is arranged to surround a stent-conveyance tube segment that is proximally displaced from the guidewire-retaining segment, for advancement of the stent together with the stent-conveyance tube along the guidewire into a body lumen of a human subject, and (ii) when the stent is disposed, in the stent-advancement configuration, at a target deployment location within the lumen, a proximal-direction withdrawal of the stent-conveyance tube is effective to cause the guidewire to breach the laterally-breachable portion of the guidewire-retaining segment so as to decouple the guidewire from the tube without longitudinal displacement of the guidewire.

In some embodiments, it can be that when the assembly is advanced along the guidewire in the stent-advancement configuration, the guidewire-retaining segment is effective to retain the guidewire within.

In some embodiments, in the stent-advancement configuration, it can be that the guidewire does not interiorly traverse the tube segment surrounded by the stent.

In some embodiments, a segment of the stent-conveyance tube proximally abutting the guidewire-retaining segment can have a smaller diameter than does the guidewire-retaining segment.

In some embodiments, it can be that the distal aperture of the guidewire-retaining segment faces distally and the proximal aperture faces proximally.

In some embodiments, the assembly can additionally comprise a proximally withdrawable locking mechanism effective to maintain a position of the stent relative to the tube when the assembly is advanced along the guidewire in the stent-advancement configuration.

In some embodiments, it can be that a proximal-direction withdrawal of the stent-conveyance tube effective to cause the guidewire to breach the laterally-breachable portion of the guidewire-retaining segment can be effected by applying a first proximal-withdrawal force of at least 100 grams and no more than 20 kg, or at least 500 grams and no more than 10 kg, or at least 1 kg and no more than 5 kg, or at least 1.5 kg and no more than 2.5 kg. In some embodiments, it can be that a proximal-direction withdrawal of the stent-conveyance tube after the lateral breaching of the laterally-breachable portion of the guidewire-retaining segment by the guidewire can be effected by a second proximal-withdrawal force, lesser than the first proximal-withdrawal force. In some embodiments, the proximal-direction withdrawal of the stent-conveyance tube after the lateral breaching of the laterally-breachable portion of the guidewire-retaining segment by the guidewire can be effective to leave the stent deployed in the lumen without manipulation of the guidewire.

In some embodiments, the laterally-breachable portion of the guidewire-retaining segment can include a slit portion having opposed slit-lips either in contact with each other or displaced from each other by no more than a diameter of the guidewire. In some embodiments, the laterally-breachable portion of the guidewire-retaining segment can include a perforated and/or thinned tube-wall portion.

In some embodiments, the assembly can additionally comprise the guidewire.

In some embodiments, in the stent-advancement configuration, the stent can be the only stent engaged with the guidewire.

In some embodiments, it can be that (i) the stent is a first stent, and the assembly additionally comprises a second stent, and (ii) in the stent-advancement configuration the

second stent is arranged to surround a second stent-conveyance tube segment proximally displaced from the first stent, for advancement of the second stent into the body lumen. In some such embodiments, in the stent-advancement configuration, the guidewire can interiorly traverse the second stent-conveyance tube segment. In some such embodiments, it can be that when the second stent is disposed at a second target deployment location alongside the deployed first stent, a proximal-direction withdrawal of the stent-conveyance tube and of the guidewire is effective to leave the stent deployed in the lumen without further manipulation of the guidewire.

According to embodiments disclosed herein, a stent-deployment assembly for use with a guidewire comprises: (a) an elongated stent-conveyance tube comprising a guidewire-retaining segment (i) having a lengthways laterally-breachable portion and (ii) configured for having the guidewire traverse therethrough; and (b) a biliary stent arranged to surround a stent-conveyance tube segment that is proximally displaced from the guidewire-retaining segment, for advancement of the stent together with the stent-conveyance tube along the guidewire into a body lumen of a human subject. The assembly is characterized as follows: when the stent is disposed at a target deployment location within the lumen, a proximal-direction withdrawal of the stent-conveyance tube is effective to cause the guidewire to breach the laterally-breachable portion of the guidewire-retaining segment so as to decouple the guidewire from the tube without manipulation of the guidewire.

In some embodiments, it can be that when the assembly is advanced along the guidewire in the stent-advancement configuration, the guidewire-retaining segment is effective to retain the guidewire within.

In some embodiments, it can be that in the stent-advancement configuration, the guidewire does not interiorly traverse the tube segment surrounded by the stent.

In some embodiments, a segment of the stent-conveyance tube proximally abutting the guidewire-retaining segment can have a smaller diameter than does the guidewire-retaining segment.

In some embodiments, the assembly can additionally comprise a proximally withdrawable locking mechanism effective to maintain a position of the stent relative to the tube when the assembly is advanced along the guidewire in the stent-advancement configuration.

In some embodiments, it can be that a proximal-direction withdrawal of the stent-conveyance tube effective to cause the guidewire to breach the laterally-breachable portion of the guidewire-retaining segment can be effected by applying a first proximal-withdrawal force of at least 100 grams and no more than 20 kg, or at least 500 grams and no more than 10 kg, or at least 1 kg and no more than 5 kg, or at least 1.5 kg and no more than 2.5 kg. In some such embodiments, a proximal-direction withdrawal of the stent-conveyance tube after the lateral breaching of the laterally-breachable portion of the guidewire-retaining segment by the guidewire can be effected by a second proximal-withdrawal force, lesser than the first proximal-withdrawal force.

In some embodiments, it can be that wherein the proximal-direction withdrawal of the stent-conveyance tube after the lateral breaching of the laterally-breachable portion of the guidewire-retaining segment by the guidewire is effective to leave the stent deployed in the lumen without manipulation of the guidewire.

In some embodiments, it can be that the laterally-breachable portion of the guidewire-retaining segment includes a slit portion having opposed slit-lips either in contact with each other or displaced from each other by no more than a diameter of the guidewire. In some embodiments, the laterally-breachable portion of the guidewire-retaining segment can include a perforated and/or thinned tube-wall portion.

In some embodiments, the assembly can additionally comprise the guidewire.

In some embodiments, it can be that in the stent-advancement configuration, the stent is the only stent engaged with the guidewire. In some embodiments, it can be that (i) the stent is a first stent, and the assembly additionally comprises a second stent, and (ii) in the stent-advancement configuration the second stent is arranged to surround a second stent-conveyance tube segment proximally displaced from the first stent, for advancement of the second stent into the body lumen. In some such embodiments, it can

be that in the stent-advancement configuration, the guidewire interiorly traverses the second stent-conveyance tube segment. In some such embodiments, it can be that when the second stent is disposed at a second target deployment location alongside the deployed first stent, a proximal-direction withdrawal of the stent-conveyance tube of the guidewire is effective to leave the stent deployed in the lumen, without further manipulation of the guidewire.

According to embodiments disclosed herein, an elongated stent-conveyance tube for guidewire-aided deployment of a biliary stent in a lumen of a human body comprises: (a) a stent-conveying segment configured to have a biliary stent mounted therearound for advancement along a guidewire and into the lumen; and (b) a guidewire-retaining segment distally displaced from the stent-conveying segment, the guidewire-retaining segment comprising (i) respective distal and proximal apertures defining a guidewire-path therethrough, and (ii) a lengthways laterally-breachable portion, wherein the laterally-breachable portion of the guidewire-retaining segment is formed to include (i) a slit portion having opposed slit-lips substantially in contact with each other and/or (ii) a perforated and/or thinned tube-wall portion.

A method is disclosed, according to embodiments, for deploying a biliary stent in a lumen of a human body, using a guidewire arranged such that a distal end-section thereof is disposed within the body lumen and a proximal end-section thereof is outside the body. The method comprises: (a) passing the proximal end-section of the guidewire through respective distal and proximal apertures of a guidewire-retaining segment of a distal portion of a stent-conveyance tube so as to interiorly traverse the guidewire-retaining segment, the guidewire-retaining segment having a lengthways laterally-breachable portion; (b) arranging a biliary stent around a stent-conveyance tube segment that is proximally displaced from the guidewire-retaining segment; (c) distally advancing the stent-conveyance tube along the guidewire together with the stent arranged therearound, so as to deliver the stent to a target stent-deployment location within the body lumen; and (d) proximally withdrawing the stent-conveyance tube at least from the interior of the stent so as to deploy the stent in the lumen, without proximally withdrawing or distally advancing the guidewire, the proximal withdrawing of the tube

being effective to cause the guidewire to laterally breach the laterally-breachable portion of the guidewire-retaining segment and thereby to decouple the guidewire from the tube.

In some embodiments, the arranging of the stent can be performed after the passing of the guidewire through the respective apertures. In some embodiments, the arranging of the stent can be performed before the passing of the guidewire through the respective apertures.

In some embodiments, it can be that the arranging step is factory-performed and all other steps are performed at a medical facility.

In some embodiments, it can be that the proximal withdrawing of the tube includes applying a first proximal-withdrawal force effective to cause the guidewire to laterally breach the laterally-breachable portion of the guidewire-retaining segment, the first proximal-withdrawal force being at least 100 grams and no more than 10 kg, or at least 500 grams and no more than 5 kg, or at least 1 kg and no more than 2.5 kg, or at least 1.5 kg and no more than 2 kg. In some such embodiments, it can be that a second proximal-withdrawal force, lesser than the first proximal-withdrawal force, is effective to withdraw the stent-conveyance tube from the stent after the lateral breaching of the laterally-breachable portion of the guidewire-retaining segment by the guidewire. In some such embodiments, it can be that the arranging of the biliary stent includes engaging a locking mechanism to couple the stent to the stent-conveyance tube.

In some embodiments, the method can additionally comprise, before the proximal withdrawing of the stent-conveyance tube: disengaging the locking mechanism.

In some embodiments, a segment of the stent-conveyance tube proximally abutting the guidewire-retaining segment can have a smaller diameter than does the guidewire-retaining segment.

In some embodiments, it can be that, in the stent-advancement configuration, the guidewire does not interiorly traverse the tube segment surrounded by the stent.

In some embodiments, the stent can be deployed in the lumen without manipulating the guidewire.

In some embodiments, it can be that (i) the stent is a first stent, and the stent-conveyance tube segment is a first stent-conveyance tube segment, and (ii) the method additionally comprises: arranging a second stent to surround a second stent-conveyance tube segment that is proximally displaced from the first stent-conveyance tube segment; passing the proximal end-section of the guidewire through an aperture disposed proximally from the first stent-conveyance tube segment and distally from the second stent-conveyance tube segment, such that that the guidewire interiorly traverses the second stent-conveyance tube segment; subsequent to the proximal withdrawing of the stent-conveyance tube at least from the interior of the first stent so as to deploy the first stent in the lumen, (i) distally advancing the second stent along the stent-conveyance tube and (ii) distally advancing the stent-conveyance tube along the guidewire together with the second stent arranged therearound, so as to deliver the second stent to a second target stent-deployment location alongside the first stent; and proximally withdrawing the stent-conveyance tube and the guidewire at least from the interior of the second stent so as to deploy the second stent in the lumen, without further manipulation of the guidewire.

The present invention will be more fully understood from the following detailed description of applications thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described further, by way of example, with reference to the accompanying drawings, in which the dimensions of components and features shown in the figures are chosen for convenience and clarity of presentation and not necessarily to scale. The amended claims are not drawn to the embodiments of Figs 1-4. In the drawings:

Fig. 1 is a schematic illustration of a guide tube for deployment of a first and second stent in a lumen of a subject, in accordance with some applications of the present invention;

Fig. 2 is a schematic illustration of apparatus for delivery and deployment of a first and second stent in a lumen of a subject, in accordance with some applications of the present invention;

Figs. 3A-H are schematic illustrations depicting a general overview of a method for deploying first and second stents in a lumen of a subject, in accordance with some applications of the present invention;

Fig. 4 is a schematic illustration of an additional configuration of the guide tube for deployment of the first and second stents in the lumen of the subject, in accordance with some applications of the present invention;

Figs. 5A-B are schematic illustrations of additional configurations of a distal portion of a guide tube, in accordance with some applications of the present invention;

Figs. 6A-B are schematic illustrations of apparatus for delivery and deployment of a first and a second stent in a lumen of a subject, in accordance with some applications of the present invention;

Figs. 7A-H are schematic illustrations depicting a general overview of a method for deploying first and second stents in a lumen of a subject, in accordance with some applications of the present invention;

Figs. 8A-B are schematic illustrations of a locking mechanism comprising a lock configured to prevent motion of the first stent with respect to the guide tube; and Figs.

9A-D are schematic illustrations of locking mechanisms comprising first and second locks configured to prevent motion of the first stent and the second stent, respectively, with respect to the guide tube.

Fig. 10 is a schematic illustration of a distal portion of a stent-conveyance tube, shown engaged with a guidewire, in accordance with embodiments of the present invention.

Figs. 11A and 11B are schematic illustrations of a stent assembly and its deployment in a lumen of a human subject, in accordance with embodiments of the present invention.

Fig. 12 shows a flowchart of a method for deploying a biliary stent in a lumen of a human subject, in accordance with embodiments of the present invention.

Figs. 13A, 13B and 13D are schematic illustrations depicting a general overview of a method for deploying a stent in a lumen of a subject, in accordance with embodiments of the present invention.

Fig. 13C is a schematic illustration of a distal portion of a stent-conveyance tube, shown engaged with a guidewire, during proximal withdrawal of a stent-conveyance tube, in accordance with embodiments of the present invention.

Fig. 14 shows a flowchart of a method for deploying multiple stents in a lumen of a human subject, in accordance with embodiments of the present invention.

Figs. 15A-15E are schematic illustrations depicting a general overview of a method for deploying multiple stents in a lumen of a subject, in accordance with embodiments of the present invention.

Figs. 16A-16B are schematic illustrations of a locking mechanism comprising a lock configured to prevent motion of the first stent with respect to the guide tube;

Figs. 17A-17D are schematic illustrations of locking mechanisms comprising first and second locks configured to prevent motion of the first stent and the second stent, respectively, with respect to the guide tube.

DETAILED DESCRIPTION OF EMBODIMENTS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the

invention may be embodied in practice. Throughout the drawings, like-referenced characters are generally used to designate like elements.

A guide tube is provided for facilitating deployment of more than one stent (e.g., a first and a second stent) in a lumen of the subject. In accordance with some applications of the present invention, various configurations of the guide tube are descried herein. Specifically, Figs. 1-4 illustrate guide tube 22, and Figs. 5-9D illustrate guide tube 220, in accordance with some applications of the present invention. It is noted that both guide tube 22 and guide tube 220 are configured to deliver the first and second stents into the lumen of the subject without removing guide tubes 22 and 220 or a guidewire used during the procedure from the body of the subject following deployment of the first stent and prior to mounting the second stent. The first and second stents are typically mounted onto guide tubes 22 and 220 in advance of a procedure, and subsequently advanced into the subject's body to be deployed within the lumen of the subject, as will be described hereinbelow.

The present detailed description begins with a description of a guide tube 22, which is used to deploy multiple stents in a lumen of the subject, in accordance with some applications of the present invention.

Reference is made to Figs. 1 and 2.

Fig. 1 is a schematic illustration of guide tube 22, in accordance with some applications of the present invention. As shown, guide tube 22 is shaped to define a proximal end 30 at a proximal portion 24 of guide tube 22, and a distal end 32 at a distal portion 26 of guide tube 22.

Guide tube 22 is additionally shaped to define a guidewire-engaging portion 122, shown as a hole 40 through a wall 36 of guide tube 22 at distal portion 26 of the guide tube. Guide tube 22 is further additionally shaped to define a slit 28 extending proximally along wall 36 of guide tube 22, from distal end 32 of the guide tube. A proximal end 29 of slit 28 is located distally to proximal end 30 of guide tube 22. Additionally, proximal end 29 of slit 28 is located proximally to hole 40.

Typically, hole 40 is disposed at an angular offset alpha of 90 - 180 degrees, e.g., 180 degrees, from slit 28, with respect to a central longitudinal axis A1 of the guide tube. Alternatively, a smaller angle alpha is used (e.g., an angle alpha of approximately 60 degrees is shown in Fig. 2). As used in the present application, including in the claims, a "central longitudinal axis" of an elongate structure is the set of all centroids of transverse cross-sectional sections of the structure along the structure. Thus, the cross-sectional sections are locally perpendicular to the central longitudinal axis, which runs along the structure. (If the structure is circular in cross-section, the centroids correspond with the centers of the circular cross-sectional sections.) The central longitudinal axis of a curved elongate structure is curved, rather than straight.

Typically, a distance D1 between a center of hole 40 and distal end 32 of guide tube 22 is at least 5 mm and/or less than 200 mm e.g., between 5 and 200 mm.

For some applications, hole 40 is shaped to define an elliptical hole having a major axis W1 which is typically oriented in parallel with longitudinal axis A1 of guide tube 22. The major axis is typically 1.5 – 4 times longer than a minor axis W2 of hole 40. For example, hole 40 has major axis W1 having a length of 5 – 10 mm and minor axis W2 having a length of 0.5 – 1.0 mm.

Slit 28 defines two slit edges 27 that are parallel to central longitudinal axis A1 of guide tube 22, typically a distance D2 between a first one of the slit edges and a second one of the slit edges being 0.45 – 0.9 mm. For some applications, when guide tube 22 is viewed from distal end 32 of guide tube 22, an angle theta of 10-80 degrees, e.g., 20-70 degrees, is formed that is defined by: (a) a first line extending from the central longitudinal axis to a first one of the slit edges, and (b) a second line extending from the central longitudinal axis to a second one of the slit edges.

Reference is still made to Figs. 1 and 2. Fig. 2 is a schematic illustration of apparatus 20 for delivery and deployment of a first stent 52 and a second stent 54 in a lumen of a subject, in accordance with some applications of the present invention.

For some applications, apparatus 20 comprises guide tube 22 (as described hereinabove with reference to Fig. 1), and first and second stents 52 and 54 respectively.

As shown, first and second stents 52 and 54 surround guide tube 22, second stent 54 being disposed proximally to first stent 52 and surrounding proximal portion 24 of guide tube 22. First stent 52 is typically disposed over guide tube 22 such that a proximal end 53 of first stent 52 is disposed distally to proximal end 29 of slit 28 of guide tube 22 while a distal end 55 of first stent 52 is disposed proximally to hole 40.

First stent 52 is shaped to define a proximal flap 524 and a distal flap 522, and second stent 54 is shaped to define a proximal flap 540 and a distal flap 542. The flaps are generally configured to facilitate anchoring of the stents to lumens in which the stents are deployed.

For some applications, a distal end 59 of second stent 54 is disposed proximally to proximal end 29 of slit 28. For other applications, distal end 59 of second stent 54 is disposed distally to proximal end 29 of slit 28.

First stent 52 is slidably deployed off of distal end 32 of guide tube 22. Additionally, second stent 54, is also shaped and sized to be advanceable over guide tube 22, typically subsequently to deployment of first stent 52 off of distal end 32 of guide tube 22.

For some applications, first and second stents 52 and 54 each have a length L1 of 5 – 15 cm, and slit 28 also has a length L2 of 5 – 15 cm. Typically, slit 28 has a length that is greater than the length of first stent 52. For some applications, slit 28 has a length that is: (a) greater than a length of first stent 52, and (b) less than a sum of the length of first stent 52 and a length of second stent 54.

Apparatus 20 is typically advanced into a lumen of the subject, and guide tube 22 facilitates placement of first and second stents 52 and 54 within the lumen of the subject.

Reference is now made to Figs. 3A-H, which depict a general overview of a method for use of apparatus 20 for deploying first and second stents 52 and 54 in a lumen of a subject, in accordance with some applications of the present invention. Typically, stents 52 and 54 are deployed in the lumen of the subject, e.g., a common bile duct of the subject, in order to manage strictures of the lumen. In accordance with some applications of the present invention, apparatus 20 is configured such that first stent 52 is advanced

into the lumen of the subject against a guidewire, and second stent 54 is advanced into the lumen over the guidewire (i.e., surrounding the guidewire).

Reference is made to Fig. 3A. In accordance with some applications of the present invention, apparatus 20 (comprising guide tube 22 and first and second stents 52 and 54, as described hereinabove with reference to Fig. 2) is used in combination with a guidewire 12 to deploy stents 52 and 54 alongside each other in the lumen. Guidewire 12 is typically threaded through guide tube 22 such that following the threading:

(a) guidewire 12 enters a lumen of guide tube 22 from a distal-end 32 opening of guide tube 22, 14

(b) guidewire 12 passes out of the lumen of guide tube 22 through hole 40 of guide tube 22,

(c) first stent 52 is constrained from distal motion past hole 40 of guide tube 22, due to guidewire 12 being disposed within hole 40,

(d) guidewire 12 passes into the lumen of guide tube 22 through proximal end 29 of slit 28, and

(e) first stent 52 is constrained from proximal motion past proximal end 29 of slit 28, due to guidewire 12 being disposed within slit 28.

Following threading of guidewire 12 through guide tube 22 as described hereinabove, apparatus 20 is advanced into a body of the subject, e.g., into the small intestine, and into lumen 4 of the common bile duct, as shown in Fig. 3A. As shown, first stent 52 is advanced distally over guide tube 22 and against guidewire 12 (i.e., an outer surface of first stent 52 is disposed against guidewire 12). Due to threading of guidewire 12 as described hereinabove, stent 52 is advanced distally in lumen 4 while it is constrained from distal motion past hole 40 of guide tube 22. Constrained motion of stent 52 (particularly due to guidewire 12 being disposed within hole 40) typically allows for stent 52 to be advanced to a desired deployment site within lumen 4 in a controlled manner (i.e., inhibiting uncontrolled distal motion of stent 52, thus allowing the physician to safely perform the implantation at the desired deployment site).

Additionally, due to guidewire 12 being disposed within slit 28, first stent 52 is constrained from proximal motion past proximal end 29 of slit 28, allowing the physician to advance stent 52 in a controlled manner.

Reference is now made to Figs. 3B-H.

When first stent 52 reaches a desired deployment site within lumen 4, guidewire 12 is removed from hole 40 of guide tube 22, by pulling guidewire 12 proximally in the direction indicated by arrow 11, as shown in Fig. 3B. Guidewire 12 is then typically advanced distally in lumen 4 as indicated by arrow 13 (Fig. 3C). Guidewire 12 is thus maintained within lumen 4 and is not removed from lumen 4 at this stage. Removal of guidewire 12 from hole 40 typically releases first stent 52 and allows for guide tube 22 to be pulled proximally in the direction indicated by arrow until guide tube 22 is removed from stent 52, and stent 52 can be deployed in lumen 4 (Fig. 3D). While pulling guide tube 22 proximally in the direction indicated by arrow 15, guidewire 12 slides through slit 28 of guide tube 22 and is consequently centered within a lumen of the guide tube (Fig. 3E). Centering of guidewire 12 in guide tube 22 facilitates using guidewire 12 for deployment of second stent 54 within lumen 4. Positioning of guidewire 12 in guide tube 22 using slit 28 allows second stent 54 to be advanced over guidewire 12, whereas first stent 52 was advanced against (but not while around) guidewire 12.

As shown in Fig. 3F, and indicted by arrow 17, second stent 54 is advanced distally in lumen 4 over guide tube 22 and over guidewire 12 (which is the lumen of guide tube 22). As shown in Fig. 3G, second stent 54 continues to be distally advanced in lumen 4 (as indicted by arrows 19) until a desired deployment site is reached alongside first stent 52 (Figs. 3F-G). Once second stent 54 is deployed alongside first stent 52, guide tube 22 and guidewire 12 are retracted by being pulled in a proximal direction, as indicated by arrow 21 in Fig. 3H.

As described in Figs. 3A-H, use of apparatus 20 in accordance with some applications of the present invention, allows for deployment of second stent 54 subsequently to deployment of first stent 52, while maintaining guidewire 12 within lumen 4. Additionally, apparatus 20 allows for deployment of second stent 54 subsequently to deployment of first stent 52, without removing apparatus 20 from the

body of the subject following deployment of first stent 52 in order to mount second stent 54. Notably, first and second stents 52 and 54 are typically disposed at the same time on guide tube 22 (also as shown in Fig. 2) when advanced into the subject's body, to be deployed within the lumen using the techniques described herein.

Reference is made to Figs. 1-9D. It is noted that for some applications first and second stents 52 and 54 comprise self-expandable stents.

It is additionally noted that stents are described by way of illustration and not limitation. The scope of the present invention includes the use of any other drainage tube or tube-like structure configured to relieve stricture of a lumen of a subject.

Reference is now made to Figs. 3A-4. Fig. 4 is a schematic illustration of an additional configuration of guide tube 22 for deployment of first and second stents 52 and 54 in the lumen of the subject, in accordance with some applications of the present invention. As described hereinabove with reference to Figs. 1-3H, guidewire-engaging portion 122, embodied as hole 40, is configured to engage guidewire 12 in such a way that it inhibits distal motion of first stent 52 past guidewire-engaging portion 122 of guide tube 22, due to guidewire 12 being engaged by 16 portion 122 (e.g., disposed within hole 40). Guidewire-engaging portion 122 is shown in Figs. 1- 3H as hole 40 by way of illustration and not limitation. It is noted that guidewire-engaging portion 122 may be shaped to define any other configuration suitable for engaging guidewire 12 in such a manner that will grasp or otherwise hold guidewire 12 and thereby inhibit distal motion of first stent 52 past guidewire-engaging portion 122 when stent 52 is advanced distally against guidewire 12. It is noted that the techniques described herein with reference to Figs. 3A-H apply to guidewire-engaging portion 122 as shown in Fig. 4 as well. As shown in Fig. 4, for some applications, edges 27 of slit 28 are shaped to define guidewire-engaging portion 122. Typically, distance D2 between a first one of the slit edges and a second one of the slit edges is 0.45 – 0.9 mm. However, at guidewire-engaging portion 122, a distance D3 between slit edges 27 is smaller than distance D2, such that, for example, D2 is 2 - 5 times larger than D3. Typically, distance D3 between slit edges 27 is 0.09 mm - 0.45 mm, e.g., greater than 0.15 mm and/or less than 0.4 mm. Typically, guidewire-engaging portion 122 shown in Fig. 4 has a length that is 5 – 10

times longer than D3, e.g., 0.45 mm - 4.5 mm, e.g., greater than 1 mm and/or less than 3.5 mm.

As shown in Fig. 4, guidewire 12 is typically engaged by, and locked into, the narrowed area in slit 28 which defines guidewire-engaging portion 122. Engaging guidewire 12 by guidewire-engaging portion 122 typically allows for first stent 52 to be advanced to a desired deployment site within the lumen of the subject in a controlled manner (i.e., inhibiting uncontrolled distal motion of stent 52 when stent 52 is advanced distally against guidewire 12, thus allowing the physician to safely perform the implantation at the desired deployment site).

In other words, when guidewire 12 is disposed (i) at least in part in a lumen of guide tube 22, (ii) passing through an opening at distal end 32 of guide tube 22, (iii) passing through guidewire-engaging portion 122 of guide tube 22, and (iv) passing through proximal end 29 of slit 28, first stent 52 is (i) constrained from distal motion past guidewire-engaging portion 122, and (ii) constrained from proximal motion past proximal end 29 of the slit 28. Additionally, when guidewire 12 is disposed (i) at least in part in a lumen of guide tube 22, (ii) passing through an opening at distal end 32 of guide tube 22, (iii) passing through guidewire-engaging portion 122 of guide tube 22, and (iv) passing through proximal end 29 of slit 28, second stent 54 is constrained from distal motion past the proximal end of the slit.

Once first stent 52 is in a desired deployment site in the lumen of the subject, guidewire 12 is released from guidewire-engaging portion 122 by pulling guidewire 12. Removal of guidewire 12 from guidewire-engaging portion 122 typically releases first stent 52 and allows guide tube 22 to be pulled proximally in the direction indicated by arrow (as shown in Fig. 3D) until guide tube 22 is removed from stent 52, and stent 52 can be deployed in the lumen of the subject.

It is noted that for other applications, guidewire-engaging portion 122 may comprise a clip or any other suitable apparatus for engagement of guidewire 12.

Reference is now made to Figs. 5A-B and 6A-B.

Figs. 5A-B and 6A-B are schematic illustration of guide tube 220, in accordance with some applications of the present invention. Guide tube 220 is generally the same as guide tube 22 expect for where indicated otherwise.

As shown, guide tube 220 has a distal portion 260 and, proximal thereto, a proximal portion 240. Guide tube 220 is additionally shaped to define a guidewire-engaging portion 222 at distal portion 260 of guide tube 220. Typically, a proximal end 262 of guidewire-engaging portion 222 is located distally to a proximal end 300 of guide tube 220.

Typically, guide tube 220 is additionally shaped to define a hole 400 in the wall of the guide tube 220, hole 400 being located proximally to proximal end 262 of guidewire-engaging portion 222 and distally to proximal end 300 of the guide tube. Typically, a distance between distal end 320 of guide tube 220 and hole 400 is at least 4 cm and/or less than 18 cm (e.g., 4-18 cm). Typically, there is no hole in the wall of guide tube 220 that is within 10 mm from distal end 320 of the guide tube. (More generally, there is typically no hole having a diameter of less than 1 cm in the wall of guide tube 220 that is within 10 mm from distal end 320 of the guide tube.)

For some applications, guidewire-engaging portion 222 is shaped to define a slit 280 extending proximally along the wall of guide tube 220, from distal end 320 of the guide tube. Slit 280 typically has a length of at least 1 mm and/or less than 70 mm (e.g., 1-70 mm). For example, the slit may have a length of at least mm and/or less than 30 mm (e.g., 25-30 mm). A proximal end 262 of slit 280 is located distally to proximal end 300 of guide tube 220. Additionally, 18 proximal end 262 of slit 280 is located distally to hole 400. Typically, proximal end 262 of slit 280 is located 5-40 mm from distal end 320 of the guide tube.

For some applications, slit 280 is shaped to define two lips 282 (hereinafter, "slit lips 282") that are in contact with each other to define a closed-slit configuration in the absence of any forces applied to slit lips 282, and that are disengageable from each other, typically by application of a force to slit lips 282, to define an opened-slit configuration.

Alternatively, guidewire-engaging portion 222 is shaped to define a weak spot 284, e.g., a splittable portion, configured to tear in response to force applied to weak spot 284 (e.g., by guidewire 12 as shown hereinbelow in Fig. 7B). It is noted that Figs. 5A and 6A-B show (as indicated by double headed arrow A1) the two options of the guidewire engaging portion 222 being shaped to define either a slit 280 or a weak spot 284. This is by way of illustration and not limitation; it is noted that with respect to Fig. 5B, guidewire engaging portion 222 may be shaped to define slit 280.

Reference is still made to Figs. 5A-B and 6A-B. As shown, guide tube 220 assumes a collapsed configuration in a portion of guide tube 220 that is typically proximal to guidewire engaging portion 222 and distal to hole 400 (shown in the exploded view in boxes 94, 95, 96 and 97 in Fig. 6A, and in the exploded view in box 98 in Fig. 5A). Alternatively, guide tube 220 may assume varying diameters along a length of the guide tube, e.g., a diameter that is smaller in the portion of guide tube 220 that is typically proximal to guidewire engaging portion 222 and distal to hole 400 (shown in the exploded view in box 100 in Fig. 5B, and in the exploded view in boxes 102, 104, and 106 in Fig. 6B). For some applications, there may be a single portion of the guide tube 220 with a smaller diameter that extends from guidewire engaging portion 222 to hole 400 (such as is shown in Figs. 6A-B). Alternatively, for some applications, the diameter of guide tube 220 may be smaller in two separate portions of guide tube 220: (i) in a vicinity of guidewire engaging portion 222, proximal to guidewire engaging portion 222, and (ii) in a vicinity of hole 400, distal to hole 400. In between these two portions, guide tube 220 may assume its larger diameter. Alternatively, for some applications, guide tube 220 may have a substantially constant diameter along substantially the entire length of guide tube 220. Typically, guide tube 220 is configured for use with guidewire 12, and the collapsed, or the varying diameter configurations of guide tube 220, allow the guidewire to generally pass in and out of a lumen of guide tube 220.

Reference is still made to Figs. 5A-B and 6A-B. Figs. 6A-B are schematic illustrations of apparatus 200 for delivery and deployment of a first stent 52 and a second stent 54 in a lumen of a subject, in accordance with some applications of the present invention.

As shown, apparatus 200 comprises guide tube 220 (as described hereinabove with reference to Figs. 5A-B and 6A-B), and first and second stents 52 and 54 respectively. As shown, first and second stents 52 and 54 surround guide tube 220, second stent 54 being disposed proximally to first stent 52 and surrounding proximal portion 240 of guide tube 220. First stent 52 is typically disposed over guide tube 220 such that a distal end 55 of first stent 52 is disposed proximally to proximal end 262 of guidewire-engaging portion 222, and proximal end 53 of first stent 52 is disposed distally to hole 400.

Typically, a distal end 59 of second stent 54 is disposed proximally to first stent 52 and proximally to hole 400.

First stent 52 is slidably deployable off of distal end 320 of guide tube 220. Additionally, second stent 54 is also shaped and sized to be advanceable over guide tube 220, typically subsequently to deployment of first stent 52 off of distal end 320 of guide tube 220. Apparatus 200 is typically advanced into a lumen of the subject, and guide tube 220 facilitates placement of first and second stents 52 and 54 within the lumen of the subject.

Reference is now made to Figs. 7A-H, which depict a general overview of a method for use of apparatus 200 for deploying first and second stents 52 and 54 in a lumen of a subject, in accordance with some applications of the present invention. Typically, stents 52 and 54 are deployed in the lumen of the subject, e.g., a common bile duct of the subject, in order to manage strictures of the lumen. In accordance with some applications of the present invention, similarly to apparatus 20, apparatus 200 is configured such that first stent 52 is advanced into the lumen of the subject against guidewire 12, and second stent 54 is advanced into the lumen over guidewire 12 (i.e., surrounding the guidewire), as shown.

Reference is first made to Fig. 7A. In accordance with some applications of the present invention, apparatus 200 (comprising guide tube 220 and first and second stents 52 and 54, as described hereinabove with reference to Figs. 5A-B and 6A-B) is used in combination with a guidewire 12 to deploy stents 52 and 54 such that they are placed

alongside each other in the lumen. Guidewire 12 is typically threaded through guide tube 220 such that following the threading:

(a) guidewire 12 enters a lumen of guide tube 220 from a distal-end 320 opening of guide tube 220,

(b) guidewire 12 passes out of the lumen of guide tube 220 at guidewire-engaging portion 222 and disposed against an outer surface of first stent 52,

(c) first stent 52 is constrained from distal motion past guidewire-engaging portion 222 of guide tube 220, due to guidewire 12 being disposed in guidewire-engaging portion 222,

(d) guidewire 12 passes into the lumen of guide tube 220 through hole 400 proximally to first stent 52, such that guidewire 12 is surrounded by guide tube 220 and second stent 54, and

(e) first stent 52 is constrained from proximal motion past hole 400, when guidewire 12 is disposed within hole 400.

It is noted that the exploded view in box 110 in Fig. 7A only shows guidewire engaging portion 222 being shaped to define a slit 280. This is by way of illustration and not limitation; alternatively, guidewire engaging portion 222 may be shaped to define weak spot 284. Similarly, it is noted that the exploded view in box 112 in Fig. 7A only shows the collapsed configuration of the portion of guide tube 220 proximally to guidewire engaging portion 222. Alternatively, this portion of guide tube 220 may utilize the varying diameter configuration as shown in Figs. 5B and 6B.

Following threading of guidewire 12 through guide tube 220 as described hereinabove, apparatus 200 is advanced into a body of the subject, e.g., into the small intestine, and into lumen 4 of the common bile duct, as shown in Fig. 7A. As shown, first stent 52 is advanced distally over guide tube 220 and against guidewire 12 (i.e., an outer surface of first stent 52 is disposed against guidewire 12). Due to threading of guidewire 12 as described hereinabove, stent 52 is advanced distally in lumen 4 while it is constrained from distal motion guidewire-engaging portion 222. Constrained motion of

stent 52 typically allows for stent 52 to be advanced to a desired deployment site within lumen 4 in a controlled manner (i.e., inhibiting uncontrolled distal motion of stent 52, thus allowing the physician to safely perform the implantation at the desired deployment site).

Additionally, due to guidewire 12 being disposed in hole 400, first stent 52 is constrained from proximal motion past hole 400, allowing the physician to advance stent 52 in a controlled manner.

Reference is now made to Figs. 7B-H.

When first stent 52 reaches a desired deployment site within lumen 4, guidewire 12 passes through, i.e., exits, guidewire-engaging portion 222 of guide tube 220, typically by pulling guide tube 220 proximally, causing lateral exiting of guidewire 12 through guidewire-engaging portion 222, as shown in Fig. 7B. Guidewire 12 is shown exiting the lumen of guide tube 220 at guidewire-engaging portion 222 by passing out of slit-lips 282. It is noted that guidewire-engaging portion 222 is shown as a slit by way of illustration and not limitation. For some applications, guidewire-engaging portion 222 is shaped to define a weak spot 284 as described herein with reference to Figs. 5A-B and 6A-B, and guidewire 12 passes out of the lumen of the guide tube by tearing the weak spot.

As shown in Fig. 7B, guidewire 12 laterally exits guidewire-engaging portion 222 without being advanced distally or proximally. (This is in contrast to the application described in Figs. 3B and 3C in which guidewire 12 is removed from the guidewire-engaging portion in the distal portion of the guide tube, by pulling guidewire 12 proximally in the direction indicated by arrow 11, shown in Fig. 3B. Guidewire 12 is then typically advanced distally in lumen 4 as indicated by arrow 13 (shown in Fig. 3C) in order to facilitated subsequent deployment of stent 52.) As shown in Fig. 7B, guidewire-engaging portion 222 is arranged to allow passing guidewire 12 out of the guidewire-engaging portion 222 without the need to pull the guidewire proximally to release the guidewire from the guide tube. Instead, guidewire 12 “pops out” of guidewire-engaging portion 222 in a lateral direction, e.g., in response to guide tube 220 being pulled back proximally.

It is additionally noted with respect to Fig. 7B, that in accordance with some applications of the present invention, there is a fixed distance of at least 1 mm and/or less than 80 mm (e.g., 1- 80 mm) between first stent 52 and second stent 54 (not shown in Fig. 7B) due to locking of second stent 54 such that it is prevented from distal motion, prior to deployment of first stent 52. An example of such a locking mechanism is described hereinbelow with reference to Figs. 9A-D. For some applications, the fixed distance is at least 5 mm, and for some applications, the fixed distance is less than 25mm.

Reference is made to Fig. 7C. Following removal of guidewire 12 from guidewire-engaging portion 222, guidewire 12 is maintained within lumen 4 and is not advanced proximally or distally in the lumen. Removal of guidewire 12 from guidewire-engaging portion 222, as shown in Fig. 7B, typically allows subsequent deployment of first stent 52, by guide tube 220 being withdrawn proximally. In particular, guide tube 220 is typically pulled proximally in the direction indicated by arrow A3 until guide tube 220 is removed from stent 52, and stent 52 is thereby deployed in lumen 4. It is noted that during deployment of first stent 52, guidewire 12 is maintained within lumen 4 and is not advanced proximally or distally in the lumen.

Subsequently to deployment of first stent 52, second stent 54 is advanced over guide tube 220 and over guidewire 12. Optionally, guide tube 220 is advanced distally in the direction indicated by arrow A4 (Fig. 7D). Second stent 54 is advanced distally as indicted by arrow A5 in lumen 4, over guide tube 220 and over guidewire 12 (which is in the lumen of guide tube 220), as shown in Figs. 7E-F. It is noted that during deployment of second stent 54, guidewire 12 is maintained within lumen 4 and is not advanced proximally or distally in the lumen.

As shown in Figs. 7F, second stent 54 continues to be distally advanced in lumen 4 until a desired deployment site is reached alongside first stent 52. Once second stent 54 is disposed alongside first stent 52 (Fig. 7F), guidewire 12 (and guide tube 22, if present) is retracted by being pulled in a proximal direction and out of the body of the subject, as shown in Figs. 7G-H.

As shown in Figs. 7A-H, use of apparatus 200 in accordance with some applications of the present invention, allows for deployment of second stent 54

subsequently to deployment of first stent 52, while maintaining guidewire 12 in a generally constant location within lumen 4. Additionally, apparatus 200 allows for deployment of second stent 54 subsequently to deployment of first stent 52, without removing apparatus 200 from the body of the subject following deployment of first stent 52 in order to mount second stent 54. Notably, first and second stents 52 and 54 are typically mounted at the same time on guide tube 220 (as shown in Figs. 6A-B) when advanced into the subject's body, to be deployed within the lumen using the techniques described herein.

Reference is now made to Figs. 8A-B and 9A-D, which are schematic illustrations of locking mechanisms configured to prevent motion of first stent 52 and second stent 54 with respect to the guide tube. The locking mechanisms are typically employed in order to allow first and second stents 52 and 54 to be advanced together over the guide tube in a controlled manner within the lumen of the subject. Once the physician removes each locking mechanism, the respective stent can be deployed off the distal end of the guide tube in the lumen. It is noted that the locking mechanisms described herein with reference to Figs. 8A-B and 9A-D, may be applied to stent 52 and second stent 54 and guide tubes 22 and 220 shown in Figs. 1-7H. Figs. 8A-B and 9A-D refer to guide tube 220 by way of illustration and not limitation. It is to be understood that the locking mechanisms described with reference to Figs. 8A-B and 9A-D may also be used with guide tube 22.

Reference is first made to a first lock 600 for preventing proximal and distal motion of first stent 52 with respect to guide tube 220, as illustrated in Figs. 8A-B, 9A, and 9D. Typically, first lock 600 is configured to prevent proximal motion of first stent 52 past a location that is at least 1- 80 mm (e.g., 2-80 mm, e.g., 5-80 mm, e.g., 5-mm) distal to distal end 59 of second stent 54. Additionally, first lock 600 is configured to prevent distal motion of stent 52, such that stent 52 does not slip off the distal end of guide tube 220 while it is being advanced in the lumen of the subject until a desired implantation location is reached, and the physician removes first lock 600.

Typically, first lock 600 comprises a first locking wire 610 and a locking loop 620.

Locking loop 620 is typically secured to guide tube 220 by the loop being looped through two lateral holes 614 in guide tube 220 (Figs. 9A and 9D).

First locking wire 610 typically comprises a thin metal wire having a diameter of 0.1-0.35 mm, e.g., 0.2 mm. First locking wire 610 typically runs from the proximal portion of apparatus 200 between guide tube 220 and an inner surface of first and second stents 52 and 54, and is threaded through locking loop 620 (typically being accessed by locking loop 620 via a hole in the wall of first stent 52).

First locking wire 610 exits first stent 52 through distal end 55 of stent 52 and is disposed adjacent to the side of guide tube 220 distal to distal end 55. For some applications, such as is shown in Figs. 8A and 9A, locking wire 610 passes through a lateral hole 612 in the side of guide tube 220, travels across guide tube 220, and leaves guide tube 220 via an additional lateral hole 612 in the opposite side. Locking wire 610 then runs proximally along the inner surface of first stent 52, outside of guide tube 220. This locks first stent 52 in place and prevents distal or proximal motion of the stent. Additionally, when first locking wire 610 passes through lateral holes 612, slit lips 282 are brought in contact with each other, to maintain slit 280 in a closed state.

Alternatively, such as is shown in Figs. 8B and 9D, after locking wire 610 is threaded through locking loop 620, locking wire 610 continues to run distally outside of guide tube 220.

Once stent 52 is in the desired location in the lumen of the subject, the physician pulls first locking wire 610 proximally, thereby releasing the locking of first stent 52 by disengaging locking wire 610 from locking loop 620. This disengaging allows proximal motion of guide tube 220, whereby first stent 52 is deployed distally off guide tube 220. It is noted that distal flap 542 of first stent 52 is not shown in Figs. 8A-B and 9A-D for clarity.)

Reference is now made to a second lock comprising locking wire 640 for preventing distal motion of second stent 54 with respect to guide tube 220, as illustrated in Figs. 9B-C.

As shown in Fig. 9B, for some applications, second stent 54 is shaped to define a hole 544 in a portion of second stent 54 (e.g., in flap 540). Additionally, a pusher tube 700 disposed proximally to second stent 54 and configured to push second stent 54 off of guide tube 220, is shaped to define a hole 706 in a portion of the pushing tube (e.g., in a distal extension portion 702 of the pushing tube).

Second locking wire 640 passes through the hole 544 in the portion of second stent 54 and through hole 706 in the portion 702 of pusher tube 700 to prevent distal motion of stent 54. Subsequently to deployment of first stent 52, second locking wire 640 is removed from holes 544 and 706, releasing second stent 54 from being locked. Subsequently, second stent 54 is deployed off the distal end of guide tube 220.

For some applications, such as is shown in Fig. 9B, after passing through holes 544 and 706, second locking wire 640 loops back towards pusher tube 700, and then runs proximally along the inner surface of pusher tube 700, outside of guide tube 220.

Alternatively, for some applications, such as is shown in Fig. 9C, after passing through holes 544 and 706, second locking wire 640 continues to run distally along the inner surface of second stent 54, outside of guide tube 220.

Reference is still made to Figs. 8A-B and 9A-D. it is noted that first lock 600 is not arranged to utilize guidewire 12 to prevent distal, or proximal motion of first stent 52. It is additionally noted that locking wire 640 is not arranged to utilize guidewire 12 to prevent distal motion of second stent 54.

In summary of the applications of the present invention described hereinabove with reference to Figs. 8A-B and 9A-D, first and second stents 52 and 54 are both locked to guide tube 220 pre-procedurally, i.e., before insertion of guide tube 220 into the subject's body.

Reference is made to Figs. 9A and 9D. For some applications, locking wires 610 and 640 are disposed in respective lumens in a wall of pusher tube 700.

Reference is made to Figs. 1-9D. It is noted that for some applications, apparatus 20 and 200 are configured to deploy more than two stents, e.g., three or four stents, in the lumen of the subject (configuration not shown).

Reference is still made to Figs. 1-9D. It is noted that apparatus 20 and 200 are described with reference to lumen 4 of a common bile duct by way of illustration and not limitation. The scope of the present invention includes use of apparatus 20 and 200 in any suitable lumen to deploy multiple stents, tubes, or other apparatus in the lumen. For example, techniques and apparatus described herein may be used in a urethra, and/or in a ureter, and/or in a pancreatic duct, and/or in an esophagus, and/or in a trachea of the subject. Additionally, or alternatively, techniques and apparatus described herein may be used to deploy two or more prostatic stents.

According to embodiments, a stent assembly includes a biliary stent mounted on a catheter tube adapted for conveying the stent to a target deployment location within a lumen of a human subject, for example, to maintain flow viability of a bile duct. The assembly is configured for advancement along a guidewire which is typically inserted into the subject's body in advance of deploying the stent. A distal end of the guidewire is disposed within the target lumen, and the proximal end remains outside the body. In the case of employing short-wire systems, the guidewire can be externally locked. The terms 'distal' and 'proximal' are used throughout this disclosure and the appended claims as follows: 'distal' means further into the body (along an insertion path) from a point of entry into the body, while 'proximal' means closer to the point of entry into the body. Where the terms are used in reference to apparatus outside of a patient's body, a distal portion or distal end is that portion or end of the apparatus configured to be inserted into the body first, while a proximal end or proximal portion is either inserted last or may never be inserted (as in the case of a guidewire, for example). Additionally, when used relatively, e.g. 'distally displaced from' or 'proximal of', the meaning is, respectively, closer to the distal end than' or 'closer to the proximal end than'.

As will be further described hereinbelow and in the accompanying figures, a catheter tube (alternatively called, equivalently, 'guide tube,' 'stent-conveyance tube,' or, simply, 'tube') for conveyance of the stent is disclosed as having, at or near a distal tip,

arrangements for engaging a guidewire. Apertures are provided on either end of a longitudinal guidewire-engaging or guidewire-retaining segment of the tube, and the guidewire can be threaded through these apertures so as to traverse the interior of the guidewire-retaining segment of the tube. The guidewire does not interiorly traverse the tube segment proximal to the guidewire-retaining segment, and thus 'leaves' the interior of the tube, at least temporarily, at the proximal aperture. The distal aperture can be at the distal tip of the tube, or it can be displaced proximally from the tip. It is preferable that the distal aperture faces distally, i.e., faces in a direction in which the distal tip is facing, within 15° of that direction, or within 30° of that direction, or within 45° of that direction. The proximal aperture preferably faces proximally, i.e., faces in a direction opposite to the direction in which the distal tip is facing, or within 15° of that 'opposite' direction, or within 30° or within 45° of that 'opposite' direction. Thus, when the guidewire exits the proximal aperture, it is directed to continue alongside the tube (and alongside the stent that surrounds the tube) proximal to the proximal aperture.

With the guidewire passing through the interior of the guidewire-retaining segment, the tube can be advanced along the length of the guidewire with little resistance from the guidewire, for example pushed forward by an additional stent engaged with the guidewire or by a 'pusher' catheter engaged with the guidewire. The stent can be mounted on the tube before or after the tube is engaged with the guidewire, so as to surround a segment of the tube that is proximal to the guidewire-retaining segment. There can be a gap between the guidewire-retaining segment and the stent-carrying segment.

The configuration in which the stent is mounted on the tube so as to surround a segment that is proximal to the guidewire-retaining segment, and in which the tube is engaged with the guidewire in that the guidewire passes through the interior of the guidewire-retaining segment, is referred to herein as the 'stent-advancement configuration' of the stent assembly.

The guidewire-retaining segment is configured to retain the guidewire therewithin during the advancement of the stent into the body lumen in the stent-advancement configuration. In some embodiments, the relative longitudinal stability of the position of the stent relative to the tube is accomplished using a locking stent as will be discussed

hereinbelow. The guidewire-retaining segment has a lengthways, laterally breachable portion, making the guidewire-retaining segment laterally breachable by the guidewire. The guidewire-retaining segment of the tube is designed to be laterally breached by the guidewire when a shearing force is applied, beginning at the proximal aperture when the tube is proximally withdrawn once the stent is deployed and anchored in the lumen (and any locking system is 'unlocked'). The laterally-breachable portion can be a weakened or pre-breached sidewall of the guidewire-retaining portion, as will be discussed in greater detail hereinbelow with respect to Figs. 10 and 11A-11B.

Once the stent has been advanced to a target stent-deployment location in the lumen of the patient's body, e.g., the bile duct, the stent-conveyance tube can be withdrawn proximally so as to leave the stent deployed in the lumen. The stent is preferably self-anchoring with one or more anchor flaps maintaining the position of the stent against the force used to withdraw the tube, such that the stent slides off the distal end of the tube. Once the proximal aperture of the guidewire-retaining reaches the edge of the stent, the guidewire exiting the proximal aperture is trapped against the proximal aperture by the unmoving stent, and the resulting shearing force causes the guidewire to breach the laterally-breachable portion of the guidewire-retaining segment. Continued application of the force causes the guidewire to laterally exit the breached guidewire-retaining segment and thus be disengaged or decoupled therefrom. The force necessary to breach the laterally-breachable portion of the guidewire-retaining segment can be at least 100 grams and no more than 20 kg. In various embodiments, the necessary force can be at least 500 grams and no more than 10 kg, or at least 1 kg and no more than 5 kg, or at least 1.5 kg and no more than 2.5 kg. Once the guidewire-retaining portion is completely breached, the force necessary to withdraw the tube from the anchored stent can be less than the force required to breach the guidewire-retaining portion.

We now refer to the figures, and in particular to Fig. 10, which shows a schematic illustration of a distal portion of a stent-conveyance tube **220** according to a non-limiting example. The tube **220** is elongated in that it is many times (e.g., 100 or 200 or more) times longer than it is thick. The tube **220** is shown as engaged with the distal end of a guidewire **12** for purposes of illustrating some of the features of the tube **220** and the

manner in which it engages with the guidewire **12**. Distal and proximal directions with respect to the tube and stent are shown by means of arrow **1001**.

As shown in Fig. 10, a first distal segment **222** is demarcated by a distal aperture **320** and a proximal aperture **262**. In some embodiments, the distal aperture is not necessarily at the distal tip (the tip of the distal portion of the tube **220**) but rather is displaced proximally therefrom. In such embodiments, the distal aperture **320** preferably faces distally, or within 15° or 30° or 45° of the distal direction. Similarly, the proximal aperture **262** preferably faces proximally, as shown in Fig. 10, or within 15° or 30° or 45° of the proximal direction. A main purpose of the engagement of the tube **220** with the guidewire **12** is to enable distal advancement of the tube, along with one or more stents conveyed by the tube **220**, to a target stent-deployment location within a lumen of a subject's body; therefore it can be desirable for the guidewire-engaged segment of the tube (with the guidewire engaged within) to traverse the length of the guidewire with a minimum of resistance, and a suitable angling of the apertures **320**, **262** can contribute to the lowering of resistance from frictional and other forces. The guidewire-engaged segment **222** is also called a guidewire-retaining segment in this disclosure because the segment is designed to retain the guidewire therewithin as the tube traverses the guidewire. The guidewire-retaining segment **222** includes a lengthways laterally-breachable portion **278** which is configured to enable the retained guidewire **12** to breach the guidewire-retaining segment **222** laterally when a suitable shearing force is applied, as will be discussed in further detail hereinbelow.

It can be seen in Fig. 10 that a segment **232** proximal to the guidewire-retaining segment **222** has a diameter less than that of the guidewire-retaining segment, and it can be readily understood that the difference in diameters enables use of a straightforward design for the proximal aperture **262**, i.e., formed as to face proximally as in the Fig. 10 example. In other examples of a stent-conveyance tube **222** according to embodiments (not illustrated), the diameter of proximal segment **232** can be the same as or greater than the diameter of guidewire-retaining segment **222**, and the proximal aperture **262** can be positioned and angled accordingly. In any case, after exiting the guidewire-retaining

segment **222** via the proximal aperture, the guidewire **12** extends proximally outside the tube **222** and does not interiorly traverse the next segment **232.**

Referring now to Figs. 11A and 11B, examples of configuring the distal end of a stent assembly **101** are illustrated schematically. The stent assembly **101** includes the stent-conveyance tube **220** of Fig. 10 together with a biliary stent **52** mounted on the tube **220** so as to surround a segment of the tube **220**. In some embodiments, the stent assembly additionally includes the guidewire **12**. The stent **52** is displaced proximally from the guidewire-retaining segment **222**, and is not necessarily contiguous to the guidewire-retaining segment **222**, i.e., in the example shown there is an intervening segment **232** as was shown in Fig. 10. As shown in Figs. 11A and 11B, the guidewire **12** extends proximally outside of the tube **220** after exiting the proximal aperture **262** and continues proximally alongside the stent **52**.

The differences between the examples of Fig. 11A and Fig. 11B are to be found in the specific cross-section design of segment **232** (and of more proximal segments of the tube **220**), and in the specific design of the laterally-breachable portion **278**.

With respect to the cross-section of segment **232**, **i**n the example shown in Fig. 11A, the cross-section of the tube **220** at segment **232** (as shown in Detail Box **98**) is open and U-shaped. In other words, proximal to the guidewire-retaining segment **222**, the tube need not be a complete cylinder. The respective section of the tube can be formed with a open U-shape, or can be a collapsed or crushed segment of a completely cylindrical segment. Use of the U-shape can be helpful in some designs for facilitating the routing of guidewire **12** as it exits the proximal aperture **262**. In contrast to the U-shape example of Fig. 11A, the cross-section of the tube **220** at segment **232** is a complete circle in the example shown in Fig. 11B, i.e., the tube **220** is shaped as a complete cylinder in segment **232**. The segment of the tube **220** surrounded by the stent **52** can likewise employ either cross-section, and can simply continue the design choice of intermediating segment **232**. Neither segment is limited to the specific designs illustrated in the non-limiting examples of Figs. 11A and 11B, and any cross-sectional design can be employed.

With respect to the design of the laterally breachable portion **278** of the guidewire-retaining segment **232**, the first of the two cross-sectional detail boxes labeled A1 in Fig. 11A shows that the laterally breachable portion **278** can include a slit **280** shaped to define two 'lips' **282** ('slit lips') that are in contact with each other, or nearly in contact with each other but not farther apart than the diameter of the guidewire **12**, to define a closed-slit configuration in the absence of any forces applied to slit lips **282**. The slit lips **282**, are displaceable from each other, typically by suitable application of a force to cause the displacement, to define an opened-slit configuration. The second of the two cross-sectional detail boxes labeled A1 in Fig. 11A shows that the laterally breachable portion **278** can include a weakened sidewall portion **284**, which is splittable/breachable by the guidewire **12** in response to a suitably applied force. A third example of a design of the laterally breachable portion **278** is shown in the detail box in Fig. 11B, in which the laterally breachable portion **278** is shown to be perforated, and thus splittable/breachable by the guidewire **12** in response to a suitably applied force. Design of the laterally breachable portion **278** is not limited to the specific designs illustrated in the non-limiting examples of Figs. 11A and 11B, and any functionally equivalent design that suitably enables the lateral breaching of the guidewire-retaining segment **222** can be used.

One or more anchor flaps **522** are formed on the external surface of the stent **52**, so that when the stent **52** is deployed at a target location within a lumen of the subject, the one or more anchor flaps are effective to anchor the stent in place by catching or snagging on the interior wall of the lumen.

Referring now to Fig. 12, a method is disclosed for deploying a biliary stent in a lumen of a human body. As illustrated by the flow chart in Fig. 12, the method comprises:

Step **S01** passing an end, e.g., a proximal end, of the guidewire **12** through the guidewire-retaining segment **222** of the stent-conveyance tube **220** via respective distal and proximal apertures **320**, **262**; and

Step **S02** arranging the stent **52** on the stent-conveyance tube **220**, proximal to the guidewire-retaining segment **222**. As mentioned earlier, there can be an additional

segment **232** intermediating between the guidewire-retaining segment **222** and the tube segment on which stent **52** is mounted.

As shown in the flowchart, **Steps S01** and **S02** can be carried out in either order, i.e., first Step **S01** and then Step **S02**, or first Step **S02** and then Step **S01**. As an example, it may be desirable to have the tube **220** engaged with the guidewire **12** before mounting the stent **52** on the tube **220**. As another example, it may be desirable to have the stent **52** in place on the tube **220** before engaging the tube **220** with the guidewire **12**.

After carrying out Steps **S01** and **S02**, the stent assembly **101** can be seen to be in a 'stent-advancement configuration' in which the guidewire **12** passes through the distal and proximal apertures **320**, **262** so as to interiorly traverse the guidewire-retaining segment **222**, and the stent **52** is arranged to surround a stent-conveyance tube segment that is proximally displaced from the guidewire-retaining segment **222**, for advancement of the stent **52** together with the stent-conveyance tube **220** along the guidewire **12** into a body lumen of a human subject.

The method additionally comprises:

Step **S03** advancing the stent-conveyance tube **220** along the guidewire **12** together with the stent **12**, i.e., with guidewire-retaining segment **222** engaged with the guidewire **12**, to deliver the stent **52** to a target location in a lumen, e.g., a bile duct, of a patient; and

Step **S04** proximally withdrawing the stent-conveyance tube **220** to deploy the stent in the lumen, without manipulating the guidewire. The term 'without manipulating the guidewire' describes a situation wherein the stent **52** is anchored in the lumen by one or more anchor flaps **522** and is substantially immobilized (e.g., won't move longitudinally more than 1 mm, or more than 2 mm, or more than 3 mm, or more than 5 mm, or more than 10 mm) so as to resist longitudinal forces associated with withdrawing the stent-conveyance tube **220**.

Steps of the instant method for deploying a biliary stent in a lumen of a human body using a stent assembly **101**, according to embodiments of the present invention, will be explained in greater detail in connection with Figs. 13A-C.

Fig. 13A shows, schematically, a stent assembly **101** such as any one the stent assembly **101** of Figs. 11A-11B upon 'arrival' of the stent **52** at a target location, with the stent assembly **101** still in the 'stent-advancement configuration' as described hereinabove, in a lumen **4** of a patient. In terms of the method steps described in the preceding paragraphs, Figs. 11A-11B are 'snapshots' of a stent assembly **101** after carrying out Steps **S01** and **S02**, and Fig. 13A is a snapshot after carrying out Step **S03**.

In the particular example of the stent assembly **101** illustrated in Fig. 13A the tube segment **232** proximal to the guidewire-retaining segment **222** has the 'crushed U-shape' cross-section shown in Fig. 11A, and uses the slit **280** / 'slit-lips' **282** design option for the laterally breachable portion **278** of the guidewire-retaining segment **222**, as also shown in Fig. 11A. Selection of this design example throughout Figs. 13A-13B is for convenience only, and any of the design options of Figs. 11A-11B, or their functional equivalents, can be employed to equal benefit.

Unlike the illustrations of Figs. 11A-11B, Fig. 13A shows the proximal end of the stent **52**, and shows the guidewire **12** re-entering the interior of the tube stent-conveyance tube **220** through aperture **400**. While this configuration is optional, it can be desirable to re-engage the guidewire **12** behind (i.e., proximal to) the stent **52** in the stent-advancement configuration. As a non-limiting example, this configuration can simplify control of the guidewire and stent-conveyance tube both during stent advancement and during later withdrawal of the tube and/or guidewire. The passage of the guidewire **12** also restricts the ability of the stent **52** to slip proximally with respect to the tube **220** during the stent advancement step **S03**. In addition, as will be discussed hereinbelow, using the configuration can be advantageous if it is desired to deliver a second stent together with (i.e., immediately or soon after, and alongside) delivery of the 'first' stent.

We now refer to Figs. 13B and 13C, which schematically illustrate the dynamic of Step **S04**. Step **S04** preferably is carried out after the stent assembly **101** has been advanced along the guidewire **12** until the stent **52** is at a target location, for example, one that may have been selected in advance, or one that may have been selected by using an endoscope inserted along guidewire **12** or another guidewire. In Step **S04**, the stent-conveyance tube **220** is withdrawn proximally, i.e., in the direction of arrow **1002** of

Figs. 13B and 13C. The stent **52**, as noted hereinabove, is configured to be anchored in a wall of lumen **4** by anchor flap **522**, or at least prevented from proximal travel of more than 1 mm, of more than 2 mm, of more than 3 mm, or more than 5 mm. As indicated in Fig. 13C, the travel of the stent-conveyance tube **220** in the proximal direction causes aperture **262**, through which the guidewire **12** exits the guidewire-retaining segment **222**, to approach the distal end of stent **52**. This approaching causes a shearing force (schematically represented by arrow **1005**) to impinge upon the portion of the guidewire **12** proximal to aperture **262** and eventually of the portion of the guidewire **12** distal to aperture **262**. When the force applied in order to proximally withdraw the stent-conveyance tube **220** is in a suitable range, or alternatively/equivalently above a minimally necessary level of force, the shearing force starting at aperture **262** causes the guidewire **12** to breach the laterally-breachable portion **278** of the guidewire-retaining segment **222**. Suitable ranges of force to be applied to proximally withdraw the tube **220** so as to breach the laterally-breachable portion **278** include: at least 100 grams and no more than 20 kg, or at least 500 grams and no more than 10 kg, or at least 1 kg and no more than 5 kg, or at least 1.5 kg and no more than 2.5 kg. Once the sidewall of the tube **220** in the guidewire-retaining segment **222**, i.e., the laterally breachable portion, is breached, the guidewire **12** exits the guidewire-retaining segment **222** laterally and thus decouples or disengages from the tube **220**. The breaching is shown in the three cross-sectional detail boxes of Fig. 13B, each representing a point in time, as follows: in the leftmost detail box, the guidewire **12** is still in the interior of the guidewire-retaining segment **222**; in the center detail box, the guidewire **12** can be seen actively breaching the laterally-breachable portion; and in the rightmost detail box, the guidewire **12** can be seen to be outside of the guidewire-retaining segment **222** having exited laterally therefrom.

Thus, in Fig. 13D, it can be seen that the stent-conveyance tube **220** has been pulled back proximally at least to the extent that its distal tip is no longer distally displaced from the distal end of the stent **52**, and the stent **52** is deployed in the lumen **4**. It should be noted that the force required to continue withdrawing the stent-conveyance tube **220** after disengagement from the guidewire **12** can be of lesser magnitude than force required for breaching the laterally-breachable portion **278** of the guidewire-retaining segment **222**. The deployment of the stent **52** in the lumen **4** using the disclosed

method and stent assembly **101** can be carried out without manipulating the guidewire **12** to 'release' or disengage the tube therefrom. In particular, there is no need for causing distal or proximal movement of the guidewire **12** in order to carry out the method. Some inadvertent movement of the guidewire **12** may occur during or after Step **04**, for example from incidental contact or friction with the withdrawing tube **220**, although such movement is not substantive and does not impinge upon the scope of the invention which excludes necessitating any directed movement or manipulation of the guidewire **12**.

In some embodiments, the guidewire **12** can be left in place for use with other surgical and diagnostics instruments and tools.

In some embodiments, when the stent **52** is advanced, together with the stent-conveyance tube **220**, along the guidewire **12** to the target location in the lumen **4**, it is the only stent engaged with the guidewire **12**, i.e., there are no other stents engaged with the guidewire between the stent **52** and the proximal end of the guidewire **12**.

According to embodiments, it can be desirable to deploy more than one stent in the lumen, for example if more than stent is required to fully support a blocked passage in a duct. Thus, it may be that two, three or even more biliary stents are deployed, generally alongside one another, in the same lumen and in roughly the same portion of the lumen. The stents can all be the same size, or they can be of varying sizes. In some cases, a surgeon can accurately predict in advance how many stents (and of which sizes) are to be deployed, and, in some cases, it can happen that after one stent is deployed, or after two or more stents are deployed, a need for deploying yet another stent can be seen.

Deployment of multiple stents according to the present invention can be handled using various methods.

In a first multiple-stent deployment method, the method disclosed hereinabove for deploying a single stent using the stent-conveyance tube **220** (as described in Steps **S01 .. S04**) can be repeated. Once the stent-conveyance tube **220** has been completely withdrawn, leaving the guidewire **220** in place in accordance with the disclosed embodiments, an additional stent assembly **101** comprising a stent **52** mounted on a stent-conveyance tube **220** is advanced along the guidewire **12** to a target location in the lumen

4, i.e., alongside the already-deployed first stent **52**. The method can be repeated as many times as are necessary.

In a second multiple-stent deployment method, two stents **52**, **54** are deployed using a single stent assembly that additionally comprises a second stent **54**. (The stent **52** described with respect to Figs. 10-13D is the 'first' stent according to this method and configuration). As seen in the flowchart of Fig. 14, the second multiple-stent deployment method comprises the following steps:

Steps **S01** and **S02**, as described hereinabove, in either order;

Step **S05** threading the guidewire through the tube segment on which the second stent is mounted or is to be mounted. The guidewire **12** preferably enters/re-enters the interior of the tube **220** through aperture **400** as seen in Figs. 13A-13D; and

Step **S06** arranging the second stent **54** so as to surround a segment of the tube proximal of the first stent **52**. In embodiments, there is an intermediating gap between the first and second mounted stents, for example to permit the guidewire **12** to pass through aperture **400** into the interior of the tube **220**, including the interior of the segment on which the second stent is mounted. The guidewire **12** need not exit the tube **220** again between aperture **400** and the proximal end of the tube **220**.

As shown in the flowchart of Fig. 14, **Steps S05** and **S06** can be carried out in either order, i.e., first Step **S05** and then Step **S06**, or first Step **S06** and then Step **S05**.

After carrying out Steps **S01**, **S02**, **S05** and **S06** the stent assembly **101** can be seen to be in a 'dual-stent stent-advancement configuration' in which the guidewire **12** first passes through the distal and proximal apertures **320**, **262** so as to interiorly traverse the guidewire-retaining segment **222**, the first stent **52** is arranged to surround a stent-conveyance tube segment that is proximally displaced from the guidewire-retaining segment **222**, the guidewire **12** is further passed through aperture **400** between the two stents **52**, **54** so as to interiorly traverse the portion of the tube **220** that is proximal thereto, and the second stent is arranged to surround a second stent-conveyance tube segment that is proximally displaced from the first stent **52** and from aperture **400**. The dual-stent stent-advancement configuration is suitable for advancement of the first and

second stents **52**, **54** together with the stent-conveyance tube **220** along the guidewire **12** into a body lumen of a human subject.

The method additionally comprises:

Steps **S03** and **S04**, as described hereinabove;

Step **S07** advancing the second stent along the tube, and advancing the tube along the guidewire together with the second stent, to deliver the second stent to the target location; and

Step **S08** withdrawing the tube and the guidewire to deploy the stent in the lumen.

Steps of the instant method for deploying multiple biliary stents in a lumen of a human body will be explained in greater detail in connection with Figs. 15A-E.

Fig. 15A shows the positions of first and second stents **52**, **54** after Step **S04** and before Step **S07**. Stent **52** is deployed in the lumen **4**, and guidewire **12** is disengaged from the stent-conveyance tube **220**. Unlike Fig. 13D, which illustrated an embodiment in which the (first) stent **52** was the only stent engaged with the guidewire **12**, in Fig. 15A the second stent **54** can be seen as mounted on the tube segment proximal to aperture **400**. Optionally, tube **220** can be advanced distally in the direction indicated by arrow **A4**.

It is additionally noted with respect to Fig. 13A, that in accordance with some embodiments, there is a fixed distance of at least 1 mm and/or not more than 80 mm between the first stent **52** and the second stent **54** (not shown in Fig. 16B) due to locking of the second stent **54** such that it is prevented from distal motion, prior to deployment of first stent **52**. An example of such a locking mechanism is described hereinbelow with reference to Figs. 17A-17D. In some embodiments, the fixed distance is at least 5 mm, and for some applications, the fixed distance is no more than less than 25mm.

Referring now to Fig. 15B, the second stent **54** is shown (as indicted by arrow **A5**) as having advanced over stent-conveyance tube **220** and over guidewire **12** as well, while Step **S07** is carried out. At this point in time, the distal end of second stent **54** has advanced distally from aperture **400**, which can no longer be seen in Fig. 15B. It is noted

that during the Step **S07** deployment of the second stent **54**, the guidewire **12** is maintained within lumen **4** and is not advanced proximally or distally in the lumen **4**, at least not for purposes of carrying out the instant method.

In Fig. 15C, the position of the second stent **54** at the end of Step **S07** is shown. The second stent has been advanced into the target location alongside the first stent **52** in the lumen **4**. In some embodiments, as illustrated in Fig. 15C, a pusher tube **60** can be used to facilitate the distal advancement of the second stent **54** along the stent-conveyance tube, and/or to facilitate 'pushing' the second stent **54** off the distal end of the tube **220** when the tube **220** is proximally withdrawn in Step **S08**.

The carrying out of Step **S08** is illustrated in Figs. 15D-15E. In Fig. 15D, the stent-conveyance tube **220** can be seen to have been withdrawn from within the second stent **54**, now anchored in the lumen. Finally, in Fig. 15E, it can be seen that the guidewire **12** has been withdrawn as well.

From the foregoing discussions, it will be obvious to the skilled artisan that various methods may be used for deploying three stents, including, without limitation: employing the first method (Steps **S01 .. S04**) of deploying a single stent, three times (once for each stent), aided by the same guidewire each time, the guide wire remaining in place after at least the first and second stents have been deployed; and employing said first method of deploying a single stent, the guidewire remaining in place thereafter, and subsequently employing the method of deploying two stents (Steps **S01 .. S08**).

Discussion of stent-locking mechanisms

Reference is now made to Figs. 16A-16B and 17A-17D, which are schematic illustrations of locking mechanisms configured to prevent motion of first stent **52** and, optionally, second stent **54**, with respect to the guide tube. The locking mechanisms are typically employed in order to allow stents to be advanced together with the guide tube in a controlled manner within the lumen of the subject. Once the physician removes each locking mechanism, the respective stent can be deployed off the distal end of the guide tube in the lumen. The specific design example described hereinbelow is meant to be

illustrative and not limiting. Moreover, the description generally relates to embodiments in which two stents **52**, **54** are employed together for deployment according to the method described hereinabove with respect to Steps **S01 .. S08**, but is equally applicable, with necessary modifications, to the single-stent configurations and methods described hereinabove.

Reference is first made to a first lock **600** for preventing proximal and distal motion of first stent **52** with respect to tube **220**, as illustrated in Figs. 16A, 16B, 17A and 17D. First lock **600** is configured to prevent proximal motion of the first stent **52** past a location that is at least 1- 80 mm (e.g., 2-80 mm, e.g., 5-80 mm, e.g., 5-mm) distal to the distal end of second stent **54** if present. Additionally, first lock **600** is configured to prevent distal motion of stent **52**, such that stent **52** does not slip off the distal end of the stent-conveyance tube **220** while it is being advanced in the lumen **4** of the subject until a desired implantation location is reached, and the physician removes first lock **600**.

Typically, first lock **600** comprises a first locking wire **610** and a locking loop 620.

Locking loop **620** is typically secured to tube **220** by the loop being looped through two lateral holes **614** provided in the stent-conveyance tube **220**, shown in Figs. 17A and 17D).

First locking wire **610** typically comprises a thin metal or polymer wire having a diameter of 0.1-0.35 mm, e.g., 0.2 mm. First locking wire **610** typically runs from the proximal portion of the stent assembly **101** between tube **220** and an inner surface of first and second stents **52** and **54**, and is threaded through locking loop **620** (typically being accessed by locking loop **620** via a hole in the wall of first stent **52**).

First locking wire **610** exits first stent **52** through distal end **55** of stent **52** and is disposed adjacent to the side of guide tube **220** distal to distal end **55**. For some applications, such as is shown in Figs. 16A and 17A, locking wire **610** passes through a lateral hole **612** in the side of the tube **220**, travels across the tube **220**, and leaves the tube **220** via an additional lateral hole **612** in the opposite side. Locking wire **610** then runs proximally along the inner surface of first stent **52**, outside of the tube **220**. This

locks first stent **52** in place and prevents distal or proximal motion of the stent **52**. Additionally, in embodiments using the slit **280** / slit-lips **282 design**, when first locking wire **610** passes through lateral holes **612**, slit lips **282** are brought in contact with each other, to maintain slit **280** in a closed state.

Alternatively, such as is shown in Figs. 16B and 17D, after locking wire **610** is threaded through locking loop **620**, locking wire **610** continues to run distally outside of the tube **220**.

Once stent **52** is in the desired location in the lumen of the subject, the physician pulls first locking wire **610** proximally, thereby releasing the locking of first stent **52** by disengaging locking wire **610** from locking loop **620**. This disengaging allows proximal motion of the tube 220, whereby first stent **52** is deployed distally off guide tube **220**, e.g., in Step **S04** of Fig. 12 or Fig. 14.

Reference is now made to a second lock comprising locking wire **640** for preventing distal motion of second stent 54 with respect to stent-conveyance tube **220**, as illustrated in Figs. 17B and 17C.

As shown in Fig. 17B, second stent **54** is shaped to define a hole **544** in a portion of second stent **54** (e.g., in anchor flap **540**). Additionally, a pusher tube **700** disposed proximally to second stent **54** and configured to push second stent **54** off of guide tube **220**, is shaped to define a hole **706** in a portion of the pushing tube (e.g., in a distal extension portion **702** of the pushing tube).

Second locking wire **640** passes through the hole **544** in the portion of second stent 54 and through hole **706** in the portion **702** of pusher tube **700** to prevent distal motion of stent **54**. Subsequently to deployment of first stent **52**, second locking wire **640** is removed from holes **544** and **706**, releasing second stent **54** from being locked. Subsequently, second stent **54** is deployed off the distal end of guide tube **220**.

For some applications, such as is shown in Fig. 17B, after passing through holes **544** and **706**, second locking wire **640** loops back towards pusher tube **700**, and then runs proximally along the inner surface of pusher tube **700**, outside of guide tube **220**.

Alternatively, as is shown in Fig. 17C, after passing through holes **544** and **706**, second locking wire **640** continues to run distally along the inner surface of second stent **54**, outside of the tube **220**.

It is noted that first lock **600** is not arranged to utilize guidewire **12** to prevent distal, or proximal motion of first stent **52**. It is additionally noted that locking wire **640** is not arranged to utilize guidewire **12** to prevent distal motion of second stent **54**.

In some embodiments, locking wires **610** and **640** can be disposed in respective lumens in a wall of pusher tube **700**.

The scope of the present invention includes use of stents and stent assemblies in any suitable lumen to deploy multiple stents, tubes, or other apparatus in the lumen. For example, techniques and apparatus described herein may be used in a urethra, and/or in a ureter, and/or in a pancreatic duct, and/or in an esophagus, and/or in a trachea of the subject. Additionally, or alternatively, techniques and apparatus described herein may be used to deploy two or more prostatic stents.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and sub-combinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS

1. Apparatus for use with a guidewire, comprising:

a. first and second biliary stents; and

b. an elongated guide tube comprising a guidewire-retaining segment that includes (i) respective distal and proximal apertures defining a guidewire-path therethrough, and (ii) a lengthways laterally-breachable portion,

wherein:

i. in a stent-advancement configuration, (A) the guidewire passes through the respective apertures so as to interiorly traverse the guidewire-retaining segment, (B) the first stent is arranged to surround a guide-tube segment that is proximally displaced from the guidewire-retaining segment, for advancement of the first stent together with the guide tube along the guidewire into a body lumen of a human subject, and (C) the second stent is arranged to surround a second guide-tube segment proximally displaced from the first stent, for advancement of the second stent into the body lumen, the guidewire interiorly traversing the second guide-tube segment, and

ii. when first the stent is disposed, in the stent-advancement configuration, at a target deployment location within the lumen, a proximal-direction withdrawal of the guide tube is effective to cause the guidewire to breach the laterally-breachable portion of the guidewire-retaining segment so as to decouple the guidewire from the tube without longitudinal displacement of the guidewire.

2. The apparatus according to claim 1, wherein the first stent (a) has an outer surface disposed against the guidewire and (b) is configured to be advanced into the lumen of the subject while the outer surface is disposed against the guidewire.

3. The apparatus according to any one of claims 1-2, wherein the guidewire-retaining portion is shaped to define a slit extending proximally along a wall of the guide tube,

from a distal end of the guide tube, the slit having a length of 1-70 mm, wherein the slit is shaped to define two slit lips that are in contact with each other to define a closed-slit configuration in the absence of a disengaging force applied to the slit lips, and disengageable from each other, by application of a disengaging force to the lips, to define an opened-slit configuration.

4. The apparatus according to claim 3, further comprising a lock which:

presses the slit lips against each other in the closed-slit configuration when the guidewire is disposed in the guidewire-retaining portion to inhibit the lateral exiting of the guidewire from the guidewire-retaining portion, and

allows the lateral exiting of the guidewire from the guidewire-retaining portion in the opened-slit configuration when the lock does not press the slit lips against each other.

5. The apparatus according to any one of claims 1-2, wherein the guidewire- retaining portion is shaped to define a weak spot

(i) configured to tear in response to a disengaging force applied to the weak spot by the guidewire upon the distal portion of the guide tube being withdrawn into the first stent, and

(ii) shaped and sized to allow passage of the guidewire therethrough in the torn state thereof.

6. The apparatus according to any one of claims 1-2 further comprising:

a first lock, which prevents proximal motion of the first stent past a location that is at least 1 mm from a distal end of the second stent; and

a second lock, which prevents distal motion of the second stent past a location that is at least 1 mm proximal of a proximal end of the first stent.

7. The apparatus according to claim 6, wherein the guide tube is shaped to define two holes in a lateral wall of the guide tube, and wherein the first lock comprises a

locking wire that passes through the two holes.

8. The apparatus according to claim 6, wherein:

the second stent is shaped to define a hole in a proximal portion thereof,

the apparatus further comprises a pushing tube, disposed proximally to the second stent and configured to push the second stent off of the guide tube,

the pushing tube is shaped to define a distal extension portion characterized by having a hole therein, the distal extension portion extending into a proximal end of the second stent at least as far as the hole in the proximal portion of the second stent.

9. The apparatus according to claim 6, wherein the first lock is configured to prevent distal motion of the first stent during advancement of the first stent on the guide tube into the lumen of the subject.

10. The apparatus of claim 6, wherein

the guidewire-retaining portion is shaped to define a slit extending proximally along a wall of the guide tube, from a distal end of the guide tube, the slit being shaped to define two slit lips that are in contact with each other to define a closed-slit configuration in the absence of a disengaging force applied to the slit lips, and disengageable from each other, by application of a disengaging force to the lips, to define an opened-slit configuration; and

the first lock is arranged to press the slit lips against each other in the closed-slit configuration when the guidewire is disposed in the guidewire-retaining portion to inhibit the lateral exiting of the guidewire from the guidewire-retaining portion, and allows the lateral exiting of the guidewire from the guidewire-retaining portion in the opened-slit configuration when the lock does not press the slit lips against each other.

11. Apparatus, comprising:

a guide tube shaped to define a proximal end and a distal end of the guide tube;

a first stent surrounding the guide tube so as to be advanceable together with the guide tube into a lumen of a subject, and being slidably deployable off of the distal end of the guide tube;

a second stent, surrounding a portion of the guide tube proximal to the first stent,, and shaped and sized to be advanceable along the guide tube into the lumen, the second stent being shaped to define a hole in a proximal portion thereof;

a pushing tube, disposed proximally to the second stent and configured to push the second stent off of the guide tube, the pushing tube shaped to define a distal extension portion characterized by having a hole therein, the distal extension portion extending into a proximal end of the second stent at least as far as the hole in the proximal portion of the second stent;

a first lock, which prevents proximal motion of the first stent past a location that is at least 1 mm from a distal end of the second stent; and

a second lock, which prevents distal motion of the second stent past a location that is at least 1 mm proximal of a proximal end of the first stent, the second lock including a locking wire engaging a distal portion of the pushing tube with the hole in the distal extension portion of the pushing tube.

12. The apparatus of claim 11, wherein the distal extension portion passes out through the hole in the proximal portion of the second stent.

13. The apparatus of claim 12, wherein the locking wire enters the hole in the proximal portion of the second stent.

14. A method of delivering multiple stents to a lumen of a user, the method comprising:

a. providing an apparatus configured for use with a guidewire, the apparatus comprising (i) first and second biliary stents and (ii) an elongated guide tube comprising a guidewire-retaining segment that includes respective distal and

proximal apertures defining a guidewire-path therethrough and a lengthways laterally-breachable portion;

b. advancing the apparatus in a stent-advancement configuration to cause the first stent to reach a desired deployment site in the lumen, the stent-advancement configuration being such that (i) the guidewire passes through the respective apertures so as to interiorly traverse the guidewire-retaining segment, (ii) the first stent is arranged to surround a guide-tube segment that is proximally displaced from the guidewire-retaining segment, and (iii) the second stent is arranged to surround a second guide-tube segment proximally displaced from the first stent, the guidewire interiorly traversing the second guide-tube segment;

c. deploying the first stent, wherein the deploying includes (i) proximally withdrawing the guide tube to cause the guidewire to breach the laterally-breachable portion of the guidewire-retaining segment so as to decouple the guidewire from the tube and (ii) further proximally withdrawing the guide tube to disengage from within the first stent;

d. advancing the second stent to reach a desired deployment site in the lumen; and

e. deploying the second stent, wherein the deploying includes proximally withdrawing the guidewire and the guide tube to disengage from with the second stent

15. The method according to claim 14, wherein the deploying of the first stent and the advancing of the second stent are performed without longitudinal displacement of the guidewire.

16. The method according to either claim 14 or 15, wherein the apparatus additionally includes a first lock preventing a movement of the first stent, and the deploying of the first stent includes unlocking the first lock to allow the movement.

17. The method according to claim 16, wherein (i) the guidewire-retaining portion comprises a slit shaped to define two slit lips that are in contact with each other to define a closed-slit configuration in the absence of a disengaging force applied to the slit lips, and disengageable from each other, by application of a disengaging force to the lips, to define an opened-slit configuration; and (ii) the first lock is arranged to press the slit lips against each other , and (iii) unlocking the first lock includes allowing the lateral exiting of the guidewire from the guidewire-engaging portion in the opened-slit configuration.

18. The method according to either claim 14 or 15, wherein the apparatus additionally includes a second lock preventing a movement of the second stent, and the deploying of the second stent includes unlocking the second lock to allow the movement.

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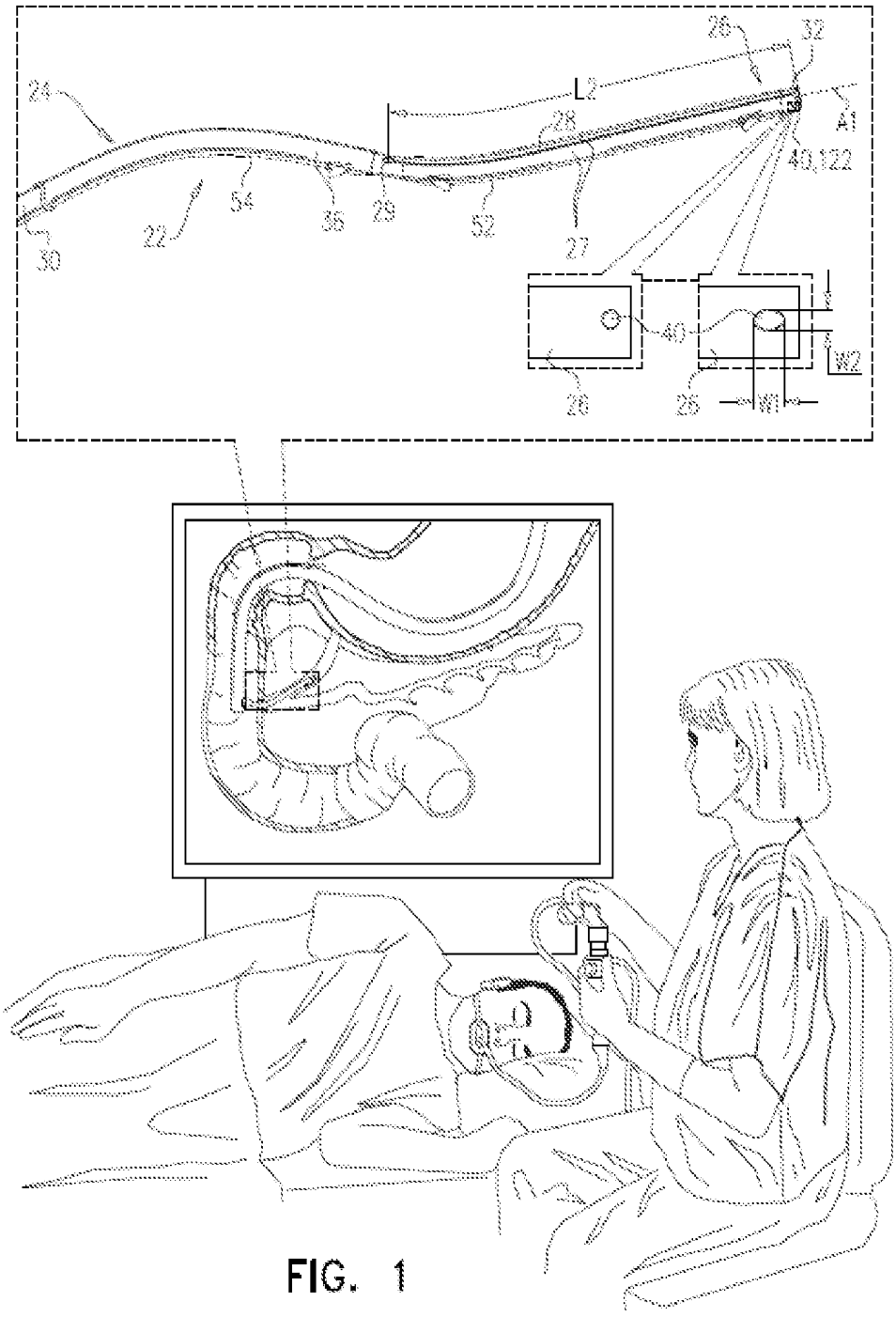

FIG. 1

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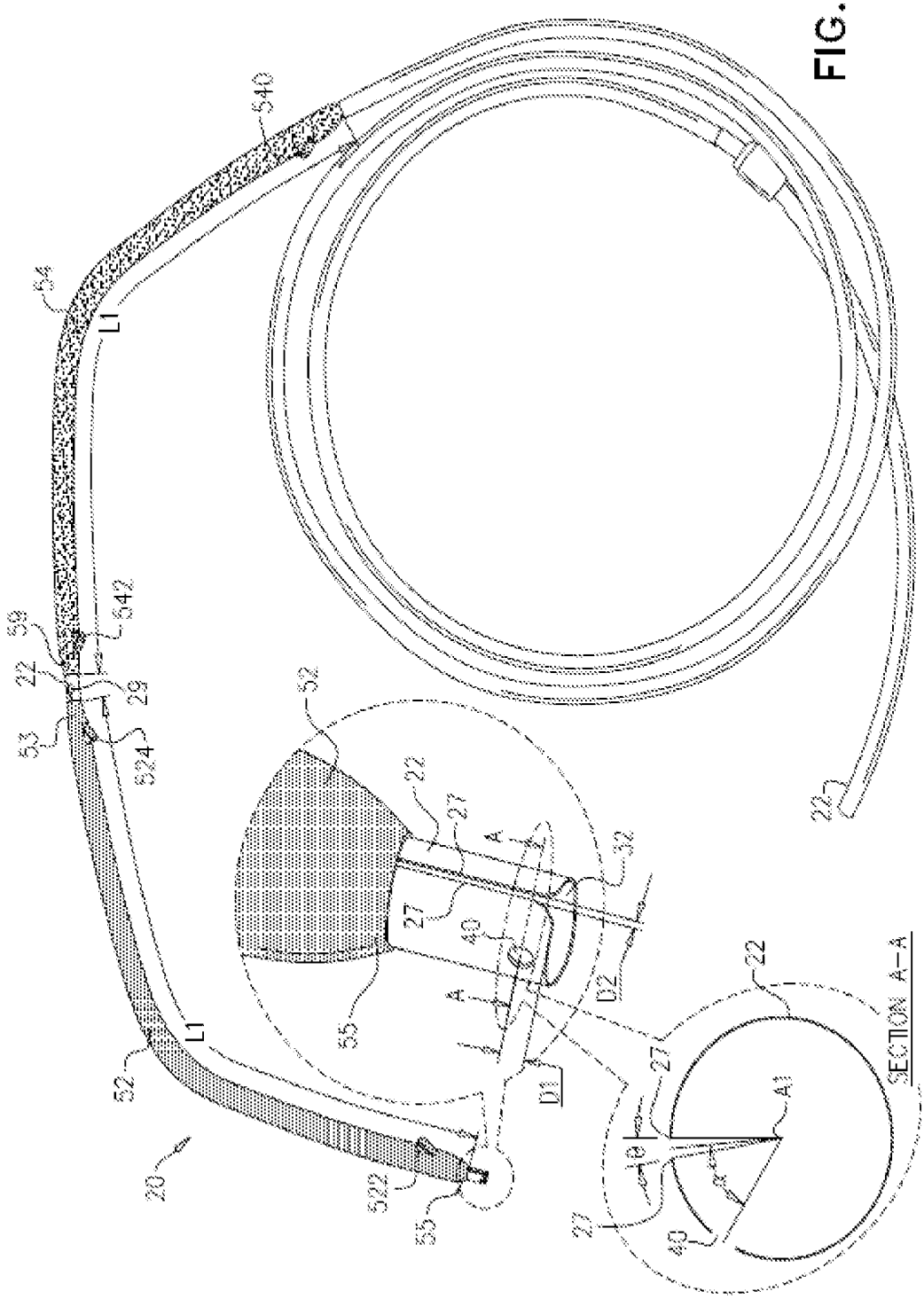

FIG. 2

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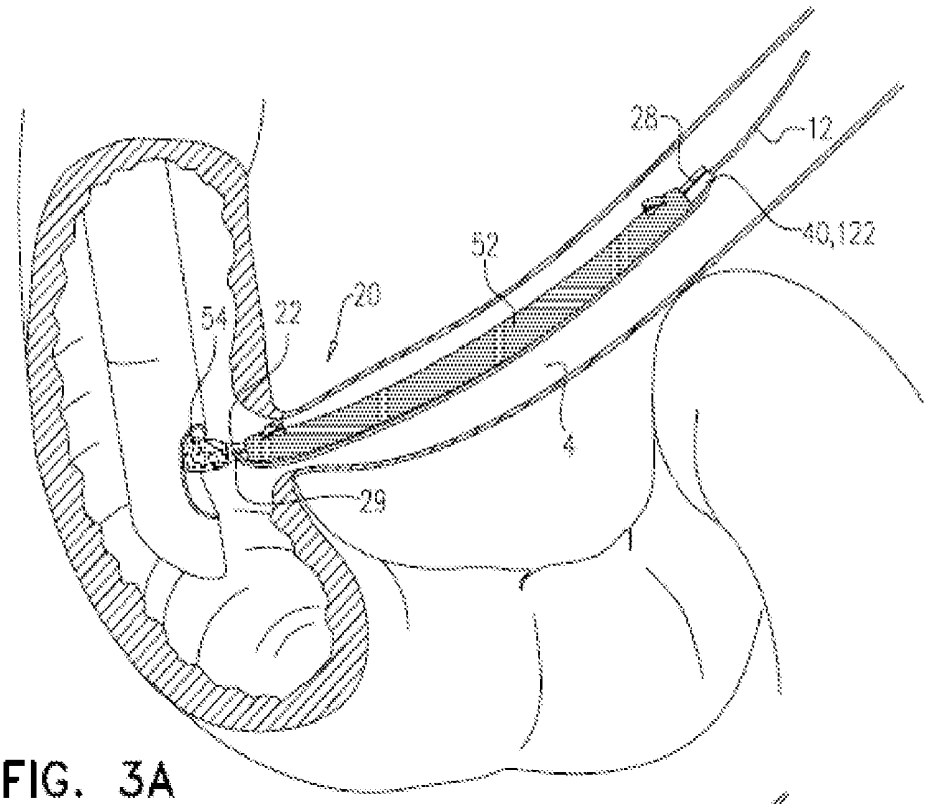

FIG. 3A

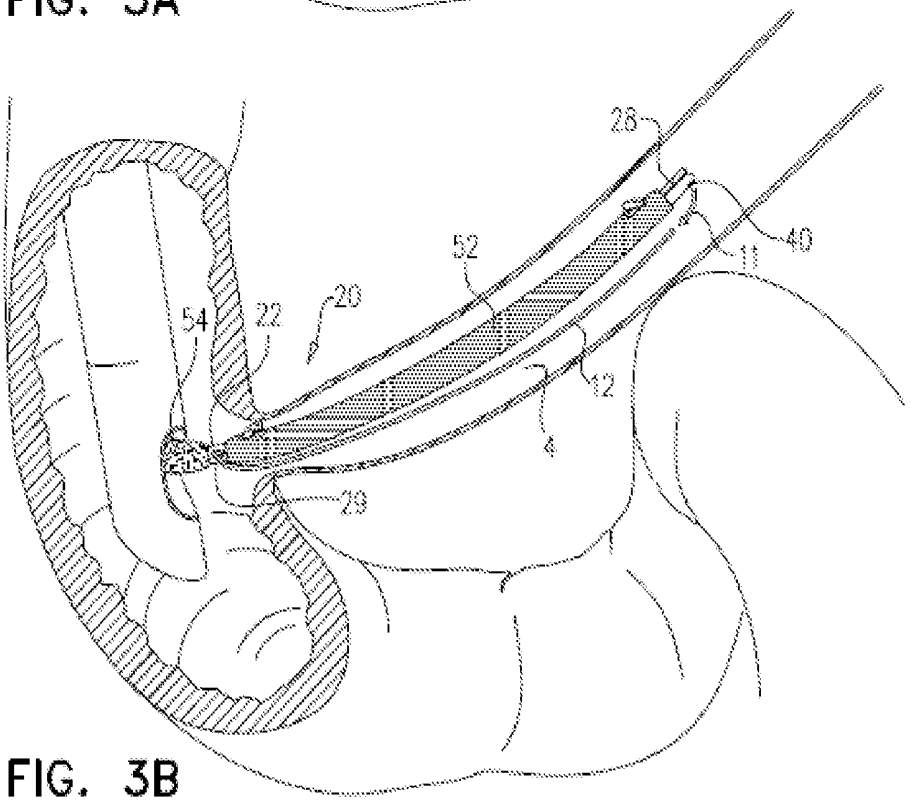

FIG. 3B

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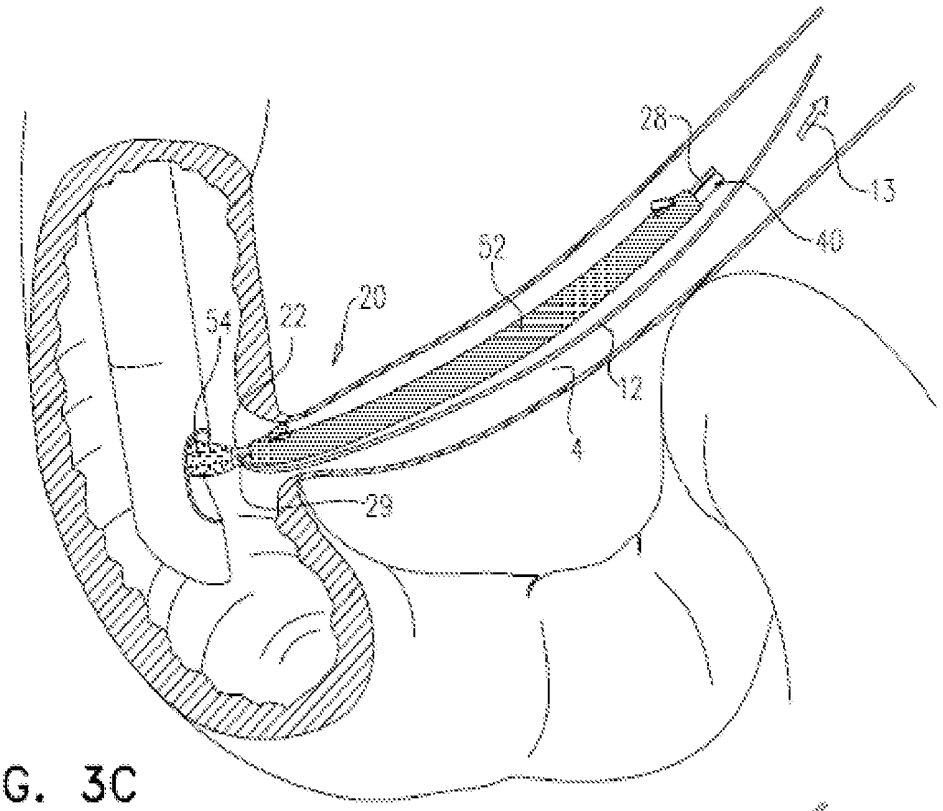

FIG. 3C

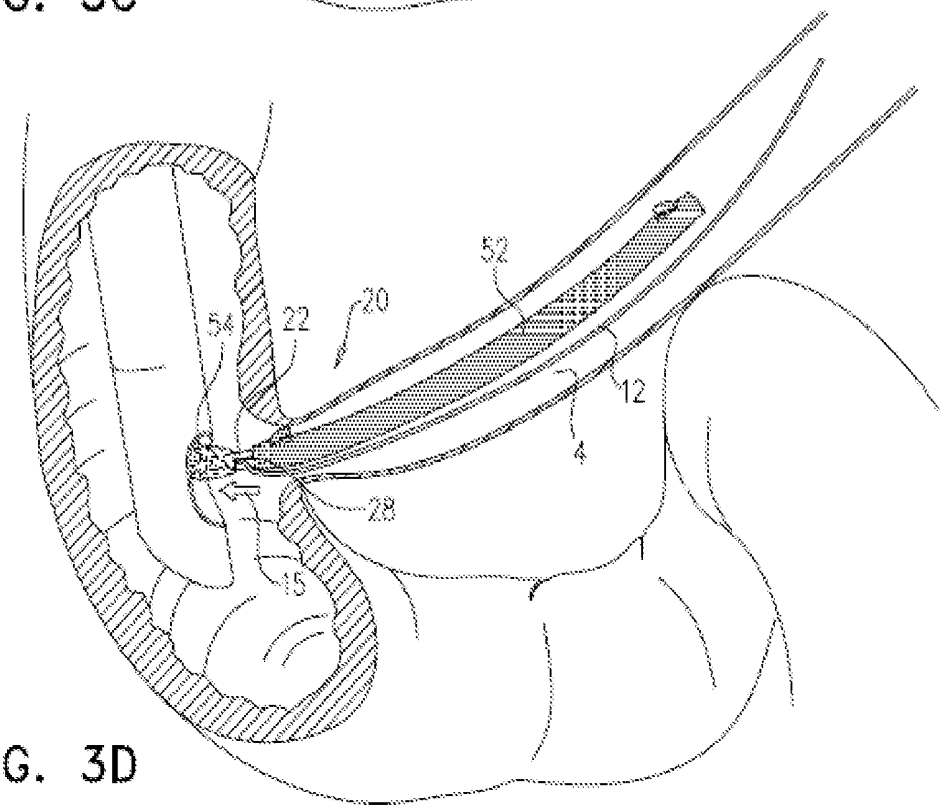

FIG. 3D

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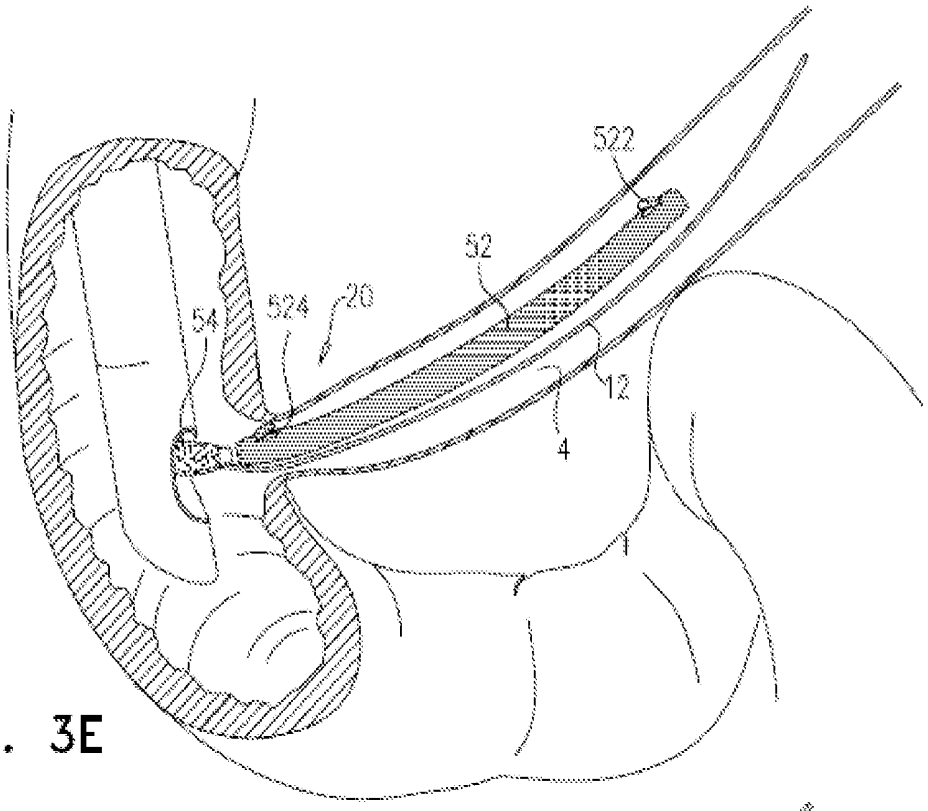

FIG. 3E

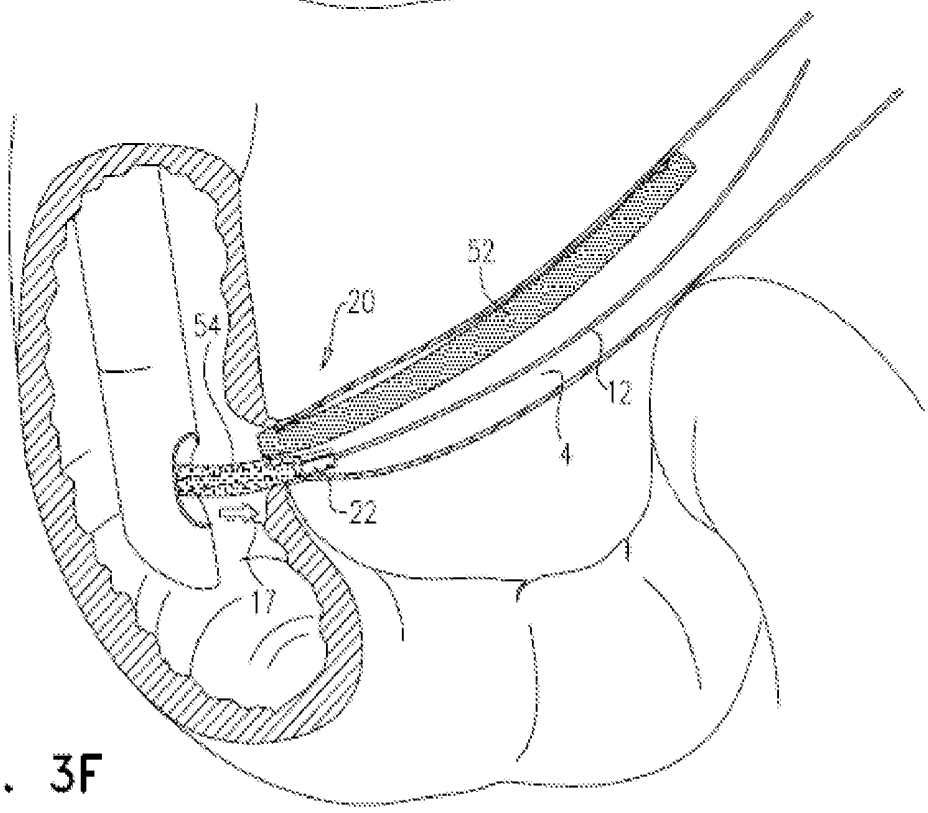

FIG. 3F

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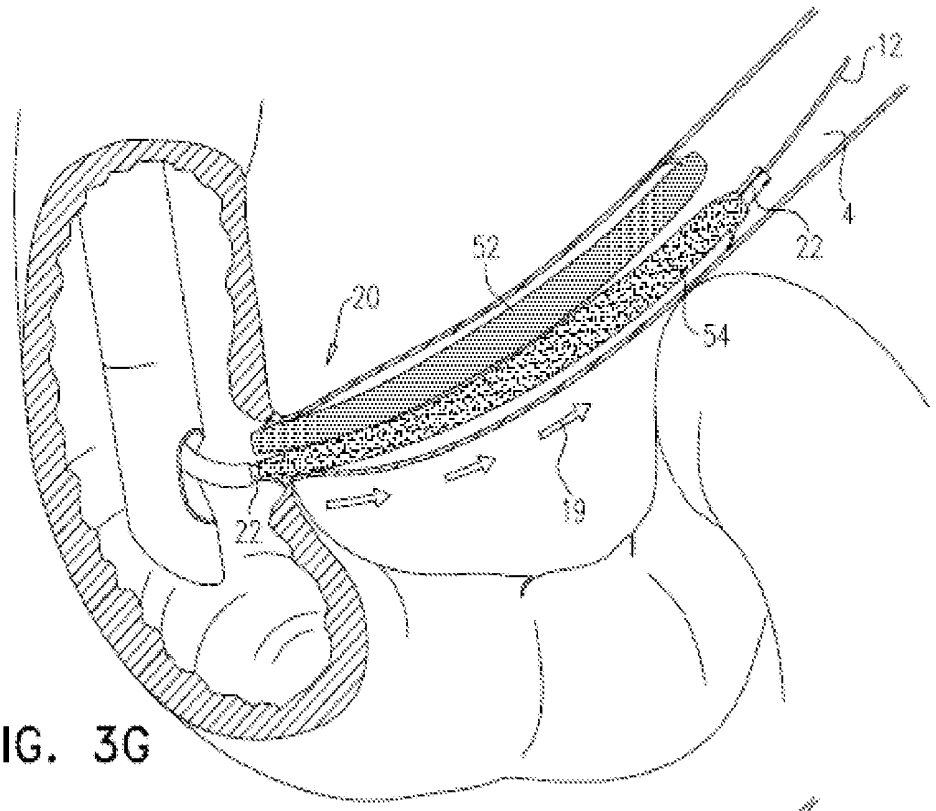

FIG. 3G

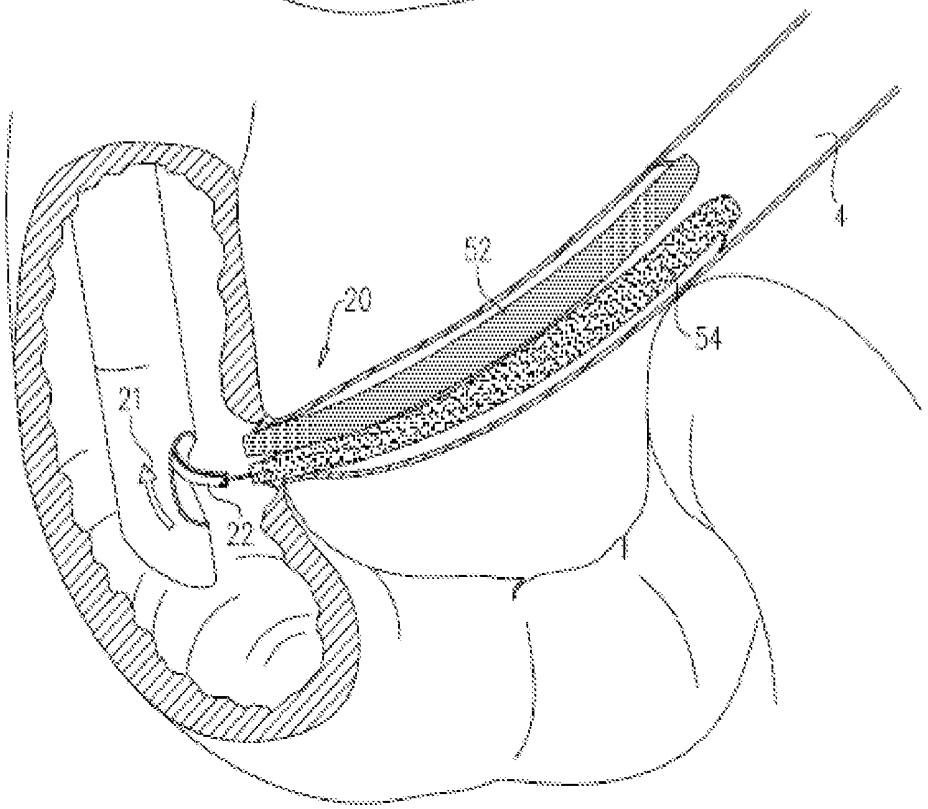

FIG. 3H

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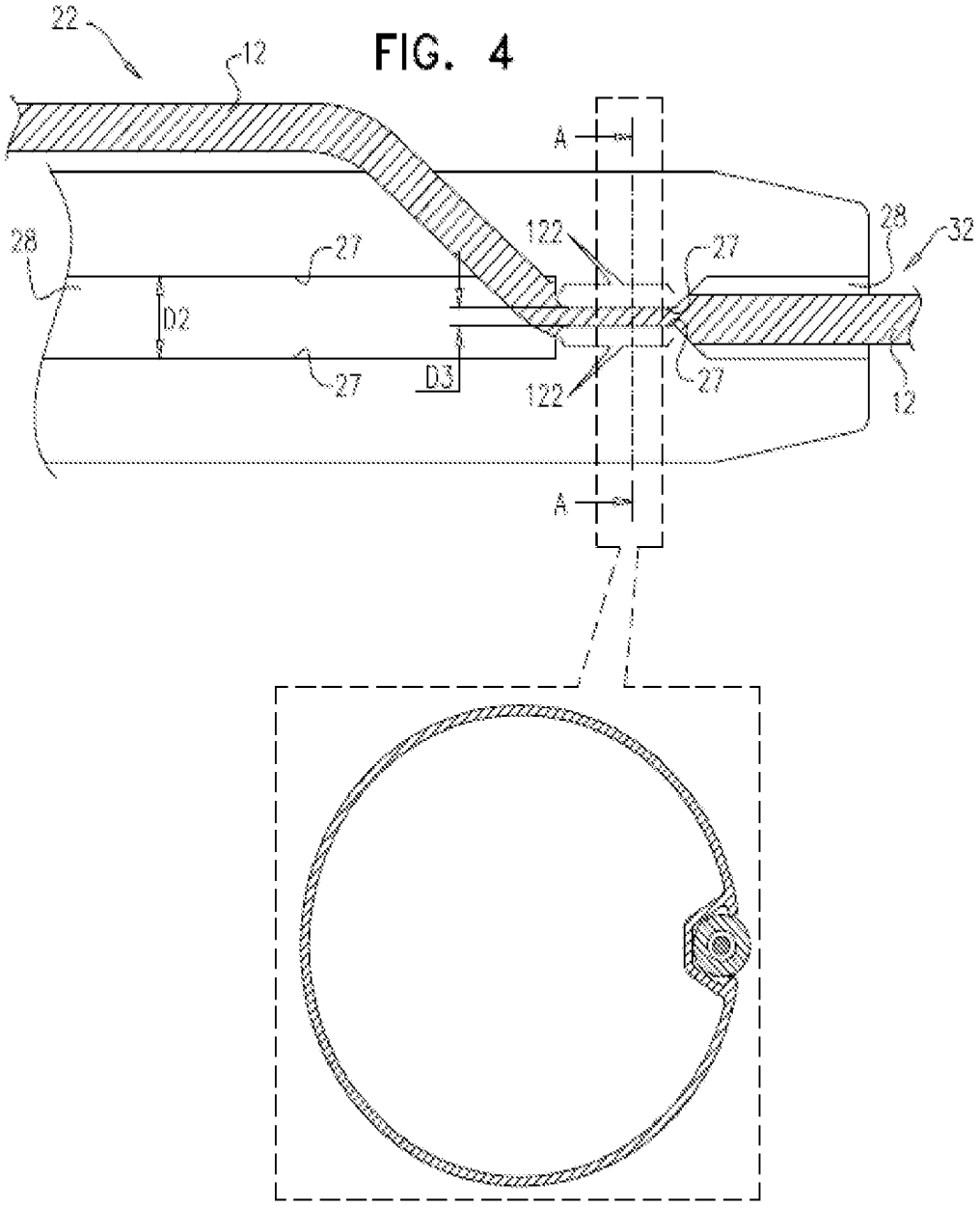
FIG. 4



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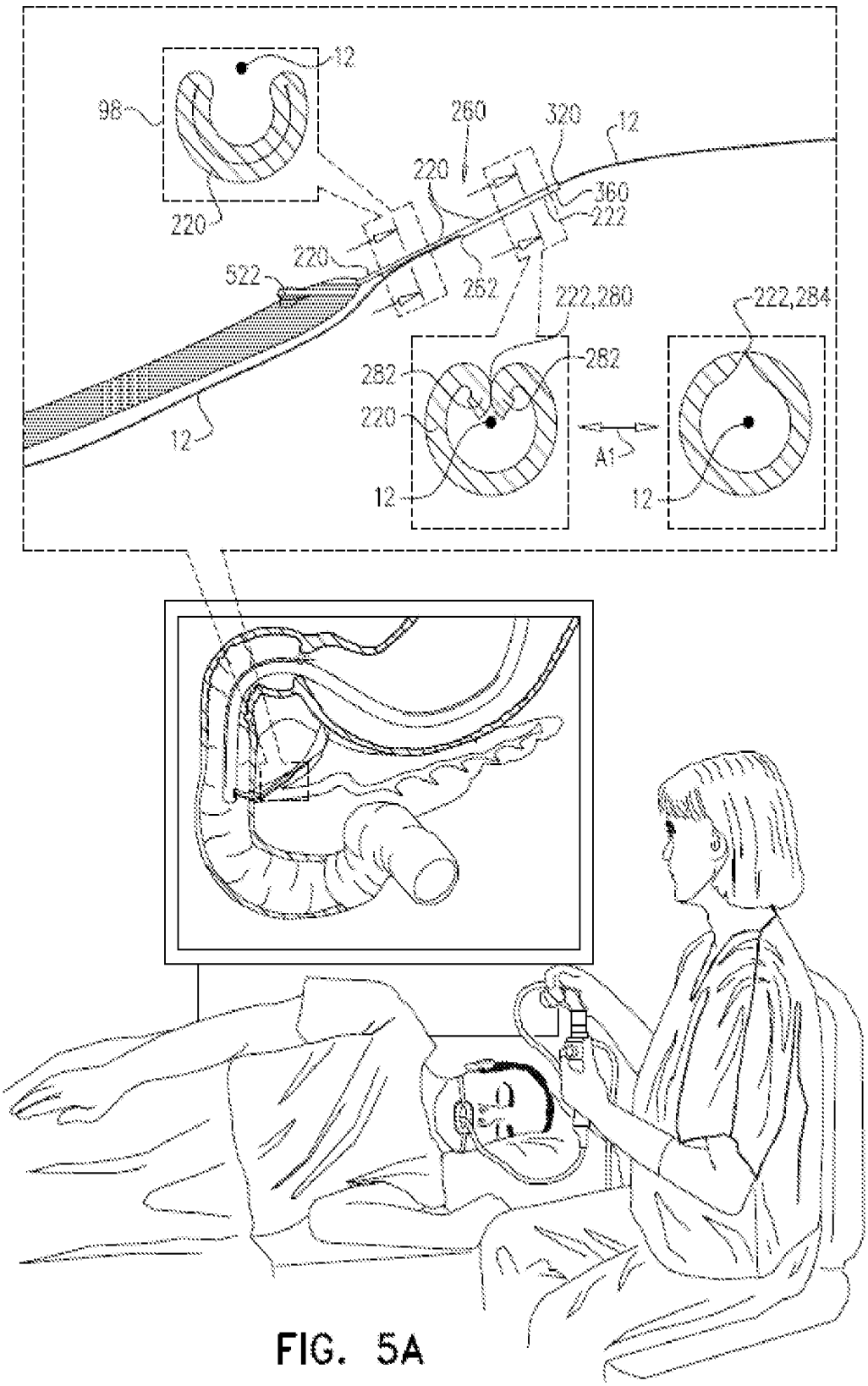

FIG. 5A

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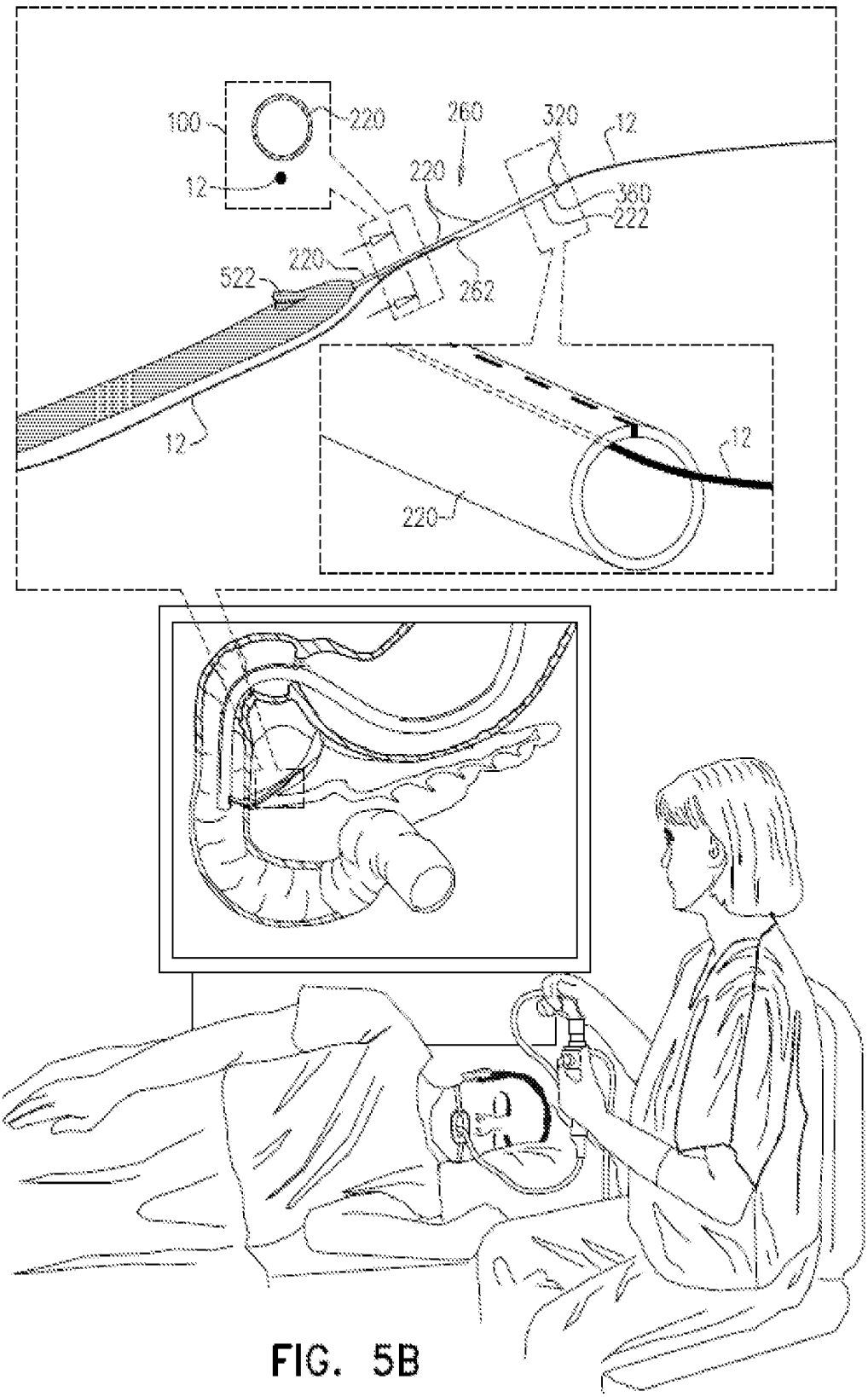

FIG. 5B

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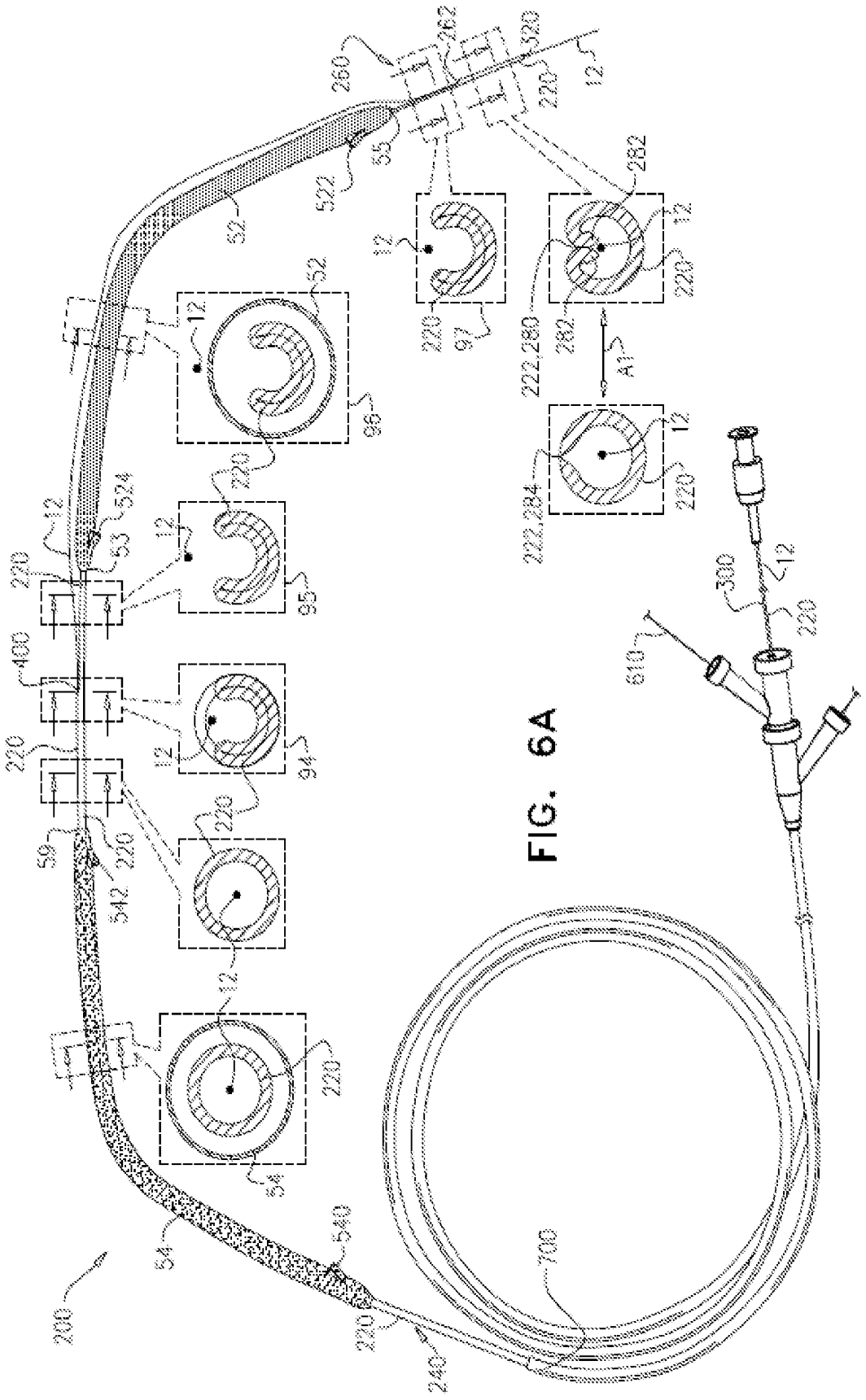

FIG. 6A

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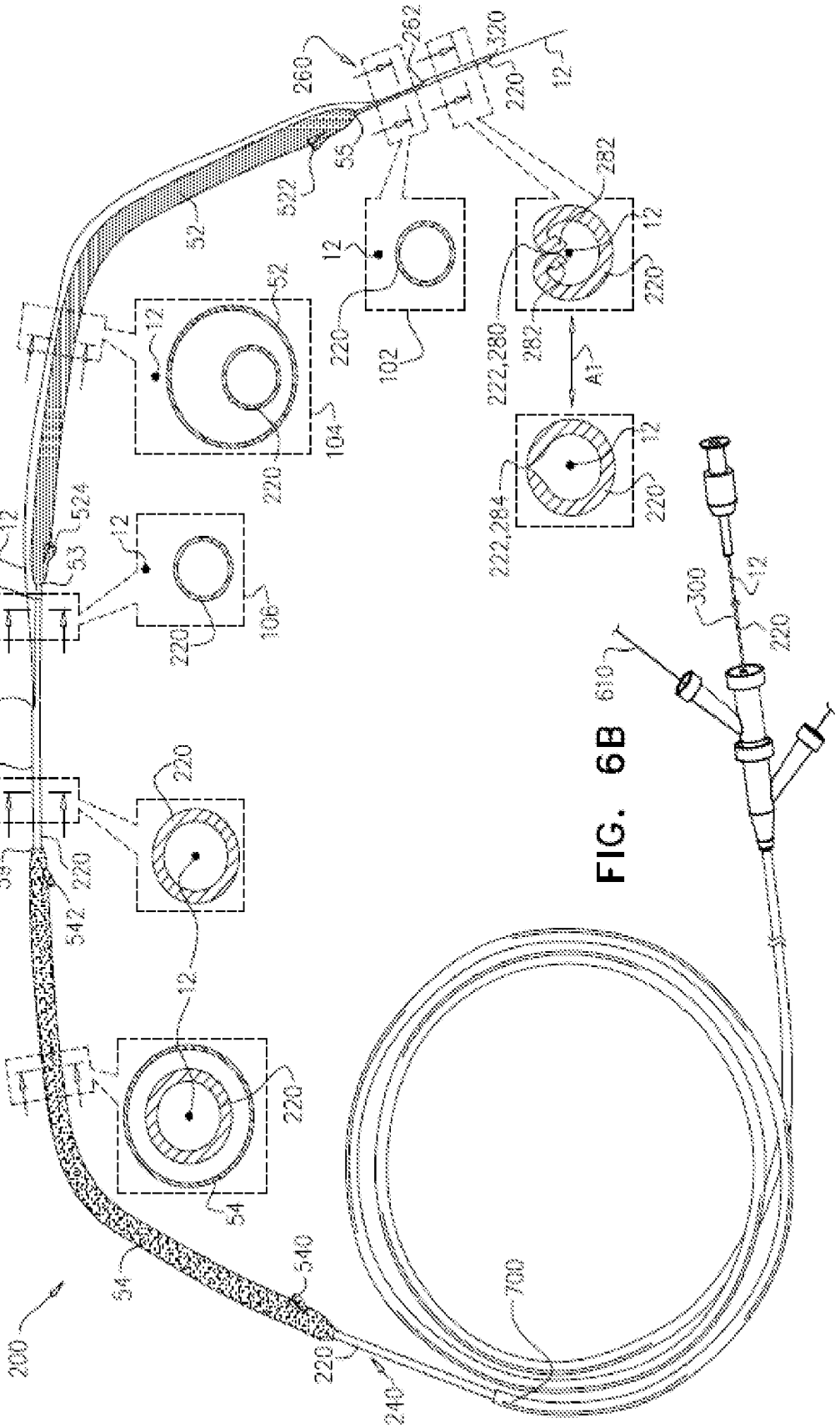

FIG. 6B

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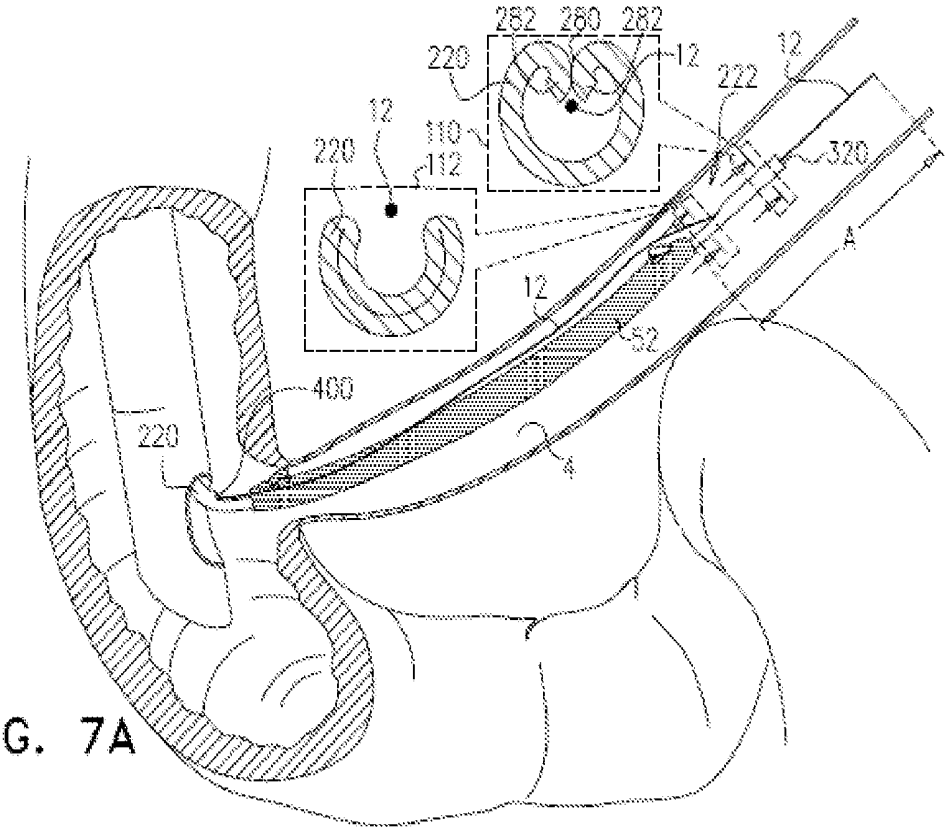

FIG. 7A

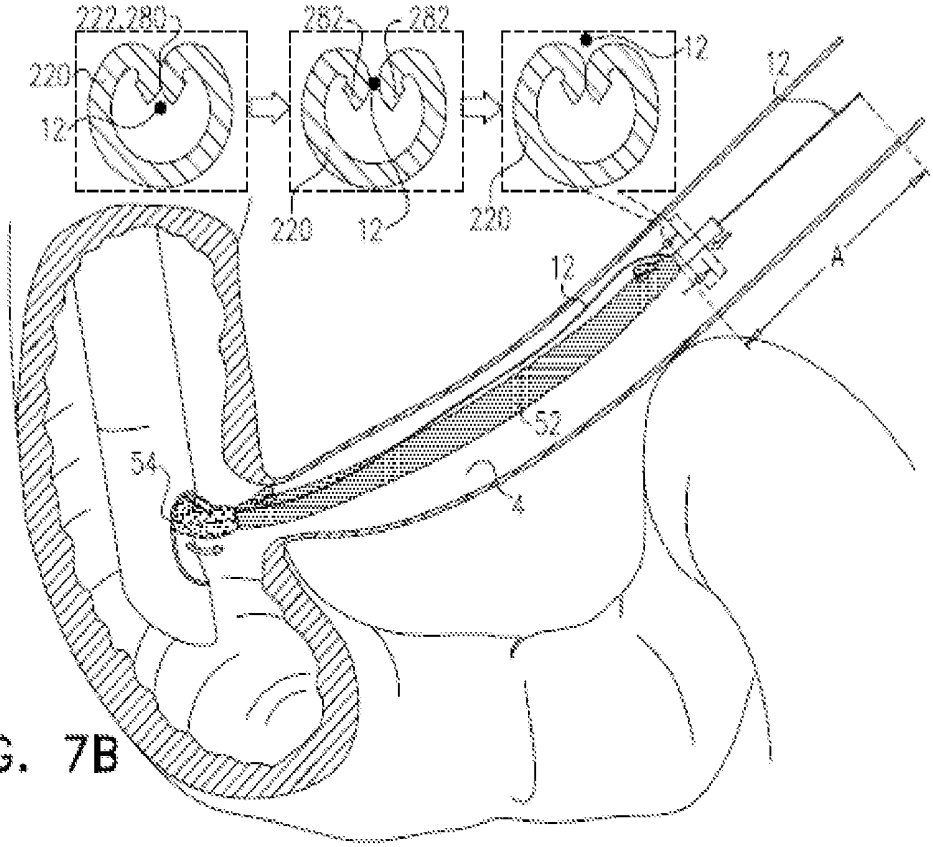

FIG. 7B

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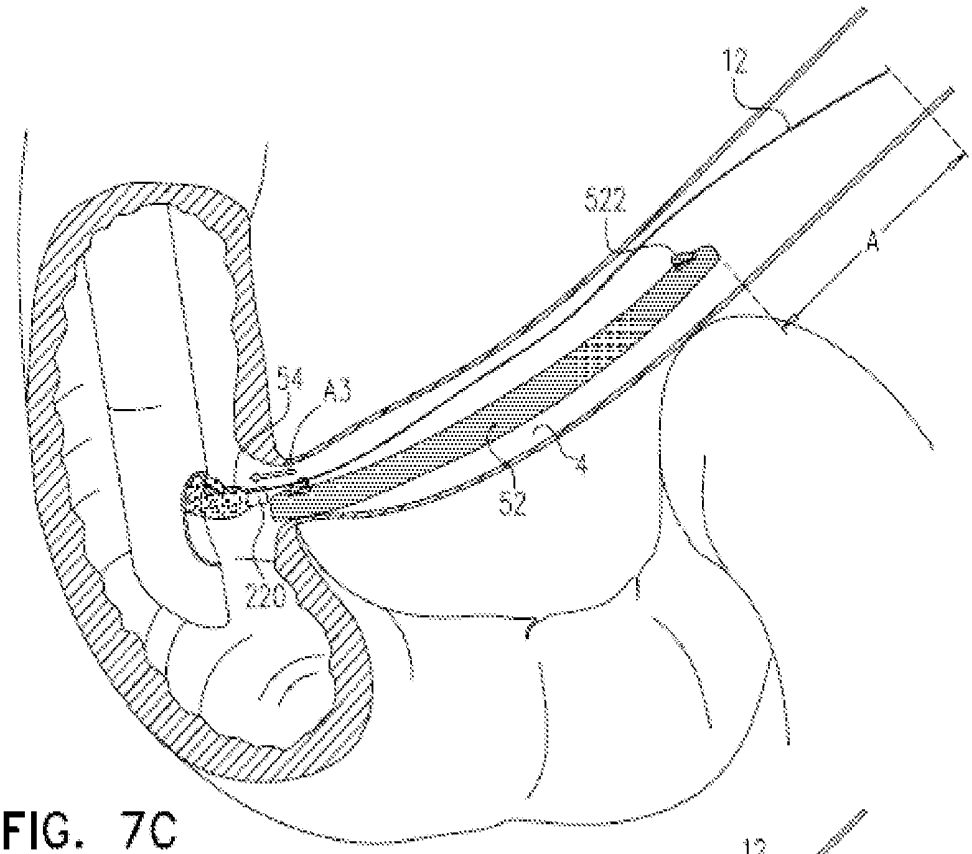

FIG. 7C

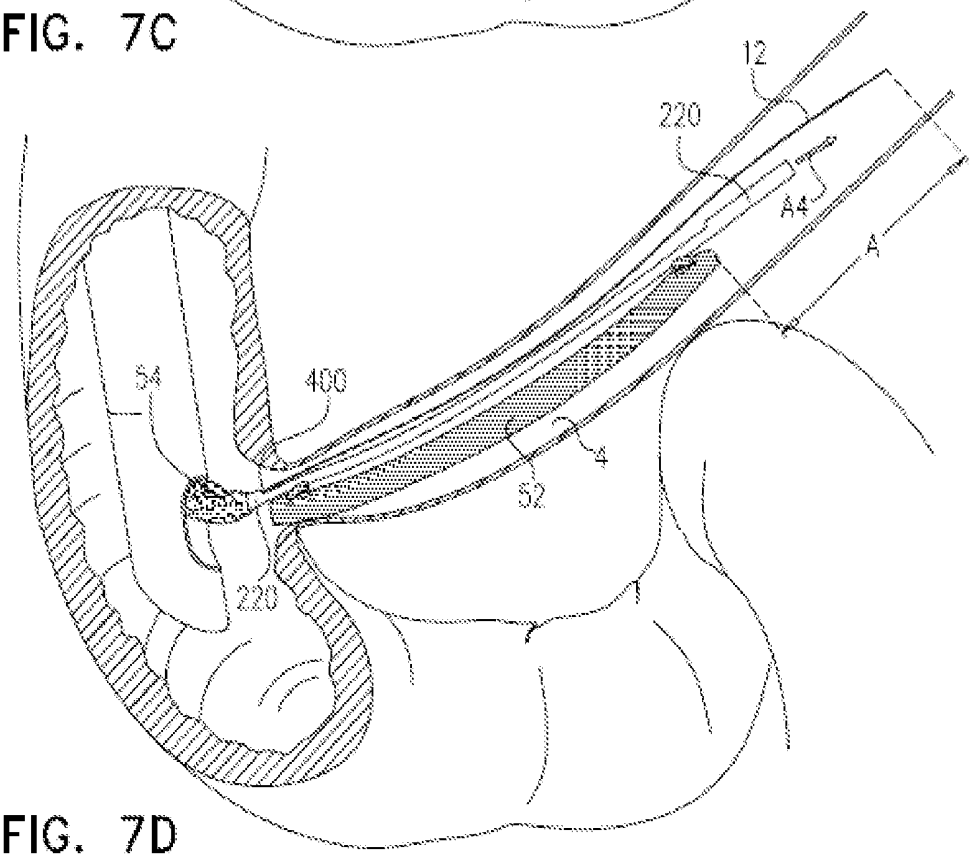

FIG. 7D

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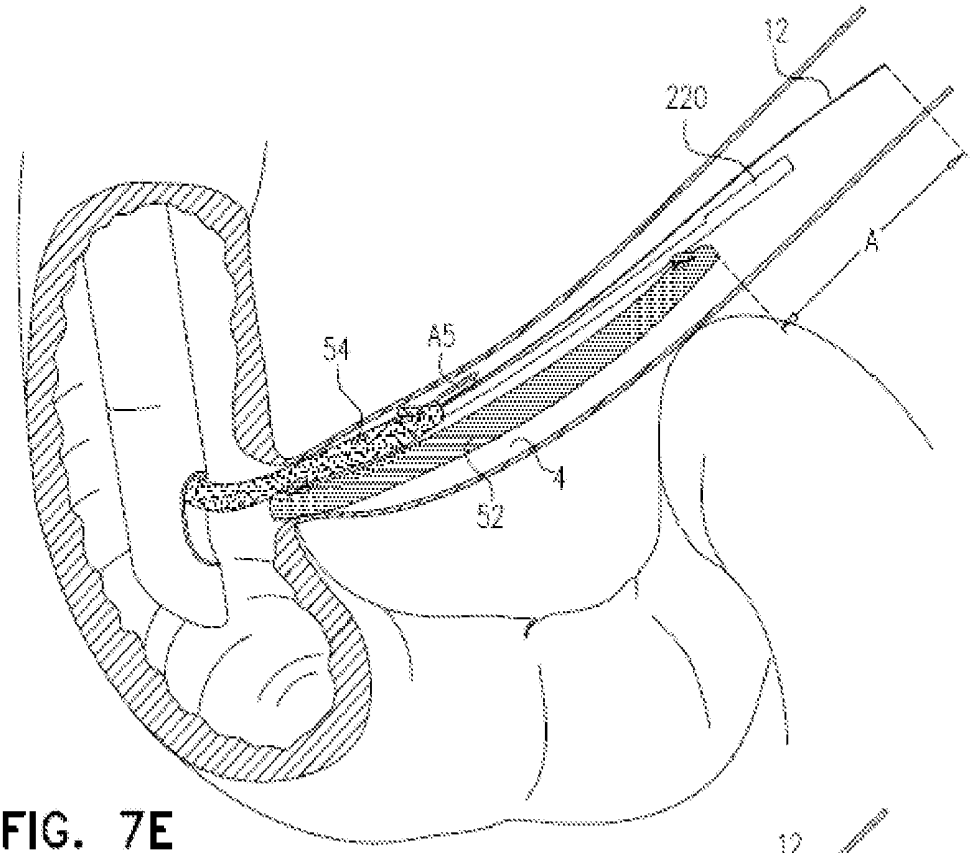

FIG. 7E

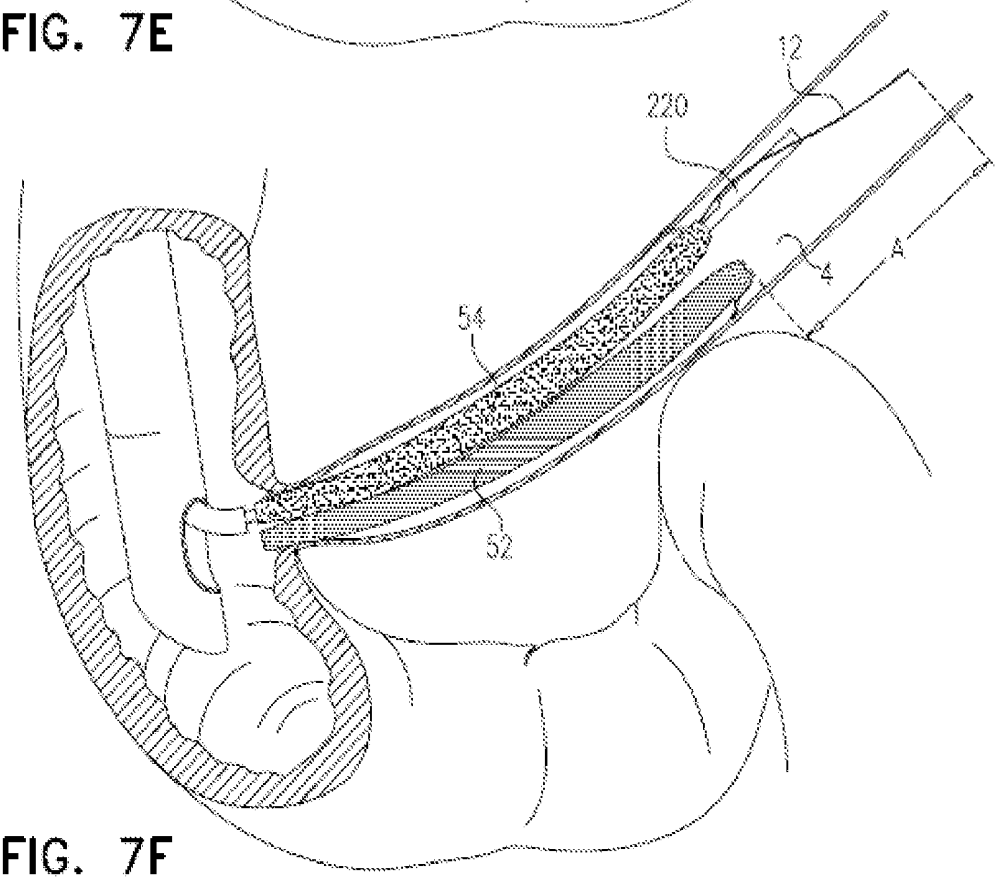

FIG. 7F

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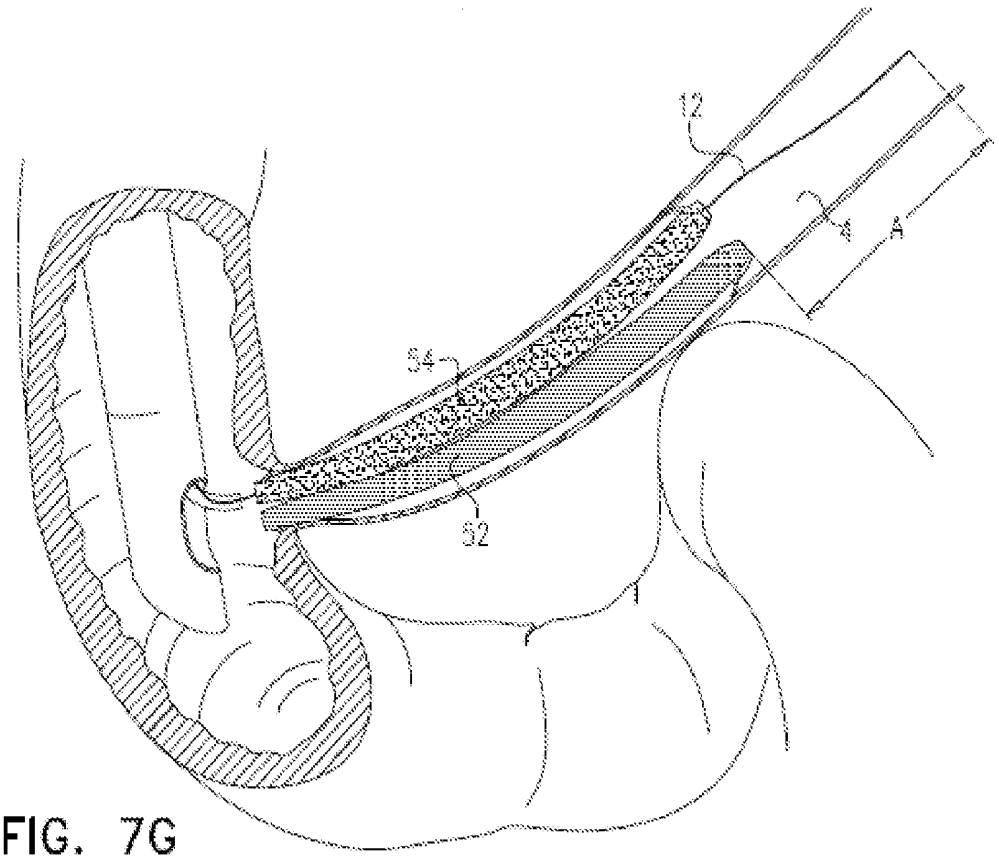

FIG. 7G

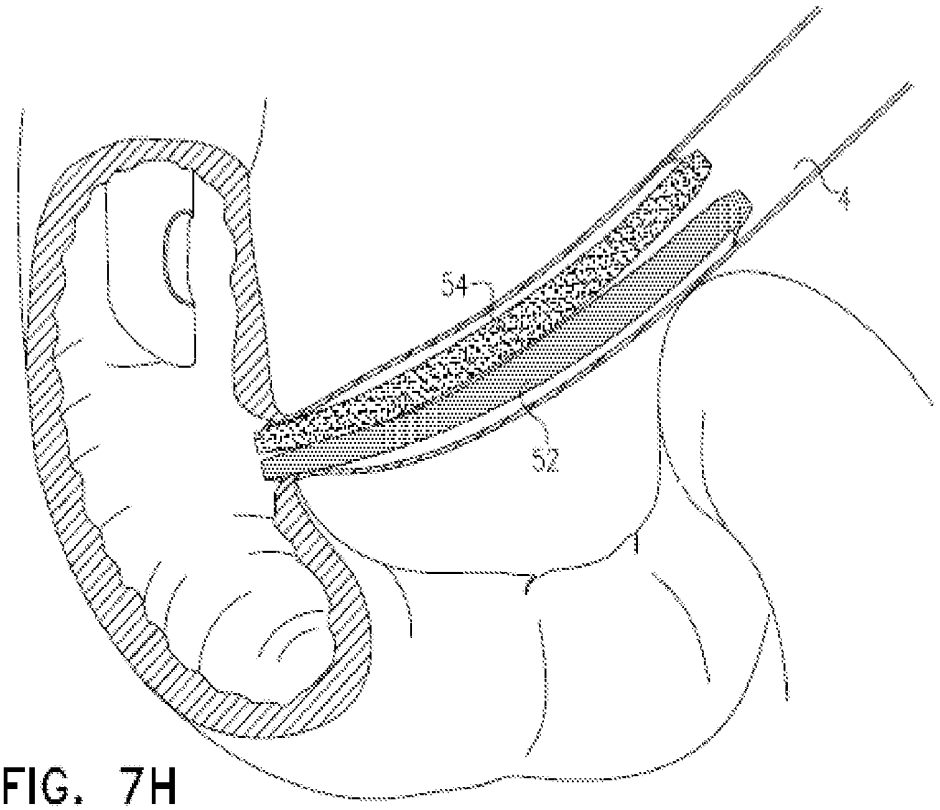

FIG. 7H

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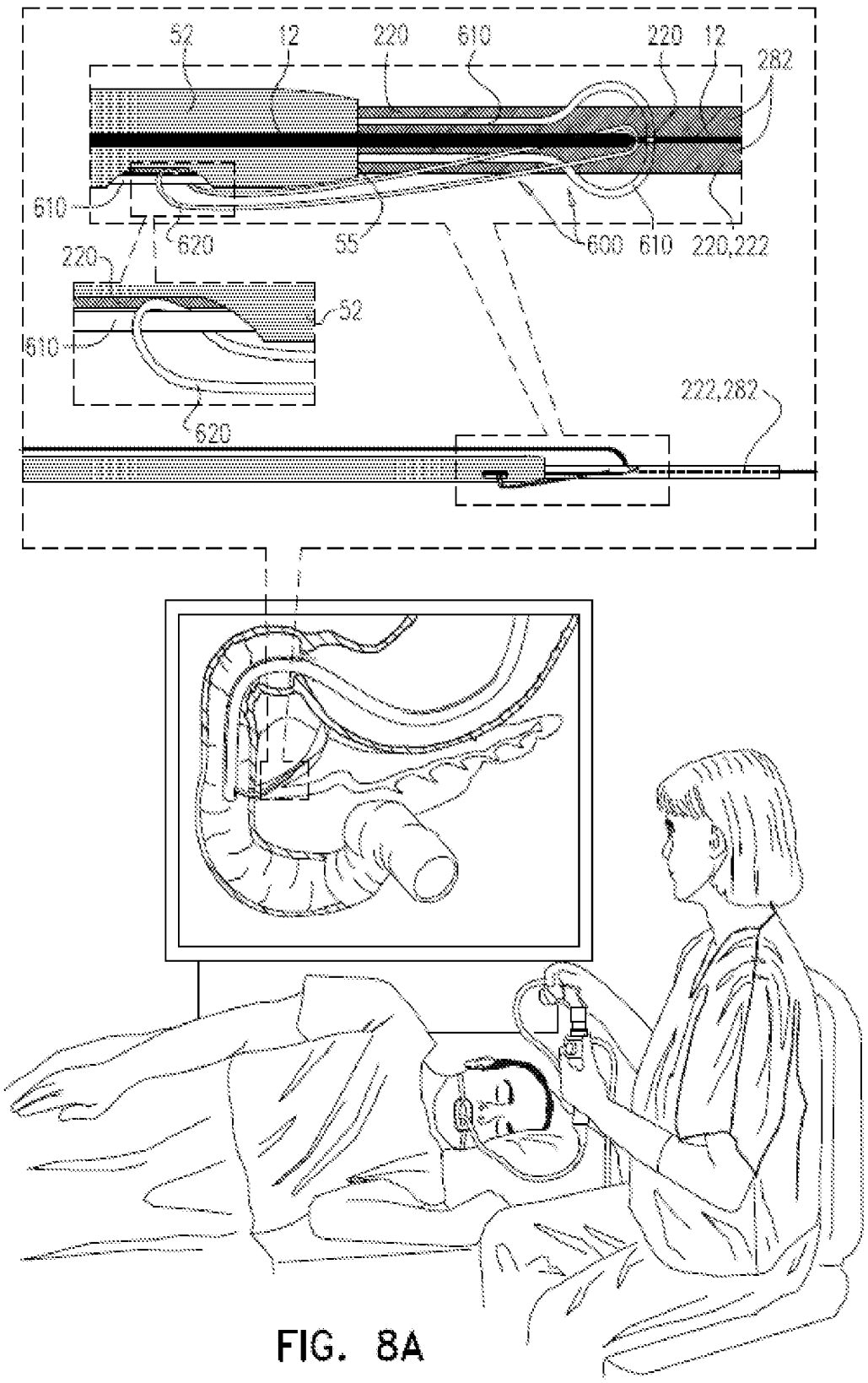

FIG. 8A

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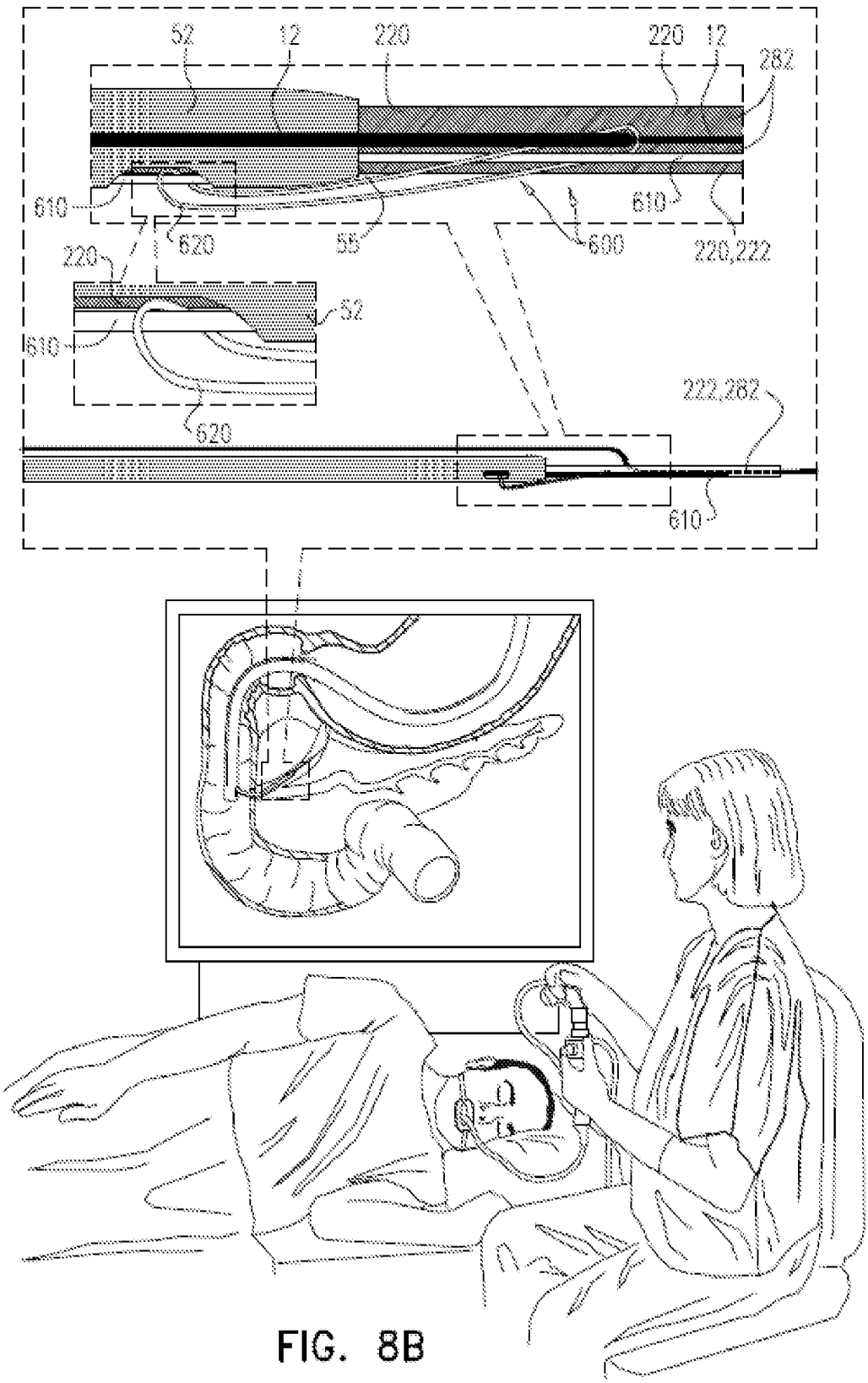

FIG. 8B

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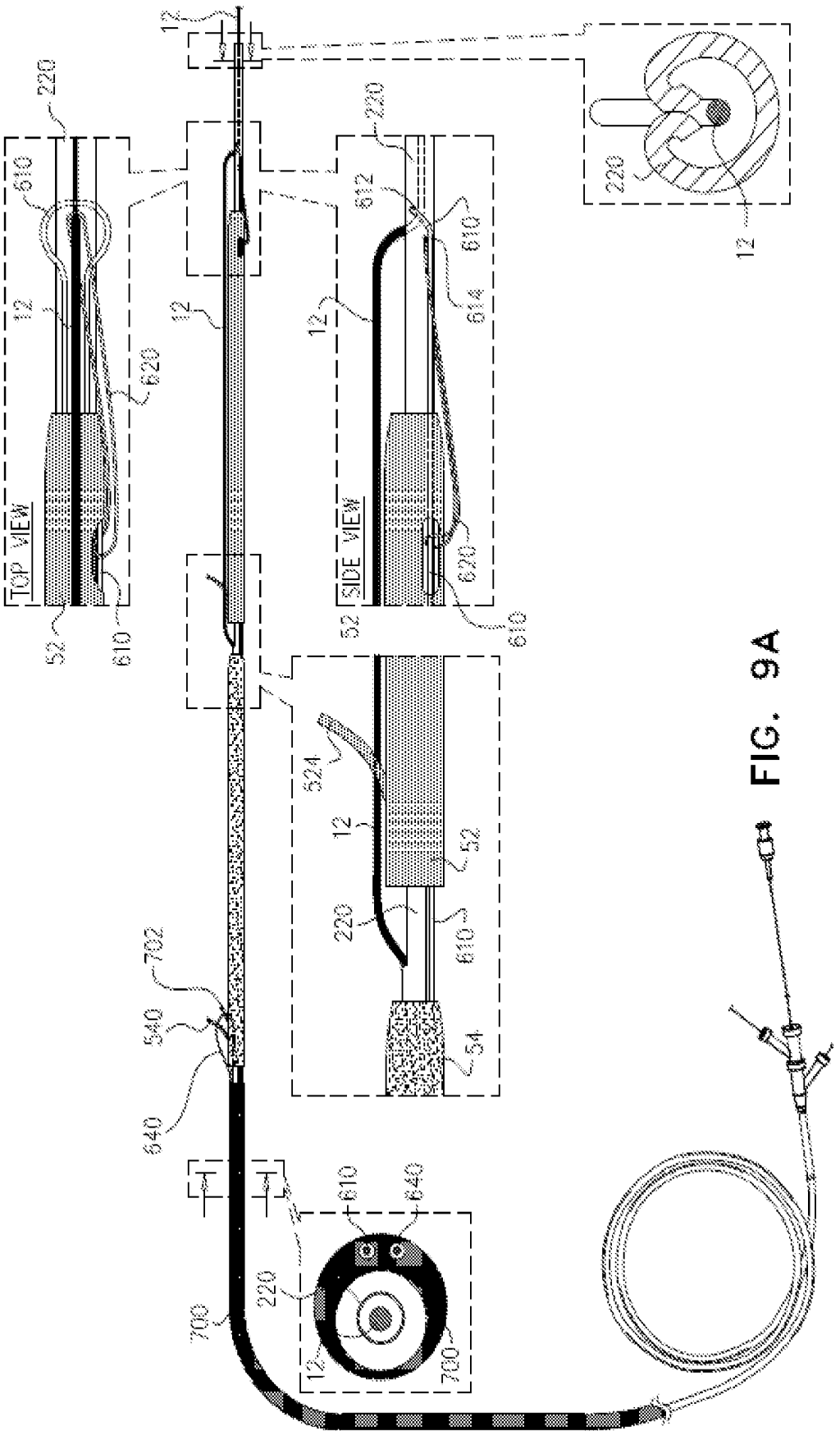

FIG. 9A

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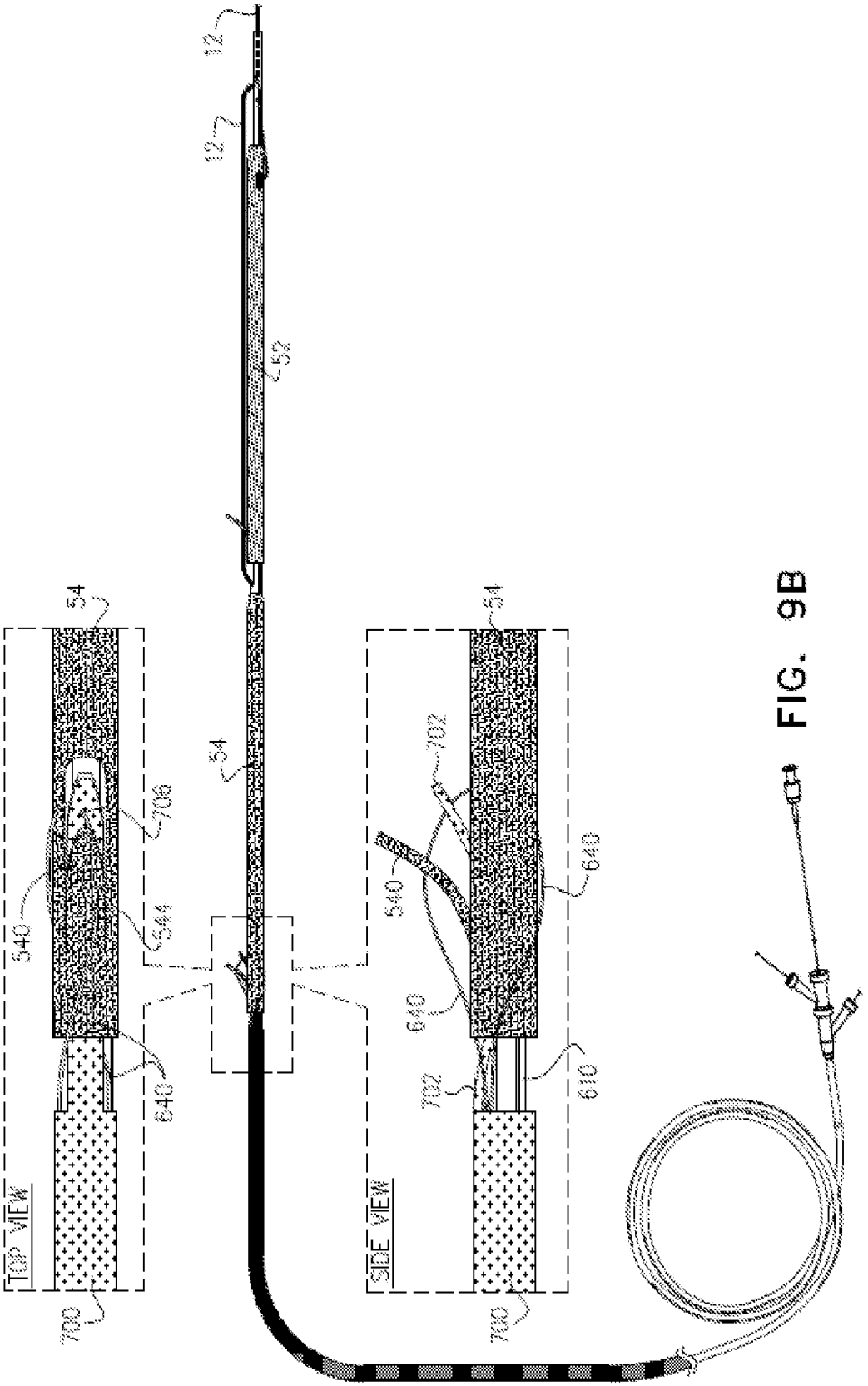

FIG. 9B

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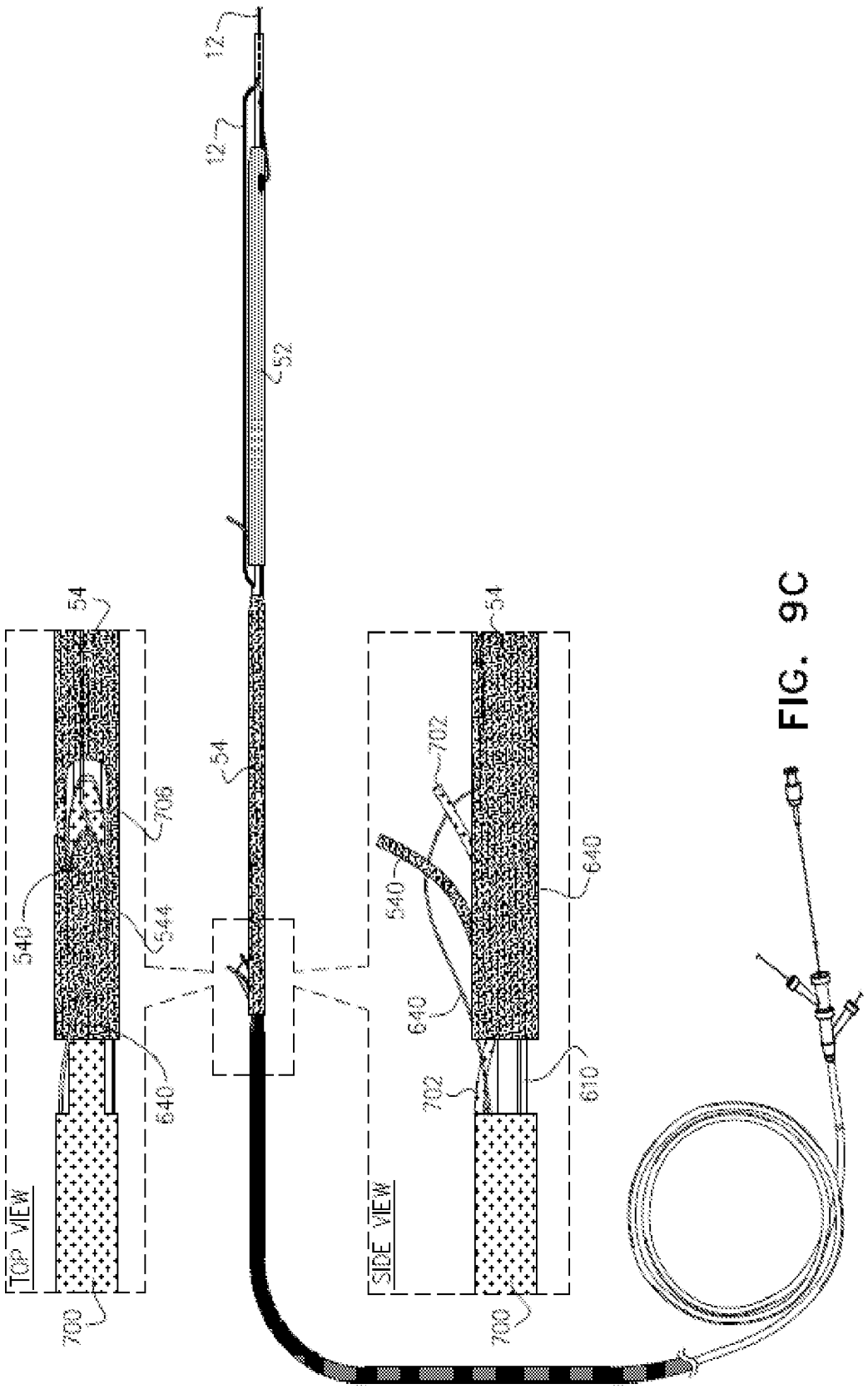

FIG. 9C

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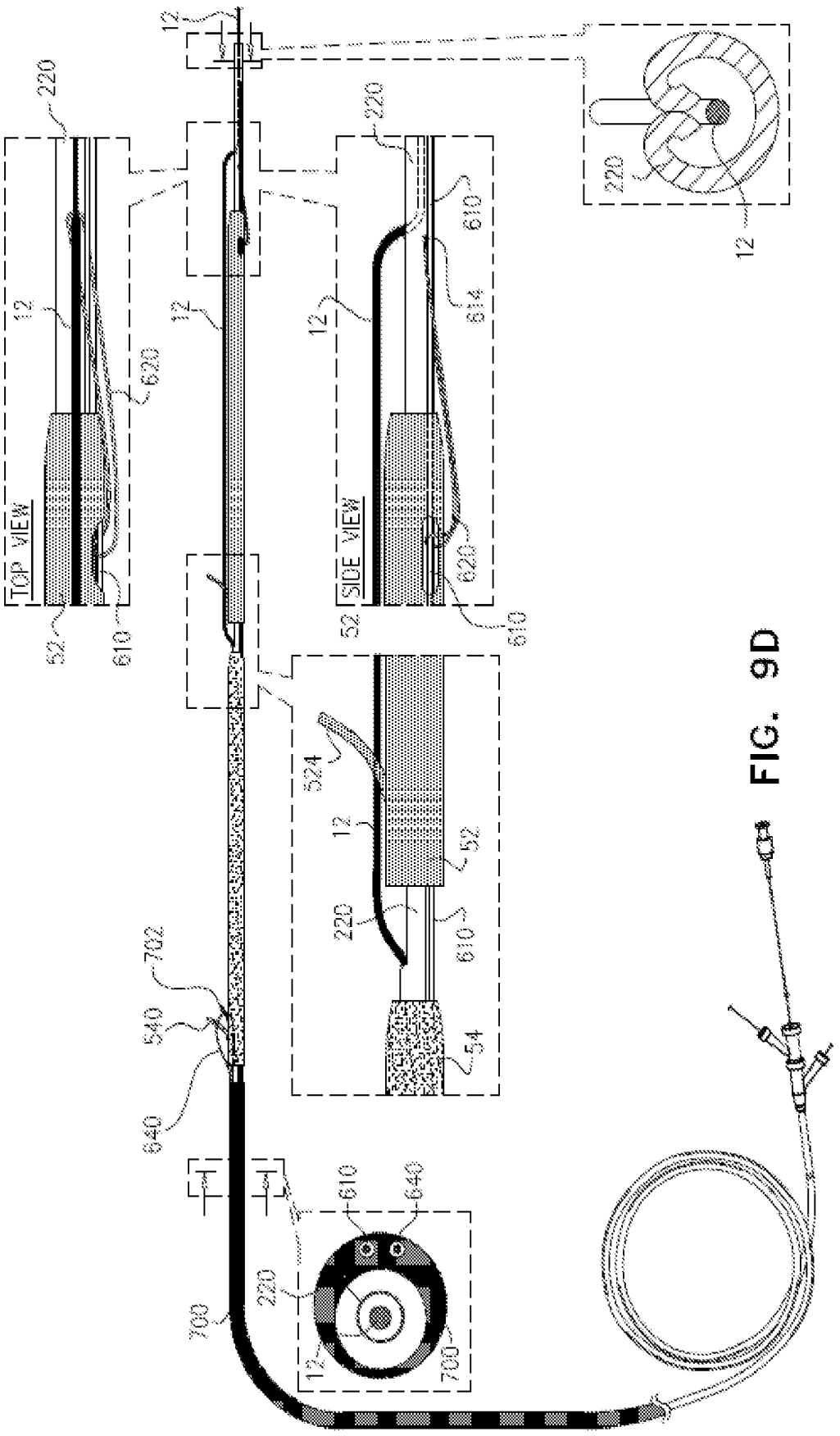

FIG. 9D

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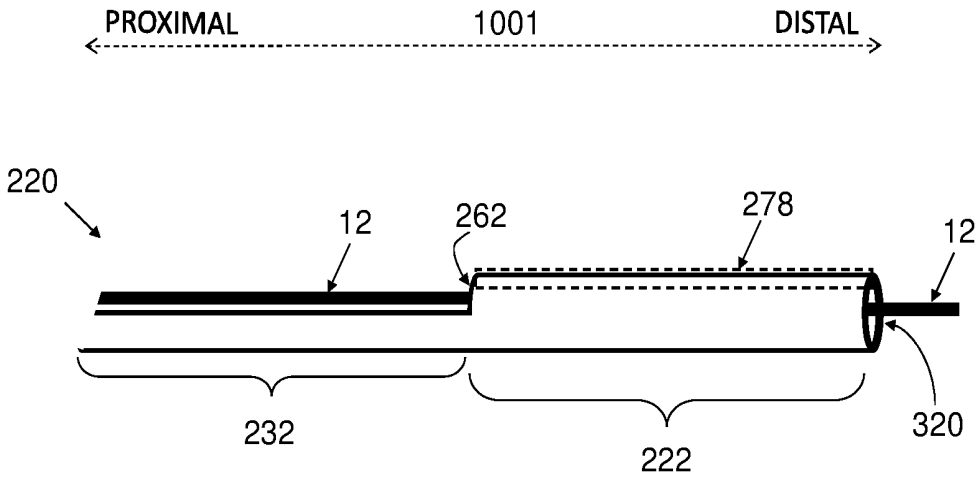

FIG. 10

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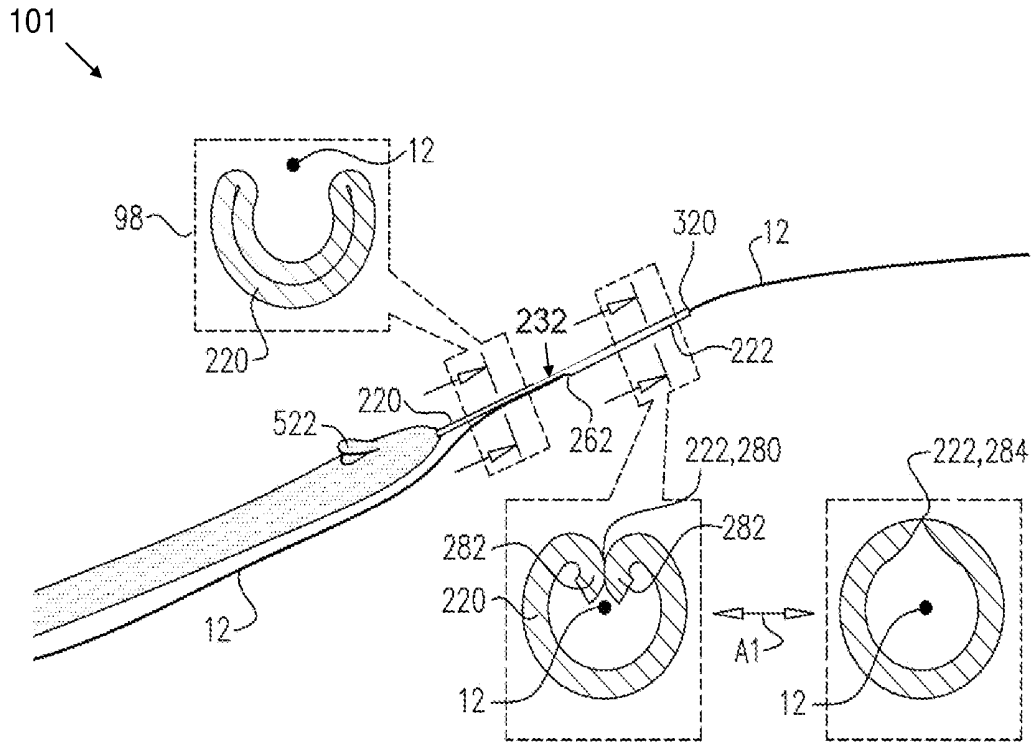

FIG. 11A

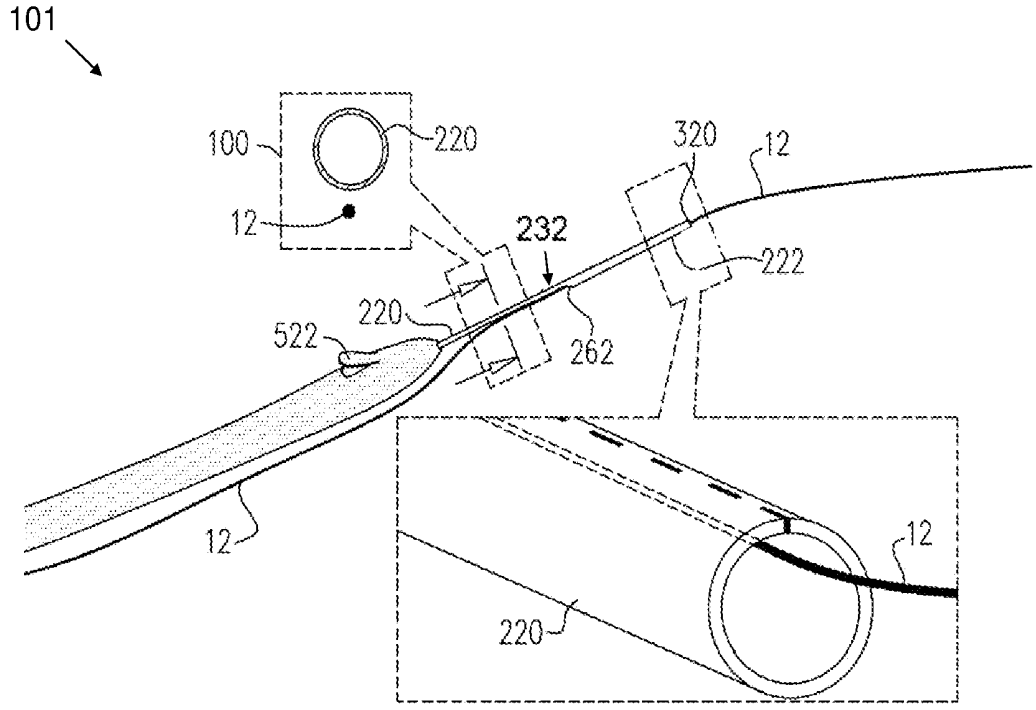

FIG. 11B

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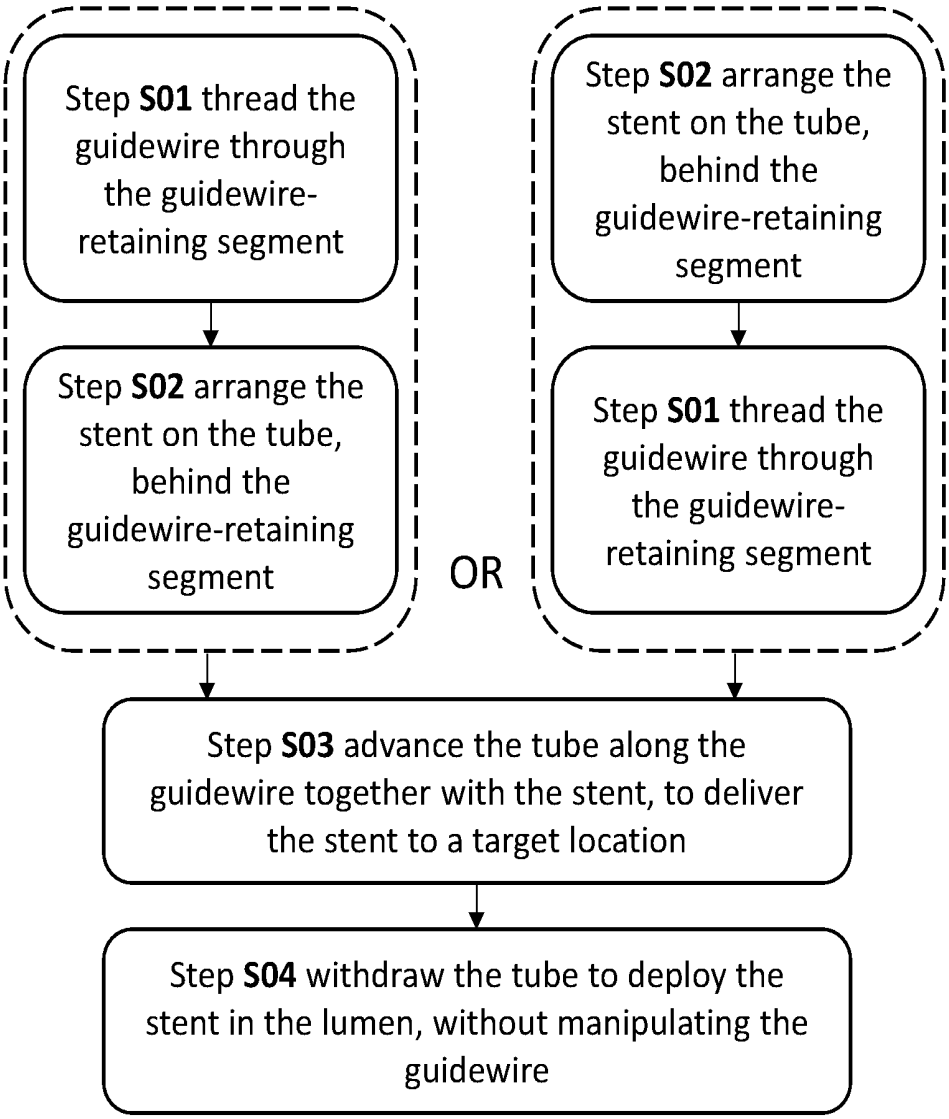

FIG. 12

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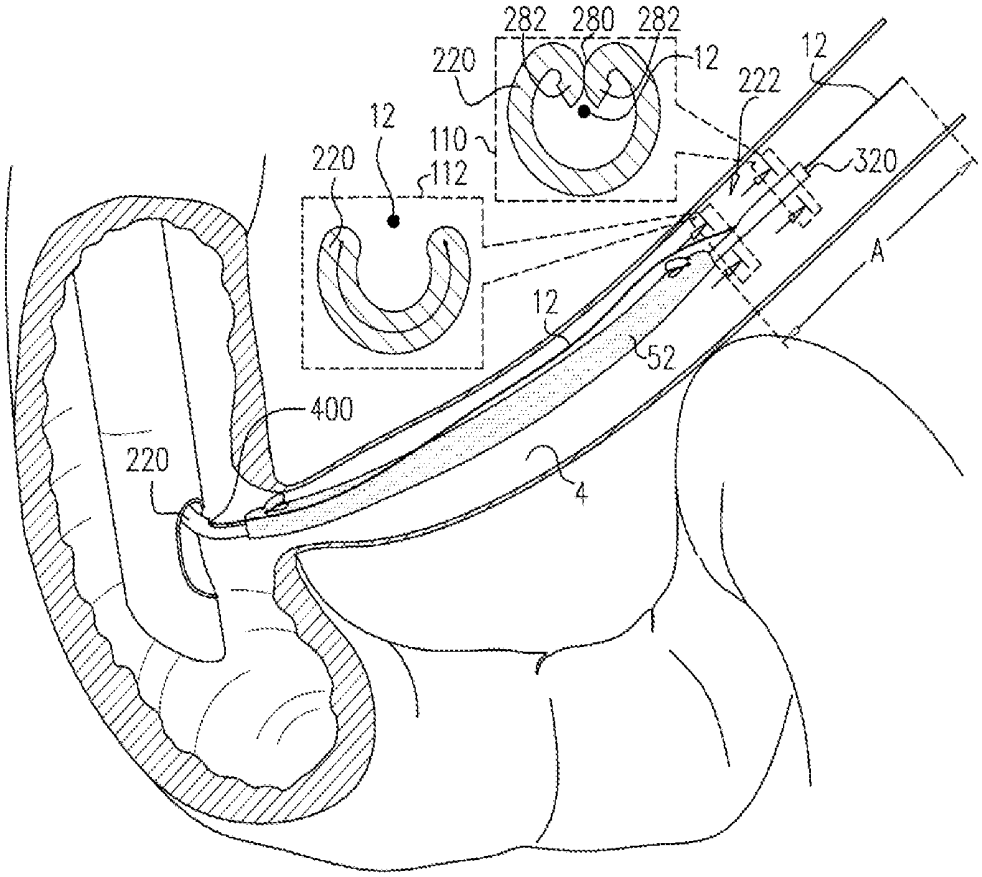

FIG. 13A

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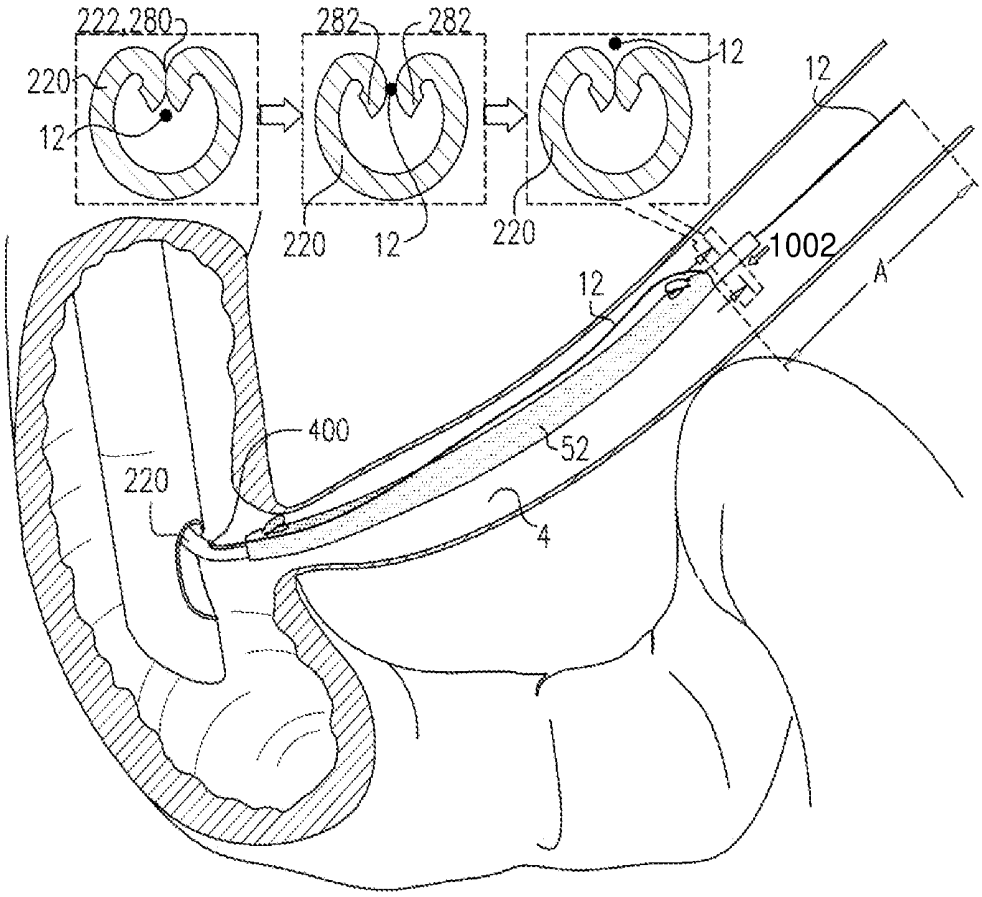

FIG. 13B

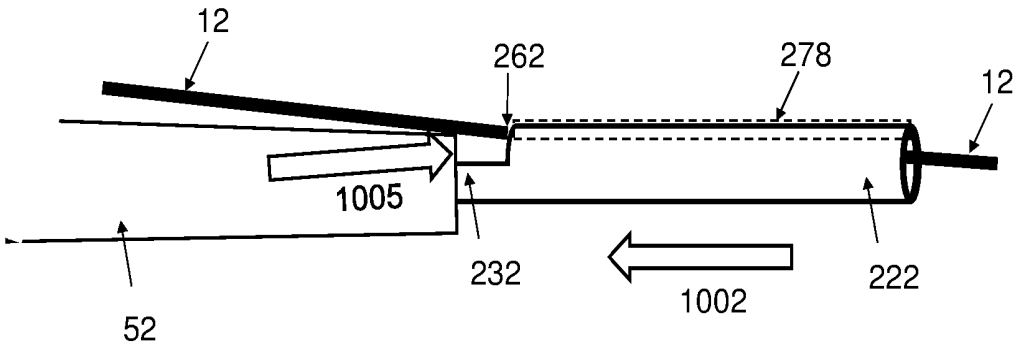

FIG. 13C

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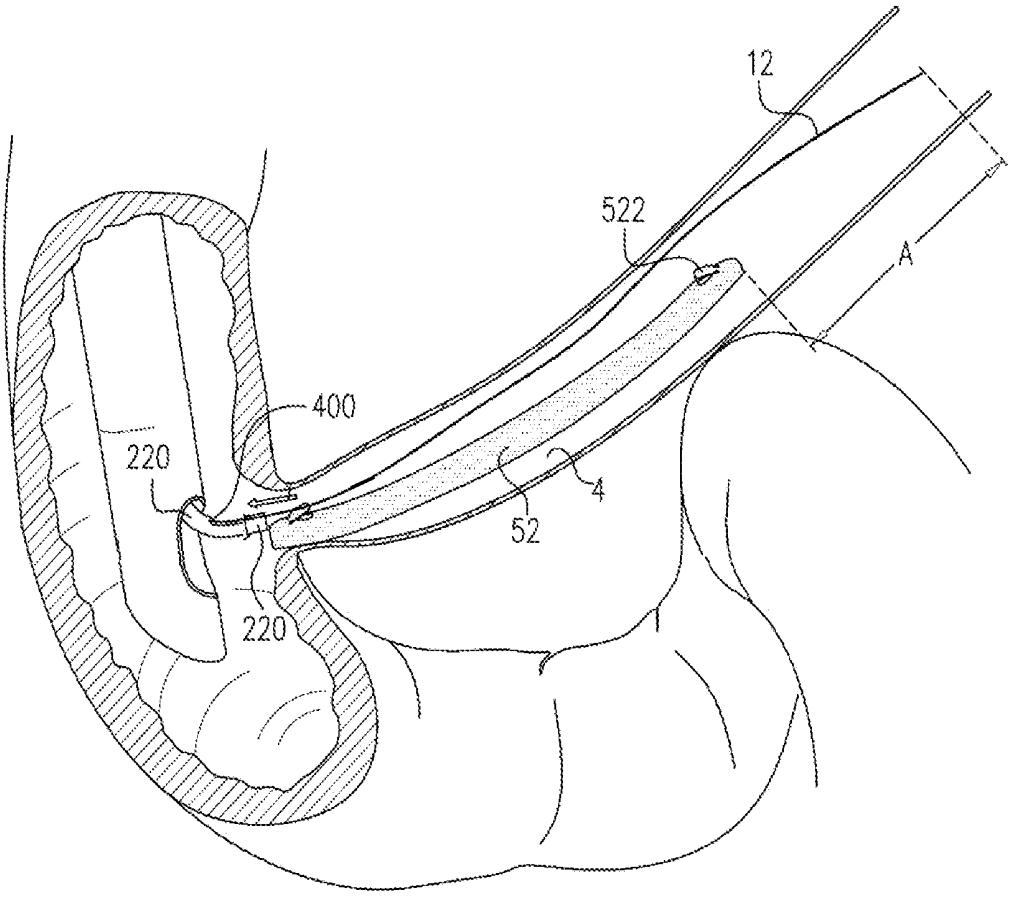

FIG. 13D

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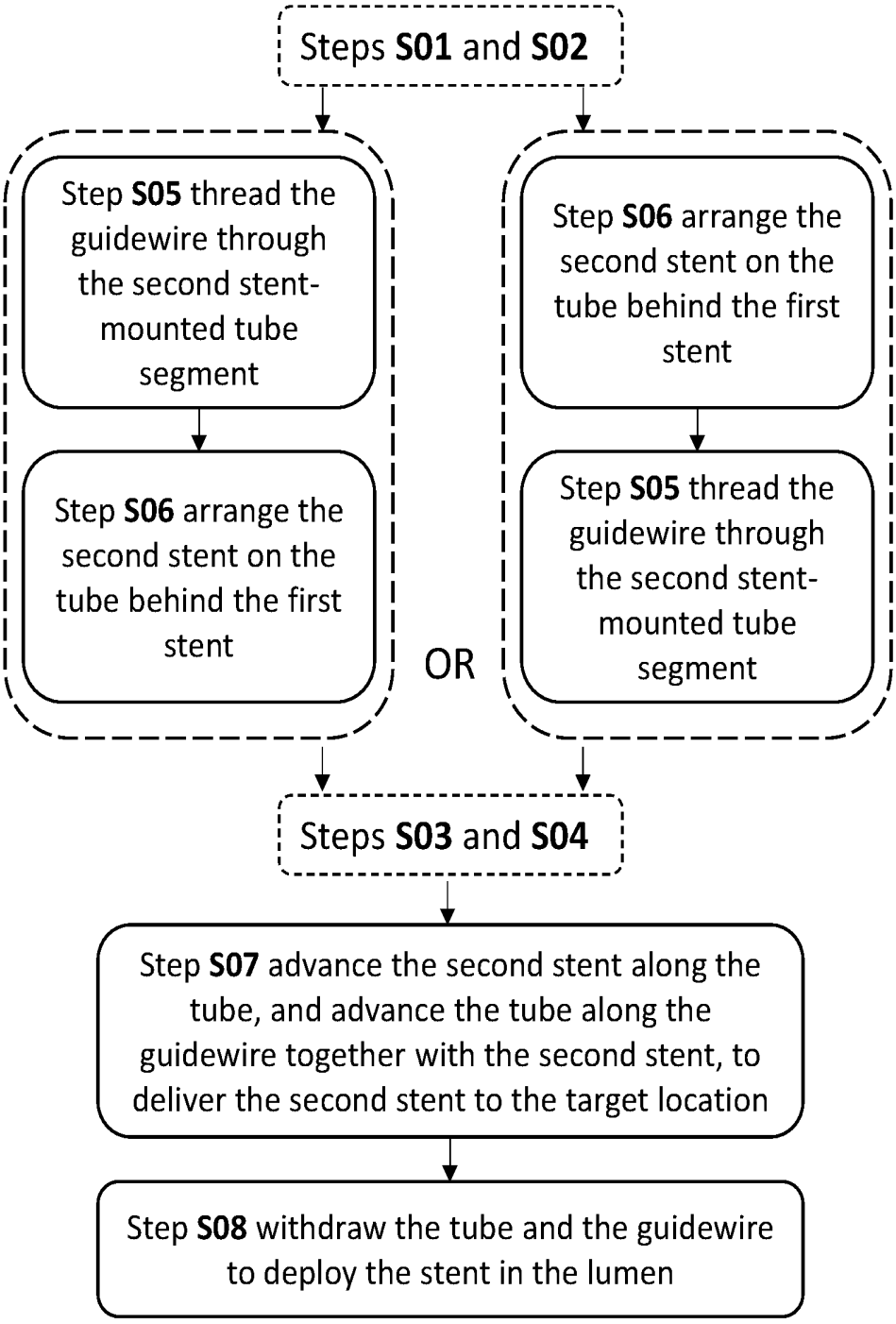

FIG. 14

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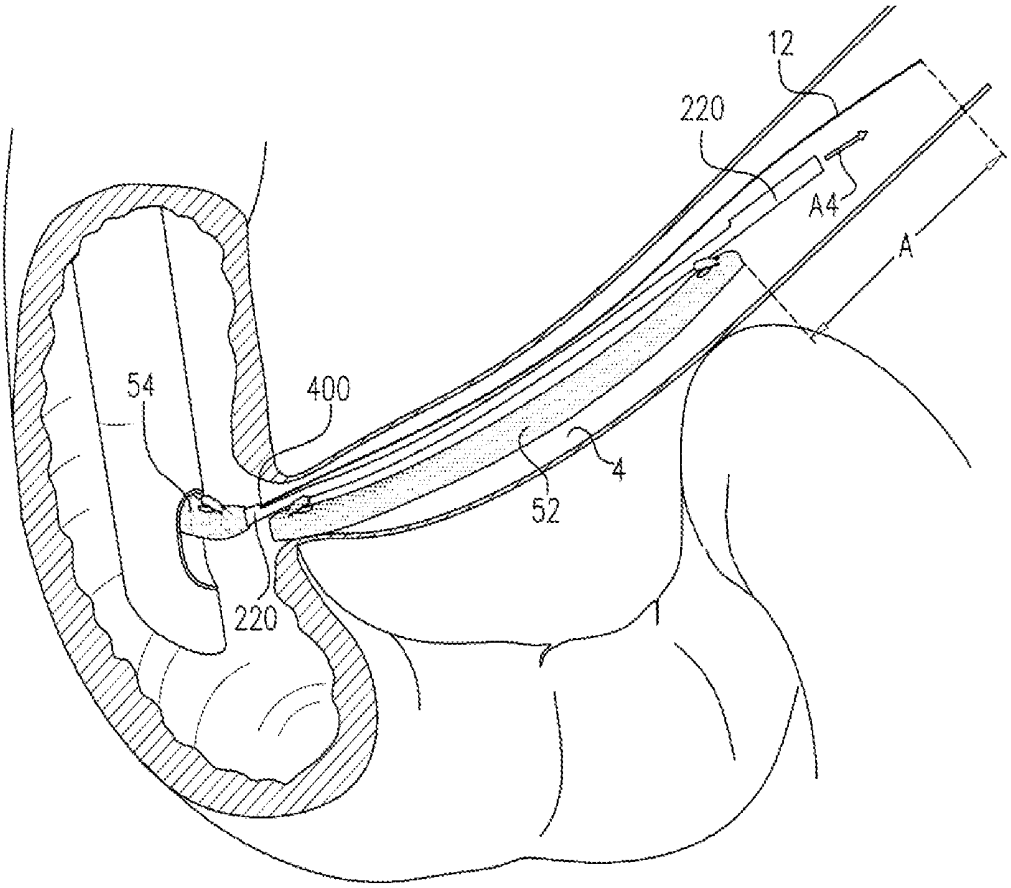

FIG. 15A

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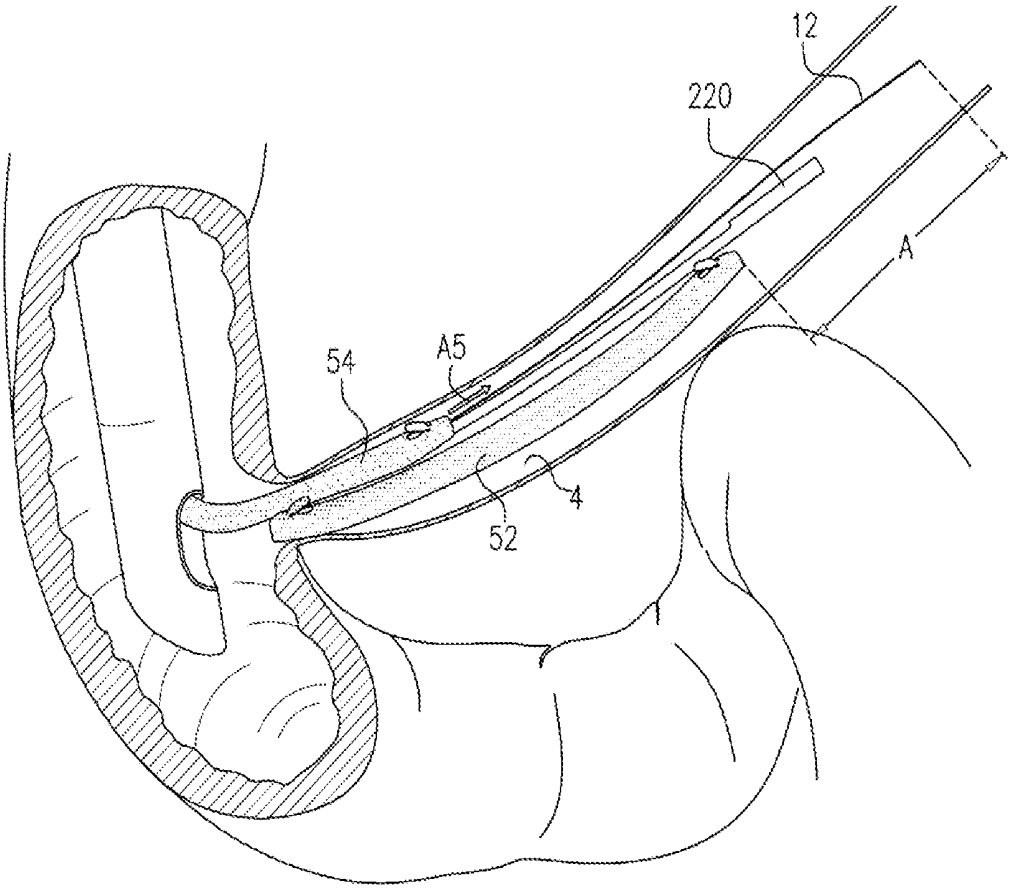

FIG. 15B

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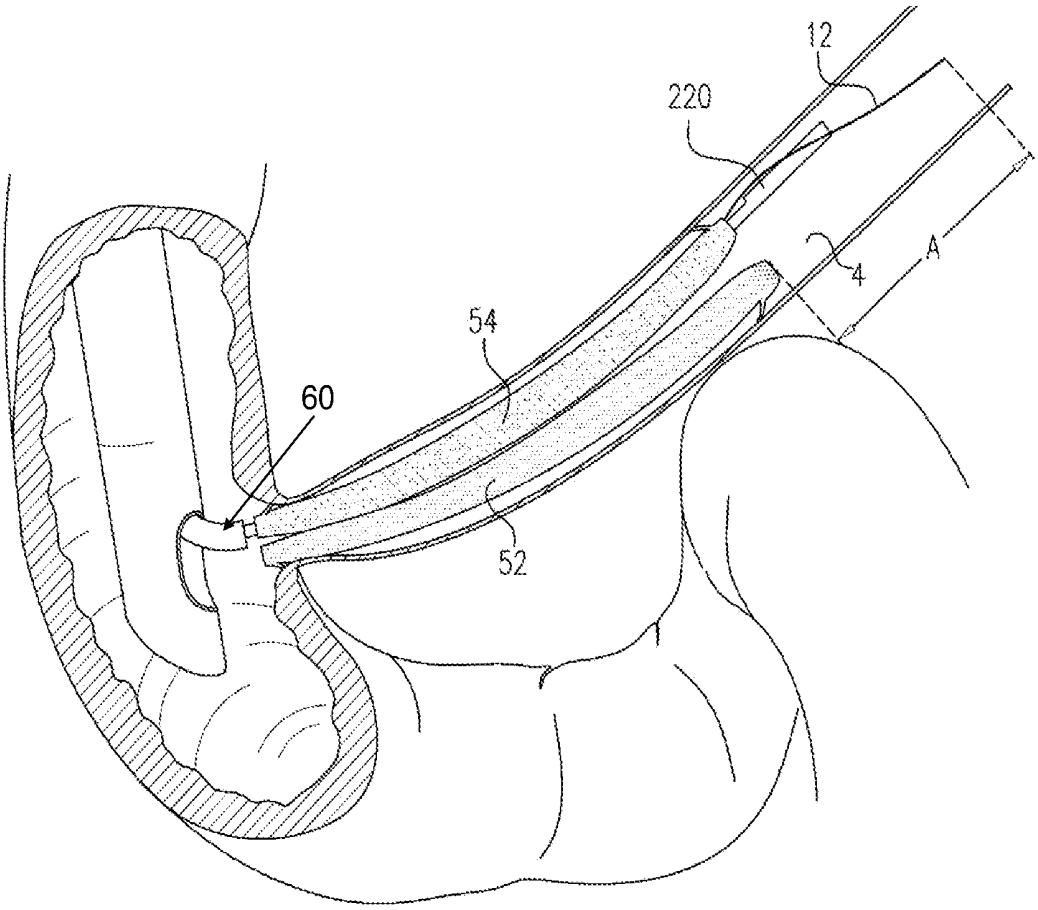

FIG. 15C

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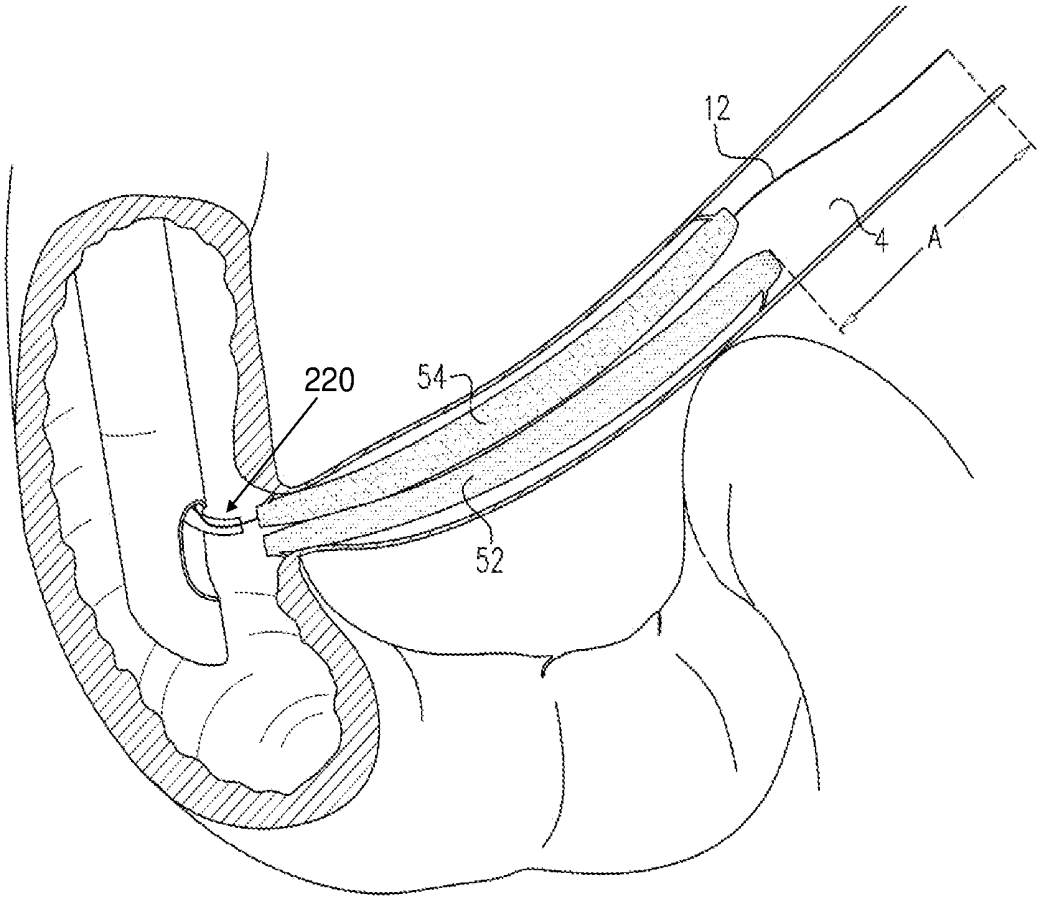

FIG. 15D

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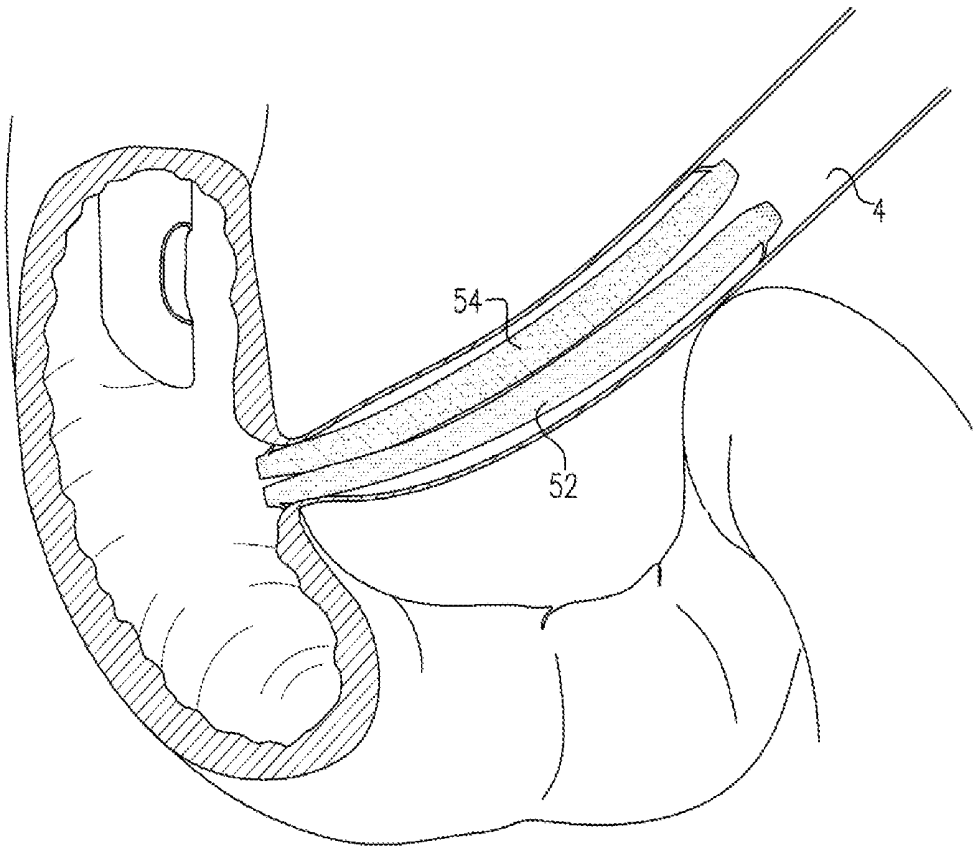

FIG. 15E

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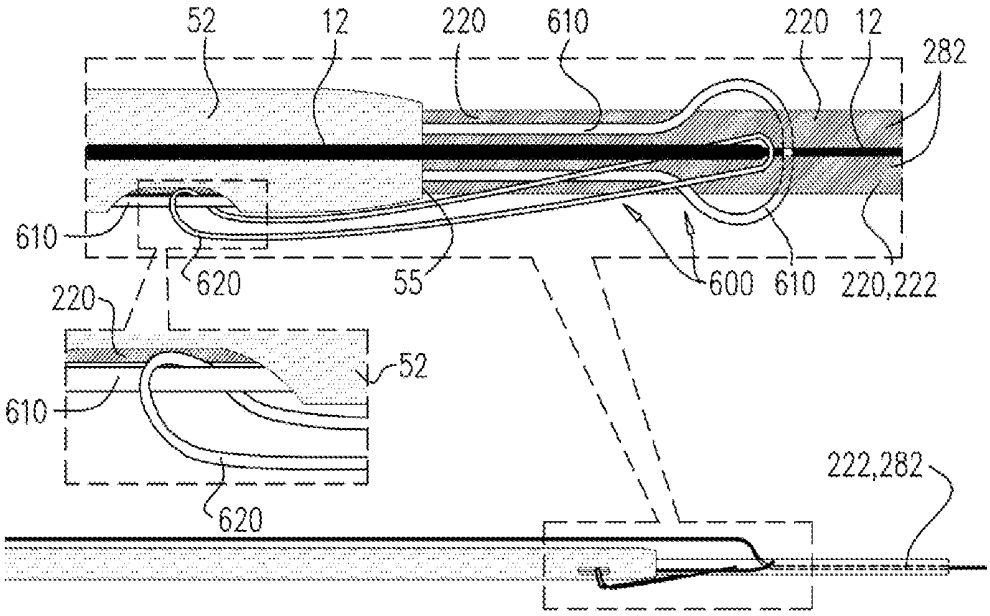

FIG. 16A

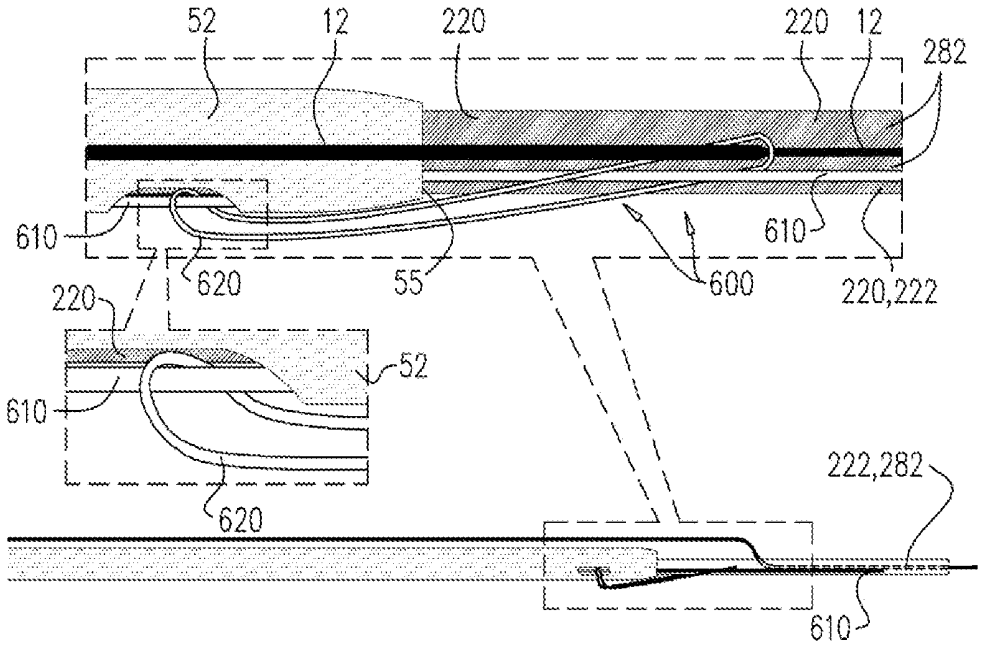

FIG. 16B

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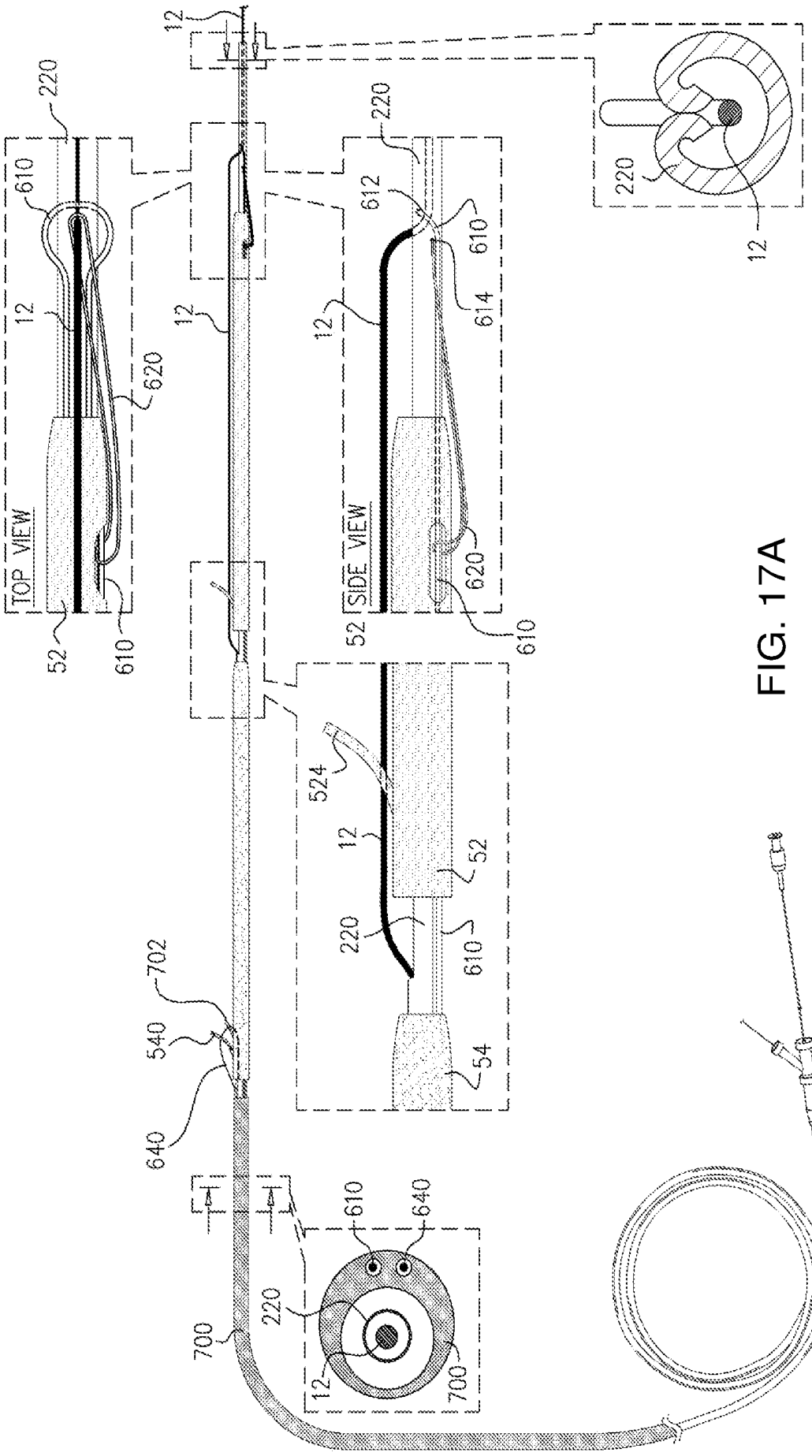

FIG. 17A

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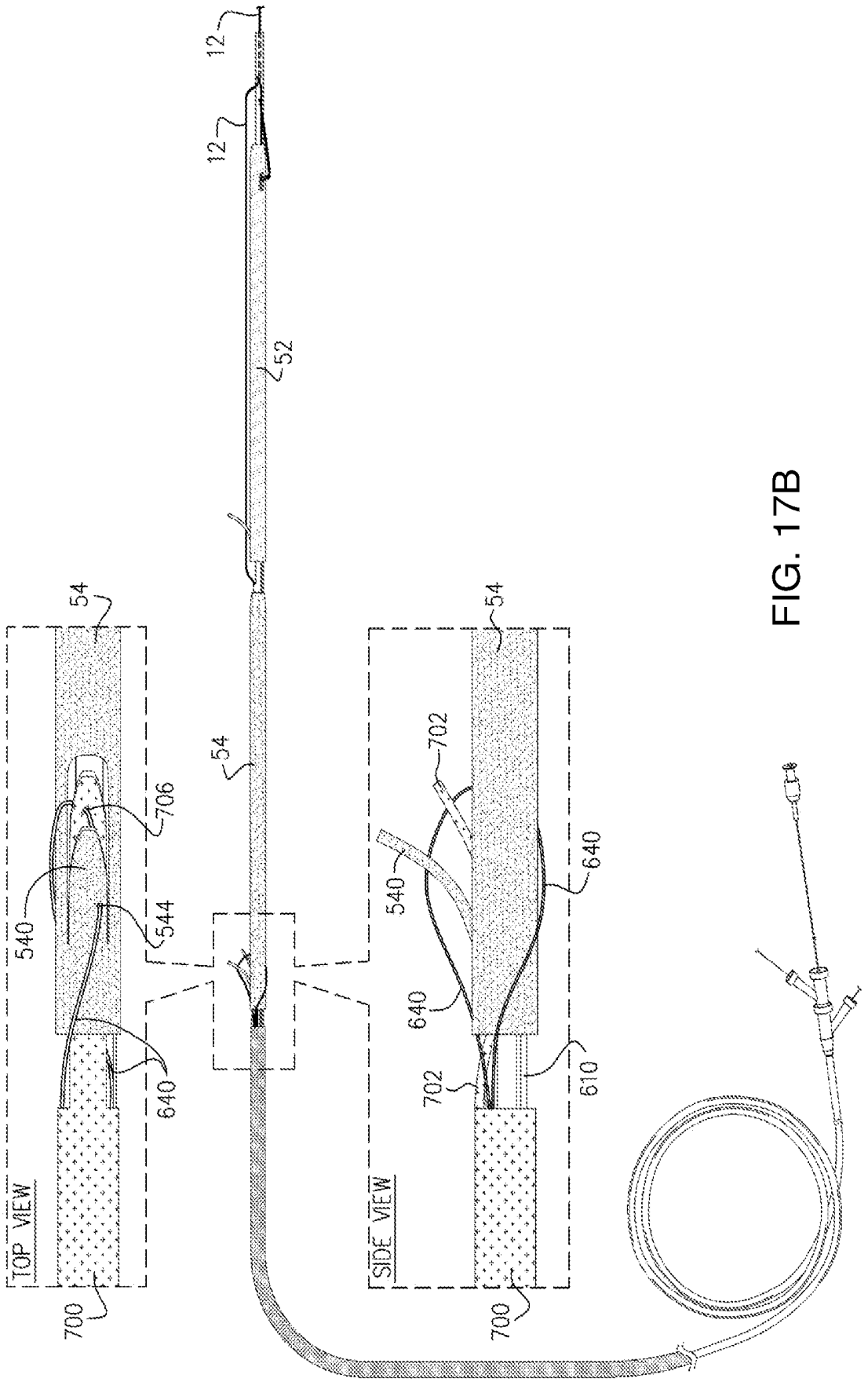

FIG. 17B

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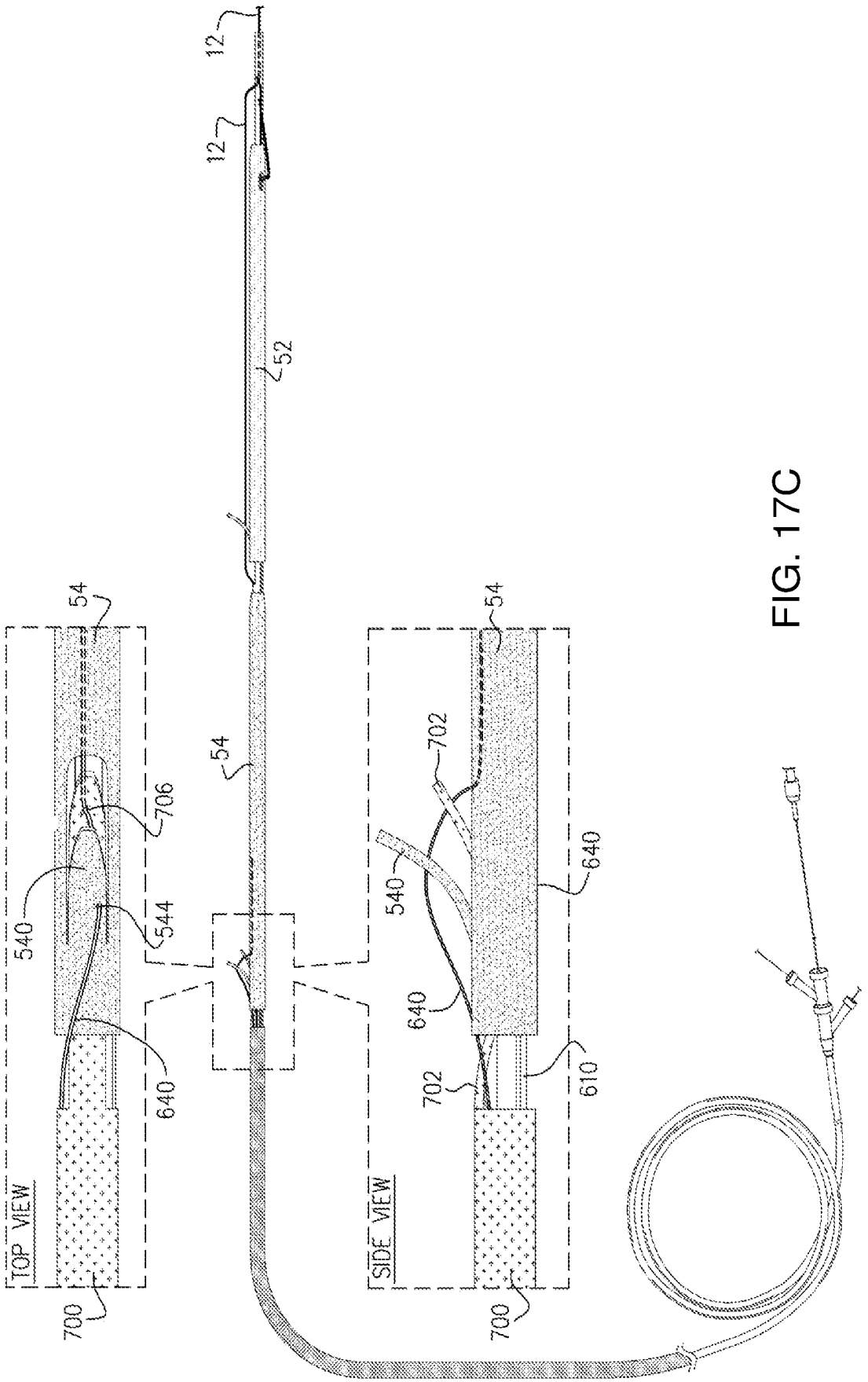

FIG. 17C

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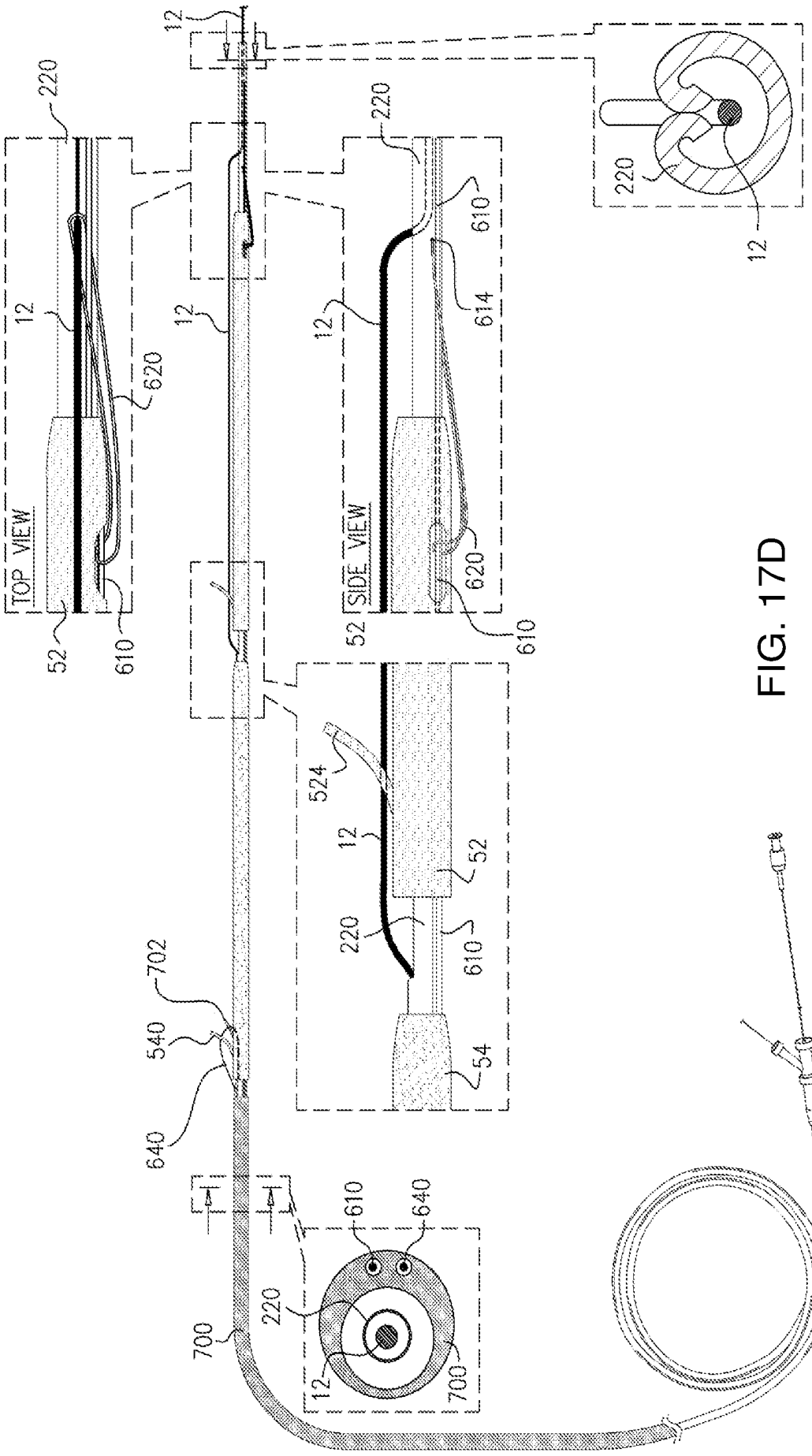

FIG. 17D