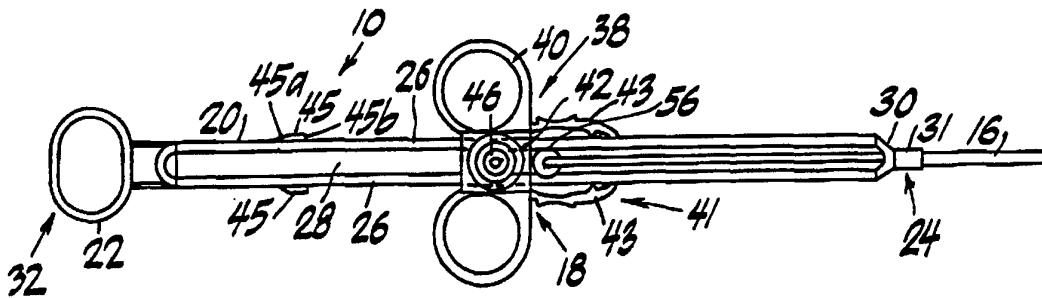




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(54) Title: SURGICAL COMBINATION INJECT AND SNARE APPARATUS



(57) Abstract

This invention is a surgical apparatus (10) for simultaneously deploying a first instrument (12) while retrieving a second instrument (14) from the distal end of a sheath (16) and vice versa with a single stroke actuator (18). The actuator includes an elongated support (20) having a provision (22) for grasping at one end thereof; a first sliding member (38) having provisions (40) for grasping and which is movable in first and second directions relative to the support; and a second sliding member (56) operably coupled to the first sliding member such that translation of the first and second sliding members is in opposite directions relative to the support. The first sliding member is connected to the first instrument, and the second sliding member is connected to the second instrument.

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SURGICAL COMBINATION INJECT AND SNARE APPARATUSField of the Invention

This invention relates generally to an apparatus for simultaneously deploying and retrieving a first instrument and a second instrument, respectively, with a single-stroke actuator, and more particularly to a surgical apparatus for performing endoscopic procedures such as biopsy or polyp resection and the like (also known as endoscopic polypectomy).

10 Description of the Prior Art

A technique developed in Japan known as Strip Biopsy Resection or Saline-Assisted Polypectomy ("SAP") enables physicians to easily remove sessile and other morphological type lesions of the gastrointestinal tract. SAP involves elevating the lesion on a bed of physiological saline solution, and then passing a standard snare device over the elevated tissue to resect the same by electrocoagulation. In the course of performing this procedure, the physician passes a sheath having an injection needle disposed therein through an endo- scope, the distal end of which is proximate to the site of the lesion within the gastrointestinal tract of the patient. The needle is then moved out of the sheath and inserted into the submucosa proximal to the lesion. A sufficient amount of saline solution is then injected into the submucosa to elevate the lesion. Once the lesion is elevated, the needle is then withdrawn into the sheath and the sheath and needle are removed from the endoscope and replaced with a snare or cauterization loop contained in a separate sheath. The snare is placed over the lesion and the overlying mucosa, tightened, and the lesion is then separated from the surrounding tissue electrosurgically. The same technique may be applied to depressed lesions as well as sessile polyps, regardless of their size.

-2-

After excision of the lesion, it is often necessary to inject a cold epinephrine solution in order to curtail any bleeding that often arises after the excision. This is critical since bleeding must be
5 stopped as soon as it starts to avoid complications from the procedure which could have adverse effects on the patient. It is therefore desirable to have the injection needle ready for quick redeployment at the site after excision of the lesion.

10 The foregoing endoscopic procedures can also be used for marking the location of a lesion or resected polyp by introducing an injection needle either before or after the use of a polypectomy snare. A diluted solution of sterilized India ink is injected into four
15 quadrants around the colon to permit surgical identification of the site. In this manner, the physician can monitor the patient endoscopically for a predetermined amount of time until complete healing of the site has been identified or various points of
20 interest can be marked for future endoscopic identification.

Surgical instruments for use in such procedures are disclosed in U.S. Patent Nos. 5,190,542 to Nakao, et al. and 5,084,054 to Bencini et al. Both patents teach
25 the use of surgical gripping instruments which facilitate the remote manipulation of an endoscopically inserted snare or cauterization loop disposed at the distal end of a sheath. Common to both disclosures is the teaching of a sliding member coupled to a support
30 assembly which allows the physician to manipulate the snare by moving the sliding member relative to the support assembly to deploy or retrieve the snare from the sheath.

These devices have disadvantages. Since the
35 Nakao and Bencini inventions can only manipulate one remote instrument at a time, the procedure time is

-3-

unnecessarily increased because the physician must continually swap the snare and injection needle devices to perform the various injection and resection steps of the biopsy process. Having an injection needle
5 continually present at the site would make such colonoscopic procedures easier, more convenient and less time consuming for the physician and patient. More importantly, in the case of sudden and severe bleeding complications, epinephrine could be delivered without
10 having to insert through the endoscope or manipulate a separate device.

As such, a need exists for a device which allows locating both the injection needle and the snare simultaneously at the site of the lesion. However, such
15 a device should not permit the deployment of the injection needle until the snare is completely withdrawn and vice versa. This is necessary to prevent complications that can arise if both instruments are accidentally deployed simultaneously. Specifically, an
20 accidental perforation with a "hot" injection needle can short-out the conductive path of the snare. Also, the snare wire and injection needle can become entangled.

In view of the aforementioned shortcomings in the prior art, it is an object of the present invention
25 to provide a surgical apparatus for simultaneously deploying and retrieving a first instrument and a second instrument, respectively, by manipulating a single actuator assembly.

It is another object of the present invention
30 to provide a surgical apparatus for deploying and retrieving a first instrument and second instrument, respectively, wherein a locking mechanism prevents inadvertent deployment and retrieval of at least one of the first and second instruments, respectively.

35 It is a further object of the present invention to provide a surgical apparatus for independently

-4-

deploying and retrieving an injection needle and a snare for electrocautery in endoscopic procedures.

It is yet another object of the present invention to provide a surgical apparatus where a first
5 medical instrument is deployed while a second medical instrument is simultaneously retrieved and vice versa from an elongated sheathing member with a single-stroke actuator assembly.

It is still another object of the present
10 invention to provide a combination inject and snare device for use in endoscopic procedures where the simultaneous, opposite deployment and retrieval of an injection needle and a snare prevents undesirable complications which can arise from the injection needle
15 short-circuiting the conductive path of, or becoming entangled with the snare.

It is still another object of the present invention to provide a combination inject and snare device for use in endoscopic procedures which eliminates
20 the need for relocating the lesion or polyp when going from one procedure (e.g., injection of polyp) to another (e.g., separation of the polyp).

It is still another object of the present invention to provide a surgical apparatus for use in
25 endoscopic procedures where an injection needle and snare are simultaneously present near the site of the procedure while disposed at the distal end of the device for independent deployment and retrieval by the physician.

It is still another object of the present invention to provide an apparatus for simultaneously
30 deploying and retrieving a first instrument and a second instrument, respectively, in which a first sliding member disposed in a support member is operably coupled
35 to a second sliding member to facilitate simultaneous opposite travel of the first and second instruments relative to the distal end of an elongated sheath.

-5-

Summary of the Invention

In accordance with the above objects of the invention and additional objects which will become apparent hereinafter, the present invention provides an apparatus generally comprised of a first instrument (e.g., a snare for electrocautery) extendable in a first direction and retractable in a second direction; a second instrument (e.g., an injection needle) extendable in the first direction when the first instrument is retracted in the second direction, and retractable in the second direction when the first instrument is extended in the first direction; a sheath, either elongated or truncated, for the first and second instruments, the sheath having a distal end if elongated for remote procedures; a support structure having integral provisions for grasping by one of the user's fingers, such as the thumb; a first slide having provisions for grasping thereof, such as a pair of finger rings, where the first slide is slidably connected to the support for movement in the first direction and the second direction relative thereto and connected to at least one of the first instrument and the second instrument; and a second slide for enabling movement of the first instrument and the second instrument in opposite directions, where the first and second slides, respectively, are operably connected by an elongated endless belt having at least first and second axels affixed relative to the support, and the endless belt is attached to both the first and second slides, respectively, for causing the second slide to move in an opposite direction relative to the first slide when the first slide is translated relative to the support.

The support is generally an elongated structure having a pair of opposed rails which define a central channel and terminate at one end in a thumb-ring for

-6-

grasping, and a tapered front portion at the opposite end for receiving an elongated sheath.

In one embodiment of the invention, the sheath includes a distal end remotely disposed from the support for guiding the first and second instruments to a remote site, such as in colonscopic procedures. The sheath includes a plurality of lumens for receiving the first and second instruments as well as for receiving additional accessories which may be required to perform the procedure, such as an observation element or guidewire. The lumens serve to insulate the instruments from each other to prevent short circuiting if a snare is used for electrocauterization.

The first slide includes a pair of finger-rings for grasping, integrally formed with or attached to a hub which is slidably disposed on the support. The first slide is movable relative to the support towards and away from the respective ends thereof by grasping the thumb-ring with the thumb, and the finger-rings on the first slide with the forefinger and index finger. A connector attached to the hub communicates electrically with a wire coupled to the snare for attachment to an external power source, instrument or measuring device.

The second slide is slidably disposed within the channel of the support to facilitate deployment and retrieval of the second instrument in conjunction with the respective retrieval and deployment of the first instrument by moving the first slide relative to the support. The second slide is coupled to an endless belt which is positioned about the first and second axels within the channel of the support such that a single stroke of the first slide relative to the support effectuates the respective simultaneous deployment and retrieval of the first instrument and the second instrument relative to the distal end of the sheath. As an option, a locking means may be incorporated into the

-7-

device to prevent inadvertent deployment of the injection needle during the procedure. In the preferred embodiment, the locking means maintains the first slide in a neutral position where both the snare and injection
5 needle are retracted within the sheath.

Brief Description of Drawings

FIG. 1A is a partial top plan view of the surgical apparatus with the first slide in the fully extended position to deploy the loop-snare, and the
10 second slide in the fully retracted position to retrieve the injection needle;

FIG. 1B is a side elevational view of the surgical apparatus with the first slide in the fully extended position to deploy the loop-snare, and the
15 second slide in the fully retracted position to retrieve the injection needle;

FIG. 1C is a partial sectional view of the surgical apparatus depicting the deployment/retrieval mechanism when the loop-snare is deployed;

20 FIG. 1D is an enlarged partial top plan view of the surgical apparatus in the fully extended position to deploy the loop-snare showing the first slide in the snare position;

FIG. 2A is a partial top plan view of the surgical apparatus with the first slide in the fully retracted position to retrieve the loop-snare, and the
25 second slide in the fully extended position to deploy the injection needle;

FIG. 2B is a side elevational view of the surgical apparatus with the first slide in the fully retracted position to retrieve the loop-snare, and the
30 second slide in the fully extended position to deploy the injection needle;

FIG. 2C is a partial sectional view depicting
35 the deployment/retrieval mechanism when the injection needle is deployed;

-8-

FIG. 2D is an enlarged partial top plan view of the surgical apparatus with the first slide in the fully retracted position to retrieve the loop-snare and deploy the injection needle;

5 FIG. 3A is an isometric view of the surgical apparatus with the first slide in the neutral position where both the loop-snare and injection needle are maintained in a retracted position within the sheath;

10 FIG 3B is an enlarged partial top plan view of the surgical apparatus with the first slide maintained in the neutral position by the locking mechanism where both the loop-snare and injection needle are maintained in a retracted position within the sheath;

15 FIG. 4 is a sectional view along lines 4-4 of FIG. 1C; and

 FIG. 5 is a sectional view along lines 5-5 of FIG. 1C.

Detailed Description of the Preferred Embodiment

20 With reference to the several views of the drawings, there is provided a surgical apparatus generally characterized by the reference numeral 10 for deploying and retrieving a first instrument 12 and a second instrument 14 from an elongated sheath 16 by manipulating an actuator assembly 18.

25 Referring now to FIGS. 1A-1D, 2A-2D, and 3A, 3B, actuator assembly 18 comprises a support 20 fabricated from a plastic material such as polycarbonate, defined by a first end 24 and a second end 32. A thumb-ring 22 is disposed at or proximal to
30 the second end 32 to facilitate grasping. Support 20 is generally an elongated structure having a pair of opposed rails 26 which define a central channel 28. Rails 26 and channel 28 terminate in a front portion 30 at the first end 24. Front portion 30 includes a
35 tapered extension 31 having a hollow bore extending therethrough for attaching sheath 16 to the support. As

-9-

shown in FIGS. 1C and 2C, a first axle 34 is disposed within channel 28 and transversely positioned near front portion 30. A second axle 36 is disposed within channel 28 and transversely positioned rearwardly toward the second end 32 relative to the first axle 34.

Sheath 16 is defined by a proximal end 15 and a distal end 19. Sheath 16 is preferably fabricated from a flexible material such as teflon and includes a plurality of lumens 17 for connecting the first and second instruments 12, 14, respectively to the actuator assembly 18, and for connecting other accessories as required (not shown). As depicted in FIG. 5, the lumens 17 are appropriately sized to receive the respective instruments and any accessories therein. If there are only two instruments for use with the apparatus, sheath 16 may or may not have additional lumens which serve no functional purpose. In the exemplary embodiment, the first and second instruments are an injection needle and loop-snare for use in, for example, a polypectomy inject and snare or like procedure.

A first slide 38 for deploying and retrieving the first instrument 12 is slidably connected to support 20. The first slide 38 includes a pair of finger rings 40 for grasping by the user, which may be integrally formed with hub 42. An elongated tongue 44 integral with hub 42 and having a distal end 45 extends longitudinally beneath the rails 26 of support 20. The first slide 38 is movable relative to support 20 towards and away from the respective first and second ends 24 and 32 thereof by grasping finger ring 22 with the thumb and finger rings 40 with the forefinger and index finger.

To prevent inadvertent deployment of either of the first instrument 12 (e.g., the loop-snare 52) or the second instrument 14 (e.g., the injection needle 63), a locking mechanism 41 includes a pair of flexible fingers 43 having detents which project from the first slide 38

-10-

and interlock with tabs 45 disposed and projecting outwardly from the rails 26 of support 20. This arrangement prevents the first slide 38 from being accidentally moved relative to the support 20 without first applying finger pressure to the flexible fingers 43 to disengage the same from the tabs 45. In the illustrative embodiment, the tabs 45 are each provided with a tapered surface 45a where such taper allows the first slide 38 to be translated forwardly into the SNARE POSITION (FIGS. 1A-1D), to deploy the loop-snare 52 without having to manually depress the flexible fingers 43. Because the opposite side of tab 45 has a non-tapered surface 45b, the first slide 38 is prevented from being pulled rearwardly past the NEUTRAL POSITION (FIGS. 3A, 3B) and into the INJECTION NEEDLE POSITION (FIGS. 2A-2D), so as to prevent inadvertent deployment of the injection needle 63.

Of course, it is contemplated that tab 45 may be provided with identical non-tapered opposed surfaces 45b to prevent any movement of the first slide 38 from the neutral position (FIGS. 3A, 3B). Thus, any deployment or retrieval of either instrument would require that the user manually depress the flexible fingers 43.

As shown in FIG. 4, a connector 46 fabricated from electrically conductive material is disposed within and attached to hub 42 and extends upwardly to facilitate attachment to an external power source, instrument or measuring device (not shown). An insulative cap 47 is attached to hub 42 and includes a hollow bore 49 to provide access to connector 46. An elongated rod 48 is attached to and in electrical contact with connector 46 at one end thereof and attached to a flexible wire 50 at the opposite end thereof. Flexible wire 50 extends through a lumen 17 of sheath 16 and includes a loop-snare 52 (i.e., the first

-11-

instrument 12) at the distal end thereof. Loop-snare 52 may be attached to wire 50 by a swagged sleeve (not shown) or by other conventional methods.

A second slide 56 is slidably disposed within
5 channel 28 of support 20 to facilitate deployment and retrieval of an injection needle 63 (i.e., the second instrument 14) in conjunction with the respective retrieval and deployment of the loop-snare 52 by moving the first slide 38 relative to support 20. The second
10 slide 56 includes a bulbous head 58 which receives an injection needle extension line 59 which in turn is coupled to an injection needle sleeve 62. The injection needle sleeve 62 extends through a lumen 17 of sheath 16 where it is connected to injection needle 63 at its
15 distal end. A first aperture 64 extending through the second slide 56 permits rod 48 to pass therethrough and move independently, i.e., in a direction of travel opposite that of the second slide 56. In this manner, rod 48 can move in a first direction of travel while the
20 second slide 56 simultaneously moves in a second direction and vice versa. A second aperture 66 permits an endless belt 68 to pass through and connect to the second slide 56 to facilitate movement thereof. Alternatively, endless belt 68 could be fastened or
25 attached to the second slide 56 by other means, such as directly to the bottom surface 57 thereof in lieu of passing through aperture 66.

Endless belt 68 is supported by the first axle 34 and the second axle 36 within channel 28 and attached
30 to the distal end 45 of tongue 44. In this manner, as shown in FIGS. 1A-1C, when the first slide 38 is translated relative to support 20 towards the first end 24 thereof, wire 50 and attached loop-snare 52 move in a first direction relative to the distal end 19 of sheath
35 16 for deployment therefrom. Simultaneously, tongue 44 of the first slide 38 causes endless belt 68 to move the

-12-

second slide 56 in a second direction (i.e., rearwardly towards the second end 32 of support 20), thereby retrieving injection needle 63 until it is disposed entirely within its lumen 17 of sheath 16. Conversely, as shown in FIGS. 2A-2C, when the first slide 38 is translated towards the second end 32 (the end containing finger end 22), rod 48, wire 50 and the attached loop-snare 52 move in the second direction to retrieve the loop-snare 52 for storage entirely within its lumen 17 of sheath 16. At the same time, tongue 44 of the first slide 38 travels in the same direction (the second direction) to cause endless belt 68 to move the second slide 56 in the first direction to ultimately deploy injection needle 63 from the distal end 19 of sheath 16.

In view of the foregoing description of the invention, it will be appreciated that a single stroke of the first slide 38 relative to the support 20 effectuates the respective simultaneous deployment and retrieval of the first instrument 12 and second instrument 14. Although the exemplary embodiment of the invention which is described and illustrated herein relates to an apparatus to facilitate the deployment and retrieval of an injection needle and snare used in endoscopic procedures such as polypectomy injection, snare and retrieval, it is anticipated that an apparatus in accordance with the invention might have many other applications where it is desirable to simultaneously deploy one structure while retrieving a second structure, regardless of whether the independent structures are remotely attached to the device by elongated provisions such as those shown and described. In this regard, certain applications may only necessitate that the first and second instruments 12, 14 be deployed and retrieved from the support 20 which itself functions as the sheath, where the remote application of the instruments is not required (e.g., a

-13-

device for providing multiple injections or the like) or in other medical applications requiring the simultaneous deployment and retrieval of separate structures.

The present invention has been shown and
5 described in what is considered to be the most practical and preferred embodiment. It is anticipated, however, that departures may be made therefrom and that obvious modifications will occur to persons skilled in the art.

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-14-

We Claim:

1. An apparatus, comprising:
a first instrument;
a second instrument;
5 sheathing means for said first and second instruments, said sheathing means having a proximal end and a distal end; and
actuator means for simultaneously
extending said first instrument relative to said distal
10 end of said sheathing means in a first direction and retracting said second instrument in a second direction relative to said distal end of said sheathing means, and for simultaneously extending said second instrument relative to said distal end of said sheathing means in
15 said first direction and retracting said first instrument in said second direction relative to said distal end of said sheathing means.
2. The surgical apparatus recited in Claim 1, wherein said first instrument comprises an injection
20 needle and said second instrument comprises a snare.
3. The surgical apparatus recited in Claim 1, wherein said actuator means comprises:
a support having means for grasping
thereof;
25 a handle having means for grasping thereof, said handle slidably connected to said support for movement in said first direction and said second direction relative thereto and connected to at least one of said first instrument and said second instrument; and
30 slide means for enabling movement of said first instrument and said second instrument in opposite directions, said slide means movable with respect to said support and operably connected to said handle.
4. The surgical apparatus recited in Claim 3,
35 wherein said operable connection between said slide means and said handle comprises an elongated endless

-15-

belt having at least first and second axles affixed relative to said support, and said endless belt is attached to said slide means and attached to said handle for causing said slide means to move in said first and
5 second directions relative to said support.

5. The surgical apparatus recited in Claim 1, further comprising locking means for maintaining said first and second instruments in a retracted position within said sheathing means, said locking means
10 requiring manual manipulation thereof to facilitate extension and retraction of at least one of said first and second instruments relative to said sheathing means.

6. A surgical apparatus, comprising:
a needle attached to an elongated
15 extension line for communicating fluids to and from said needle, said needle being extendable in a first direction and retractable in a second direction;

a snare attached to an elongated extension line and extendable in said first direction when said
20 needle is retracted in said second direction and retractable in said second direction when said needle is extended in said first direction;

sheathing means for said needle, said snare and said extension lines, said sheathing means
25 having a proximal and a distal end; and

actuator means for independently extending said needle and said snare in said first and second directions relative to said distal end of said sheathing means.

30 7. The surgical apparatus recited in Claim 6, wherein said actuator means comprises:

a support having means for grasping thereof;

a first slide slidably connected to said
35 support for movement in said first direction and said second direction relative thereto and connected to at

-16-

least one of said first instrument and said second instrument; and

a second slide for enabling movement of said needle and said snare in opposite directions said second slide movable with respect to said support and operably connected to said first slide.

8. A surgical apparatus, comprising:

a first instrument extendable in a first direction and retractable in a second direction;

a second instrument extendable in said first direction when said first instrument is retracted in said second direction and retractable in said second direction when said first instrument is extended in said first direction;

sheathing means for said first and second instruments, said sheathing means having a proximal end and a distal end;

a support having means for grasping thereof;

a handle having means for grasping thereof, said handle slidably connected to said support for movement in a first direction and a second direction relative thereto and connected to at least one of said first instrument and said second instrument; and

slide means for enabling movement of said first instrument and said second instrument in opposite directions, said slide means movable with respect to said support and operably connected to said handle.

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AMENDED CLAIMS

[received by the International Bureau on 10 August 1995 (10.08.95);
original claim 2 cancelled; original claims 1,3-8 amended;
new claim 9 added (5 pages)]

We Claim:

1. An apparatus comprising:
a first instrument including an injection
needle;
5 a second instrument including a snare;
sheathing means for sheathing said first
and second instruments, said sheathing means having a
proximal end and a distal end; and
actuator means for simultaneously
10 extending said first instrument relative to said distal
end of said sheathing means in a first direction and
retracting said second instrument in a second direction
relative to said distal end of said sheathing means, and
15 for simultaneously extending said second instrument
relative to said distal end of said sheathing means in
said first direction and retracting said first
instrument in said second direction relative to said
distal end of said sheathing means.
2. The surgical apparatus recited in Claim 1,
20 wherein said first instrument comprises an injection
needle and said second instrument comprises a snare.
3. The surgical apparatus recited in Claim 1,
wherein said actuator means comprises:
a support having means for grasping
25 thereof;
a handle having means for grasping
thereof, said handle being slidably connected to said
support for movement in said first direction and said
second direction relative thereto and connected to at
30 least one of said first instrument and said second
instrument; and
slide means for enabling movement of said
first instrument and said second instrument in opposite
directions, said slide means being movable with respect
35 to said support and operably connected to said handle.
4. The surgical apparatus recited in Claim 3,
wherein said operable connection between said slide

means and said handle comprises an elongated endless belt and at least first and second axles affixed relative to said support, said endless belt being disposed about said axles and attached to said slide
5 means and attached to said handle for causing said means to move in said first and second directions relative to said support.

5. An apparatus, comprising:
a first instrument;
10 a second instrument;
sheathing means for sheathing said first and second instruments, said sheathing means having a proximal end and a distal end; and
actuator means for simultaneously
15 extending said first instrument relative to said distal end of said sheathing means in a first direction and retracting said second instrument in a second direction relative to said distal end of said sheathing means, and for simultaneously extending said second instrument
20 relative to said distal end of said sheathing means in said first direction and retracting said first instrument in said second direction relative to said distal end of said sheathing means; and
locking means for maintaining at least one
25 of said first and second instruments in a retracted position within said sheathing means, said locking means requiring manual manipulation thereof to facilitate extension and retracting of said at least one of said first and second instruments relative to said sheathing
30 means;

6. A surgical apparatus, comprising:
a needle attached to an elongated extension line for communicating fluids to and from said needle, said needle being extendable in a first
35 direction and retractable in a second direction;
a snare attached to an elongated extension line and extendable in said first direction when said

needle is retracted in said second direction and retractable in said second direction when said needle is extended in said first direction;

5 sheathing means for sheathing said needle, said snare and said extension lines, said sheathing means having a proximal and a distal end; and

actuator means for simultaneously extending said needle in said first direction and retracting said snare in said second direction, relative
10 to said distal end of said sheathing means.

7. A surgical apparatus, comprising:

a needle attached to an elongated extension line for communicating fluids to and from said needle, said needle being extendable in a first
15 direction and retractable in a second direction;

a snare attached to an elongated extension line and extendable in said first direction when said needle is retracted in said second direction and retractable in said second direction when said needle is
20 extended in said first direction;

sheathing means for sheathing said needle, said snare and said extension lines, said sheathing means having a proximal and a distal end; and

actuator means for extending said needle
25 in said first direction and retracting said snare in said second direction, relative to said distal end of said sheathing means; said actuator means including:

a support having means for grasping thereof;

30 a first slide slidably connected to said support for movement in said first direction and said second direction relative thereto and connected to at least one of said needle and said snare; and

35 a second slide for enabling movement of said needle and said snare in opposite directions, said second slide being

movable with respect to said support and operably connected to said first slide.

8. A surgical apparatus, comprising:

a first instrument extendable in a first
5 direction and retractable in a second direction;

a second instrument extendable in said first direction as said first instrument is being retracted in said second direction and retractable in said second direction as said first instrument is being
10 extended in said first direction;

sheathing means for sheathing said first and second instruments, said sheathing means having a proximal end and a distal end;

a support having means for grasping
15 thereof, said support and said sheathing means being secured together for movement as a unit;

a handle having means for grasping thereof, said handle being slidably connected to said support for movement in a first direction and a second
20 direction relative thereto and connected to at least one of said first instrument and said second instrument; and

slide means for enabling movement of said first instrument and said second instrument in opposite directions, said slide means being movable with respect
25 to said support and operably connected to said handle.

9. An apparatus comprising:

a first instrument;

a second instrument;

sheathing means for sheathing said first
30 and second instruments, said sheathing means having a proximal end and a distal end; and

actuator means for simultaneously extending said first instrument relative to said distal end of said sheathing means in a first direction and
35 retracting said second instrument in a second direction relative to said distal end of said sheathing means, and for simultaneously extending said second instrument

relative to said distal end of said sheathing means in
said first direction and retracting said first
instrument in said second direction relative to said
distal end of said sheathing means;

5 said sheathing means and said actuator
means being secured together for movement as a unit.

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STATEMENT UNDER ARTICLE 19

No prior art is cited against Claims 2, 5 and 7. The substance of cancelled Claim 2 has been incorporated into Claim 1, and Claims 5 and 7 have been
5 rewritten in independent form.

In Nakao et al. U.S. 5,336,227, while the sheathing means (endoscope 550) houses a snare 554 and a needle 578, each of these is truly independently movable in either direction. Thus the reference fails to teach
10 "actuator means for simultaneously extending said needle in said first direction and retracting said snare in said second direction," as required by amended Claim 6.

Amended Claim 8 requires "said support and said sheathing means being secured together for movement as a
15 unit." During a typical use of the Boncini et al. apparatus, the endoscope remains in place while the apparatus moves proximally or distally relative thereto.

New Claim 9 is similar to original Claim 1 except that it further requires "said sheathing means
20 and said actuator means being secured together for movement as a unit." In fact, the actuator means is typically used by the surgeon to assist in moving the apparatus both axially and torsionally to position the apparatus in the patient. Viewed from this perspective,
25 the endoscope with which the apparatus is typically used cannot be analogous to the claimed sheathing means as there must be relative movement between the sheathing means and the endoscope. In fact, the sheathing means and the first and second instruments are passed through
30 a lumen of the endoscope precisely in order to bring the distal end of the apparatus into the desired location within the patient. Accordingly, the endoscope and the actuator means are clearly not secured together for movement as a unit.

1/7

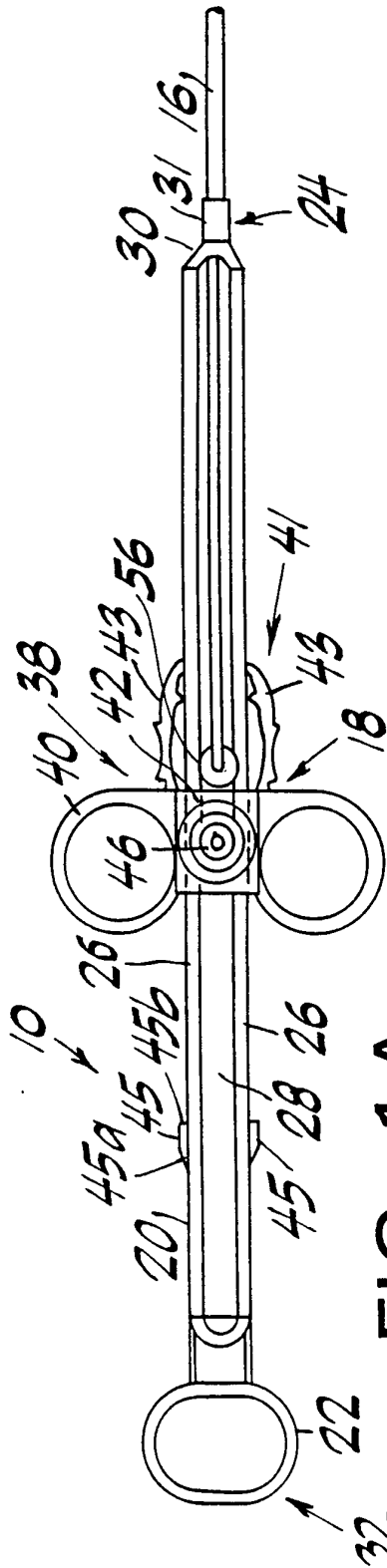


FIG. 1A

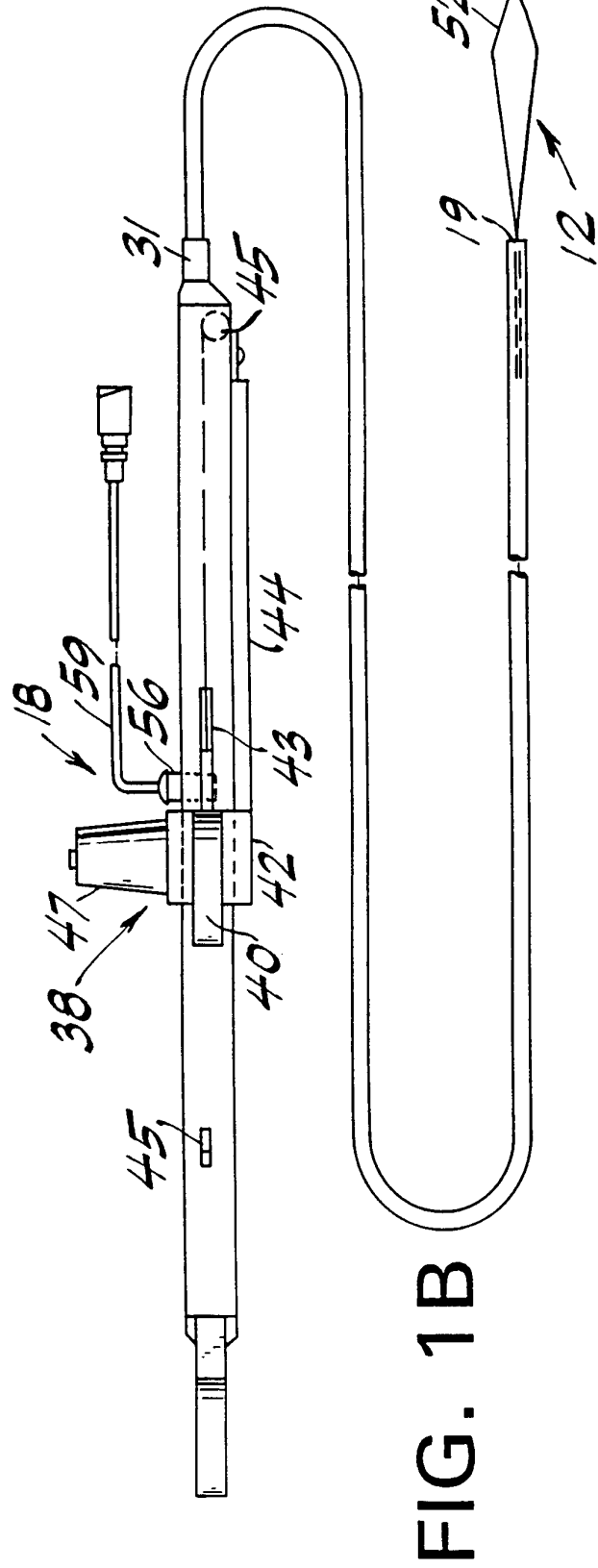


FIG. 1B

3/7

FIG. 2A

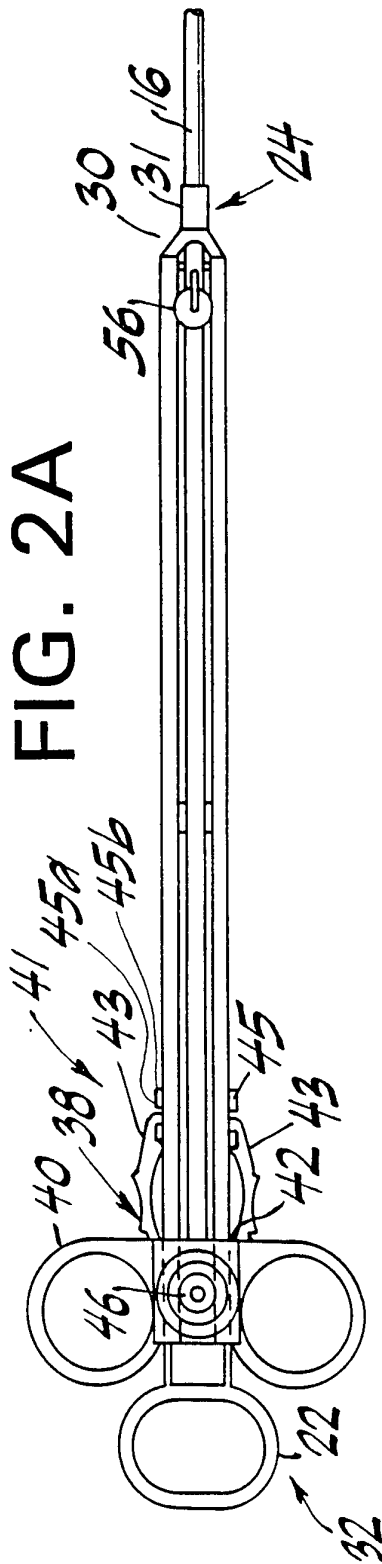
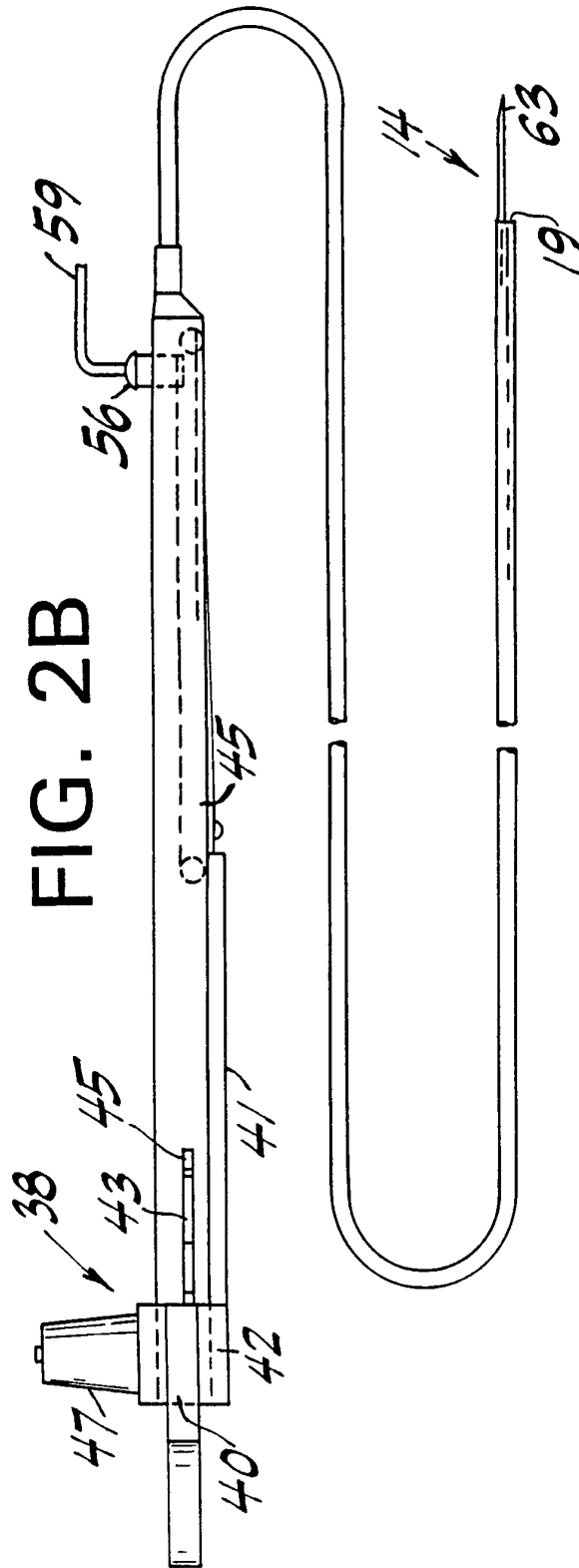
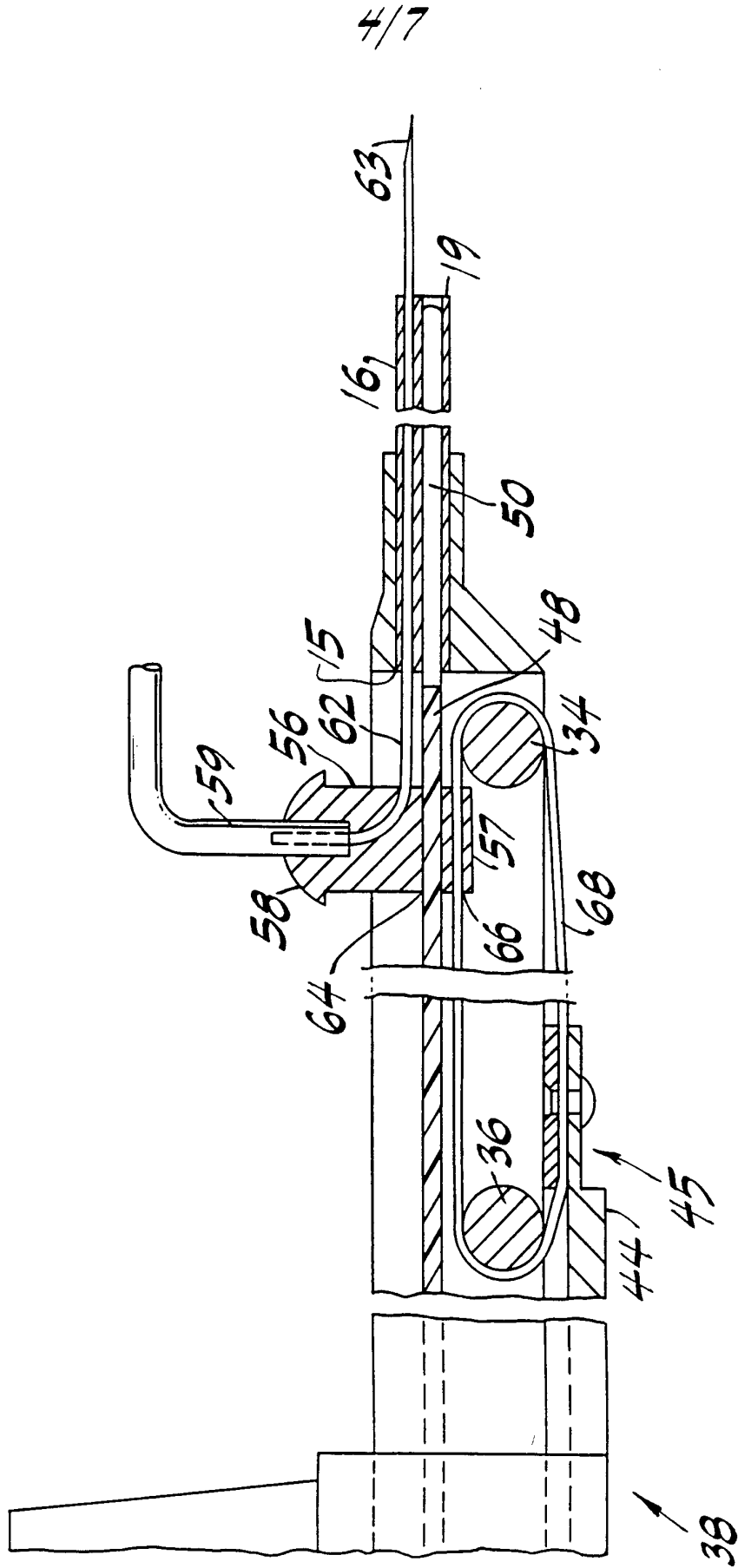


FIG. 2B





5/7

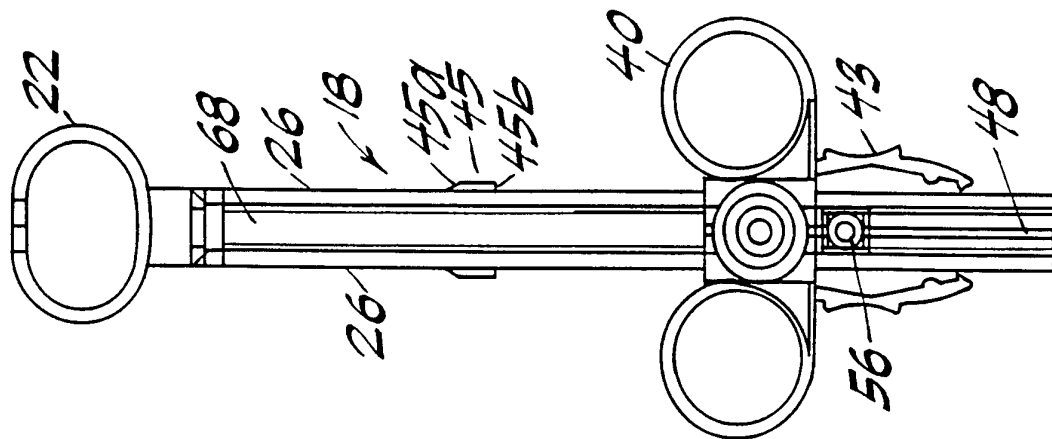


FIG. 1D

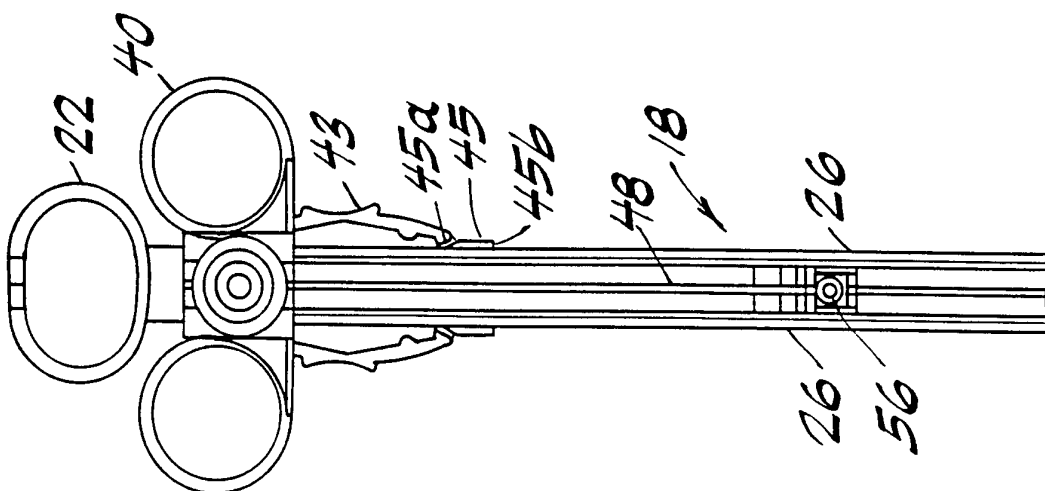


FIG. 2D

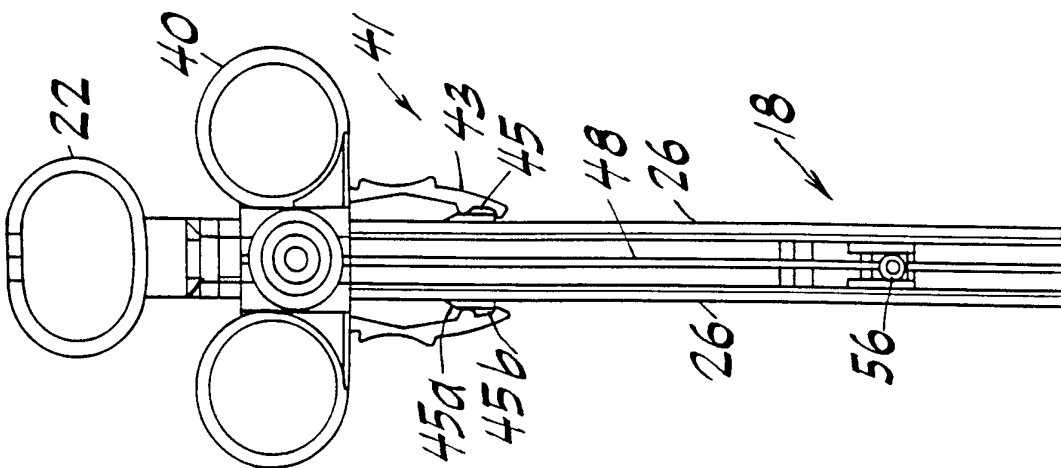


FIG. 3B

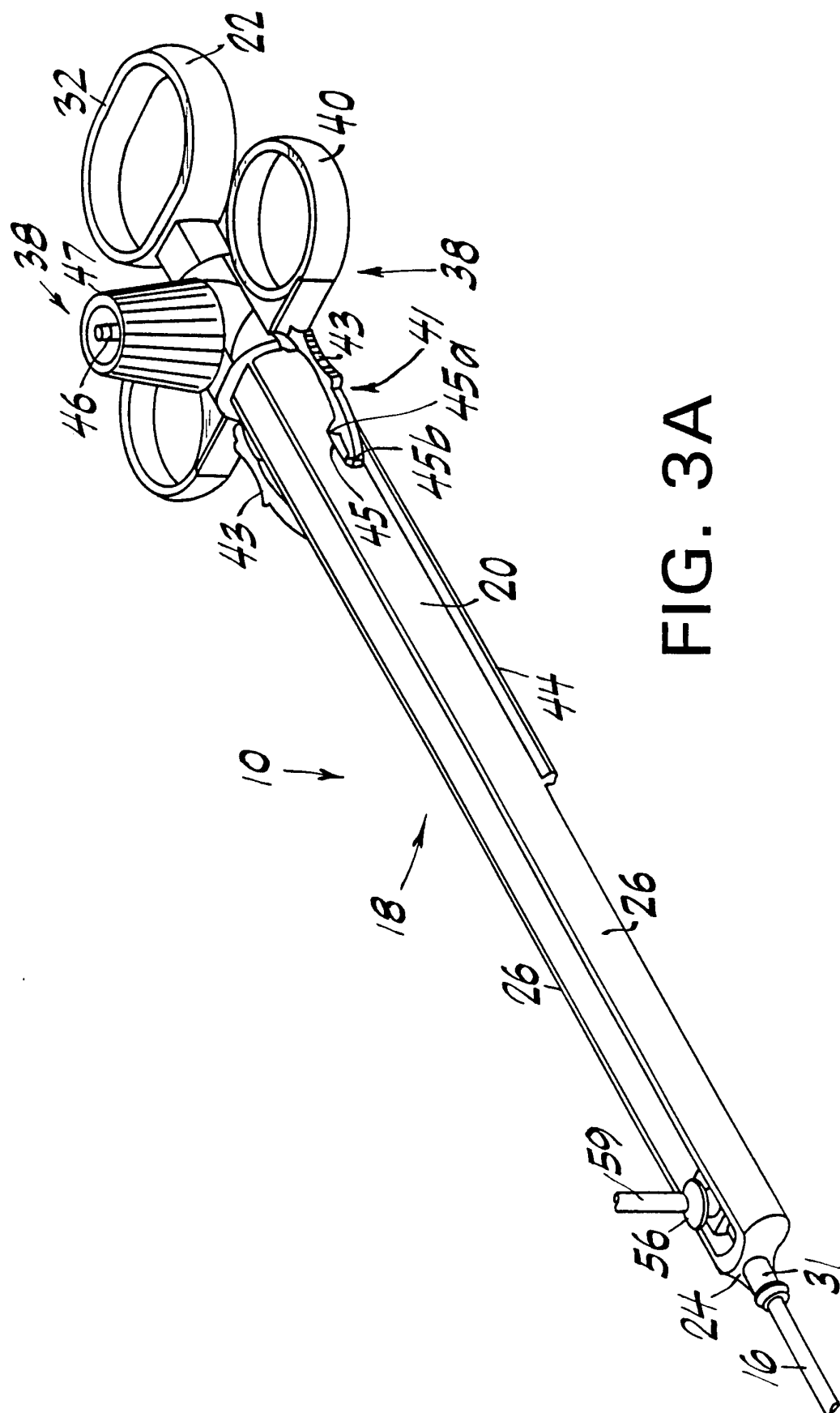


FIG. 3A

7/7

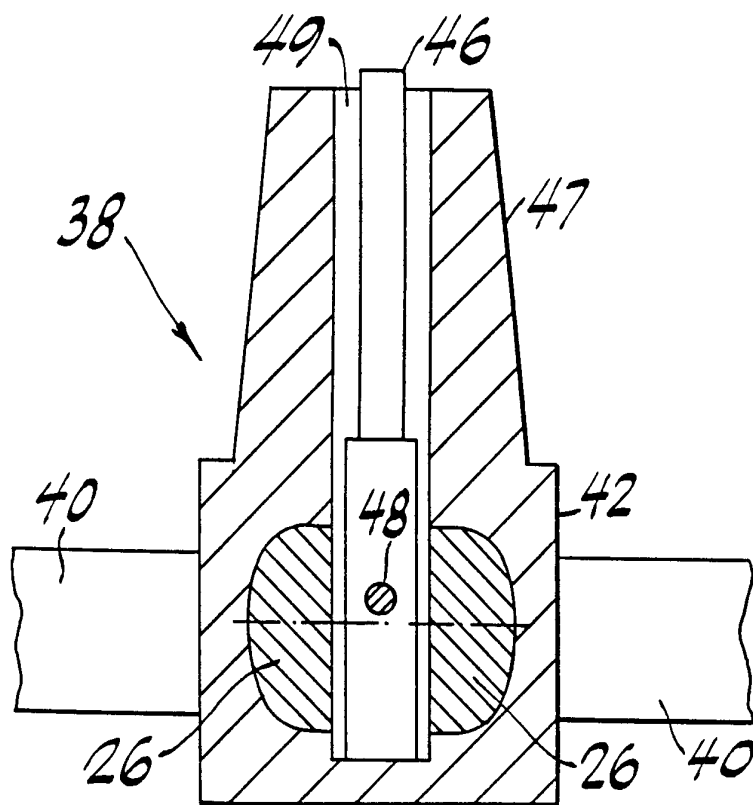


FIG. 4

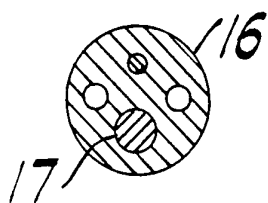


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/06380

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 19/00

US CL :604/264; 606/1, 113

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/264; 606/1, 37-50, 110, 113

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

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

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US, A, 5,336,227, (NAKAO ET AL.), 09 August 1994. See entire document.	6
Y	US, A, 5,084,054, (BENCINI ET AL.), 28 January 1992. See entire document.	1, 3, 4, 8
Y	US, A, 5,190,542 (NAKAO ET AL.), 02 March 1993. See entire document.	1, 3, 4, 8



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

10 JULY 1995

Date of mailing of the international search report

24 JUL 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

GLENN KEITH DAWSON

Telephone No. (703) 308-4304