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(54) THERMAL SUTURE WELDING APPARATUS AND METHOD

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(60) Provisional application No. 60/876,458, filed on Dec. 20, 2006, provisional application No. 60/876,196, filed on Dec. 20, 2006.

**Publication Classification**

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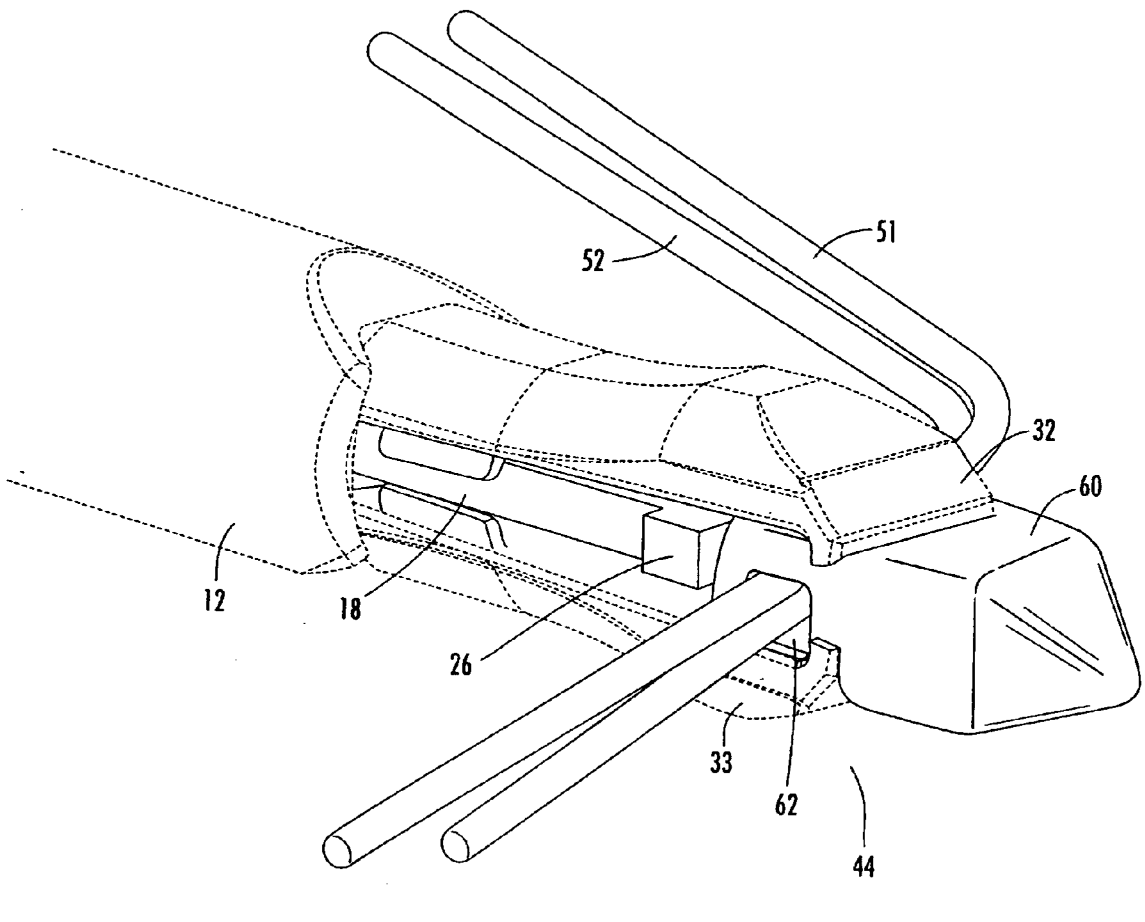
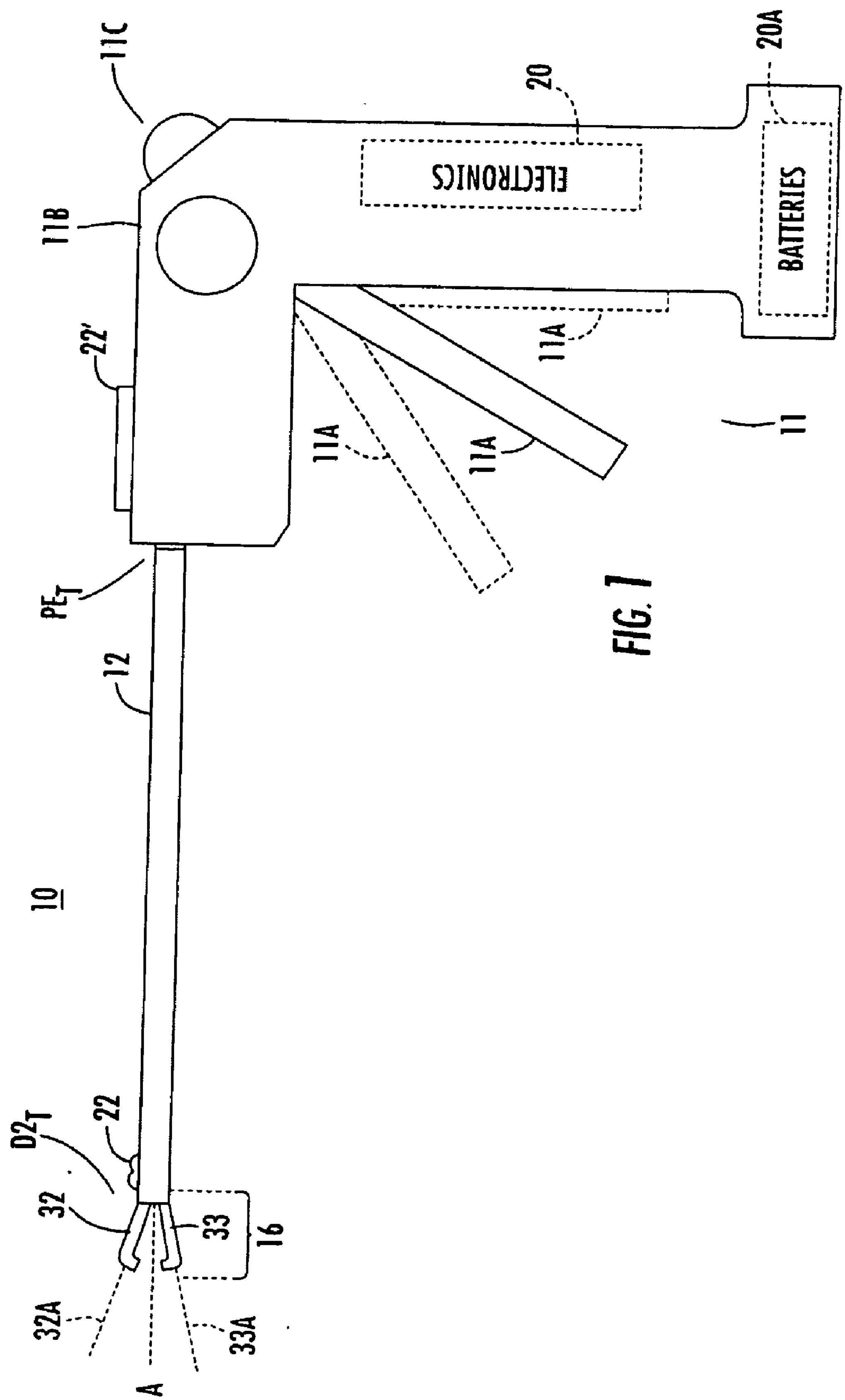
(52) **U.S. Cl.** ........................................ **606/144**; 606/139

(57) **ABSTRACT**

A method of suture welding is disclosed which includes: receiving suture segments between first and second jaw members, the first and second jaw members being in an open state. closing the first and second jaw members to captively hold and position the suture segments between the first and second jaw members; selectively applying an elongated joiner element to the suture segments where the joiner element has a selectively operative heating element facing the suture segments; and applying energy to the heating element to weld the suture segments-to-be-welded, whereby the heating element has a temperature above a predetermined threshold adapted to at least partially melt the suture segments.




10
11
11A
11A
11A
11B
11C
20
20A
ELECTRONICS
BATTERIES
22'
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33A
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FIG. 1

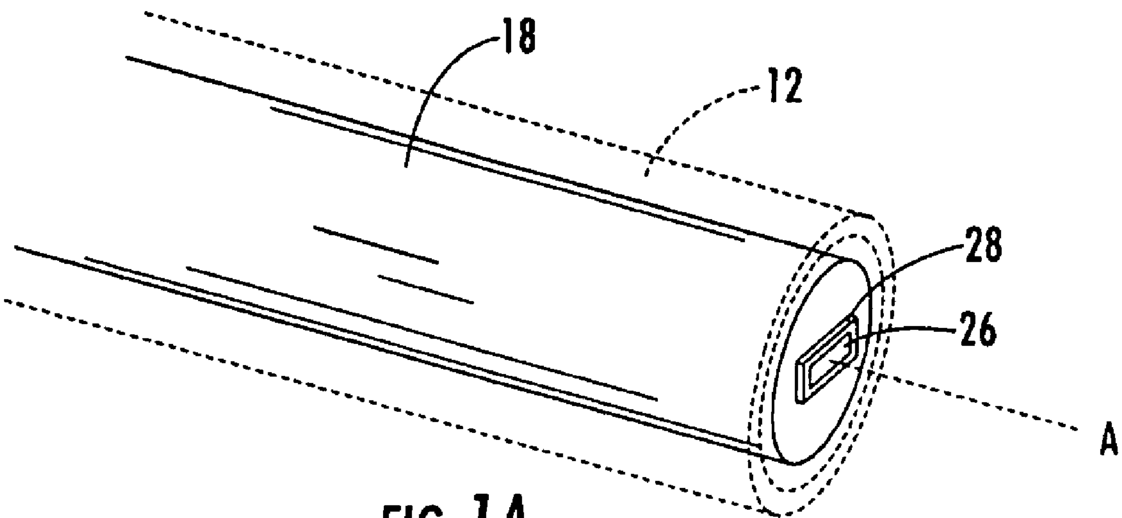


FIG. 1A

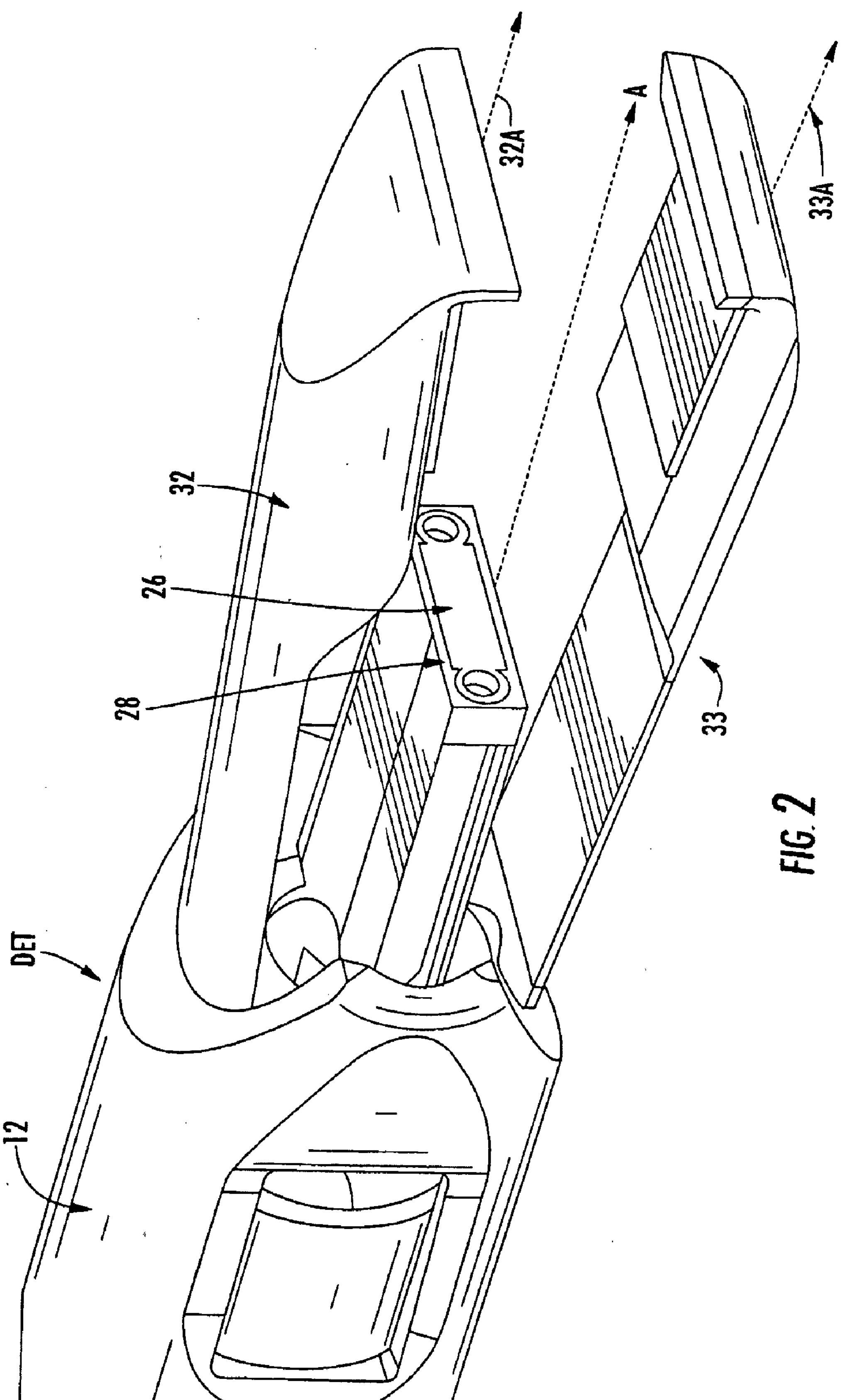


FIG. 2

LOAD POSITION

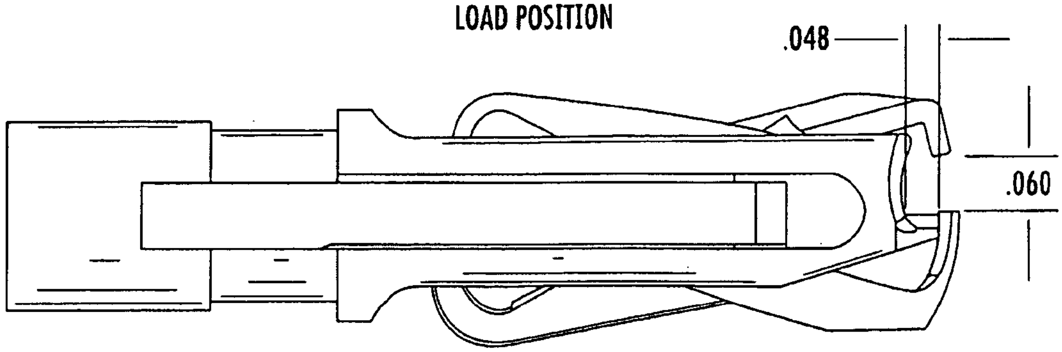


FIG. 2A

TENSION POSITION

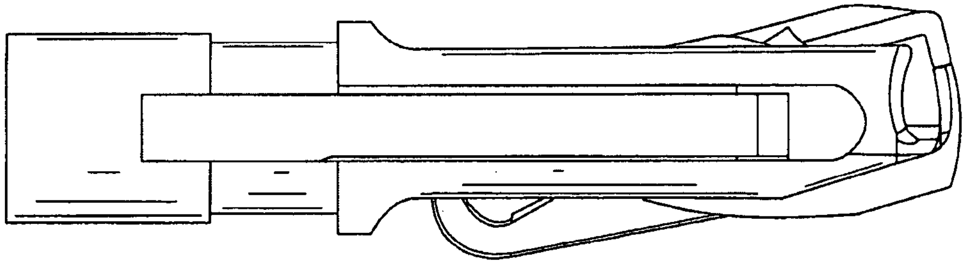

FIG. 2B

WELD POSITION

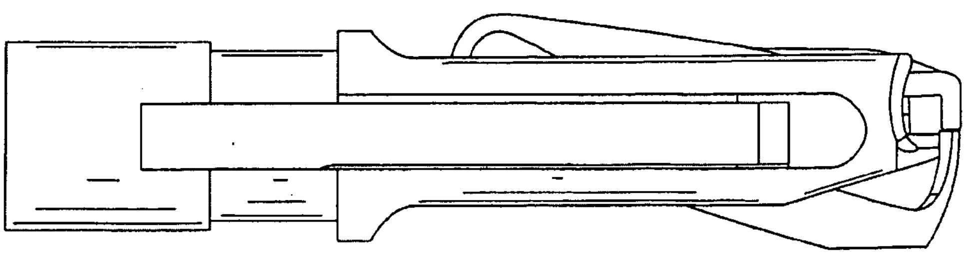

FIG. 2C

RELEASE POSITION

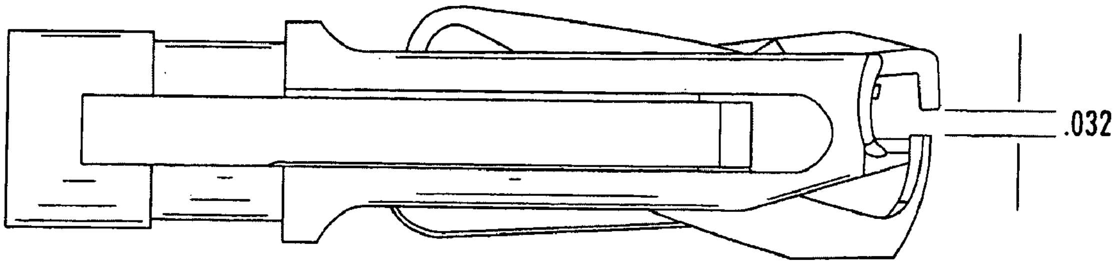


FIG. 2D

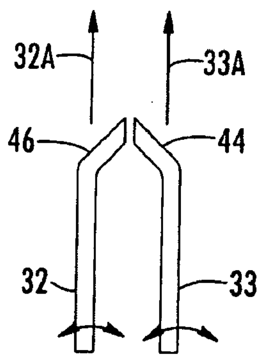


FIG. 3

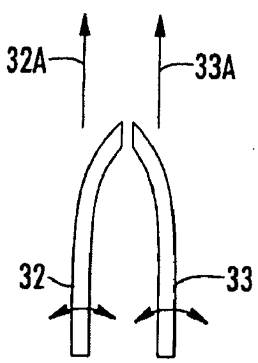


FIG. 4

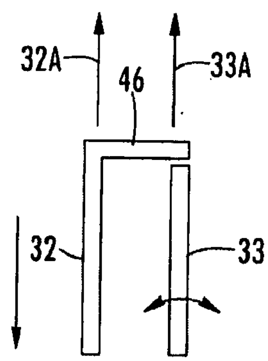


FIG. 5

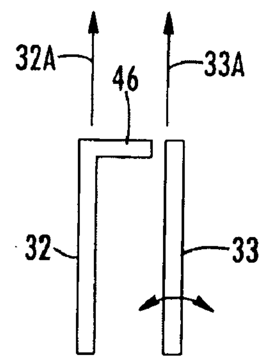


FIG. 6

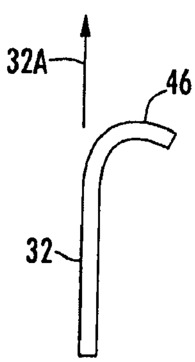


FIG. 7

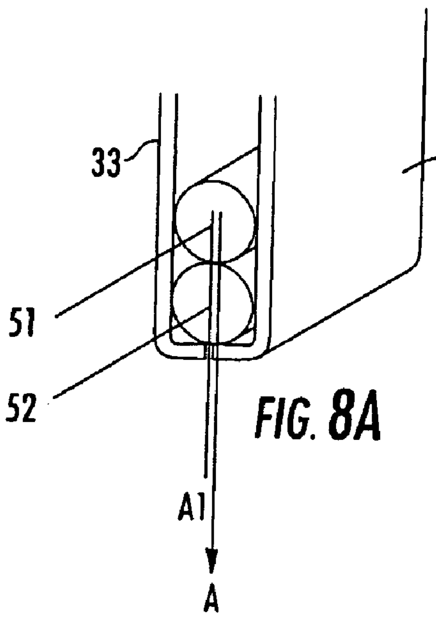


FIG. 8A

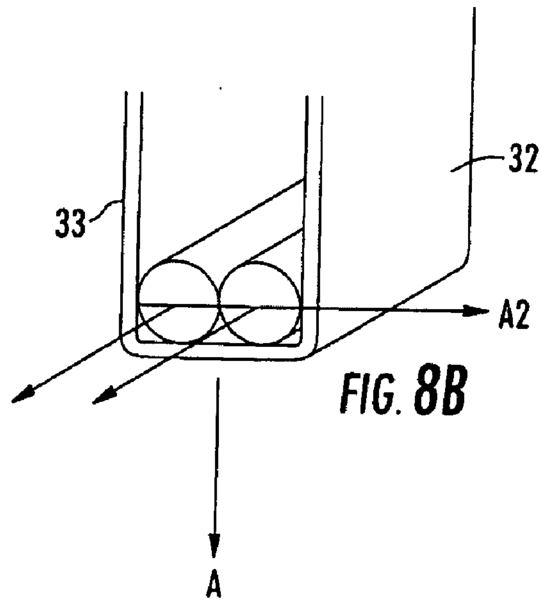


FIG. 8B

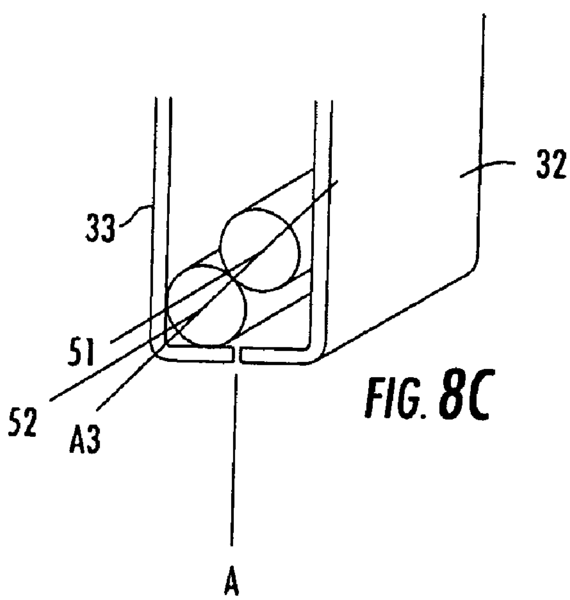


FIG. 8C

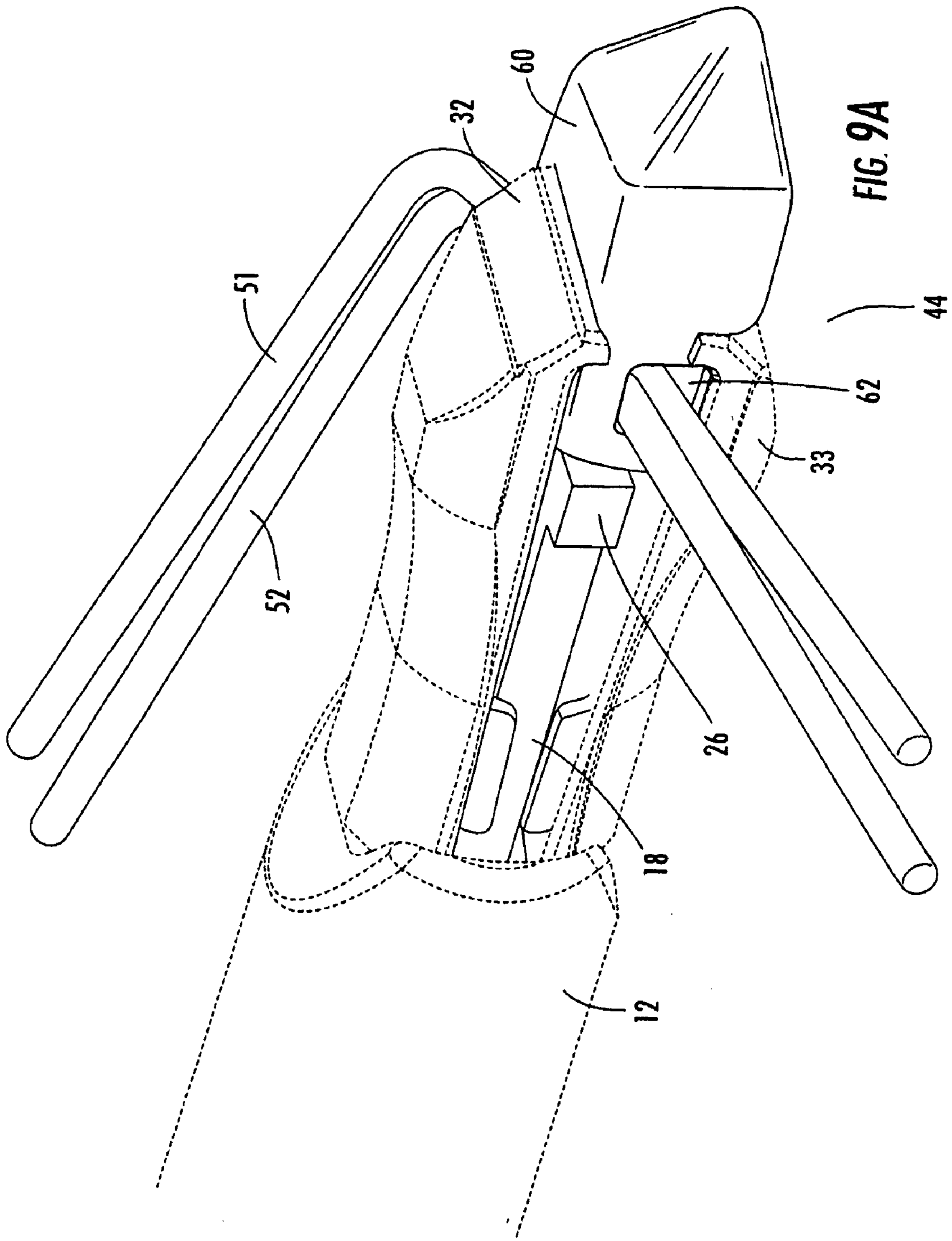


FIG. 9A

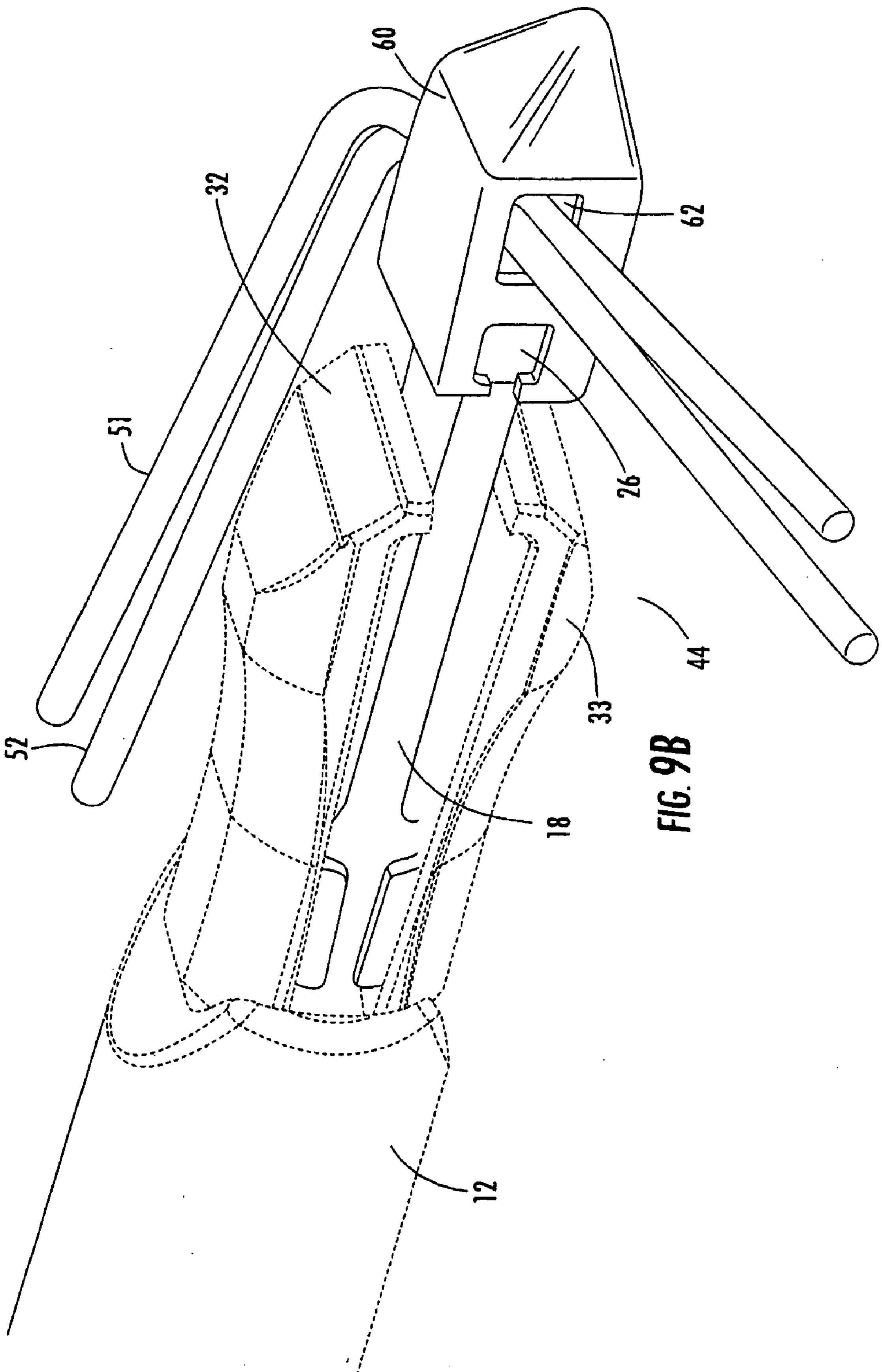


FIG. 9B

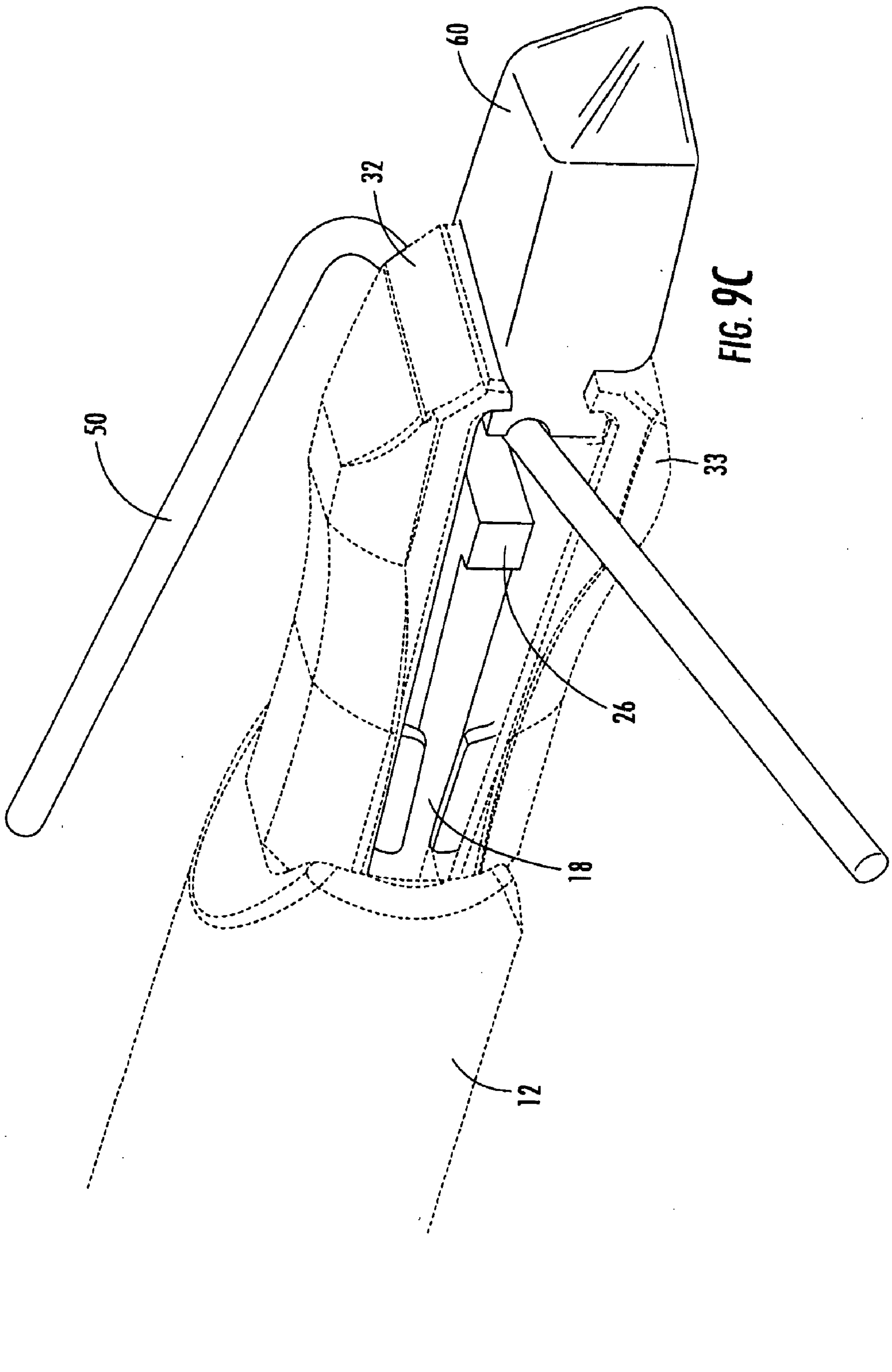


FIG. 9C

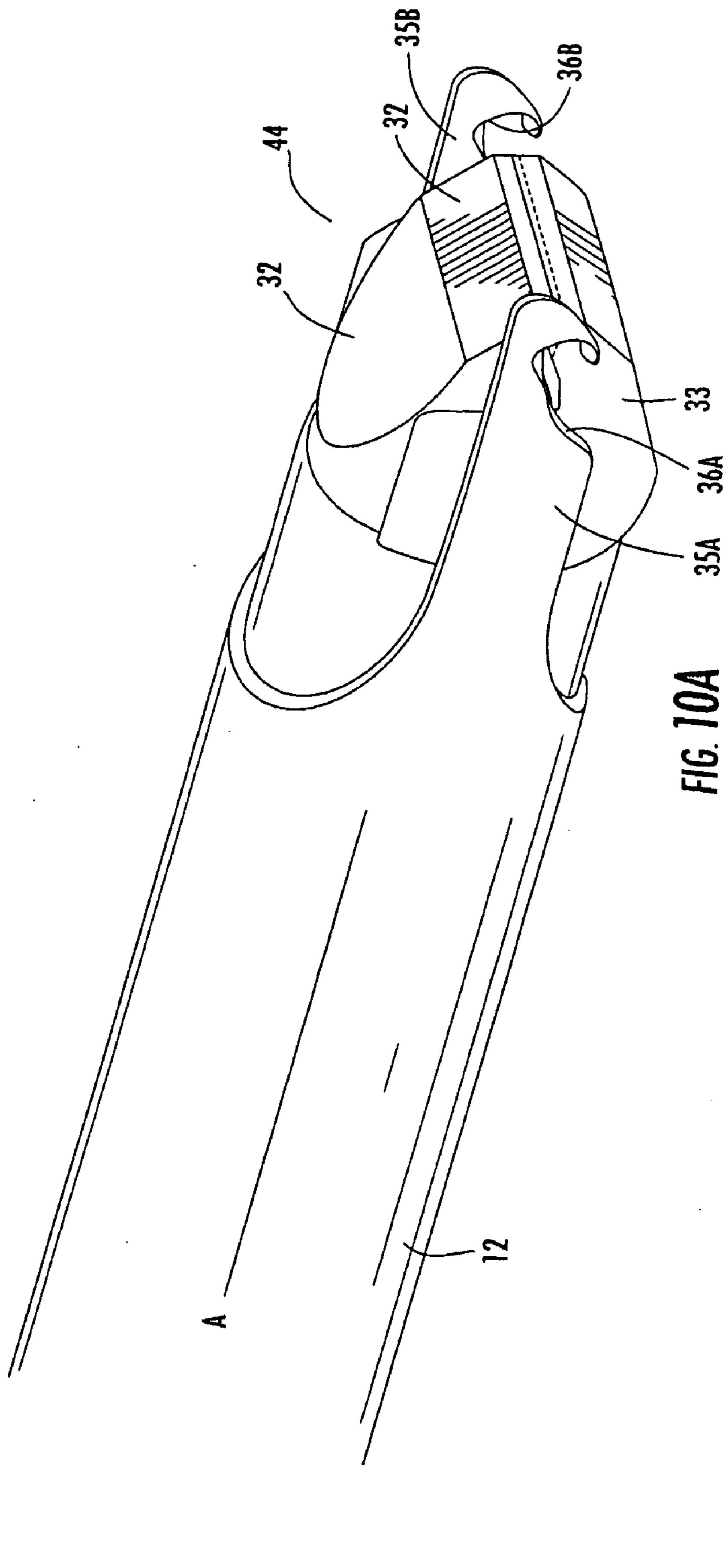


FIG. 10A

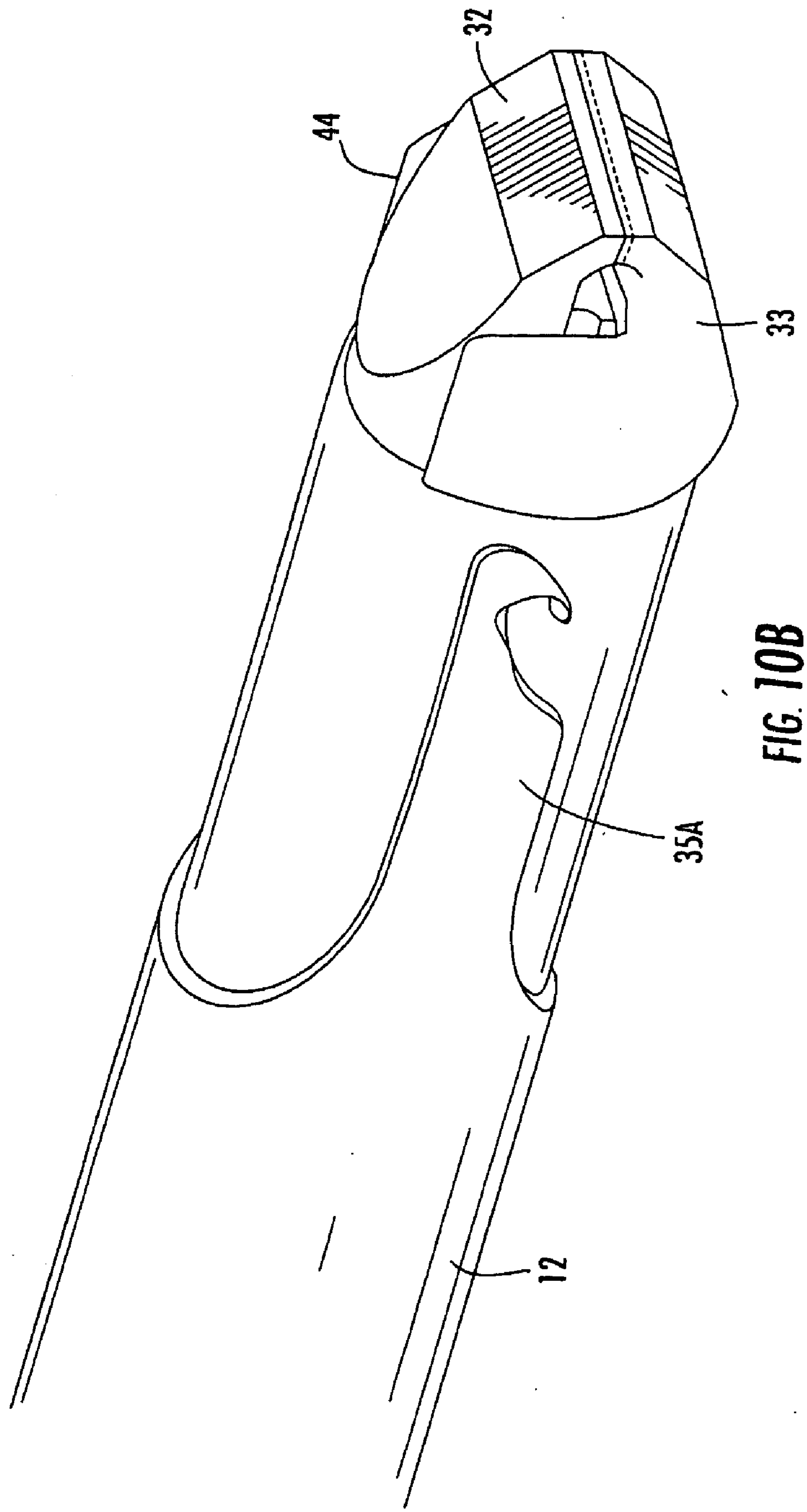


FIG. 10B

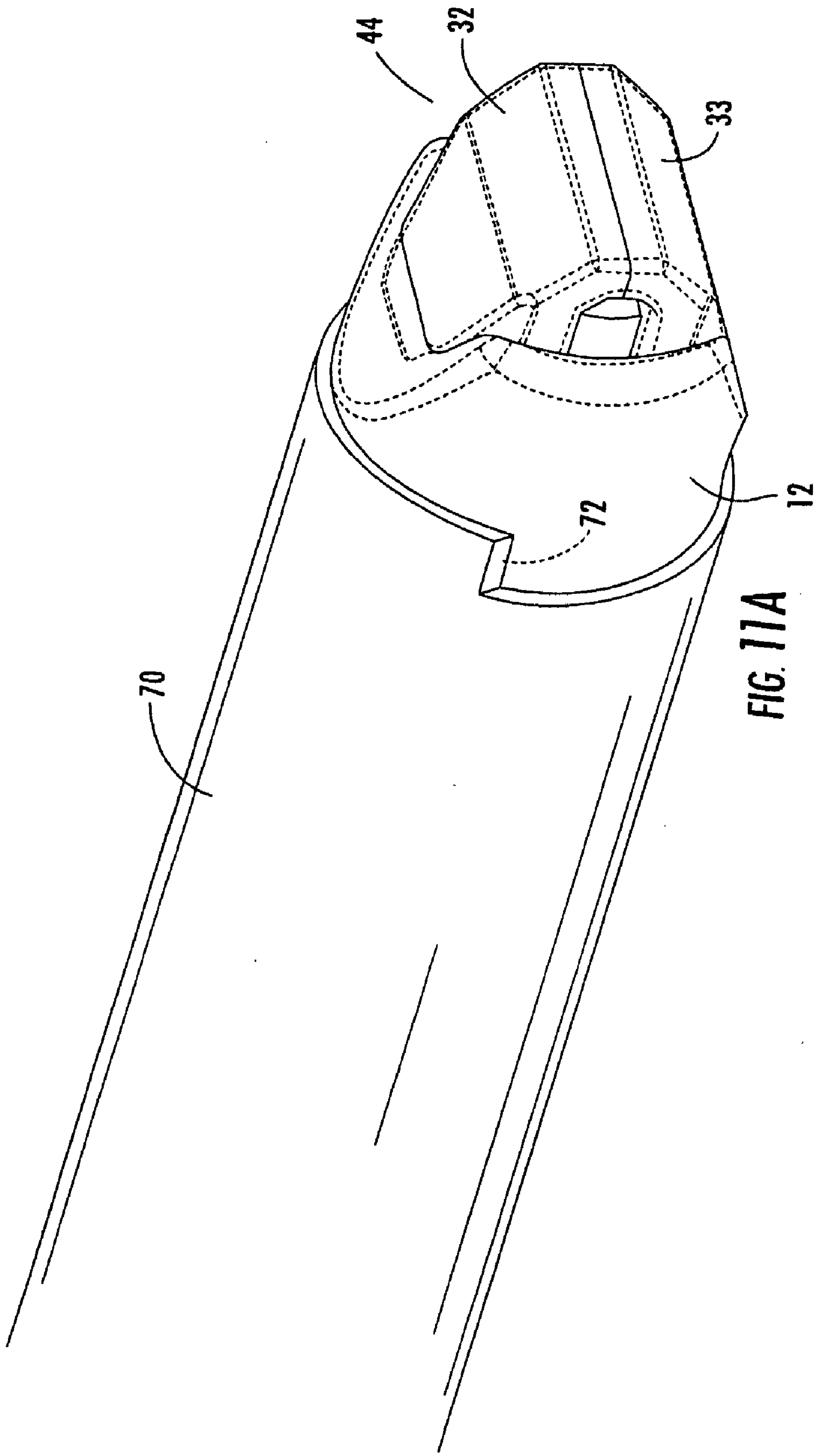


FIG. 11A

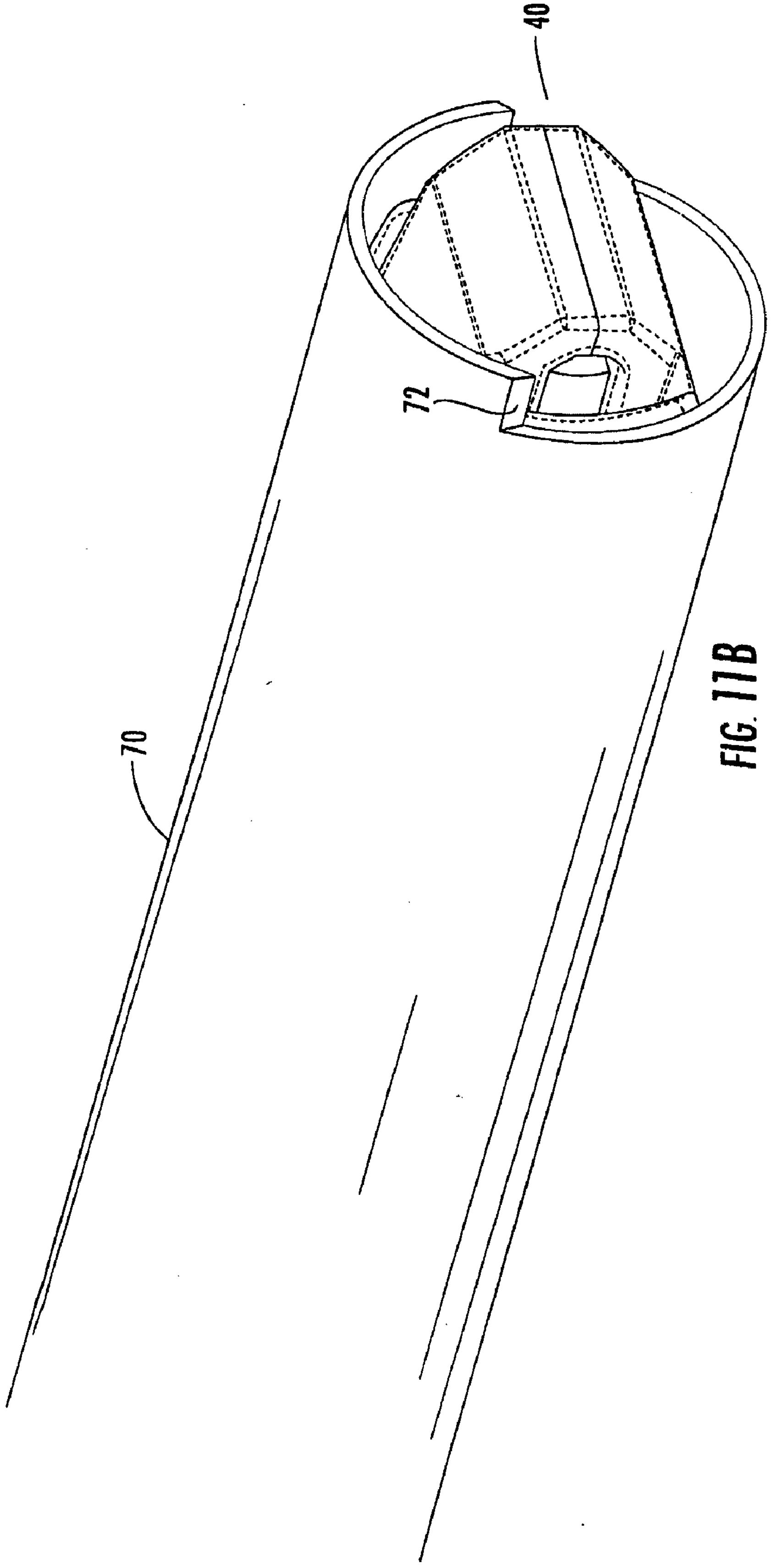


FIG. 11B

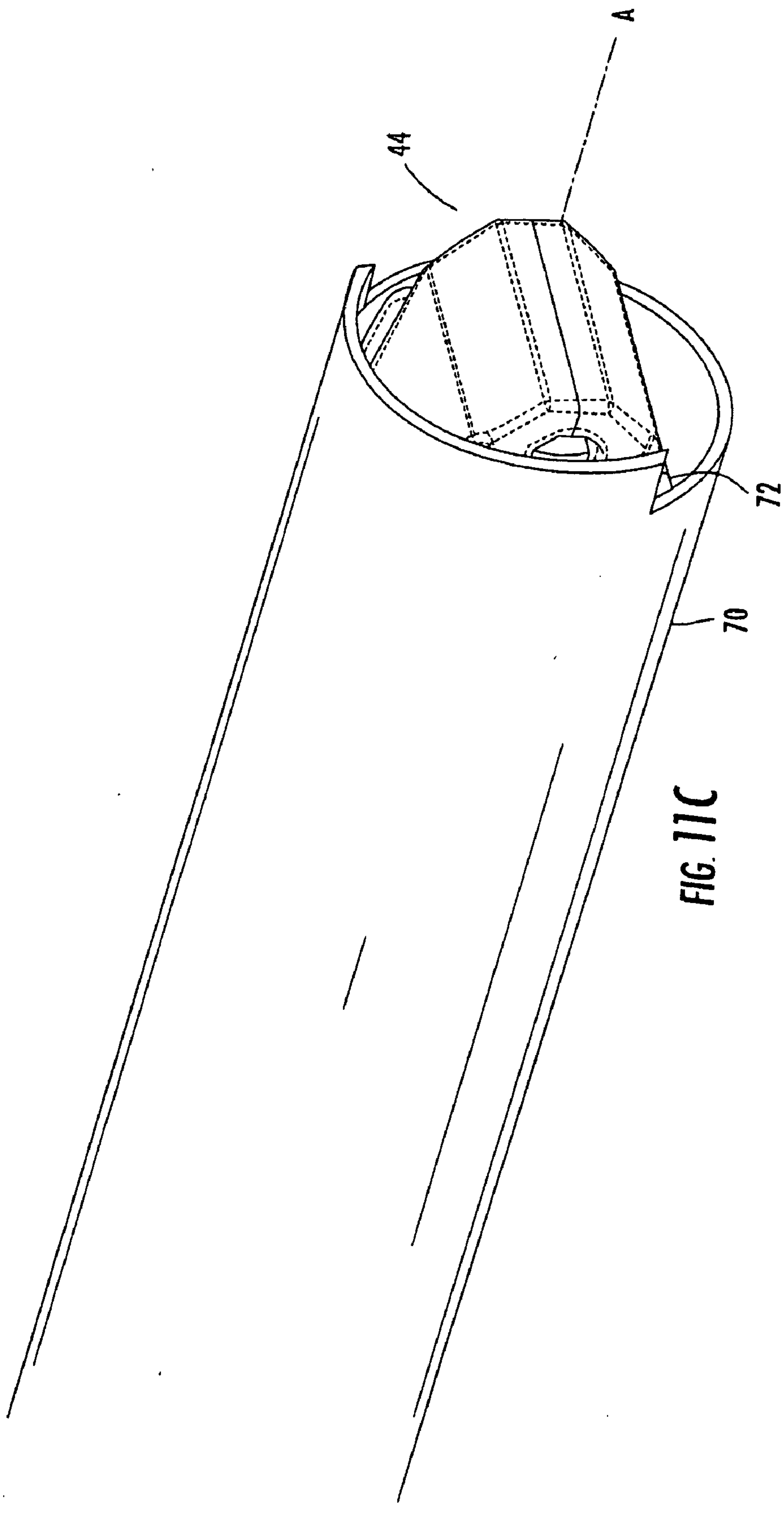


FIG. 11C

# THERMAL SUTURE WELDING APPARATUS AND METHOD

## CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. application Ser. No. 11/959,908, filed Dec. 19, 2007, which claims priority from U.S. Provisional Application Ser. No. 60/876,458 filed Dec. 20, 2006 and U.S. Provisional Application Ser. No. 60/876,196 filed Dec. 20, 2006, each of which are incorporated by reference herein in their entirety.

## BACKGROUND

[0002] The invention relates generally to improvements in suturing apparatus and suturing techniques, and more particularly to devices for making thermal suture welds during surgical procedures.

[0003] In surgical procedures, it is important to be able to form and secure sutures in place at the situs of surgery. The suture generally is directed through the portions of the tissue to be joined and formed into one or more single loops or stitches which then are knotted or otherwise secured to maintain the wound edges in the appropriate relationship to each other to facilitate proper healing. During surgical procedures involving delicate organs or tissues, or when the surgical site is relatively small or restricted, such as during endoscopic surgery, the formation of knots is cumbersome and often impractical. In such instances, a fused suture loop may be used to provide the appropriate tension on the tissue to be repaired and the appropriate strength to maintain the tissue repair as desired to allow proper healing to occur.

[0004] One method of forming suture loops often used during such surgeries is suture welding, whereby adjacent segments of the sutures are fused together upon the application of sufficient heat to the suture segments to cause partial melting and fusion of the suture segments, followed by cooling and fusion, to form one or more closed suture loops.

[0005] Such welding can occur, for example, due to direct application of ultrasonic energy to one or more of the suture segments-to-be-joined, so that vibratory motion between the suture segments causes frictional heating and consequent melting and fusion of the suture segments. Existing devices for forming welded sutures often produce undesirable heating of the surrounding tissue caused by the direct application of heat. As a result, other methods of suture welding, including ultrasonic energy-driven have increasingly been used for such endoscopic suture welding. However, ultrasonic suture welding is difficult with monofilament suture, and requires expensive metal jaws to isolate the ultrasonic energy. It is desirable to utilize thermal forms of suture welding to provide a cost-effective method of welding multifilament suture.

[0006] In the surgical procedures that are complicated, e.g., in procedures involving suturing multiple arteries, muscles, veins, and the like, in an endoscopic environment, it remains a desire to produce the welded sutures in a short time frame currently unavailable using existing apparatus and methods. For these reasons, there remains a need in the surgical field for a suture welding apparatus and methods directed to thermal suture welding to produce suture welds of improved strength and reliability for use with multifilament suture materials, in both open and restricted (e.g. endoscopic) surgical fields.

## SUMMARY

[0007] The present disclosure is directed to a method and devices for providing strong, reliable thermal welded sutures, particularly suited for use in endoscopic surgery, but is suitable also for use in an open surgical field. The invention is applicable to both monofilament suture materials and multifilament suture materials.

[0008] In one aspect, a suture welding device is disclosed which includes: an elongated tube extending along a central axis between a proximal end and a distal end, and a suture positioning assembly affixed to the distal end of the tube. The suture positioning assembly includes a first jaw member extending along a first jaw axis from a proximal end and a distal end, and a second jaw member extending along a second jaw axis from a proximal end and a distal end. At least one of the first and second jaw member includes an anvil portion at a distal end extending transverse to its respective jaw axis. The suture positioning assembly also includes a grasp assembly adapted to position the first jaw member opposite the second jaw member, the grasp assembly being selectively operative to position the first and second jaw members between two states: a first state where the first jaw member and the second jaw member are relatively divergent at the distal ends of the jaw members; and a second state where the first jaw member and the second jaw member are relatively non-divergent at the distal ends of the jaw members. The jaw members are adapted to captively hold and position suture segments-to-be-welded between the first and second jaw members when the grasp assembly is in the second state.

[0009] The suture welding device also includes an elongated joiner element extending along the central axis between a proximal end and a distal end, the joiner element having a selectively operative heating element disposed at the distal end of the joiner element; a compression and weld assembly operative to translate the joiner element along the central axis whereby in a first preparatory state, the distal end of the joiner element is relatively far from the anvil portion of the at least one jaw, and in a weld state, is relatively near and biased toward the anvil portion of the at least one jaw; and a weld controller selectively operative when the grasp assembly is in the second state and the compression and weld assembly is in the weld state, to apply energy to the heating element, whereby the heating element has a temperature above a predetermined threshold adapted to at least partially melt the suture segments captively held between the jaws.

[0010] In some embodiments, the first jaw member includes an anvil portion at the distal end extending transverse to the first jaw axis, and the second jaw member includes an anvil portion at the distal end extending transverse to the second jaw axis.

[0011] In some embodiments, the jaw members are adapted to position two suture segments of diameter D held therein in the second state with the suture segments being side-by-side transverse to the central axis, being side-by-side along the central axis, or being side-by-side along an axis oblique with respect to the central axis.

[0012] In some embodiments, the elongated tube is flexible. In some embodiments, the elongated tube is rigid.

[0013] In some embodiments, the suture segments are manufactured from materials that enable welding of such suture segments

[0014] In some embodiments, the joiner element remains within the suture positioning assembly during welding. In some embodiments, the joiner element extends beyond the suture positioning assembly during welding.

[0015] Some embodiments include an elongated sleeve member extending along the central axis. The sleeve member may include: a first hook member extending along the central axis and adjacent one side of the suture positioning assembly; having an inner surface thereof positioned transverse to the suture segments when the suture segments are captively held between the first and second jaw members; and a second hook member extending along the central axis and adjacent to a side of the suture position assembly opposite the first hook member, and having an inner surface thereof positioned transverse to the suture segments when the suture segments are captively held between the first and second jaw members. The suture positioning assembly is slidably engaged within the sleeve member to selectively cut the suture segments. In some embodiments, the first and second hook members are positioned downward relative to the central axis.

[0016] Some embodiments include an elongated sleeve member extending along the central axis from a distal end to a proximal end, where the sleeve member further includes a cutting edge along a portion of the proximal end; where the suture positioning assembly is slidably engaged within the sleeve member to selectively cut the suture segments.

[0017] In some embodiments the first jaw member extends along the first jaw axis without a flange, and the second jaw member includes a flange extending transverse to the second jaw axis in a direction at least partially towards the first jaw member. In some embodiments, the flange extends beyond a distal end of the first jaw, and, when the grasp assembly is in the second state, the distal end of the first jaw rests against a surface of the flange facing the distal end of the first jaw member. In some embodiments, when the grasp assembly is in the second state, an end of the flange distal from the second jaw axis rests against a surface of the distal end of the first jaw member facing the second jaw member.

[0018] In some embodiments, the grasp assembly includes an anchor adapted to receive the suture segments, the jaw members are adapted to captively hold and position the suture segments and the anchor between the first and second jaw members when the grasp assembly is in the second state; and the weld controller is selectively operative when the grasp assembly is in the second state and the compression and weld assembly is in the weld state, to apply energy to the heating element, whereby the heating element has a temperature above a predetermined threshold adapted to at least partially melt the anchor captively held between the jaws. In some embodiments, the anchor is a bone anchor.

[0019] In some embodiments, the elongated tube is adapted to be received in an endoscopic surgical field.

[0020] In another aspect, disclosed is a suture welding device, including an elongated tube extending along a central axis between a proximal end and a distal end, a suture positioning assembly affixed to the distal end of the tube. The suture positioning assembly includes: a hooked jaw member extending along a jaw axis from a proximal end and a distal end, and including a hooked flange portion at the distal end extending transverse to the jaw axis, the hooked flange portion being substantially curved and of sufficient length to provide a welding surface against which suture segments-to-be-welded may be compressed during welding. The hooked jaw member is adapted to captively hold and position the suture segments-to-be-welded against the welding surface. The device also includes an elongated joiner element extending along the central axis between a proximal end and a distal end, the joiner element having a selectively operative heating element disposed at the distal end of the joiner element; a compression and weld assembly operative to translate the joiner element along the central axis whereby in a first preparatory state, the distal end of the joiner element is relatively far from the welding surface, and in a weld state, is relatively near and biased toward the welding surface; and a weld controller selectively operative when the compression and weld assembly is in the weld state, to apply energy to the heating element, whereby the heating element has a temperature above a predetermined threshold adapted to at least partially melt the suture segments captively held against the welding surface.

[0021] In another aspect, a method of suture welding is disclosed which includes: receiving suture segments between first and second jaw members, the first and second jaw members being in an open state. closing the first and second jaw members to captively hold and position the suture segments between the first and second jaw members; selectively applying an elongated joiner element to the suture segments where the joiner element has a selectively operative heating element facing the suture segments; and applying energy to the heating element to weld the suture segments-to-be-welded, whereby the heating element has a temperature above a predetermined threshold adapted to at least partially melt the suture segments.

[0022] Some embodiments include aligning two or more of the suture segments side by side. In some embodiments, the first and second jaws are disposed at an end of an elongated tube having a central axis; the suture segments comprise two suture segments; and the closing the first and second jaw members to captively hold and position the suture segments between the first and second jaw members includes positioning the two suture segments with the two suture segments being side-by-side transverse the central axis, side-by-side along the central axis, or side-by-side along an axis oblique with respect to the central axis.

[0023] Some embodiments include, after closing said first and second jaw members to captively hold and position the suture segments between said first and second jaw members, tensioning one or more of the suture segments.

[0024] Some embodiments include, after applying energy to said heating element to weld the suture segments, cutting a portion of one or more of the suture segments.

[0025] In some embodiments, selectively applying a joiner element to the suture segments includes compressing the suture segments between said joiner element and a surface of said jaw members

[0026] Various embodiments may include any of the above described features, alone or in any combination. These and other features will be more fully appreciated with reference to the following detailed description which is to be read in conjunction with the attached drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0027] Embodiments are further described by the following description and figures, in which:

[0028] FIG. **1** is a schematic view of an exemplary thermal suture welding apparatus of the present invention;

[0029] FIG. 1A is a schematic view of the distal end of the compression and weld assembly of the thermal suture welding apparatus of FIG. 1;

[0030] FIG. 2 is a perspective view of an embodiment of the jaw assembly portion of the thermal welding suture apparatus of FIG. 1

[0031] FIG. 2A is a side plan view of the jaw assembly of FIG. 2 in a first, load position;

[0032] FIG. 2B is a side plan view of the jaw assembly of FIG. 2 in a second, tension position;

[0033] FIG. 2C is a side plan view of the jaw assembly of FIG. 2 in a third, companion weld position; and

[0034] FIG. 2D is a side plan view of the jaw assembly of FIG. 2 in a fourth, cutting position.

[0035] FIGS. 3-7 are side plan views of alternative embodiments of the jaw members;

[0036] FIG. 8A is a cross-sectional side view of two suture segments-to-be-joined, aligned adjacent each other within the suture positioning assembly of the apparatus of FIG. 1 where the two suture segments are disposed along the central axis of the elongate tube of the thermal welding suture apparatus;

[0037] FIG. 8B is a cross-sectional side view of two suture segments-to-be-joined, aligned adjacent each other within the suture positioning assembly of the apparatus of FIG. 1 where the two suture segments are disposed along an axis transverse to the central axis of the elongate tube of the thermal welding suture apparatus; and

[0038] FIG. 8C is a cross-sectional side view of two suture segments-to-be-joined, aligned adjacent each other within the suture positioning assembly of the apparatus of FIG. 1, where the two suture segments are disposed along an axis oblique with respect to the central axis of the elongate tube of the thermal welding suture apparatus.

[0039] FIG. 9A is a schematic view of an alternative embodiment of the thermal suture welding apparatus, having a bone anchor held within the grasper assembly.

[0040] FIG. 9B is a schematic view of the embodiment of the thermal suture welding apparatus, having a bone anchor held within the grasper assembly and beyond the end of the jaws.

[0041] FIG. 9C is a schematic view of the thermal suture welding apparatus, having a bone anchor held within the grasper assembly and for use with a single suture segment.

[0042] FIG. 10A is a schematic view of the thermal suture welding apparatus, having hook elements in an extended, deployed position.

[0043] FIG. 10B is a schematic view of the thermal suture welding apparatus as shown in FIG. 10A, having hook elements in a retracted position.

[0044] FIG. 11A is a schematic view of the thermal suture welding, having an outer sleeve rotary cutter in its retracted position.

[0045] FIG. 11B is a schematic view of the thermal suture welding apparatus as shown in FIG. 11A, showing the rotary cutter in its extended position.

[0046] FIG. 11C is a schematic view of the thermal suture welding apparatus as shown in FIG. 11B, showing the rotary cutter in its extended position and rotated approximately 45 degrees about the central axis to cut a suture extending laterally between the jaw.

[0047] Like reference numerals refer to like elements throughout the figures.

## DETAILED DESCRIPTION

[0048] As shown in FIGS. 1, 1A, and 2, an exemplary thermal suture welding apparatus 10 includes an elongate tube 12 extending from a proximal end $PE_T$ to a distal end $DE_T$ along a central axis A. The tube 12 contains therewithin a portion of a compression and weld assembly 14 (not shown in FIG. 1) and is coupled to a suture positioning assembly 16 at the distal end $DE_T$ of tube 12. A user activation/handle activation assembly 11 is affixed to the proximal end $PE_T$, of tube 12. The tube 12 may be substantially rigid or flexible, depending upon the anticipated surgical use of the apparatus 10. Many biocompatible materials, or materials coated with a biocompatible coating may be used to manufacture the tube 12 and suture positioning assembly 16, including, for example polyetheretherketone, polyphenylene sulfide, polyetherimide, and other polymers. Coatings may contain PTFE, polyimide, epoxies, alumina, silicon carbide, ceramics, and gold, titanium, or other metalized coatings. In an embodiment, the tube 12 is manufactured from stainless steel for a rigid tube 12, or from nitinol or thermoplastics for a flexible tube.

[0049] In an embodiment, the compression and weld assembly 14 comprises an actuation lever 11A (and associated mechanical coupling, not shown on the activation assembly 11), and elongate tube 12 (including therein, a joiner element 18 and a heater 26). As shown in FIG. 1A, the joiner element 18 is an elongated rod which may have a heater 26 supported thereon at its distal end. The joiner element 18 is slidably movable along the central axis A of the tube 12 within a channel 13 in tube 12 in response to user-applied forces (via lever 11A of actuation assembly 11). The joiner element 18 is adapted to be selectively driven toward distal end $DE_T$ of tube 12 to compress and weld (via heater 26) suture segments (not shown) held in place near the distal end $DE_T$ by the suture positioning assembly 16, as described in detail below.

[0050] The joiner element 18 preferably is manufactured from stainless steel hypodermic tubing, but may be manufactured from any material that provides sufficient strength to bias the heating element 26 against the suture segments-to-be-welded (not shown) as supported by an anvil-like surface (not shown) created by jaw flanges, as described in further detail below. Typically, the range of compression is between 1500 psi and 6000 psi of clamping pressure against the suture segments.

[0051] In an embodiment, and as shown in FIG. 2, the joiner element 18 includes heater 26 positioned on a heater substrate 28. In this embodiment, heater 26 is resistively heated by electrical current driven therethrough, applied via wires (not shown) extending from proximal end $PE_T$ of tube 12. The voltage used for driving the current is controlled by an external heater controller 20 that may be user controlled or computer controlled. Alternatively, the voltage may be controlled using a switched internal current source (such as a battery).

[0052] The heater element 26 preferably is manufactured from a biocompatible material (or material coated with a biocompatible material). Preferably, heater 26 has a positive thermal coefficient of resistivity (TCR). A suitable material is, for example, gold, or gold plated silver, but alternative materials may include silver, copper, platinum, nickel, or nickel iron. With that configuration, the heater 26 may be used as a heat source (to effect the thermal weld) and at the same time be used as a temperature sensor. The temperature sensor aspect of heater **26** has a resistance value which is fed back to the controller **20** (for example, in a bridge network), where it is used to control the current applied to heater **26**, so that a desired temperature-over-time profile may be provided with high precision, in a closed loop manner. The substrate **28** may be a ceramic material, such as alumina ($A_2O_3$) that acts to thermally isolate the heater **26** so that precise temperature control can be attained. In some embodiments, the substrate **28** may be a polyimide.

**[0053]** In response to user action on lever **11**A, the joiner element **18** may be slidably positioned within the elongate tube **12** for selectively and compressively driving the heater **26** against the suture segments-to-be-welded once such segments are positioned in the suture positioning assembly **16**, as described further below. In alternative embodiments, one or more heaters may be disposed on various surfaces of the suture positioning assembly, rather than on the distal end of joiner element **18**. Positioning of the joiner element **18** will vary depending on the configuration of the suture positioning assembly, the anticipated use of the apparatus **10**, and other similar variables.

**[0054]** As shown in the illustrated embodiment of FIGS. **1** and **2**, a suture cutting assembly **22** is disposed near distal end $DE_T$ of tube **12**. Suture cutting assembly **22** includes movable (along axis A) blades **34**A and **34**B disposed on opposite sides of tube **12**. The blades are operable in conjunction with associated blade windows **40**A (only one window shown) near the distal end $DE_T$ of tube **12**.

**[0055]** The blades **34**A, **34**B are movable along axis A in response to user force applied to cutter control **22**A on activation assembly **11**. For deployment to a cutting position, the user applies a force to cutter control **22**A toward the distal end $DE_T$ and along beveled surfaces **43**A (and **43**B) in tube **12** to a cutting position as shown in FIG. **2**D.

**[0056]** As described in further detail below, when the suture segments-to-be-welded **51**, **52** are securely positioned in the suture positioning assembly **16**, and then welded together, the cutting edge **42**A, **42**B of blades **34**A, **34**B trim off excess suture material from the welded suture loop (not shown).

**[0057]** The joiner element **18** is used as a compression element, such that the compression of the suture segments-to-be-welded **51**, **52** against an anvil-like surface **48** (as shown in FIGS. **2**B and **2**C) occurs while the heating element **26** is positioned against the suture segments-to-be-welded **51**, **52** in a manner that simultaneously applies pressure and heat to the target suture segments. As melting begins to occur (as a result of the applied heat), the compressive force biases the melting suture segments **51**, **52** toward each other, co-mingling the adjacent segments, to effect an optimum geometry of the ultimately welded suture segments.

**[0058]** The suture positioning assembly **16** is affixed to the distal end $DE_T$ of the elongate tube **12**, and generally comprises a pair of opposing jaws **32**, **33**, and a grasp assembly **44** (internal to tube **12**) for selectively moving the jaws **32**, **33** in scissors-like opposition to each other for captively positioning and holding the suture segments-to-be-welded **51**, **52** between the jaws (or at least against an anvil-like surface formed by the jaw flanges **46**, **47**, as discussed in further detail below), in a position for welding. The jaws **32**, **33** preferably are manufactured from a rigid biocompatible, material such as polyetheretherketone, polyphenylene sulfide, polyetherimide, and other polymers. In alternative embodiments, one or more of the jaws **32**, **33** may be manufactured from a biocompatible plastic or metallic resilient material coated with an insulator, such as an elastomer of sufficient rigidity to enable a desired compression during the application of the heat necessary for satisfactory suture welding. The jaws **32**, **33** extend along respective ones of jaw axes **32**A and **33**A. In some embodiments, jaws **32**, **33** are rigid and in other embodiments, one or both jaws **32**, **33** are flexible.

**[0059]** In an embodiment, and as shown in FIG. **2**, the jaws **32** and **33** are split anvil shaped, each jaw having a flange **46**, **47**, respectively, extending transverse to jaw axes **32**A, **33**A for both securing the suture segments-to-be-welded **51**, **52** and for providing, when in a closed position, a surface (or "anvil" **48**) against which the compression joiner element **18** may compress the suture segments-to-be-welded **51**, **52** during welding. In the illustrated embodiment, the flanges **46**, **47** are extend perpendicular to the jaw axes **32**A, **33**A and are integral with and rigidly attached to the jaws.

**[0060]** Alternative embodiments of the jaws **32**, **33** are shown in FIGS. **3**-**7**. In FIG. **3**, the flanges **46**, **47** are similar to those shown in FIG. **2** except that they are at oblique angles to jaw axes **32**A and **33**A. When positioned in a closed position, the flanges **46** and **47** form an angled anvil surface (not shown) against which the suture segments-to-be-welded are compressed during welding. In an alternative embodiment, shown in FIG. **4**, the jaws **32**, **33** do not have flanges, but are curved in a bow-like manner toward each other, such that when closed, the distal ends of the jaws **32**, **33** close to form the anvil surface **48** against which the sutures-to-be-welded are compressed during welding. In this embodiment, the jaws material preferably is of a rigid material to ensure that the jaws remain securely closed during welding and are not pushed apart during compression of the suture segments-to-be-welded.

**[0061]** FIGS. **5** and **6** show alternative embodiments of the jaws **32**, **33** whereby the bottom jaw **33** extends along the jaw axis **33**A without a flange, and the upper jaw **32** includes a flange **46**. In the illustrated embodiment of FIG. **5**, the flange **42** extends beyond the distal end of the bottom jaw **33** such that the flange **46** forms the anvil surface against which the suture segments-to-be-welded are compressed during welding. In the illustrated embodiment of FIG. **6**, the distal end of the flange **46** rests against the inner surface of the distal end of the bottom jaw **33**, again forming the anvil surface **48** against which the suture segments-to-be welded are compressed during welding. Although the illustrated embodiments of FIGS. **5** and **6** show the bottom jaw **33** without a flange and the upper jaw **32** having a flange **46**, the inverse configuration also may be used. That is, the bottom jaw **33** may include a flange **47** while the upper jaw **32** is a straight jaw extending in the direction of the central axis A without a flange.

**[0062]** In yet another embodiment of the suture positioning assembly **16**, as shown in FIG. **7**, only a single jaw **32** is used. This illustrated jaw **32** has a flange **46** positioned integral to or attached to the distal end of the jaw **32**. This illustrated flange **46** is substantially curved and of sufficient length to provide the surface against which the suture segments-to-be-welded are compressed during welding.

**[0063]** Each of these suture positioning assemblies **16** may be used together with the compression and weld assembly **14** to form the apparatus **10** of the present invention, and may be manufactured using the materials described above.

**[0064]** The grasper assembly **44** of the apparatus **10** comprises lever **11**A, jaws **32** and **33** and an intermediate mechanical linkage (for example of a conventional type). In the configuration of FIGS. **1** and **2**, the grasper assembly **44** is responsive to user control (via lever **11**A) at activation assembly **11** to selectively control jaws **32**, **33** to be between open and closed positions. With lever **11**A in a first position (POS**1** in FIG. **1**), the jaws are in an "open" position, jaws **32**, **33** are in a relatively divergent first state with their distal ends (and respective axes **32**A, **33**A) separated as shown in FIG. **1**. Position POS**1** is referred to as a "load" position where suture segments-to-be-welded can be loaded between jaws **32**, **33** for subsequent welding. POS**1** is illustrated in FIG. **2**A.

**[0065]** With lever **11**A in a second position (POS**2** in FIG. **1**), the jaws are in a "closed" position wherein, jaws **32**, **33** are in a relatively non-divergent second state with their distal ends close or touching POS**2** is referred to as a tension position wherein the suture segments-to-be-welded (not shown) can be tensioned by drawing the ends thereof around cleats **11**B using a rapid advance tensioning central **11**C on assembly POS**2** is illustrated in FIG. **2**B.

**[0066]** With lever **11**A in a third position (POS**3** in FIG. **1**) the jaws **32**, **33** are also in their closed position, and the joiner element **18** (and heater **26**) are maximally displaced toward distal end $DE_T$ and biased against the anvil-like surface **48** of the closed jaws **32**, **33**.

**[0067]** POS**3** is referred to as the "compression/weld/cut" position. In this position, suture segments-to-be-welded, which have been loaded and captured between jaws **32**, **33**, are compressed and welded by joiner element (illustrated in FIG. **2**C) and subsequently, the excess suture material is cut via cutter **22'** (illustrated in FIG. **2**D).

**[0068]** In an embodiment, the grasper assembly **44** and suture positioning assembly **16** are movable along central axis A, so that when the jaws **32**, **33** are in their open position (as shown in FIG. **1**), the jaws **32**, **33** are almost entirely beyond the distal end $DE_T$ of tube **12** and when the jaws **32**, **33** are in their closed position, the jaws **32**, **33** are retracted and are almost entirely within the tube **12**.

**[0069]** Also, when the distal end, $DE_T$ of tube **12** is deployed to a surgical site, the jaws **32**, **33** can be in their retracted position so as to minimize the cross-sectional dimensions of suture positioning assembly **16** at the distal end $DE_T$ of tube **12**.

**[0070]** In an embodiment of the invention, the suture segments-to-be-welded are manufactured from materials that enable the segments to be welded together. These materials may include polyester, Kevlar, nylon or polyethylene, by way of example. In an alternative embodiment, the suture segments may be welded to a surface treated with a material that enables the suture segments to be welded thereto. In practicing that embodiment, and by way of example, the suture segments may be welded to the surface of a bone anchor, which surface is treated with a material that enables such welding. Examples of materials that may be used in this embodiment include polyester, Kevlar, nylon or polyethylene.

**[0071]** In practicing the present invention, the surgeon prepares the suture segments-to-be-welded either by knotting or merely overlapping such suture segments. The sutures may be prepared so that the segments-to-be-welded may be readily aligned with their respective central axes parallel. In practice, for example, following such preparation, the user would use the apparatus **10** of the invention to initially grasp and captively hold the aligned (and adjacent) suture segments-to-be-welded **51**, **52** between jaws **32**, **33** so as to be in one of many orientations. For example, the aligned suture segments may be disposed with their central axes **51**A, **52**A along an axis A**1** parallel to central axis A of tube **12**, as shown in FIG. **8**A. Alternatively, as shown in FIG. **8**B, two segments of suture may be aligned with their central axes **51**A, **52**A disposed along an axis A**2** which is transverse to the central axis A or, as shown in FIG. **8**C, with their central axes **51**A, **52**A disposed along an axis A**3** which is oblique with respect to the central axis A. The specific alignment of the suture segments **51**, **52** may depend on user preference or constraints imposed during surgery. In various embodiments, the heater element **26** may be disposed on the distal end of the tube **12** as shown in FIGS. **1**, **1**A and **2**, or there may be heater elements on various interior surfaces of the jaws **32**, **33**.

**[0072]** Once the suture segments-to-be-welded **51**, **52** are prepared for alignment (for example, by ensuring the segments-to-be-welded **51**, **52** are in the desired general vicinity and with appropriate length and tension), the thermal welding apparatus **10** is moved into position in close proximity and adjacent to the suture segments **51**, **52**. As shown in FIG. **2**A, the grasp assembly **44** is activated to position the jaw members **32**, **33** in a first state wherein the distal ends of each jaw member **32**, **33** are spaced apart sufficient to allow the introduction of the suture segments **51**, **52** between the jaws **32**, **33**. Once the sutures segments-to-be welded **51**, **52** are positioned between the jaws **32**, **33**, the jaws are positioned to their second state, wherein the distal ends of the jaws **32**, **33** are close together to position and captively hold the suture segments **51**, **52**, as shown in FIG. **26**. Once in this position, with the suture segments-to-be-welded **51**, **52** captively held, the user can draw on the respective ends of the suture to effect a desired tension, for example, using one or more cleats **11**B and tension control **11**C.

**[0073]** In another embodiment, as shown in FIG. **9**A, an anchor **60** is placed in the grasper assembly **44**. The suture segments-to-be-welded **51**, **52** are threaded through an aperture **62** in the proximal end of the anchor **60**, holding the segments **51**, **52** in position. The anchor **60**, which may be a bone anchor, preferably is manufactured from a material that has material properties similar to the suture segments-to-be-welded **51**, **52**. Such properties would allow the suture segments-to-be-welded **51**, **52** to be positioned relative to and welded to the anchor **60** upon deployment of the heating element **26**. In this embodiment, the heating element **26** is mounted on the distal end of the joiner element **18** such that heat from the heater element **18** can be used to melt the top portion of the anchor member **60** into and around the suture segments **51**, **52** to effect suture welding. The grasper assembly **44** is positioned to allow jaw members **32**, **33** to contain the suture segments-to-be-welded **51**, **52** and to fit the anchor **60** in close proximity to the segments **51**, **52**. The external heater controller **20** then is selectively activated to heat the heating element **26** while the suture segments-to-be-welded **51**, **52** are compressed against the anchor **60**.

**[0074]** In another embodiment, the suture segments-to-be-welded **51**, **52** may be threaded through an aperture **62** in the body of the anchor **60** prior to the introduction of the heating element **26**. In this embodiment, the grasper assembly **44** is positioned to allow jaw members **32**, **33** to extend beyond the end of the jaw members **32**, **33** to secure the anchor **60** in, for example, bone. Thus, the heater element **26** on the joiner element **18** is used to compress the suture segments-to-be-welded **51**, **52**, using the bone into which the anchor **60** is secured to create the opposing force allowing compression without the use of jaw members **32**, **33**. Once the anchor **60** is in position, and the suture segments-to-be-welded are sufficiently compressed, the external heater controller **20** is selectively activated to heat the heater element **26**, thus welding the suture segments **51**, **52** to the anchor **60**.

**[0075]** In yet another embodiment, and as shown in FIG. **9**C, the jaws **32**, **33** hold an anchor **60** in place and a single suture **50** is positioned against the proximal surface of the anchor **60**. The anchor **60** is positioned in, for example bone, and the heater joiner element **18** is deployed against the suture **50** to melt the suture **50** against the proximal surface of the anchor **60**.

**[0076]** As illustrated in FIG. **2**C, while the sutures are captively positioned in the suture positioning assembly **16**, the compression and weld assembly **14** is activated to slidably position the joiner element **18** such that the heater **26** is in contact with and biased against the outer surface of at least one of the suture segments **51**, **52**. The weld controller **20** then is selectively activated to heat the heater **26** while the suture segments **51**, **52** are compressed between the joiner element **18** and the opposing, interior surfaces of jaws **32**, **33**.

**[0077]** The welding is caused by heating heater **26** with a desired temperature-over-time profile, to a predetermined threshold temperature and for a threshold time that is sufficient to at least partially melt the portion of one suture segment that lies adjacent to another suture segment. This time and temperature profile will depend upon the type of suture used, including the diameter and materials of the particular suture. Other factors that may affect the time and temperature profile include the amount of moisture and body fluids present at the weld site.

**[0078]** In practicing the present invention, the elongated material of the type used in surgical sutures can be a single filament, or substantially monofilamentous, and preferably polymeric. Typically, such sutures are manufactured from, but are not limited to, polymers, especially thermoplastic materials such as nylon, polypropylene, polyester (such as Dacron®), polyglycolic acid, polyglyconate, and polydioxanone. Alternatively, the suture may include multifilament forms, preferably braided, or may be of the type described and claimed in U.S. patent application Ser. No. 11/405,754.

**[0079]** As shown in FIG. **2**D, after the suture segments **51**, **52** are welded, the cutting element **22** is deployed. In an embodiment, the blades **34**A, **34**B are manually slid along the blade channels **36**A, **36**B by the user to move the sharp distal end of the blades **34**A, **34**B through the welded segments (not shown) at a point proximal to the welded suture joint. The apparatus **10** then may be retracted from the situs of surgery.

**[0080]** In another embodiment, as shown in FIG. **10**A, the blades **35**A, **35**B may have a hook configuration, which may either upward (not shown) or downward (as shown in FIG. **10**A). As shown, the hook blades **35**A, **35**B may be integral with or connected to the elongate tube **12**. In either configuration, the sharpened, cutting surface **38**A, **38**B of the blades **35**A, **35**B of this embodiment is located on the interior surface of the blades. Once the suture segments **51**, **52** are welded as described above, the hook-shaped blades **35**A, **35**B may be distally deployed, thus capturing, the suture segments **51**, **52** by the blades **35**A, **35**B as the hook travels over the extended suture segments. Then, by drawing the hook-shaped blades **35**A, **35**B back along the central axis A, the suture is pulled backward and cut as the sharpened interior surface **38**A, **38**B passes over the suture that is being held at the weld joint (not shown) within the joiner element and by the hook blades **35**A, **35**B. FIG. **10**B shows the hook-shaped blades **35**A, **35**B in the retracted position.

**[0081]** In another embodiment, as shown in FIG. **10**, the cutting element **22** may be a portion of the distal end of a tube **62** which has a sharpened edge. Once the welding process is finished, the tube **62** is rotated, cleaving the suture between the sharpened edge of the tube and the suture positioning assembly **16**.

**[0082]** In another embodiment of the invention, as shown in FIG. **11**A, an elongate sleeve **70** may be positioned over the elongate tube **12**. The sleeve **70** is configured such that a portion of the surface of proximal end of the sleeve is a sharpened edge **72**. FIG. **11**A shows the jaws **32**, **33** in a closed position as typical following suture welding. Once the suture welding is complete, the sleeve **70** is slidably positioned toward the proximal end of the apparatus **10**. In the illustrated embodiment of FIG. **11**B, the sleeve **70** is shaped such that when the sleeve **70** is fully deployed proximal to the grasper assembly **44**, the sharpened edge **72** is positioned above the ends of the suture (not shown) that extend from the grasper assembly **44**. The sleeve **70** then is rotated some degrees about central axis A, as shown in FIG. **11**C, to engage the sharpened edge **72** across the suture ends, thus severing the suture as the sleeve **70** rotates. The sleeve **70** may be moved into position prior to or following formation of the suture weld.

**[0083]** In some embodiments, the welding apparatus **10** may include heating elements of the type described in U.S. Provisional Application Ser. No. 60/876,458, which incorporated above by reference in its entirety, or in U.S. patent application Ser. No. ______, entitled Heater Assembly For Suture Welder, and filed Dec. ______, 2007, which is incorporated herein by reference in its entirety.

**[0084]** The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of the equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

**1**. A suture welding device, comprising:

A. an elongated tube extending along a central axis between a proximal end and a distal end,

B. a suture positioning assembly affixed to said distal end of said tube, said suture positioning assembly including:

i. a first jaw member extending along a first jaw axis from a proximal end and a distal end,

ii. a second jaw member extending along a second jaw axis from a proximal end and a distal end, wherein at least one of said first and second jaw member includes an anvil portion at a distal end extending transverse to its respective jaw axis;

iii. a grasp assembly adapted to position said first jaw member opposite said second jaw member, said grasp assembly being selectively operative to position said first and second jaw members between;

a first state wherein said first jaw member and said second jaw member are relatively divergent at said distal ends of said jaw members; and

a second state wherein said first jaw member and said second jaw member are relatively non-divergent at said distal ends of said jaw members;

wherein said jaw members are adapted to captively hold and position suture segments-to-be-welded between said first and second jaw members when said grasp assembly is in said second state.

C. an elongated joiner element extending along said central axis between a proximal end and a distal end, said joiner element having a selectively operative heating element disposed at said distal end of said joiner element;

D. a compression and weld assembly operative to translate said joiner element along said central axis whereby in a first preparatory state, said distal end of said joiner element is relatively far from said anvil portion of said at least one jaw, and in a weld state, is relatively near and biased toward said anvil portion of said at least one jaw; and

E. a weld controller selectively operative when said grasp assembly is in said second state and said compression and weld assembly is in said weld state, to apply energy to said heating element, whereby said heating element has a temperature above a predetermined threshold adapted to at least partially melt said suture segments captively held between said jaws.

**2**. A suture welding device according to claim **1**, wherein said first jaw includes an anvil portion at said distal end extending transverse to said first jaw axis, and wherein said second jaw includes an anvil portion at said distal end extending transverse to said second jaw axis.

**3**. A suture welding device according to claim **2**,

wherein said jaw members are adapted to position two suture segments of diameter D held therein in said second state with said suture segments being side-by-side transverse to said central axis.

**4**. A suture welding device according to claim **2**,

wherein said jaw members are adapted to position two suture segments held therein in said second state with said suture segments being side-by-side along said central axis.

**5**. A suture welding device according to claim **2**,

wherein said jaw members are adapted to position two suture segments held therein in said second state with said suture segments being side-by-side along an axis oblique with respect to said central axis.

**6**. A suture welding device according to claim **2**, wherein said elongated tube is flexible.

**7**. A suture welding device according to claim **2**, wherein said elongated tube is rigid.

**8**. A suture welding device according to claim **2**, further comprising said suture segments and wherein said suture segments are manufactured from materials that enable welding of such suture segments.

**9**. A suture welding device according to claim **2**, wherein said joiner element remains within said suture positioning assembly during welding.

**10**. A suture welding device according to claim **2**, wherein said joiner element extends beyond said suture positioning assembly during welding.

**11**. A suture welding device according to claim **2**, further comprising an elongated sleeve member extending along said central axis, said sleeve member including

i. a first hook member extending along said central axis and adjacent one side of said suture positioning assembly; having an inner surface thereof positioned transverse to said suture segments when said suture segments are captively held between said first and second jaw members; and

ii. a second hook member extending along said central axis and adjacent to a side of said suture position assembly opposite said first hook member, and having an inner surface thereof positioned transverse to said suture segments when said suture segments are captively held between said first and second jaw members wherein said suture positioning assembly is slidably engaged within said sleeve member to selectively cut said suture segments.

**12**. The suture welding device of claim **11**, wherein said first and second hook members are positioned downward relative to said central axis.

**13**. The suture welding device of claim **2**, further comprising an elongated sleeve member extending along said central axis from a distal end to a proximal end, wherein said sleeve member further comprises a cutting edge along a portion of said proximal end;

wherein said suture positioning assembly is slidably engaged within said sleeve member to selectively cut said suture segments.

**14**. The suture welding device of claim **1**, wherein the first jaw member extends along the first jaw axis without a flange, and the second jaw member includes a flange extending transverse to the second jaw axis in a direction at least partially towards the first jaw member.

**15**. The suture welding device of claim **14**, wherein the flange extends beyond a distal end of the first jaw member, and, when the grasp assembly is in the second state, the distal end of the first jaw rests against a surface of the flange facing the distal end of the first jaw.

**16**. The suture welding device of claim **14**, wherein, when the grasp assembly is in the second state, an end of the flange distal from the second jaw axis rests against a surface of the distal end of the first jaw facing the second jaw.

**17**. The suture welding device of claim **1**, wherein the elongated tube is adapted to be received in an endoscopic surgical field.

**18**. The suture welding device of claim **1**,

wherein the grasp assembly comprises an anchor adapted to receive the suture segments,

wherein said first and second jaw members are adapted to captively hold and position the suture segments and said anchor between said first and second jaw members when said grasp assembly is in said second state; and

wherein the weld controller is selectively operative when said grasp assembly is in said second state and said compression and weld assembly is in said weld state, to apply energy to said heating element, whereby said heating element has a temperature above a predetermined threshold adapted to at least partially melt said anchor captively held between said jaw members.

**19**. The suture welding device of claim **18**, wherein the anchor comprises a bone anchor.

**20**. A suture welding device, comprising:

A. an elongated tube extending along a central axis between a proximal end and a distal end,

B. a suture positioning assembly affixed to said distal end of said tube, said suture positioning assembly including:

i. a hooked jaw member extending along a jaw axis from a proximal end and a distal end, and including a hooked flange portion at said distal end extending transverse to said jaw axis, said hooked flange portion being substantially curved and of sufficient length to provide a welding surface against which suture segments-to-be-welded may be compressed during welding;

wherein said hooked jaw member is adapted to captively hold and position the suture segments-to-be-welded against said welding surface;

C. an elongated joiner element extending along said central axis between a proximal end and a distal end, said joiner element having a selectively operative heating element disposed at said distal end of said joiner element;

D. a compression and weld assembly operative to translate said joiner element along said central axis whereby in a first preparatory state, said distal end of said joiner element is relatively far from said welding surface, and in a weld state, is relatively near and biased toward said welding surface; and

E. a weld controller selectively operative when said compression and weld assembly is in said weld state, to apply energy to said heating element, whereby said heating element has a temperature above a predetermined threshold adapted to at least partially melt said suture segments captively held against said welding surface.

**21**. A method of suture welding comprising:

receiving suture segments between first and second jaw members, said first and second jaw members being in an open state.

closing said first and second jaw members to captively hold and position the suture segments between said first and second jaw members;

selectively applying a joiner element to the suture segments; said joiner element having a selectively operative heating element facing the suture segments;

applying energy to said heating element to weld the suture segments, whereby said heating element has a temperature above a predetermined threshold adapted to at least partially melt the suture segments.

**22**. A method according to claim **21**, further comprising aligning two or more of the suture segments side by side.

**23**. A method according to claim **21**, further comprising, after closing said first and second jaw members to captively hold and position the suture segments between said first and second jaw members, tensioning one or more of the suture segments.

**24**. A method according to claim **21**, further comprising, after applying energy to said heating element to weld the suture segments, cutting a portion of one or more of the suture segments.

**25**. A method according to claim **21**, wherein the selectively applying a joiner element to the suture segments comprises compressing the suture segments between said joiner element and a surface of said jaw members

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