

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



DELEGATURA PROPIEDAD INDUSTRIAL

División de Nuevas Creaciones

PCT
SOLICITUD

PATENTE DE INVENCION

ENTRADA EN FASE NACIONAL

21. EXPEDIENTE No.

05-122677

54. TITULO EQUIPO SUTURADOR ENDOSCOPICO CON PUNTOS MULTIPLES E INTUBACION

UNICA

51. CLASIFICACION INTERNACIONAL

71. SOLICITANTE C. R. BARD, INC.

DOMICILIO MURRAY HILL, NJ 07974, ESTADOS UNIDOS DE AMERICA

74. APODERADO JUAN PABLO CADENA SARMIENTO

22. SANTAFE DE BOGOTA, D.C.

PETITORIO

AS: 99.727



SUPERINDUSTRIA Y COMERCIO
Indicacion : 051126/7 00000003
Fecha (AMD) : 2005-12-12 16:31:07
Tramite : 011 PCT-PATENT 379 FASE NACT 411 PRESENTAC
Dependencia: 2000 DIVISION D: NUEVAS CREACIONES

FORMULARIO ÚNICO DE SOLICITUD DE PATENTE
PCT
ENTRADA EN FASE NACIONAL

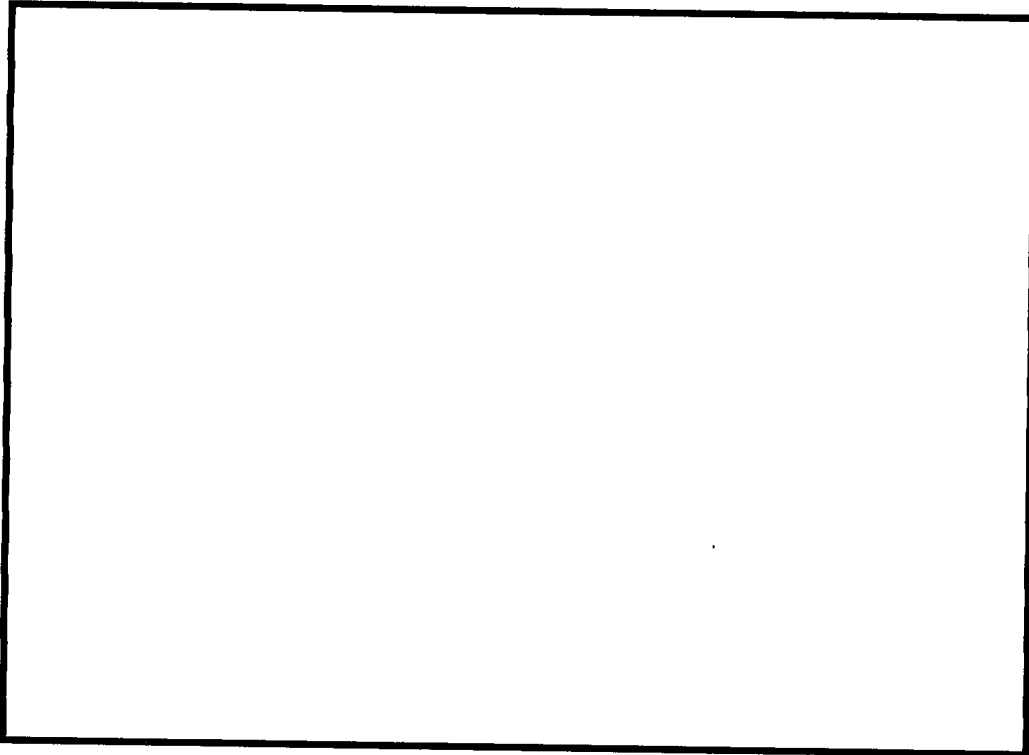
1		SOLICITUD DE:	
☒ Patente de Invención.		☐ Patente de Modelo de Utilidad.	
☐ Capítulo I.		☒ Capítulo II.	
2	Nombre: C.R. BARD, INC.		IDENTIFICACION
SOLICITANTE (71)	Dirección: 730 Central Avenue, Murray Hill, NJ 07974 Estados Unidos de América		
	Nacionalidad o Domicilio: Estados Unidos Lugar de Constitución: Estados Unidos Teléfono: Fax: E-mail		C.C. ☐ NIT ☐ C.E. ☐ Otro ☐ Cual _____ Número _____
3	Nombre: JUAN PABLO CADENA SARMIENTO		IDENTIFICACION
REPRESENTANTE O APODERADO	Dirección: Cra. 7 No. 16-56 Piso 9 Teléfono: 380-2200 Fax: 380-2700 E-mail:		
			C.C. ☒ NIT ☐ C.E. ☐ Otro ☐ Cual _____ Número 80.410.337 TP 57492
4	Nombre: Richard A. Gambale, Peter J. Lukin, Paul Dicesare, Christopher Battles, Jeffrey Radziunas, Danial Ferriera		
INVENTOR (ES) (72)	Dirección: 382 Dunstable Road, Tyngsboro, MA 01879 (US); 28 Russell Lane, Lancaster, MA 01523 (US); Eastern Connecticut (US); New Haven, CT (US) Wallingford, CT (US); Milford, CT (US) Nacionalidad o Domicilio: Estados Unidos de América		
5 PCT (86)			
Solicitud Internacional No. PCT/US2004/015670 Fecha 17-05-2004			
Publicación Internacional No. WO 2004/103189 A1 Fecha 02-12-2004			
Título (54): EQUIPO SUTURADOR ENDOSCÓPICO CON PUNTOS MÚLTIPLES E INTUBACIÓN ÚNICA			
7 Clasificación Internacional (51) A 61 B 17/10			

10

ANEXOS

- ☒ Comprobante de pago de la tasa de presentación de la solicitud. \$443.000
- ☐ Documento que acredite la existencia y representación legal cuando el solicitante sea persona jurídica.
- ☐ Poderes, si fuere el caso (Fotocopia anexa).
- ☐ Documento de cesión del inventor al solicitante o a su causante.
- ☐ Declaraciones.
- ☒ Copia de la solicitud internacional. (Resumen, descripción, reivindicaciones, dibujos)
- ☒ Traducción de la solicitud internacional al castellano. (Resumen, descripción, reivindicaciones, dibujos)
- ☐ Copia del examen preliminar efectuado por la IPEA.
- ☐ Traducción del examen preliminar efectuado por la IPEA.
- ☐ De ser el caso, copia del contrato de acceso.
- ☐ De ser el caso, documento que acredite la licencia o autorización de uso de conocimientos tradicionales de las comunidades indígenas.
- ☐ De ser el caso, certificado de depósito del material biológico.
- ☐ Arte final 12x12.
- ☐ De ser el caso, información sobre otras solicitudes de patente o títulos obtenidos en el extranjero por el mismo titular o su causante, relacionadas parcial o totalmente con la invención de esta solicitud.
- ☒ Otros: Tarjeta de Propietarios

11 FIGURA CARACTERÍSTICA:



12 Solicito la concesión de la patente:

NOMBRE: JUAN PABLO CADENA SARMIENTO

[Handwritten mark]

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Radicación : 05122677 00000000 Folio: 170
Fecha (PMO): 2005-12-02 16:31:07
Trámite : 011 PCI-PATENT 379 FASE NAU1 411 PRESENTAC
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

RECIBO OFICIAL DE CAJA : 05 - 79,116
FECHA : OCTUBRE 12 DE 2005

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Vr. PAGO
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO POPULAR	050-00110-6	30714338	12/10/2005	9,270,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01	SOLICITUDES	
		1 TRAMITES DE SOL. DE PATENTE DE IN	443,000.00
		TOTAL :	\$ 443,000.00

SON: CUATROCIENTOS CUARENTA Y TRES MIL PESOS

RESPONSABLE : *[Signature]*

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

PATENTE ☒ PCT/US2004/015670 MODELO DE UTILIDAD ☐ DISEÑO INDUSTRIAL ☐

SOLICITANTE/S. RAZON SOCIAL O APELLIDOS Y NOMBRES C.R. BARD, INC.

DOMICILIO MURRAY HILL, NJ 07974, ESTADOS UNIDOS DE AMERICA

APODERADO JUAN PABLO CADENA SARMIENTO

TITULO EQUIPO SATURADOR ENDOSCOPICO CON PUNTOS MULTIPLES E INTUBACION UNICA

CLASIFICACION

EXPEDIENTE No. FECHA DE SOLICITUD ROLLO MICROFILM

CERTIFICADO No. FECHA DE CONCESION VIGENCIA DESDE HASTA

PRORROGA CAMBIO DE NOMBRE

TRASPASO A

INVENTOR (ES) RICHARD A. GAMBALE, PETER J. LUKIN, PAUL DICESARE, CHRISTOPHER BATTLES,

OTROS JEFFREY RADZIUNAS, DANIAL FERRIERA

OFICINA DE COMUNICACIONES

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

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
2 December 2004 (02.12.2004)

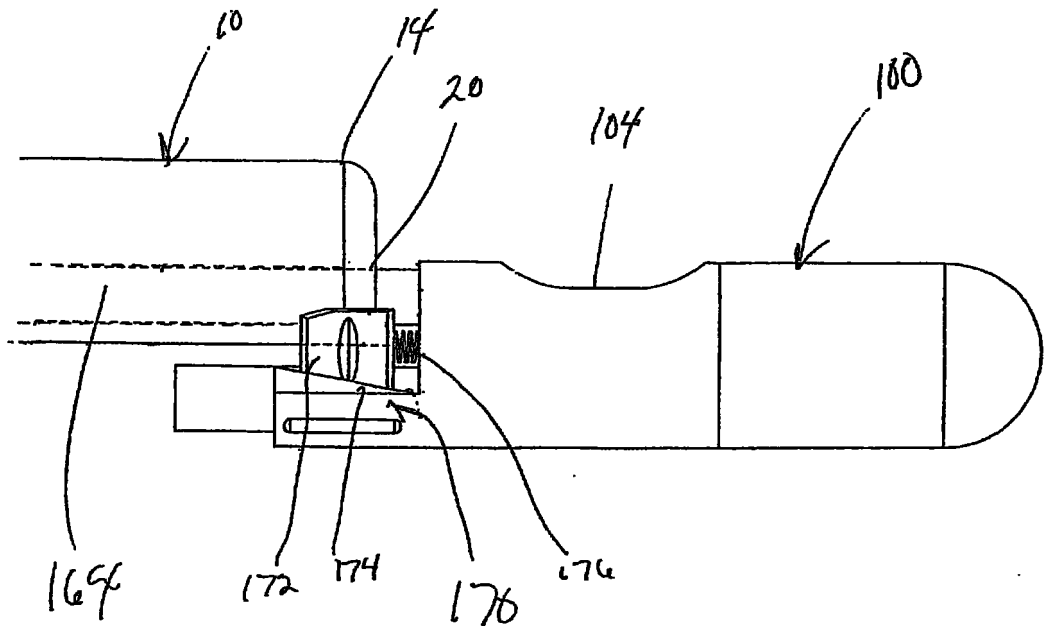
PCT

(10) International Publication Number
WO 2004/103189 A1

- (51) International Patent Classification⁷: A61B 17/10, 17/04, 17/12, 17/06 Wallingford, CT (US). FERRIERA, Danial; Milford, CT (US).
- (21) International Application Number: PCT/US2004/015670 (74) Agent: HERSH, Joyce, C.; Kirkpatrick & Lockhart LLP, 75 State Street, Boston, MA 02109-1808 (US).
- (22) International Filing Date: 17 May 2004 (17.05.2004) (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/471,248 16 May 2003 (16.05.2003) US
- (71) Applicant: C.R. BARD, INC. [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).
- (72) Inventors: GAMBALE, Richard, A.; 382 Dunstable Road, Tyngsboro, MA 01879 (US). LUKIN, Peter, J.; 28 Russell Lane, Lancaster, MA 01523 (US). DICESARE, Paul; Eastern Connecticut (US). BATTLES, Christopher; New Haven, CT (US). RADZIUNAS, Jeffrey;
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,

[Continued on next page]

(54) Title: SINGLE INTUBATION, MULTI-STITCH ENDOSCOPIC SUTURING SYSTEM



(57) Abstract: Provided is an endoscopic suturing system for joining internal body tissues in a variety of procedures. The system comprises a suturing capsule (100) releasably mountable to the distal end (14) of an endoscope (10) and capable of forming multiple stitches in tissue at a plurality of locations without requiring withdrawal of the capsule (100) from the patient between stitches. Also enclosed is a suture lock (120) to secure the placed stitch that is delivered by a device introduced through the working channel of the indwelling endoscope (10). Suitable control handles (16) for the suturing capsule (100) and for the suture lock delivery device (500) positioned at the proximal end (12) of the endoscope (10) are provided to facilitate operation by the user.

WO 2004/103189 A1



SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

SINGLE INTUBATION, MULTI-STITCH ENDOSCOPIC SUTURING SYSTEM

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/471,248, filed on May 16, 2003, the entire teachings of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to devices and methods for securing together tissues of the human body. In particular, the invention pertains to an endoscopic suturing system.

BACKGROUND OF THE INVENTION

Endoscopic apposition devices are devices that can be used in the body of a patient without the need to make an external incision in the patient, the device being controlled externally of the patient by endoscopic means. The device may comprise a sewing or stapling device for use in flexible endoscopy, though it is also applicable to devices for use in rigid endoscopy. Such devices have been found to be useful in the treatments of the digestive system, with the endoscope being inserted through a patient's esophagus. In particular, such devices have been found useful in treating gastro-esophageal reflux disease (GERD). In a procedure for treating GERD, stitches are placed to form tissue plications at the junction of the esophagus and stomach. The minor anatomical change resulting from the plication formation appears to relieve the symptoms of GERD in some patients.

Sewing devices of this general type are described in, for example, U.S. Pat. Nos. 5,080,663 and 5,792,153, which are incorporated by reference herein. Those patents disclose a sewing device for passing a thread through a tissue portion, which comprises a hollow needle movable between a first position in which it is out of the tissue portion and a second position in which it passes through the tissue portion, and a thread carrier adapted to be attached to the thread and being receivable within the hollow needle. The sewing device comprises a body, which defines a cavity within which the tissue portion can be held by means of suction, and the hollow needle is mounted for movement in the body between the first and second positions.

Two particular embodiments are described a single stitch sewing device, and a multiple stitch sewing device. In the single stitch device the thread carrier is transported by the needle through the tissue as the latter passes from its first position to its second position. When the needle returns to its first position, the thread carrier is left behind in the distal end of the sewing capsule. In the multiple stitch device, the same procedure occurs, but it is followed by a further step in which the hollow needle travels from its first position to its second position, picks up the thread carrier, and returns it. A second stitch may be formed during the next step. The whole sequence of steps is repeated as many times as may be required to form the desired number of stitches.

After placement of the sutures through the tissue, the suture must be secured tightly by knots or by a mechanical locking device. U.S. App. Nos. 10/220,413 ("Suture Clips, Delivery Devices and Methods", filed March 13, 2003) and 10/275,534 ("Tissue Capturing and Suturing Device and Method", filed November 6, 2002), which are incorporated by reference herein in their entirety, disclose mechanical locking devices for securing a suture in an internal body location that are deliverable by an endoscope. These applications correspond to PCT Publication Nos. WO 01/66001 and WO 01/89393, respectively. However, due to their large size, these systems require that the endoscope be removed from the patient in order for the delivery device to be navigated to the suture location.

Minimizing the number of intubations and reducing the procedure time during which the patient must be kept under conscious sedation are important considerations in any endoscopic procedure. Prior art suturing devices must be withdrawn from the patient for each successive stitch made with the single-stitch embodiment. The use of the devices is, thus, time consuming, cumbersome and of some risk to the patient due to the multiple intubations and danger of perforation of the esophagus. It would be desirable to provide an endoscopic tissue apposition device that minimizes procedure time and the number of intubations while still making and securing multiple stitches during the procedure.

30

SUMMARY OF THE INVENTION

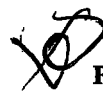
The present invention provides an endoscopic tissue apposition device capable of securing multiple tissue sites together with only one intubation of an endoscope carrying a suturing capsule at its distal end into the patient. To place the sutures, the

system provides a suturing capsule that may be releasably secured to the distal end of a variety of commonly used endoscopes. The suturing capsule comprises a tissue suction chamber for capturing a section of tissue, a needle slidable along a needle track that passes through the suction chamber and a suture tag joined to a suture that
5 is releasably securable to the needle.

To make multiple stitches without requiring removal of the device for reloading of suture thread, the capsule also includes a suture catch at its distal end, distal to the suction chamber, to receive the suture tag from the needle as it is passed through captured tissue. After carrying the suture tag and suture from a proximal side of
10 captured tissue through to the distal side of the tissue, the tag can be left behind in the suture tag catch and needle withdrawn proximally leaving the suture passed through the captured tissue portion. A suture tag lock is provided on the needle to selectively capture the suture tag on the needle when it is delivered and picked up from the suture tag catch at the distal end of the capsule. Tissue then can be released from
15 the capsule and either the tag recaptured by the needle in readiness for another stitch through a different captured tissue portion (approaching from the proximal side of the tissue) or the tag can be left in place and another tissue portion captured so that when the needle is advanced distally to capture the tag, the proximally withdrawing needle will carry suture through the tissue in a proximal direction. By shuttling the tag and its
20 associated suture through a series of captured tissue portions in this fashion, a plurality of stitches can be formed without requiring removal of the capsule for reloading.

The needle and suture tag lock are selectively operated from the proximal end of the endoscope by a control handle. The control handle is releasably securable to
25 the proximal end of the endoscope such that it is in communication with the working channel port of the endoscope handle. Control shafts joined to the handle extend through the working channel of the endoscope and control operation of the needle and the suture tag lock by their longitudinal movement initiated at the handle. The handle may have one longitudinal operating member to control both the movement of the
30 needle and the release and securement of the suture tag lock.

Because there are four stages of needle operation during the tag shuttling through a tissue portion, when only a single longitudinal member is provided on the handle, a segmented operation of the longitudinal control member is preferred to indicate to the user which stage of needle operation is occurring. For example, the



control member should indicate to the user a first stage when the longitudinal member is not depressed and the needle with tag loaded is proximal to the suction chamber. When the needle is advanced through tissue and is releasing the tag, bottoming out of the longitudinal member against the handle indicates the second stage of operation.

- 5 The longitudinal member should return automatically to withdraw the needle proximally while leaving the tag behind in the suture tag catch (the third stage). The handle should provide an idle position at the third stage in which the needle is withdrawn proximally from the tissue without the tag and is in readiness to drive distally again to pick up the tag. During automatic return of the needle proximally,
- 10 such as by a return spring, vacuum also can be discontinued automatically at the end of the return stroke so the tissue portion is released with suture thread now passing through it. Stage four occurs when the needle is advanced distally again to recapture the suture tag (either with tissue suctioned into the chamber or to reposition the tag prior to tissue capture). Depression of the longitudinal operation member again
- 15 initiates stage four when the needle has reached the distal end of its stroke and recaptured the suture tag. Release of the longitudinal operation member from stage four returns the handle and the needle back to their initial state: stage one.

- The suturing capsule control handle may also include vacuum controls to selectively suction tissue into the suction chamber during the course of suturing. A
- 20 vacuum supply routed through the handle may then be conveniently turned on by the user by a switch on the handle. Optionally, a vacuum interlock feature may be provided that prevents operation of the device if a sufficient negative line pressure is not achieved to insure that tissue is fully suctioned into the chamber so that the needle and suture achieve a sufficient penetration depth. The vacuum control may also
- 25 include a feature that automatically discontinues vacuum to the suction chamber once the needle has completed its proximal withdrawal stroke from the tissue. Additionally, the control handle may employ other useful features such as a suture tensioning mechanism to keep the suture taut during the procedure so that it moves proximally and distally with the movement of the needle rather than just distally, which may lead
- 30 to bunching up the suture material in the suction chamber area.

After stitches have been formed through the several selected tissue locations, the suture leads must be secured to hold the suture tightly in position through the tissue. The present suturing system also provides a suture lock that may be applied to the suture leads to secure them with a delivery device that may be passed through

the working channel of the endoscope so that removal of the endoscope is not required in order to complete the procedure. The suture lock comprises a ring and a plug sized to frictionally engage the inside surface of the ring so that suture leads passing through the ring become captured between the two components. To secure a suture, the suture leads are guided through the ring, and it is advanced to the suture location at which point the plug may be inserted into the ring while holding the suture taut so that it becomes captured in a tightened condition through the tissue.

The suture lock may be delivered to the tissue location and secured by a delivery device comprising a shaft and distal operating end that are passable through the working channel of the endoscope and a control handle at the proximal end of the shaft for controlling the operating end to assemble the ring and plug. The distal operating end of the delivery device should comprise a receptacle to hold at least one ring and one plug in the disassembled configuration so that it can be guided to the suture location with suture leads passing through the open ring. The receptacle may be configured as a cage defined by four arms attached in a hinged fashion only at their proximal ends to a central bushing member to permit their distal ends to be selectively closed or opened to release an assembled plug and ring. The fingers of the cage must remain closed during assembly of the plug into the ring to provide resistance to the assembly force of inserting the ring into the plug, but then may be selectively opened to release the secured suture lock.

To selectively open and close the arms of the cage and to sever the suture lead after assembly of the suture lock is completed, an outer sleeve slidable over the fingers of the cage may be provided. When the cage member is proximally within the sleeve such that the sleeve is over the distal ends of the fingers, the free distal ends of the fingers remain held radially inward in a closed configuration to retain the ring and plug. When the cage is moved distally relative to the sleeve so that the sleeve is positioned proximally over the hinged area of the fingers, the distal free ends of the fingers are permitted to spread apart radially to permit release of the ring and plug. To assemble the ring and plug while the fingers of the plug are restrained closed, the plug is pushed distally into the ring by a pusher shaft that slides longitudinally relative to the cage that holds the ring from longitudinal movement during assemble. After the plug has been inserted into the ring and the cage has been moved distally relative to the sleeve, the hinged fingers resiliently spring open (distal ends move radially outward) to release the plug and ring assembly.

The cage, outer sleeve and pusher should be joined to a control handle at the proximal end of the endoscope by control shafts, longitudinally slidable through the working channel of the endoscope to cause movement of the distal components to operate the distal end effectively, the handle may include two control members
5 available to the user to achieve the needed relative motion to assemble and release the ring and plug. The handle should include at least one longitudinal slidable member joined to the pusher in order to advance the plug into the ring and an outer sheath joined to the cage and outer sheath to resist the distal longitudinal movement of the pusher and to achieve sliding movement of the outer sleeve to open the cage
10 fingers.

It is an object of the present invention to provide an endoscopic suturing system that is capable of creating stitches in multiple distinct internal tissue areas while requiring only one intubation of the endoscope or insertion of a laproscope.

It is another object of the present invention to provide an endoscopic suturing
15 capsule that provides a tissue suction chamber and a needle slidable through tissue captured therein to deliver a suture carrying tag through successively captured tissue portions to form a stitches in each separate portion.

It is another object of the present invention to provide a control handle for a multiple stitch endoscopic suturing capsule that permits the user to input only a single
20 longitudinal movement of a control mechanism in order to complete a stitch of suture through a tissue portion and return the system to a state of readiness for a second stitch.

It is another object of the present invention to provide an endoscopic suturing system comprising a suturing capsule having a needle and suture tag capturable on
25 the needle by a suture lock and a suture catch in the capsule, a control handle for operating the components of the suture capsule, a suture lock for securing the leads of suture delivered to tissue and a suture lock delivery device for assembling and releasing the suture lock at the internal tissue location.

It is another object of the present invention to provide a suture lock comprising
30 a ring and a plug frictionally engageable within the ring to capture suture leads therebetween and a suture lock delivery device having a shaft and distal operational member and receptacle passable through the working channel of an endoscope and a control handle positionable at the proximal end of an endoscope to operate the distal

member to deliver, assemble and release the ring and plug components of the suture lock to secure a suture.

BRIEF DESCRIPTION OF THE DRAWINGS

5 The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying diagrammatic drawings wherein:

FIG. 1 is a diagrammatical representation of an endoscope carrying the suturing system of the present invention;

10 FIG. 2 is a diagrammatical representation of the suture lock delivery device of the present invention;

FIGS. 3A and 3B are diagrammatic representations of a ring and plug suture lock;

FIG. 4 is an isometric transparent view of a suturing capsule;

15 FIG. 5 is an isometric transparent view of a suturing capsule shell attached to the distal end of an endoscope;

FIG. 6 is a side view of a suturing capsule attached to the distal end of an endoscope by a reverse wedge attachment mechanism;

20 FIG. 7A is a side view of a suturing capsule of the present invention indicating an area A of detail that is shown on FIG. 7B;

FIG. 7B is a detail view of area A shown in FIG. 7A;

FIG. 8 is a side view of a needle and suture tag locked on the needle by a suture tag lock device;

25 FIG. 9 is a sideview of a needle carrying a suture tag with the suture tag lock in the unlocked position;

FIG. 10 is an isometric transparent view of the suturing capsule with the needle and suture tag advancing distally to the suture catch;

FIGS. 11-14 illustrate various stages of the suture tag and needle entering the suture tag catch in the capsule;

30 FIG. 15 is an overhead view of the suture tag catch with a suture tag captured;

FIG. 16 is a side view of a suturing capsule control handle;

FIG. 17 is a sectional view of a suture control handle;

FIG. 18 is a detailed sectional view of the control handle of FIG. 17;

FIG. 19A is a sectional view of the suture control handle; FIGS. 19B and 19C are detailed views of components shown in the sectional view of FIG. 19A;

FIG. 20 is an overhead view of an around-the-world pawl track;

FIG. 21 is a sectional view taken along the line A-A shown in FIG. 20;

5 FIG. 22 is an illustration of a ratchet pawl track;

FIG. 23 is an isometric view of a cylindrical ratchet pawl;

FIG. 24 is a sectional view of the control handle fully advanced in the distal direction;

10 FIG. 25 is a sectional view of the control handle in an intermediate stage in which the needle has deposited the suture tag in the suture catch at the distal end of the capsule;

FIGS. 26A and 26B are side views of the suture lock of the present invention;

FIG. 27 is an isometric view of the suture lock delivery device;

FIG. 28 is a sectional view of the suture lock delivery device;

15 FIG. 29 is a side view of the suture lock delivery device;

FIG. 30 is a isometric view of the suture lock delivery device;

FIG. 31 is an isometric sectional view of the suture lock delivery device taken along the line A-A shown in FIG. 29;

20 FIG. 32 is a sectional view of the suture lock delivery device with assembled ring and plug;

FIG. 33 is a sectional view of the suture lock delivery device taken from FIG. 29 in the orthogonal plane;

FIG. 34 is a sectional view of the suture lock delivery device with bushing and cage extended distally;

25 FIG. 35 is a sectional isometric view of the suture lock delivery device with bushing and cage extended distally;

FIG. 36 is a sectional view of the suture lock delivery device with fingers extended radially outward to release a ring and plug;

30 FIG. 37 is a side sectional view of the suture lock delivery device control handle;

FIG. 38 is a side sectional view of the suture lock delivery device control handle in the depressed configuration;

FIGS. 39-54 are diagrammatical illustrations of the various steps of the suturing process of the present invention;

FIGS. 55-63 are diagrams representing various stages of the suturing process of the present invention.

DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

5 FIGS. 1-3B show the components of the single intubation, multi-stitch endoscopic suturing system. In FIG. 1 is shown the endoscopic suturing device comprising a suturing capsule 100 that is releasably secured to the distal end 14 of an endoscope 10. The capsule 100 is operated by a control handle 200 releasably mounted to the proximal end 12 of the endoscope 10 adjacent to the endoscope control handle 16. The suturing system operates to place sutures through tissue at
10 internal locations within a patient accessible by an endoscope.

FIG. 2 shows another component of the single intubation system: a suture lock delivery device 500, which is sized to extend through the working channel of an endoscope. Extended through an endoscope, the distal operating end 540 of the
15 delivery device extends outside of the distal end 14 of an endoscope while the control handle 16 extends from the proximal end 12 of an endoscope so that it may be operated by a user. The delivery device 500 is configured to apply suture lock devices such as shown in FIGS. 3A and 3B. The suture locks of FIGS. 3A and 3B comprise a ring 502 to which is inserted a plug 504 sized to become frictionally
20 engaged in the opening of the ring. As shown in FIG. 3B when sutures 18 are passed through ring 502, insertion of the plug 504 causes the suture to become trapped and locked between the outer surface of the plug and the inner surface of the ring, effectively securing the suture leads 18 in the tissue. A comprehensive discussion of suitable suture lock devices including presentation of alternate suitable examples of
25 such suture locks is presented in pending U.S. App. Nos. 10/220,413 and 10/275,534, incorporated by reference herein. Although each of the components shown in FIGS. 1-3B may be used separately in endoscopic suturing procedures and provide utility for their intended purpose, use of the components together enables endoscopic suturing providing multiple stitches to a plurality of internal locations and securing them with a
30 single intubation of an endoscope into a patient.

Suturing Capsule

FIG. 4 is an isometric transparent view of the suturing capsule 100. The capsule 100 comprises a cylindrical body 102 having an atraumatic shape to reduce

the chance of trauma to internal tissues during operation. The capsule is similar in configuration and operation to that disclosed in U.S. patent 5,792,153 discussed above. The capsule includes a suction port 104 open to a tissue suction chamber 106 into which tissue portions to be sutured may be collected under vacuum introduced
5 into the chamber. The capsule is configured to receive a needle 108 slidable through a needle track 110 formed through the capsule. The needle may be a solid stainless steel shaft with a sharpened distal tip 112 and be joined at its proximal end to a pusher shaft 184 that extends proximally from the suture capsule, through the working channel of the endoscope. The pusher shaft exits the proximal end of the endoscope
10 where it may be joined to and manipulated by a control handle as will be discussed below. When the needle is moved longitudinally through the needle track, it traverses the suction chamber 106 so that tissue suctioned into the chamber will be penetrated by the distally advancing needle.

The needle 108 carries an annular suture tag 114 that fits closely about the
15 outside surface of the needle. The tag has proximal and distal ends, and can have a decreasing taper from its proximal end to its distal end to create a low profile as the needle and suture tag are advanced distally through tissue. Joined to the suture tag is one end of a suture 18 that will be carried through a suctioned tissue portion when the needle carrying the suture tag 114 is advanced distally. The suture may be attached
20 by passing through an opening in the tag and forming an enlarged tip or knot on the suture so that it is too large to fit back through the tag. The suture tag is releasably and selectively secured to the outside surface of the needle by a suture tag lock 120. The suture tag lock is also remotely operable from the proximal end of the endoscope by a suture tag lock shaft 122 that is slidable over the needle control shaft and needle
25 108.

Full distal advancement of the needle places the suture tag 114 within the confines of a suture tag catch 140. After penetrating a captured tissue portion and entering the suture catch, the suture tag lock 120 may be released and the needle withdrawn proximally leaving behind the suture tag 114 in a nest area 142 of the
30 suture tag catch. The suture tag catch comprises a Y-shaped structure 144 having two resilient arms 146. The resilient arms are joined together at the base of the Y-shaped member 144 and extend longitudinally in a proximal direction terminating in a free-end having an inwardly curved prong 148 to catch the proximal facing surface 116 after the tag 114 has entered the nest 142. After capture and release of the

5 suture tag into the suture tag catch 140, the needle may be withdrawn proximally and the tissue released from the suction chamber 106 with a suture 18 left passing through the tissue and having one end joined to the captured suture tag at the distal end 103 of the capsule and the other end of the suture extending into the needle track 110, through the working channel of the endoscope and exiting the proximal end of the endoscope.

10 FIG. 5 shows another isometric view of a suturing distal end of an endoscope 10 having attached to it a shell of a suturing capsule 100 with internal components removed. Suction port 104 opens to the suction chamber 106. At the bottom of the suction chamber are several aspiration ports 160, shown in phantom, through which negative pressure is introduced to the suction chamber to selectively capture a tissue portion to be sutured. The vacuum is introduced to the aspiration ports 160 through vacuum tube 162 extending proximally from the capsule 100 and joined to a separate vacuum line (not shown) that extends along the exterior of the endoscope 10.

15 The cutaway view of the distal end 14 of the endoscope 10 shown in FIG. 5 shows a working channel 20 and viewing channel 22. Other channels that may pass through the endoscope such as for light source or for a liquid cleaning source have been omitted for clarity. The capsule 100 is joined to the distal end of the endoscope by a proximally extending guide tube 164 (shown in phantom) inserted into the 20 working channel 20 of the endoscope. The guide tube 164 is rigid and extends proximally from the proximal end of the capsule 105 of the capsule to protrude a short distance into the working channel 20 of the endoscope. The guide tube 164 is open to receive the needle track 110 assembly through which the needle slides during operation.

25 As shown in FIGS. 5 and 6, the capsule may be secured to the distal end 14 of the endoscope by a reverse wedge securement mechanism 170. A reverse wedge and an endoscopic accessory securement mechanism is fully described in pending U.S. App. No. 10/275,226, filed February 11, 2003, and titled "Endoscopic Accessory Attachment Mechanism", which is incorporated herein by reference in its entirety. It is 30 also disclosed in published PCT application WO 01/87144. The basic elements of the reverse wedge securement mechanism include a wedge component 172 slidable on a ramp surface 174 to become wedged between the distal end of the endoscope 14 and the ramp surface 174 as it slides up the ramp. Leverage against the distal end of the endoscope is maintained by the presence of the guide tube 164 through the working

channel 20. Return spring 176 maintains force against the wedge member 172 so that it is biased upward along the ramp surface 174 to maintain wedge contact with the endoscope.

FIG. 7A is a side view of the suture capsule 100 not mounted on an endoscope and indicating an area of detail of the needle track 110 presented in FIG. 7B. The needle track 110 resides in the guide tube 164 extending proximally from the capsule 100 as shown in FIG. 7B. Guide tube 164 is the outermost tubular structure of the needle track and as mentioned above provides a mounting structure for engaging the internal surface of the working channel of an endoscope to securely mount the capsule. The guide tube may be formed as part of the capsule and therefore formed of the same rigid material such as stainless steel. The proximal end of the guide tube 166 has a beveled cut across its opening that tapers downward to enable circumferential alignment of the control components, including other needle track components as they are advanced from the proximal end of the endoscope through the working channel into the capsule 100 as will be explained below.

Most of the components of the needle track are contained within an outer sheath 180 that extends the full length of the working channel of the endoscope, from the control handle at the proximal end to the guide tube 164 of the capsule 100. The outer sheath 180 and the needle track components associated with it are advanced through the proximal end of the endoscope into the guide tube 164 after the capsule has already been mounted to the distal end of the endoscope. The guide tube may be made of any strong but flexible material such as the polymer polyetheretherketone (PEEK). The outer sheath has a flattened portion 182 along its distal portion that resides within the guide tube 164 after assembly to permit passage of the suture 18 so that it may continue proximally through the working channel of the endoscope and out the proximal end without being required to extend through the outer sheath 180.

The innermost component of the needle track is the needle 108. The needle may have an enlarged spear-shaped distal end 109 to interact with the suture tag lock as will be discussed later. The distal tip 112 of the needle is sharpened pierce tissue and the proximal end of the needle is joined to a pusher shaft 184 that extends to the control handle mounted at the proximal end of the endoscope.

Slidable over the shaft of the needle 108 over its entire length is a locking sleeve 124 of the suture tag lock system 120. The locking sleeve 124 is a stainless steel hypotube of approximately 0.016 inch I.D. sized to fit closely over the outside

surface of the needle shaft, which measures approximately 0.0155 inch. The locking sleeve is also adjoined to the control handle at the proximal end of the endoscope. The distal end of the locking sleeve has two longitudinal notches extending proximally from the distal tip of the sleeve to a depth of approximately 0.080 inch to define two locking splines 126. As described more fully below, when the locking sleeve is advanced distally relative to the needle, the locking splines ride over the enlarged spear shape 109 of the needle 108, become splayed radially outward to create locking surfaces 128 that prevents distal sliding of the suture tag 114.

Outside of the locking sleeve is positioned a stiffener sleeve 130. The stiffener sleeve, formed from a rigid material such as stainless steel hypotubing extends over the needle and locking sleeve only along their distal portions, contained within the guide tube 164. The locking sleeve helps to insure that the needle remains parallel to the longitudinal axis of the endoscope during longitudinal sliding movement within the capsule 100.

External to the outer sheath 180 is bonded an outer shroud 132, formed from a semi-rigid polymer material such as PEEK that serves to additionally maintain the alignment of the needle and needle track assembly 110 within the guide tube 164 of the capsule 100. The outer shroud 132 serves as a bushing to absorb the space between the outer sheath 180 and the inside surface of the guide tube 164. The top of the shroud has a longitudinal slot 133 extending the full length of the shroud to permit passage of the suture 18 without interference as it slides with the suture tag 114 and needle 108. The bottom of the shroud 132 receives a transversely inserted alignment pin 134 that protrudes slightly from the exterior surface of the shroud. The protrusion of the alignment pin 134 interferes with the slash cut of the proximal end 166 of the guide tube. When the outer sheath and needle track assembly 110 are advanced distally through the working channel of an endoscope during assembly of the system, the guide pin catches on the distal end 166 of the guide tube 164 and further distal advancement of the outer sleeve and shroud cause the alignment pin to follow the slash cut and rotate the assembly as needed so that the alignment pin becomes bottomed out at the distal most portion of the slash cut 167. This positioning of the alignment pin insures that the needle track assembly 110 is aligned circumferentially with the guide tube 164 and suturing capsule 100 so that the suture does not become twisted or tangled during operation of the needle and tag during suturing.

FIG. 8 shows a side view of the needle 108 carrying a suture tag 114 locked from distal sliding movement by a suture tag lock 120. The suture tag 114 is annular, defining a through bore that is sized to closely fit over the locking sleeve 124. The stiffening sleeve 130, adhered to the locking sleeve 124 terminates just prior to the distal end of the locking sleeve leaving a carrying space over which the suture tag 114 may reside during delivery on the needle 108. The diameter of the stiffener sleeve 130 is slightly greater than that of the through bore of the suture tag 114 to provide a backstop to prevent the suture tag from sliding proximally relative to the needle and locking sleeve 124.

As described above, the distal end of the needle is formed to have a spear shape 109 formed by a proximal increasing barrel taper 111 converging with a distal increasing barrel taper 113 to create an increased diameter portion 115 of the spear shaped tip 109.

When the needle is withdrawn proximally into the locking sleeve 124 of the suture tag lock 120, the locking splines 126 ride up over the proximal barrel taper of the needle causing them to become splayed radially outward. The splayed splines 126 effectively increase their profiles to an extent such that the through bore 118 of the suture tag cannot fit over it, which locks the suture tag 114 in place on the needle.

To release the suture tag so that it may slide distally relative to the needle as would be desired when leaving the tag in the suture tag catch 140 during suturing procedure, the needle 108 is moved distally relative to the locking sleeve 124. Movement of the needle distally relative to the locking sleeve moves the proximal barrel taper to the reduced diameter of the needle shaft 107 and the splines 126 resiliently conform to the reduced diameter, returning radially inward to define a smaller profile over which the through bore 118 of the suture tag 114 may pass. The enlarged diameter portion 115 of the needle, without the added thickness of the two splines 126 from the locking sleeve 124, also defines a profile over which the through bore 118 of the suture tag 114 may pass freely.

An isometric transparent view of the capsule 100 showing the suture tag catch 140 is shown in FIG. 10. In the figure, the needle is approaching the suture tag catch 140 while the suture tag 114 is locked in position on the needle by suture tag lock 120. The needle traverses the suction chamber 106 on its way to deliver the tag to the suture tag catch 140, which is positioned on the distal side of the suction chamber 106. Tissue is not shown in the figure for clarity. The suture tag catch 140 comprises

a Y-shaped member 144 having two resilient arms 146 joined together at the base of the Y and having free ends that terminate in inwardly facing prongs 148 to catch the proximal face 116 of the suture tag 114. The area around the resilient fingers 146 is configured to closely fit the cylindrical tapered tip of the suture tag 114 to hold it
5 securely and defines a nest 142 where it will be securely maintained during its retention in the catch.

In operation, the suture tag catch 140 operates to retain the tag by the steps described below with references to the sectional views presented in FIGS. 11-14. In FIG. 11, the needle is shown advancing into the Y-shaped member 144 such that its
10 distal tip 112 is within the nest area 142 but the suture tag 114 has yet to pass the inwardly projecting prongs 148 of the arms 146. As shown in the sectional views of FIGS. 11 and 12, as the needle proceeds distally, the sharpened distal tip 112 of the needle enters the base 147 of the Y-shaped member 144 causing the resilient arms 146 to be spread apart to assist with entry of the suture tag 114 into the nest 142 past
15 inwardly projecting prongs 148. During this stage, the needle is advanced distally relative to the locking sleeve 124 of the suture tags 124 of the suture tag lock 120 to release the suture tag lock and permit the needle to be slipped out from the suture tag during its proximal withdrawal stroke.

After seating of the suture tag 114 in the nest 142, as shown in FIG. 12, the
20 beginning of the proximal withdrawal stroke may find the resilient arms 146 at the suture tag catch still slightly open due to the presence of the sharpened tip of the needle 112 in the base 147 of the Y-shaped member 144. Proximal withdrawal of the needle in this condition may cause the suture tag to stick to the needle due to residual frictional forces and thus not be captured by the prongs 148 against the proximal 116
25 of the suture tag. Accordingly, a frictional rub strip 149 may additionally be provided through the nest area 142 to provide a frictional surface on the capsule in the nest area that serves to hold the tag in the nest even if the resilient arms 146 have not yet sprung back to close around the proximal face 116 of the tag (FIG. 12). The frictional rub strip may be a polymer insert.

30 After slight proximal withdrawal of the needle such that the sharpened tip 112 is removed from the base of the Y 147, the arms 146 will close around the suture tag 114 so that prongs 148 engage the proximal face 116 of the tag (FIG. 14). As shown in the overhead view of FIG. 14, after the needle 108 is withdrawn proximally, the tag remains captured by the suture tag catch 140 within the nest 142. In the captured

position, resilient arms 146 return to a closed position such that inwardly projecting prongs 148 engage the proximal face 116 of the suture tag 114 holding it from proximal movement out of the nest. The nest 142 also serves to retain the tag 114 in alignment, so that it does not move distally or laterally during the suturing procedure
5 so that when the needle returns to pick up the tag, it will be in alignment with the through bore 118 of the suture tag 114.

The steps for retrieval of the tag are substantially the reverse of the steps illustrated for delivering the tag to the suture catch. In returning to retrieve the tag, the needle is advanced distally again into the area of the suture tag catch while in the
10 unlocked position (shown in FIG. 10). After the needle has bottomed out at the base of the Y 147, the needle may be slid proximally relative to the suture tag lock 120 so that the locking splines 126 ride up on the proximal barrel taper 111 of the needle creating the locked condition shown in FIG. 15. In the locked position, a proximal withdrawal for supply to the needle will overcome the restraining force presented by
15 the prongs 148 against the proximal face 116 of the tag, causing the resilient arms 146 to deform slightly and permit passage of the tag 114 along with the needle in its proximal withdrawal stroke.

Suture Capsule Control Handle

20 A side view of a suitable suture control handle 200 is shown in FIG. 16. Although one example of an endoscope is described herein as the illustrative embodiment, it should be understood that other configurations for the control handle may be suitable to operate the suture capsule as required. The control handle must provide means that permit the operator to drive the needle pusher shaft and the suture
25 tag locking sleeve 124 longitudinally and relative to each other to operate the capsule through the steps outlined above. Additionally, the handle should be releasably securable to the proximal handle assembly of an endoscope 210 at the opening port to the working channel of the endoscope through which the needle pusher shaft and suture tag locking sleeve will be inserted. Additionally, it may be preferable to route
30 the vacuum source line through the control handle so that the operator can selectively introduce and discontinue vacuum as appropriate to capture and release tissue during the suturing procedure. Alternatively, the control handle can involve a vacuum control switch which includes an interlock feature to prevent longitudinal movement of the

handle control members until a pre-established vacuum pressure is achieved in the suction chamber.

The control handle shown in FIG. 16 includes a collet 204 at its distal end 202 for connection to an endoscope control handle 210 at the proximal end 12 of an endoscope 10. The collet screws onto the port normally provided for the working channel of most endoscopes while permitting a through hole through which the needle pusher shaft 184 and suture tag lock sheath 124 may pass in slidable fashion.

The control handle also comprises a vacuum switch housing 208 as joined to the collet 204 and directs the vacuum line assembly through the body of the handle 200. The handle further comprises a main body portion 206 housing the components that translate longitudinal movement of plunger 216 into the segmented longitudinal movements of the needle pusher shaft 184 and suture tag locking sleeve 124. Visual markings 218 may be placed on the plunger to indicate to the user (by showing remaining bars of the marker not inserted into the main body 206) at which stage of deployment the control handle is in a given moment.

FIG. 17 presents a sectional view of the main body 206 of the control handle showing the mechanism that translate longitudinal movement of the plunger 216 to movement of the needle and suture tag lock assembly. FIG. 18 is a detailed sectional view of the main body 206 shown in FIG. 17. It is noted that the handle position shown in FIGS. 16-18 represents the initial state of the system in which the needle and tag remain in the needle track 110 on the proximal side of the suction chamber 106 prior to the first suture stroke.

FIGS. 17, 18 and 19A show a sectional view of the control handle in its initial position. The plunger 216 is engaged with both a locking sheath carrier 220 which is joined to the suture tag locking sleeve 124 and engaged with a needle carrier 230 that is engaged with the needle pusher shaft 184. The plunger engages the needle carrier 230 by pushing against plunger carrier 240 pushing against needle deployment spring 244, which is in engagement with the needle carrier 230 when the plunger is pushed distally relative to the main body 206 of the handle. When the plunger carrier 240 is slid distally, it slides through main carrier 248 to keep it in longitudinal alignment within the handle.

The plunger 216 is also in engagement with the locking sheath carrier 220 by engagement of a pawl arm 250. The distal end 252 of the pawl arm engages the locking sheath carrier 220 directly by contact with a small spring 254. The pawl arm

extends proximally over the needle deployment spring such that its proximal end 256 engages an around-the-world pawl track 258 retained in the plunger carrier 240 as shown in detail in FIG. 19B. An overhead view of the pawl track 258 is shown in FIG. 20 with a sectional view presented taken along the line A-A presented in FIG. 21. The
5 around-the-world track is three-dimensional such that as the proximal pawl arm travels in the track, its elevation changes to guide the pawl fully along the track in one direction despite only input of longitudinal movement from the plunger.

A handle return spring 260 surrounds the entire assembly of the plunger carrier 240 needle deployment carrier and pawl arm so that a proximal resilient force is
10 always present against the plunger 216 throughout deployment. An additional feature may be added to the handle to insure that a partially deployed needle is not withdrawn proximally prematurely.

A plunger ratchet assembly 270 insures that the plunger travels only in a distal direction until it has reached its maximum distal stroke length before permitting
15 proximal return of the plunger. This feature insures that the operator must complete the distal delivery stroke of the needle to insure that it is fully released in the proximal direction so that no attempt is made to withdraw the suture capsule assembly while the needle is partially or fully inserted through a suctioned tissue portion. The ratchet assembly 270 comprises a ratchet track 272 shaped as a parallelogram with a distally
20 extending straight track portion 274. A cylindrical ratchet pawl assembly 276 with projecting pawl arm 278 configured to ride within the track during longitudinal movement of the plunger 216 is secured in a ratchet pawl recess 280 formed in the main body 206 of the housing. Ratchet teeth 282 are formed on one side of the parallelogram ratchet track 272 so that ratchet action occurs only during distal
25 movement of the plunger 216 during the period in which the needle will be traversing the suction chamber of the capsule. The linear portion of the ratchet track 274 represents distal travel of the needle prior to traversing the suction chamber. The side of the parallelogram without ratchet teeth represents travel by the ratchet pawl arm 278 during the proximal return stroke of the plunger 216, which need not be controlled
30 by ratchet action for safety reasons.

Operation of the control handle and the corresponding movement of the components of the suturing capsule will be described in connection with FIGS. 17, 18, 19A, 24 and 25. From the initial position shown in FIGS. 17, 18 and 19A, the user begins operation of the control handle by first turning on the vacuum supply switch

224 (FIG. 16) to open the vacuum input line 214 (connected to a supply of vacuum) to the vacuum output line 212 that extends along the endoscope to the suturing capsule 100. The introduction of vacuum causes tissue to be sucked into the suction chamber 106 and the suturing process may be initiated.

5 From the initial position shown in FIGS. 17, 18, and 19A of the handle, the user depresses the plunger 216 fully as shown in FIG. 24 to drive the needle distally, traversing the suction chamber 106 and driving the suture tag 114 into the suture catch assembly 140 as shown in FIG. 14. Depression of the plunger 216 serves to push the plunger carrier 240 distally through the handle, compressing needle
10 deployment spring 244 and following compression of that spring, moving the needle carrier 230 distally by a stroke length equivalent to that traveled by the plunger 216. The locking sheath carrier 220 is also moved distally during the full distal stroke of the plunger 216 although by a magnitude slightly less than that achieved by the needle carrier 230 due to the travel of pawl 256 and pawl track 258 during the distal
15 movement of the plunger carrier 240.

As best shown in FIG. 20, the initial position of the proximal end of the pawl arm 256 and the pawl track 258 is represented by reference numeral 261. When the plunger carrier 240 first moves distally, the pawl arm slides in the pawl track to the second position indicated at 262 before any movement of the
20 pawl arm 250 occurs. After reaching the second position at 262, the pawl arm then begins to travel with the plunger carrier 240 during the remainder of the initial distal stroke of the plunger 216. That movement following the bottoming out of the pawl arm at position 262 serves to move the locking sleeve distally but not as far as the distal movement of the needle. The further distal advancement of the needle created by the
25 pawl mechanism causes disengagement of the suture tag lock 120 as shown in FIG. 9 so that the suture tag 114 can be left behind the suture tag catch 140.

When the user releases the plunger from its fully depressed configuration shown in FIG. 24, the plunger returns to an intermediate position shown in FIG. 25. In this position, the needle is withdrawn proximally from the suture tag catch to a position
30 that is proximal to the suction chamber 106. The tag 114 is left behind in the suture tag catch 140. The needle and suture tag lock remain in the same relative unlocked position at this stage. The needle and suture tag locking sleeve 124 remain in the same relative position due to the locking effect of the pawl track 258. As shown in FIG. 25 and FIG. 20, the pawl arm 256 is now maintained in the third position shown

at reference numeral 263 of the pawl track which serves to maintain the needle carrier 230 advanced relative to the locking sheath carrier 220. The entire assembly has been moved proximally by the return force of the handle return spring 260 which generated an automatic proximal return stroke for all components including the
5 plunger 216, plunger carrier 240, and by virtue of pawl arm 250, both the needle carrier 230 and locking sheath carrier 220.

To advance the needle a second time to retrieve the suture tag, either after a second tissue portion has been suctioned into the suction chamber 106 or prior to suctioning another tissue area, the user again advances the plunger 216 distally to its
10 fully distal stroke. This final stroke in the sequence serves to move all components to the maximum distal travel as previously shown in FIG. 24. However, because the pawl arm 256 is guided to the location identified by reference numeral 264 in the pawl track 258 shown in FIG. 20, the proximal return stroke experienced by the handle under the resilient force of handle spring 260 will cause the pawl arm 256 to follow the
15 track back to its initial position 261.

The pawl arm 256 is guided through this specific pattern in the around-the-world track 258 due to the elevation change of each segment of the track shown in the cross-sectional drawing of FIG. 21. Because the pawl arm is formed to have a resilient downward bias, as it travels through each segmented elevation change, it
20 resiliently springs down to the next level once it is reached. As a result, during the final proximal return stroke, the pawl returns to the original position at 261 which creates a relative movement between the suture tag lock sheathing 124 and needle 108 such that the locking splines 126 are again splayed outward by the spear-shaped distal end 109 of the needle to lock the suture tag 114 in place. The plunger ratchet
25 mechanism permits full return to its original position shown in FIG. 17. As the pawl arms 278 follows a descending path in the three-dimensional track 272 to proceed away from the ratchet teeth 282 to the bottom of the stroke at 274. The needle deployment spring 244 also resiliently expands to provide proximal motion for the entire needle and suture tag lock sheath assembly. The resulting configuration of the
30 handle is that shown in FIG. 17 and the capsule is returned to its initial state with the needle, suture tag withdrawn to the proximal side of the suction chamber 106.

Suture Lock and Delivery Device

The suture lock and suture lock delivery device of the present invention contribute to the utility of the system by providing a mechanism for securing the suture that avoids the cumbersome task of knot tying it provides a mechanical suture retainer that can be delivered through the working channel of the endoscope obviating the need to re-intubate with another instrument to complete the procedure. The suture lock and delivery device described herein is similar to that disclosed in pending U.S. Patent Application No. 10/275,534 corresponding to PCT Publication No. WO 01/89393. The entirety of the U.S. Patent Application is incorporated by reference herein in its entirety.

The suture lock of the present invention is shown in FIGS. 26A and B. FIG. 26A, a disassembled suture lock as shown comprising a ring 502 having a through bore 503 sized to receive with frictional engagement a plug 504 to capture a suture 18 that has been passed through the through bore 503. FIG. 26B shows the assembled configuration of the ring and plug suture lock with the plug 504 inserted into the through bore 503 of the ring 502 to capture the suture 18 between the surfaces of the plug and ring. It is noted that in FIG. 26B that the gap between the plug and the ring has been exaggerated to illustrate that the suture 18 is present between those two components, but it should be understood that the suture is tightly engaged between them so that it cannot slide through.

FIG. 27 shows the operating distal end 510 of a suture lock delivery device 512. The operating distal end is attached to a shaft 514 that is of sufficient length to extend through the full length of the working channel of an endoscope and protrude at the proximal end for engagement with a control handle 550 (shown in FIGS. 27 and 28-36 that follow), the components of the distal operating end of the suture lock delivery device can be seen. The device comprises an outer sleeve 516 through which is slidable a cage 518 defined by plurality of rigid fingers 520 inchedly attached at their proximal ends 522 to a bushing member 524. Circumferentially spaced fingers are mounted to the distal end 226 of the bushing 224 such that when the fingers are extended beyond the sleeve 516 they resiliently spring open radially at their distal ends 521. In their closed configuration, the fingers define a cage that serves as a receptacle 528 for the disassembled plug and ring components that must be navigated to the suture location through the working channel of the endoscope. The receptacle defined by the cage 518 serves to maintain the plug and ring in alignment so that they may be assembled easily at the remote location.

As shown in FIG. 27, when the suture placement in the tissue has been completed, the components of the needle and suture tag lock assembly, along with the control handle are removed from the endoscope working channel in their entirety. Though the capsule remains mounted on the distal end of the endoscope, the working channel provides adequate space for introduction of the suture lock delivery system device 512. The distal operating member 510 has sufficient space to operate as it protrudes from the distal end of the working channel of the endoscope in the suction cavity 106 of the capsule. When the distal operating member of the suture lock delivery device is inserted into the proximal end of the working channel of the endoscope, the suture leads 18 that extend through the working channel and through the tissue are first inserted through the ring 502 through its distal end, exiting its proximal end and being positioned around the plug 504 such that they extend through a proximal opening 530 of the sleeve 516 so that they can be held tight as the device is advanced to the internal location (FIG. 28-30).

With the suture threaded through the device and the device advanced to the suture location, the suture may be pulled tightly to gather the tissue portions that have been sutured and the device operated to cinch the suture leads and lock them in place to hold the tissue. The operation of the suture lock delivery device and operation of assembling the ring and plug and releasing the assembled component is preferably accomplished with a single distal stroke of a control handle actuator.

FIGS. 37 and 38 show a control handle that is configured for operating a delivery device with a single distal stroke of a control mechanism. The control handle 550 comprises a housing 552 with formed finger rings 554 to provide leverage in the users hand when depressing the plunger 556 distally. Extending distally from the control handle 550 is an outer shaft 558 protected by a short piece of strain relief 560 to prevent kinking in the area adjacent to the handle. The proximal end 562 of the outer shaft is joined to the body 552 of the handle. The proximal end 562 of the outer shaft is securely fastened to the body of the handle by bonding to a bushing 566 that is welded into the interior of the handle body 552. The distal end of the outer shaft 564 is joined to the outer sleeve 516. An inner shaft 570 is visible through the outer shaft 558 to operate a pusher 534 that pushes the plug 504 into the ring 502 during assembly in the cage 518. The inner shaft 570 is joined at its proximal end 571 to the plunger body 556. When the plunger is depressed, the inner shaft 570 moves distally to push the plug into the ring for assembly. The plunger shaft 556 is joined to a

bushing 574 that is slidable with a close fit inside of a channel 576 in the body 552 of the handle. A return spring 578 mounted in the channel 576 between plunger bushing 574 and outer tube bushing 566 serves to resiliently push the plunger back to its proximal position after being fully depressed distally. A pusher stiffener 580 may be added to the inner shaft to enhance its resistance to buckling under the compressive loading that occurs during assembly of the plug into the ring.

Though the handle is provided with a single longitudinal pusher control in the form of a plunger 556, the capability for performing several functions at the distal end is provided by a locking structure that is automatically released solely by the longitudinal movement of the pusher through its ring and plug assembly stroke. As seen in FIGS. 31-36, bushing 524, the ring 502 and plug 504 are held in the receptacle 528 defined by the cage 518 prior to assembly (FIG. 31). The ring 502 is maintained distally against the radially inward curved tips 523 of the fingers 520. Because the inwardly curved tips 523 define a diameter that is smaller than that of the ring, the ring cannot slide past the tips until the fingers are opened. The plug 504 is maintained in alignment with the through bore 503 of the ring by placement in the bore of bushing 524.

As seen in FIG. 31 immediately proximal to the aligned plug 504 is the distal end 532 of the pusher 534. When the plunger 556 of the control handle 550 is pushed distally, the inner shaft 570 pushes the pusher distally to insert the plug 504 into the ring 502 as is shown in FIG. 32. At this stage, the suture has been captured between the plug 504 and ring 502, but the assembled ring and plug must be released from the receptacle 528 defined by the cage 518. To accomplish this, the bushing 524 and cage 518 are made slidable relative to the outer sleeve 516 up to the point of where the proximal end of the fingers are hingedly attached to the bushing so that the distal ends of the fingers 521 may resiliently spring apart to release the assembled ring and plug.

To maintain the bushing and fingers stationary within the outer sleeve during assembly of the ring and plug but triggering release of the bushing and cage to slide distally relative to the sleeve after assembly of the ring and plug, locking balls 542 riding within recesses 544 formed in the bushing 524 are employed. The pusher shaft 534 forms the bottom surface of the recess that holds the locking balls. The space of the recesses 544 forces the balls into engagement with locking holes 546 formed in

the outer sleeve 516. When the locking balls are forced into the locking holes 546, the bushing 524 and cage 518 cannot slide relative to the outer sleeve 516.

The locking balls can be triggered to release from the locking holes 546 at the moment the plug has been fully inserted into the ring 502 by forming a reduced diameter portion along the pusher shaft that corresponds to the stroke length required to complete insertion of the plug into the ring. When the reduced diameter portion reaches the locking balls, the recess in which they are contained enlarges, immediately releasing their engagement force against the locking holes 546 of the outer sleeve 516. The rounded surface of the balls immediately permits disengagement from the locking holes 546 and enables the bushing 524 with cage 518 and assembled ring and plug all to move distally relative to the sleeve if distal forces are maintained on the pusher shaft 534. The reduced diameter portion of the pusher is indicated at 548 in FIG. 32, which reaches the locking balls 542 at the moment the pusher has extended sufficiently to place the pusher plug 504 into the ring 502. Distal force is maintained on the bushing 524 by engagement of an enlarged diameter portion of the pusher beginning at 549 engaging the proximal end of the bushing 541 (FIG. 32).

With continued distal movement of the pusher 534, the bushing and cage assembly slide distally relative to the outer sleeve 516 as is shown in FIGS. 34 and 35. After the cage has been fully exposed from the outer sleeve, the fingers 520 resiliently spring open radially to permit release of the assembled ring and plug as is shown in FIG. 36. Excess suture leads are severed as the bushing crushes the sutures against sharpened edge 531 of sleeve opening 530 during the distal advancement of the bushing and cage 518. When the plunger 556 at the control handle 550 is released, return spring 578 causes the plunger to move proximally, which withdraws the pusher proximally until the first large diameter segment engages the proximal end of the bushing 524 pulling the bushing and cage back into the sleeve 516 under continued proximal movement of the pusher 534.

30 Operation

The operation of single intubation suturing system described above will now be explained with reference to schematic illustrations shown in FIGS. 39-54 in conjunction with drawings presented in FIGS. 55-63. In operation of the device, the suturing capsule 100 is first mounted to the distal end of an endoscope 10 as shown



in FIG. 39. With the needle 108 and the suture tag 114 positioned proximal to the suction chamber 106, the capsule endoscope assembly are advanced through a natural body lumen to the intended tissue location. This configuration is also shown in FIG. 55.

5 After reaching the intended tissue location, vacuum is applied to draw a tissue portion 117 into the suction chamber 106 as is shown in FIGS. 41 and 56.

After tissue 117 has been suctioned, the needle 108 and suture tag 114 may be advanced distally through the tissue so that the needle and tag exit and enter the suture tag catch 140 as is shown in FIGS. 42, 57 and 58. Next, the suture tag 114 is
10 released and the suture tag catch 140 and the needle is withdrawn proximally leaving the suture 18 placed through the tissue portion as is shown in FIGS. 43 and 59.

As shown in FIGS. 45, 60 and 61, the vacuum is discontinued and the tissue is released from the suction chamber 106 with the suture 18 passing through the tissue. After the tissue is released, either another tissue portion at a different location may be
15 suctioned to be penetrated by the open needle and sutured during the proximal withdrawal stroke of the suture tag 114 through the tissue or, before applying suction to capture another tissue portion, the needle may be advanced distally to pick up the suture tag 114 and withdraw it proximally so that the suture will be advanced in the distal direction through the second tissue portion that is captured. In the figures, the
20 latter method is illustrated wherein the suture tag is first retrieved and brought back proximally prior to the next suture.

In FIGS. 45 and 62, it is shown that after release of the first sutured tissue portion 117, the needle 108 is advanced distally to recapture the suture tag in the suture tag catch 140. After the tag is secured onto the needle by the suture tag lock
25 120, the needle and tag assembly can be withdrawn proximally back into the needle track 110 at the proximal site of the suction chamber as is shown in FIGS. 46, 47 and 63. After the needle is retracted proximally with the suture tag, a second tissue portion 119 may be aspirated into the suction chamber and the above process repeated to place another suture at a second tissue location using the same suture 18
30 as is shown in FIGS. 48-50. After a desired number of tissue portions have been sutured with the suture material 18, the needle and control handle components related to the suturing device may be removed from the working channel of the endoscope and the suture lock delivery device 500 loaded with a ring 502 and plug 504 lock device may be inserted through the working channel of the endoscope so that the

distal operating end 510 of the device extends into the suction chamber 106 of the capsule 100. As shown in FIGS. 52 and 53, a ring and plug 502 and plug 504 may be applied to the ends of the suture 18 to secure the suture to hold the tissue portions 117 and 119 together tightly. After the suture lock is applied, the suture lock delivery
5 . device 500 may be removed from the working channel of the endoscope as shown in FIG. 54 and the endoscope removed from the patient.

2/1

Having thus described the invention what we desire to claim and secure by letters patent is:

Claims

1. An endoscopic tissue suturing device comprising:
a suturing capsule having a tissue suction chamber, needle track and a suture
5 tag catch, wherein the suture tag catch is positioned distal to the tissue suction
chamber,
a needle slidable in the needle track and along a pathway that passes through
the tissue suction chamber, a suture tag lock on an exterior surface of the needle, and
a suture tag capturable on the exterior surface of the needle by the suture tag
10 lock and that is releasable from the needle into the suture tag catch when the suture
tag lock is released.
2. An endoscopic tissue suturing device as defined in claim 1 wherein the suture
tag lock changes its position relative to the exterior surface of the needle to create a
15 locking surface that engages the suture tag to prevent distal sliding movement of the
tag relative to the needle.
3. An endoscopic tissue suturing device as defined in claim 2 wherein the exterior
surface of the needle is shaped to engage the suture tag lock when the lock is moved
20 longitudinally relative to the needle to form the locking surface.
4. An endoscopic tissue suturing device as defined in claim 3 wherein the suture
lock comprises at least two locking splines that are spread open as they slide over an
enlarged surface of the needle to create the locking surface that holds the suture tag
25 from longitudinal movement.
5. An endoscopic tissue suture device as defined in claim 1 wherein the suture
tag catch comprises two resilient arms bound together at one end of their ends in a Y-
configuration each with a prong-shaped free end having an inwardly projecting edge
30 configured to engage a surface of the suture tag.
6. An endoscopic tissue suturing device as defined in claim 5 wherein the suture
capsule further comprises a cavity which is configured to closely fit around the surface

of the suture tag while permitting movement of the resilient arms of the suture tag catch.

7. An endoscopic tissue suturing device as defined in claim 1 wherein the suture
5 tag is annular and slides over an exterior surface of the needle.

8. An endoscopic tissue suturing device as defined in claim 7 wherein the tag has
proximal and distal ends and is tapered at least at its distal end to present a low profile
as the needle is advanced distally through tissue.

10

9. An endoscopic tissue suturing device as defined in claim 4 wherein the needle
is solid and has a spear-shaped distal end with straight tapered barrel surfaces
extending from the proximal and distal directions meeting at a central increased
diameter section to define an enlarged shape.

15

10. An endoscopic tissue suturing device as defined in claim 1 further comprising a
control handle releasably securable to a proximal end of an endoscope and having at
least one longitudinal control member joined to a shaft extending through a working
channel of an endoscope to control the longitudinal movement of the needle.

20

11. An endoscopic tissue suturing device as defined in claim 10 wherein the handle
further comprises a control mechanism for actuating the suture tag lock during a
portion of a stroke of the longitudinal control member that operates the needle.

25 12. An endoscopic tissue suturing device as defined in claim 11 wherein the
longitudinal control member of the handle includes an around-the-world pawl and
track mechanism oriented to cause movement of a suture tag lock control shaft during
only a portion of the longitudinal stroke of the control mechanism that operates the
needle.

30

13. An endoscopic tissue suturing device as defined in claim 10 wherein the control
handle further includes a vacuum control switch including an interlock feature that
prevents longitudinal movement of the handle control members until a pre-established
vacuum pressure to the suction chamber of the capsule is achieved.

14. A single intubation multiple stitch endoscopic suturing system comprising:
a suturing capsule releasably securable to a distal end of an endoscope and
having a needle slidable in a needle track;
5 a suction chamber for receiving tissue;
a suture tag joined to a suture and slidable over the needle;
a selectively releasable suture tag lock on the needle;
a suture tag catch distal to the suction chamber and configured to frictionally
engage the suture tag;
10 a suturing capsule control handle releasably securable to a proximal end of an
endoscope and comprising at least one longitudinal control member attached to one
end of a control shaft having at its other end a connection to the needle so that
longitudinal movement of the control member results in corresponding movement of
the needle;
15 a suture lock comprising a plug frictionally engageable within a ring to capture a
suture therebetween;
a suture lock delivery device comprising a shaft having distal and proximal
ends and having a sufficiently small diameter to be slidably receivable through a
working channel of an endoscope and sufficient length to extend at least the length of
20 the endoscope;
a suture lock carrier at its distal end comprising a cage defined by a plurality of
arms longitudinally arranged and hinged at their proximal ends;
a suture cutter slidable on the cage;
a suture lock delivery device control handle comprising a longitudinal slide for
25 actuating a pusher extending through the shaft to push the plug into the ring and
advance the cage distally relative to the sleeve to open the fingers and release the
assembled ring and plug.
15. A method of suturing a plurality of tissue folds, comprising:
30 providing:
a suturing capsule having a tissue suction chamber, needle track and a
suture tag catch, where the suture tag catch is positioned distal to the tissue suction
chamber;

a needle slidable in the needle track and along a pathway that passes through the tissue suction chamber, a suture tag lock on an exterior surface of the needle,

5 a suture tag releasably secured to and about the needle by the suture tag lock and that is releasable from the needle into the suture tag catch when the suture tag lock is released; and

a suture attached to the suture tag;
suctioning a tissue fold into the tissue suction chamber;
advancing the needle, suture tag and suture into and through the tissue fold;
10 capturing the suture tag in the suture tag catch;
releasing the suture tag from the needle;
retracting the needle through and out of the tissue fold;
releasing the tissue fold from the tissue suction chamber;
advancing the needle to the suture tag catch and into the suture tag;
15 capturing the suture tag on the needle;
releasing the suture tag from the suture tag catch;
retracting the needle and attached suture tag to a position proximal to the tissue suction chamber;
advancing the suturing capsule to another area of tissue;
20 suctioning a tissue fold into the tissue suction chamber;
advancing the needle, suture tag and suture into and through the tissue fold;
capturing the suture tag in the suture tag catch;
releasing the suture tag from the needle;
retracting the needle through and out of the tissue fold;
25 releasing the tissue fold from the tissue suction chamber; and
securing the ends of the suture with a suture clip;
thereby suturing the tissue folds.

FIG. 1

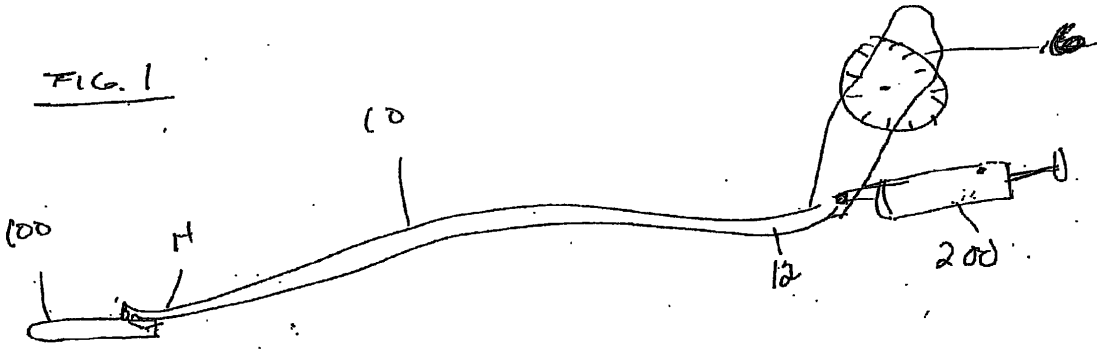


FIG. 2

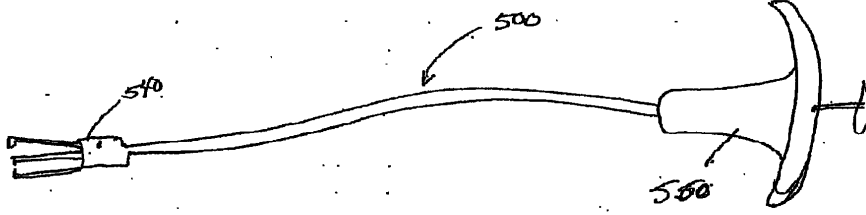


FIG. 3A

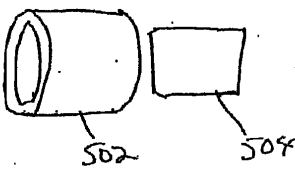
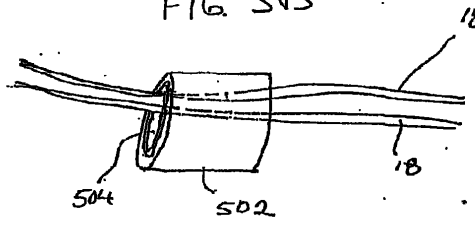


FIG. 3B



39

FIG. 4.

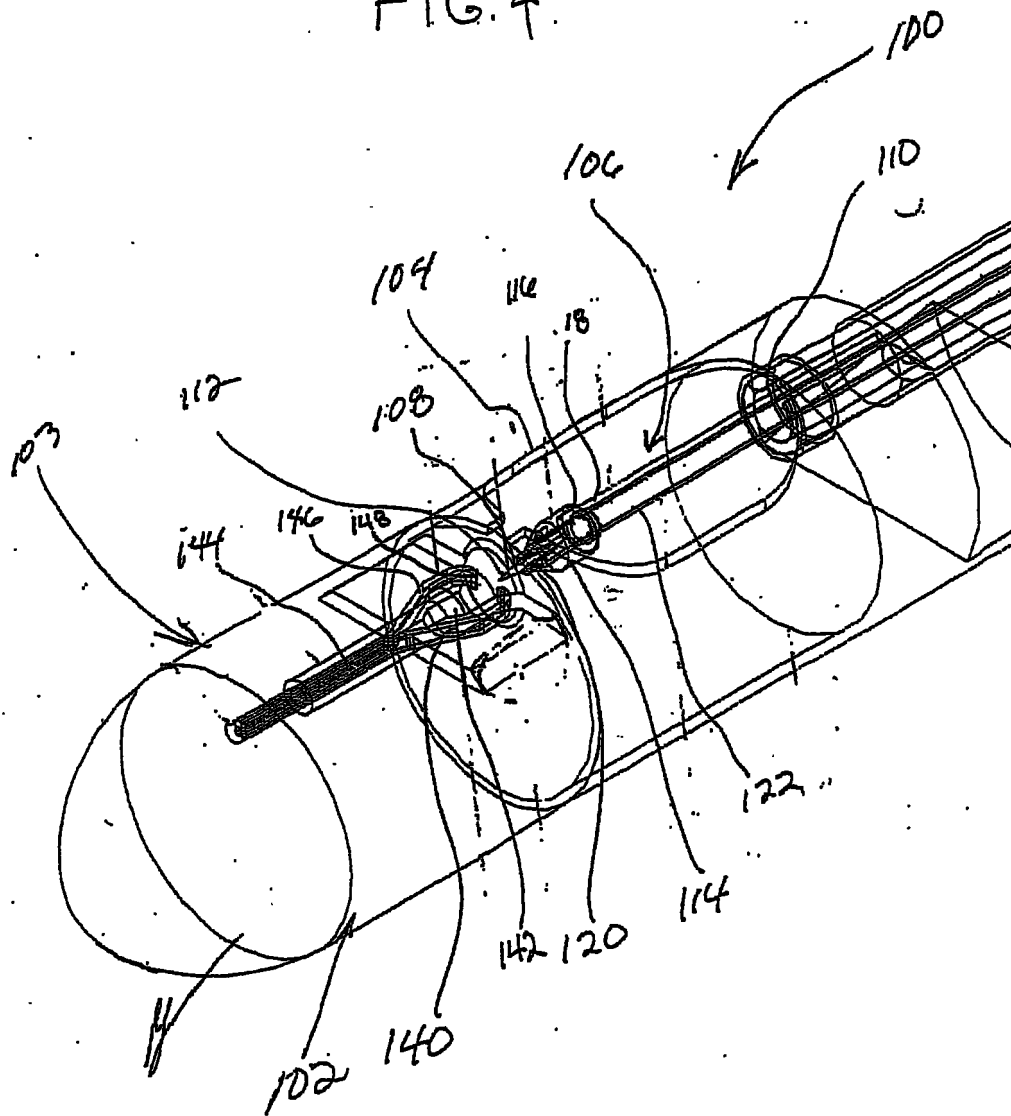


FIG. 5

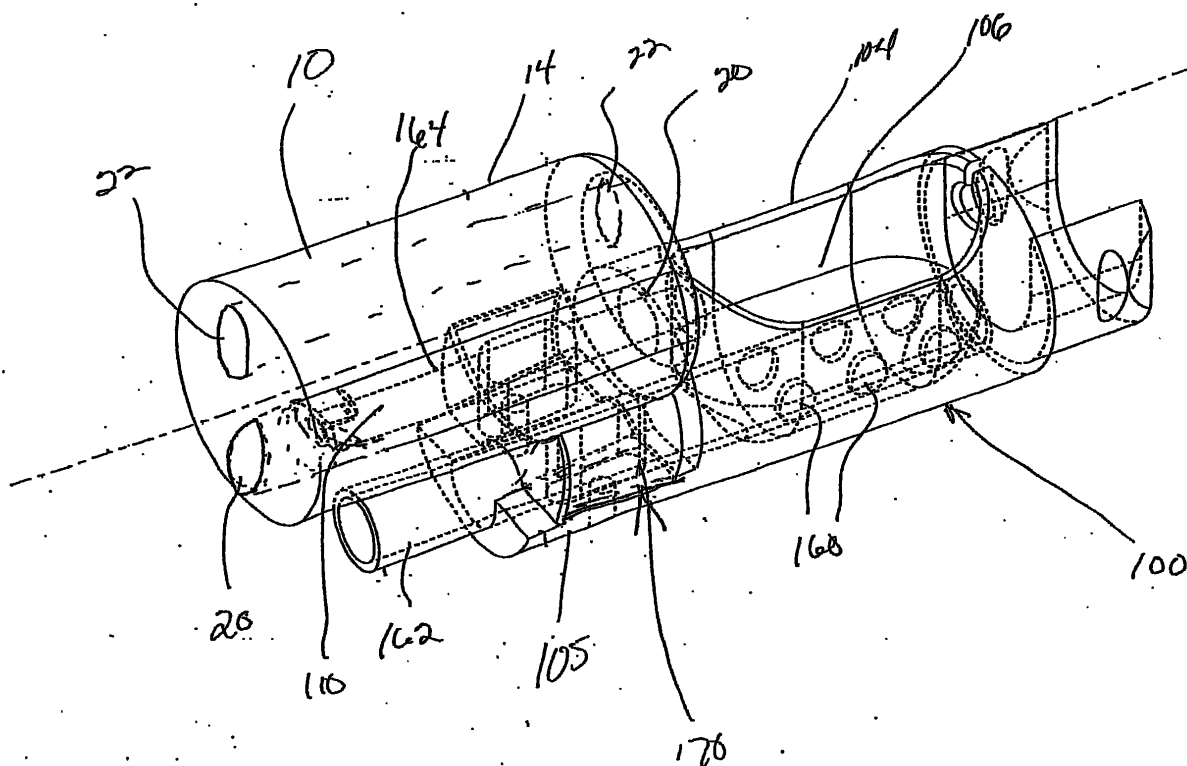


FIG. 6

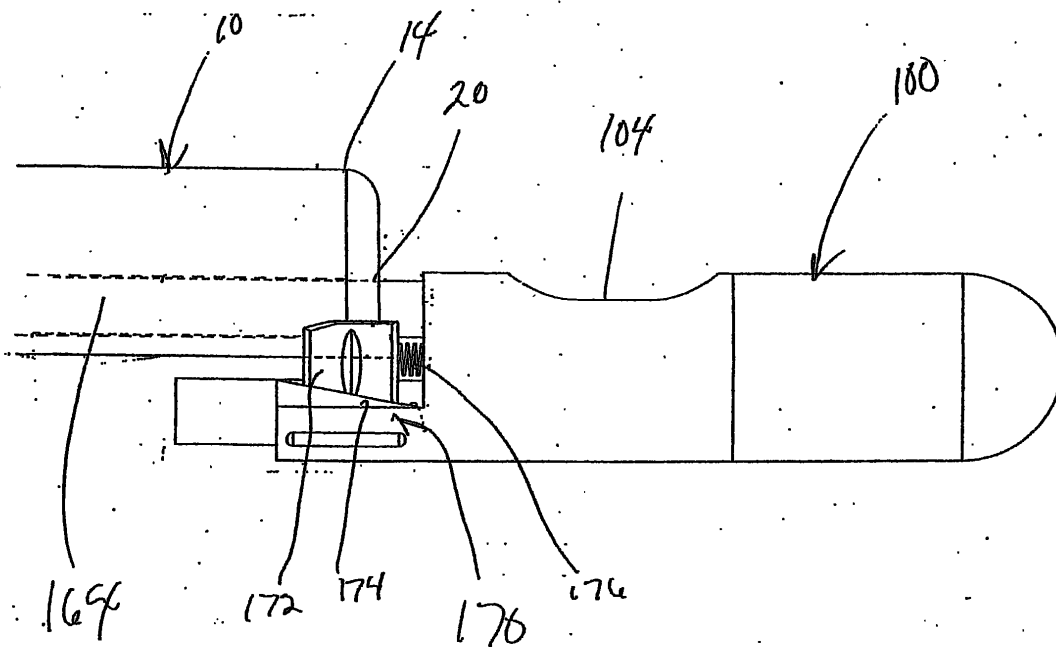


FIG. 7B

42

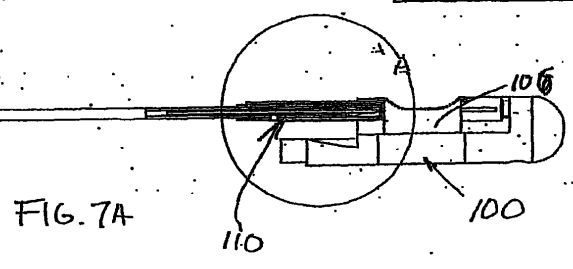
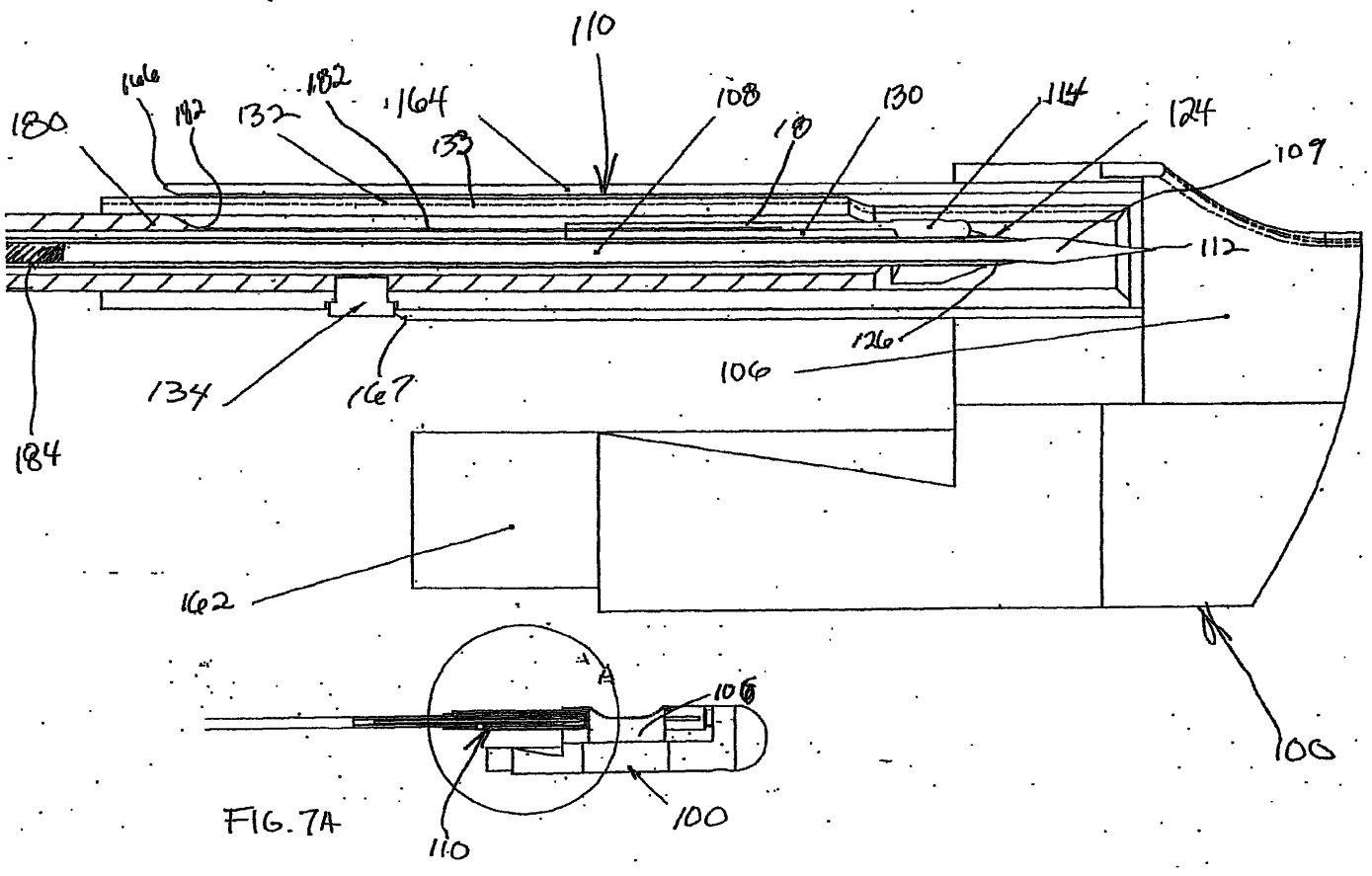
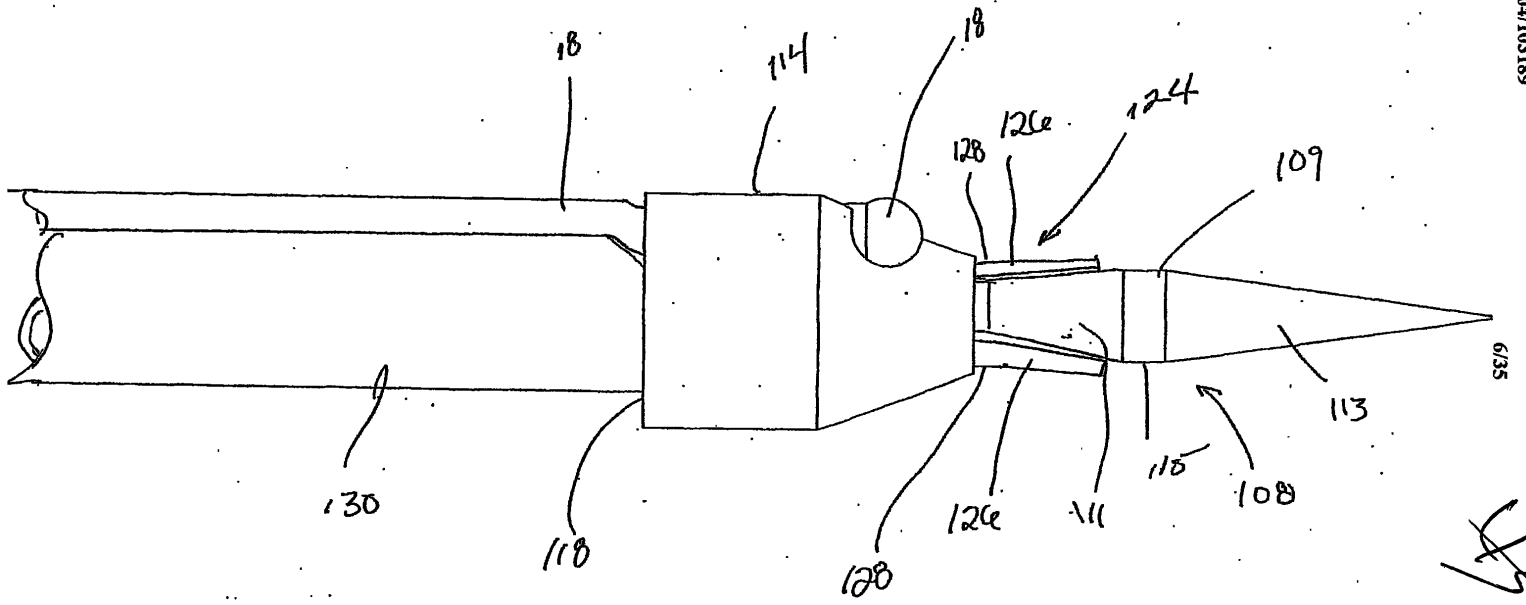


FIG. 8

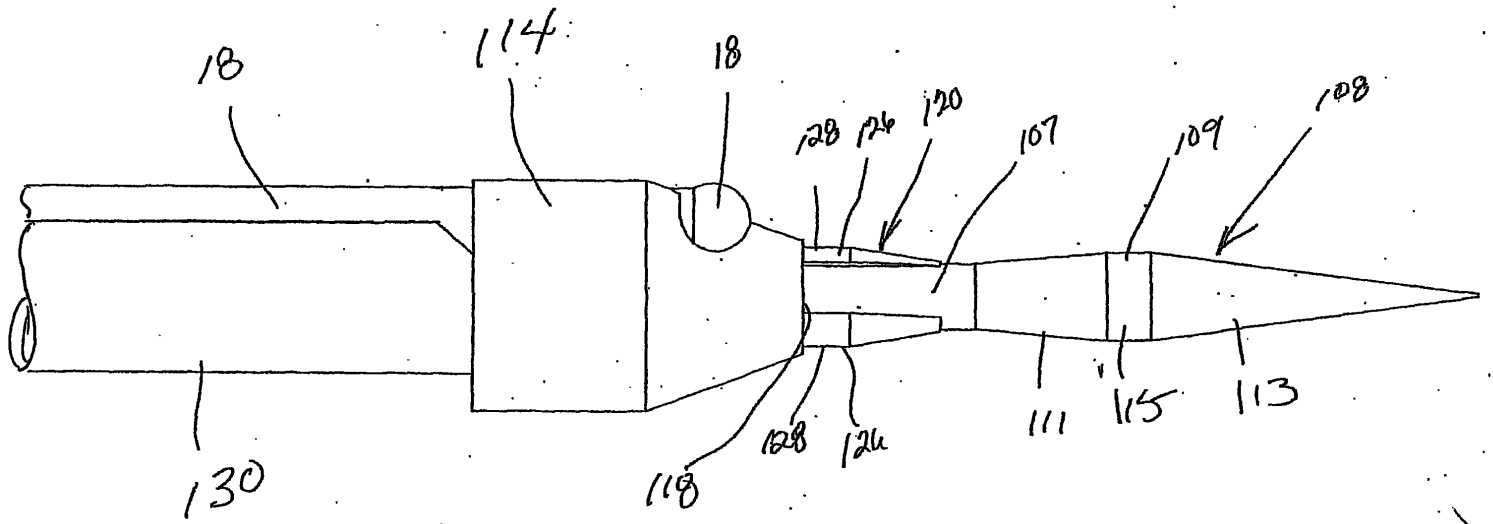
WO 2004/103189



PCT/US2004/015670

FIG. 9

WO 2004/103189



7/35

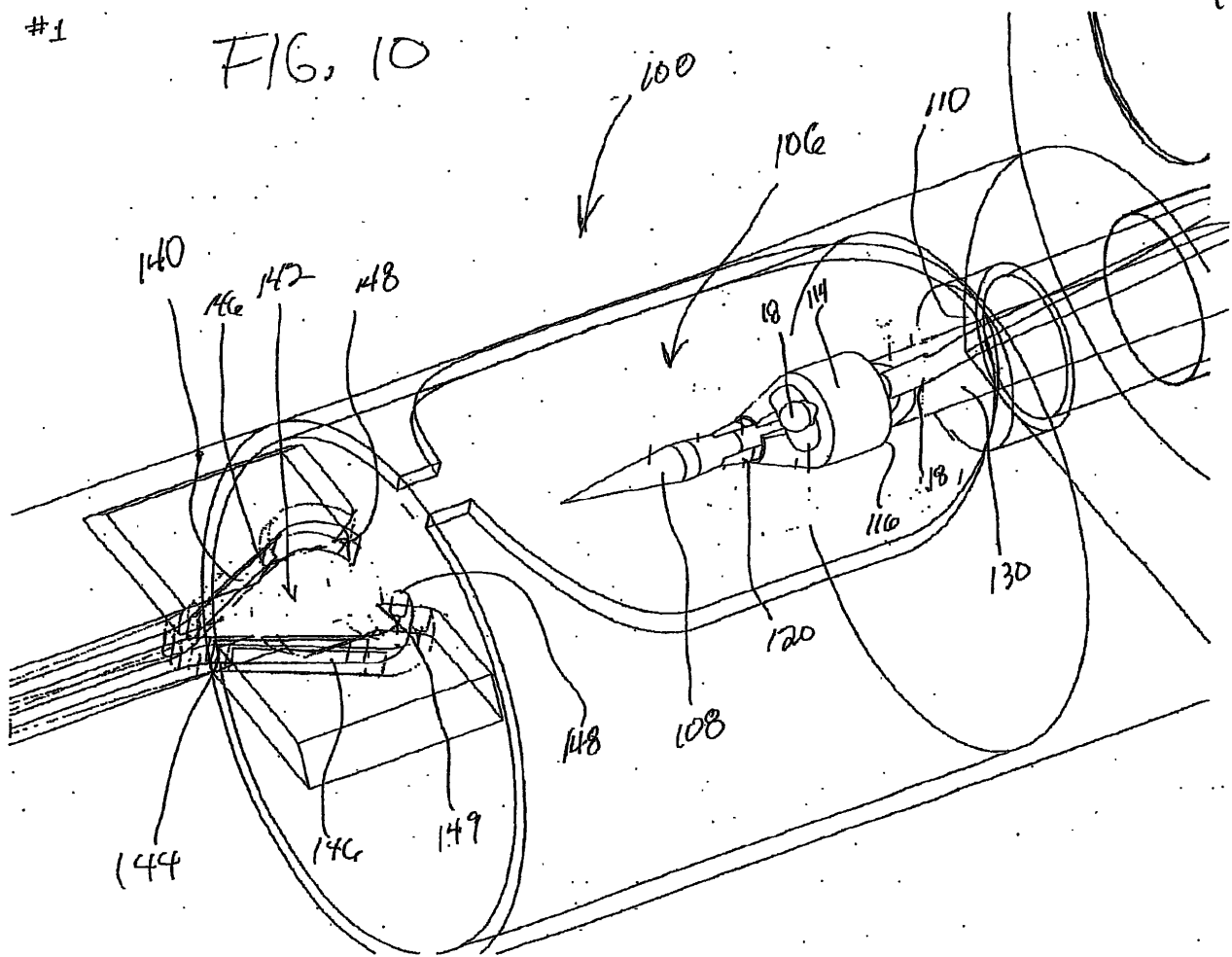
~~Handwritten signature~~

PCT/US2004/015670



#1

FIG. 10



~~46~~

FIG. 11

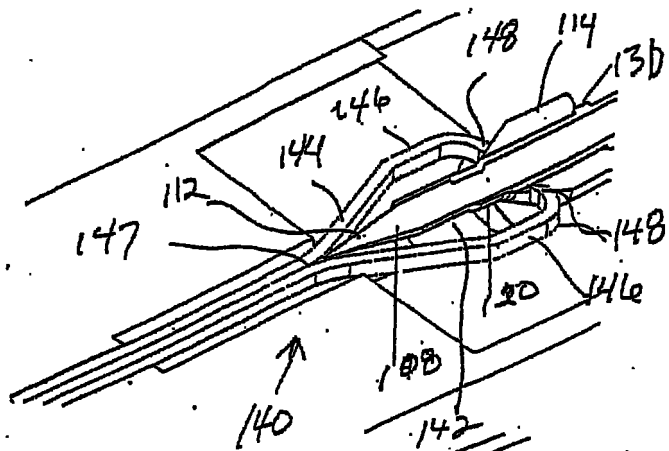


FIG. 12

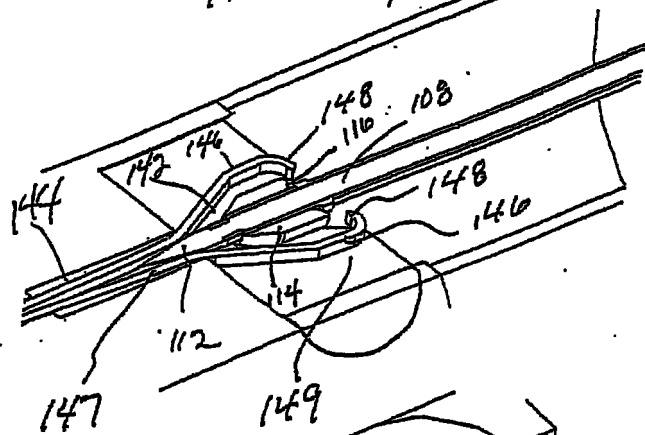


FIG. 13

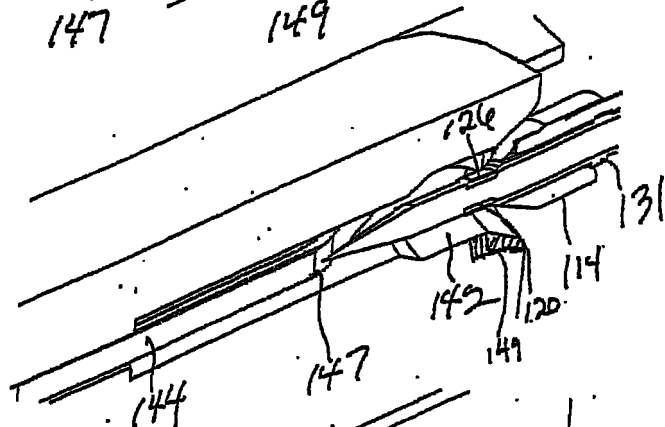


FIG. 14

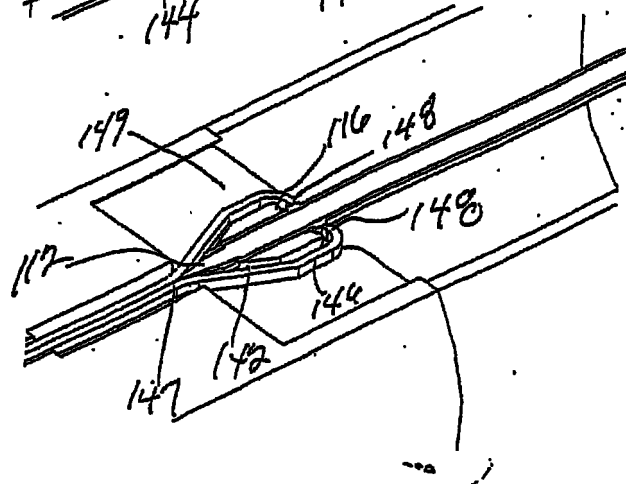
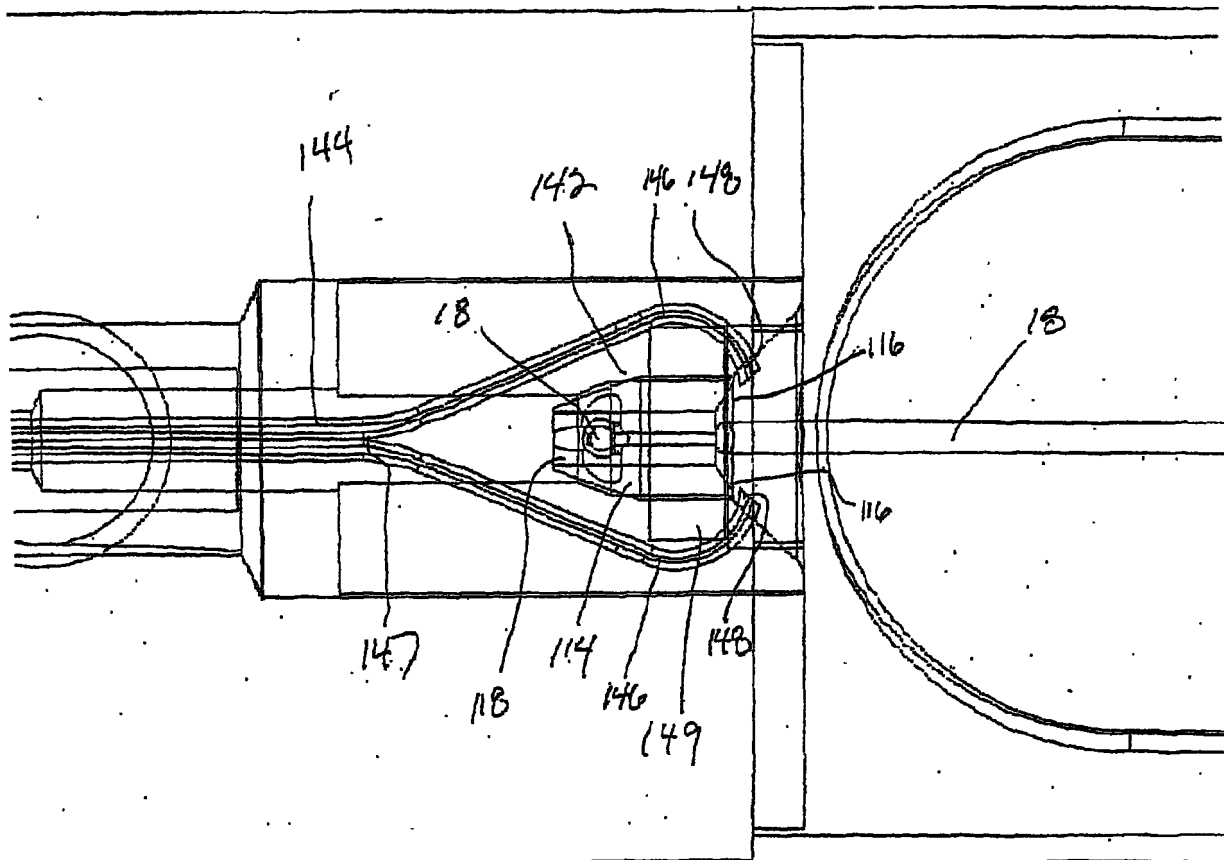


FIG. 15



TAB CAPTURED BY
LOCKING FINGERS

48

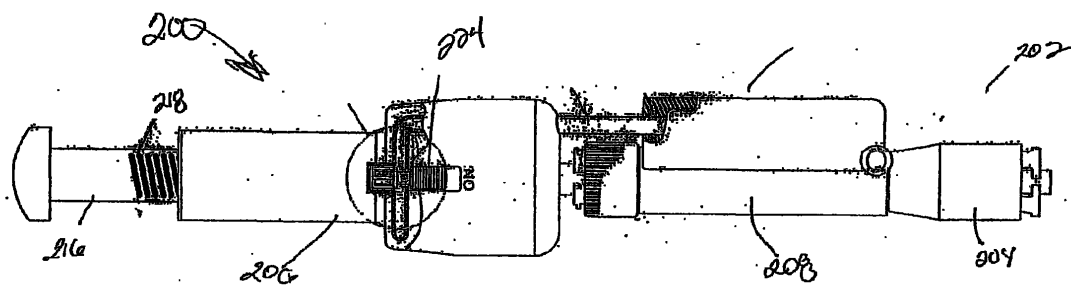


FIG. 16

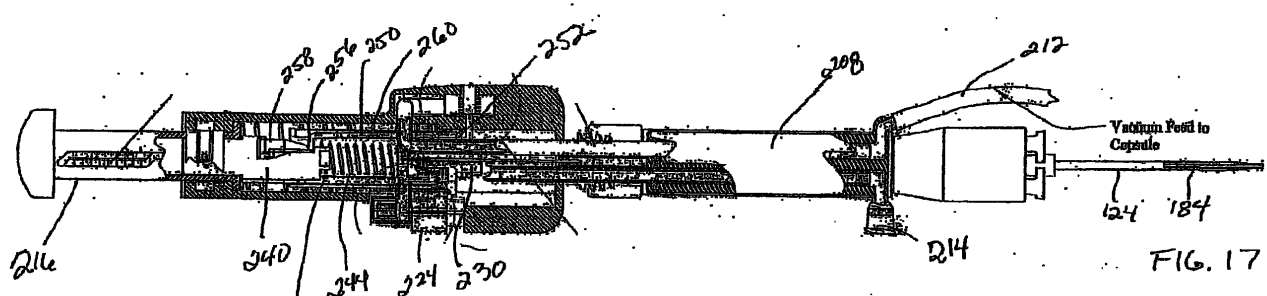


FIG. 17

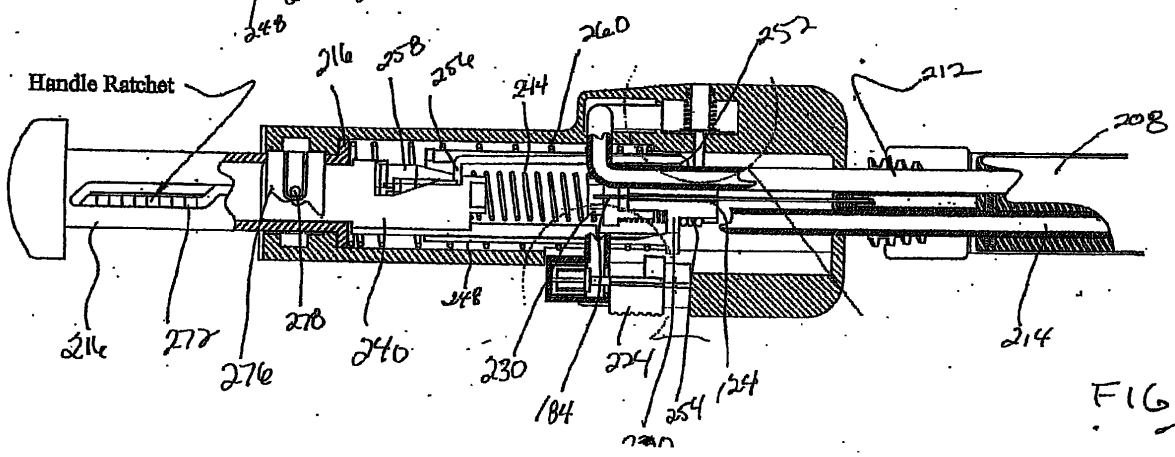


FIG. 18

FIG. 19B

FIG. 19C

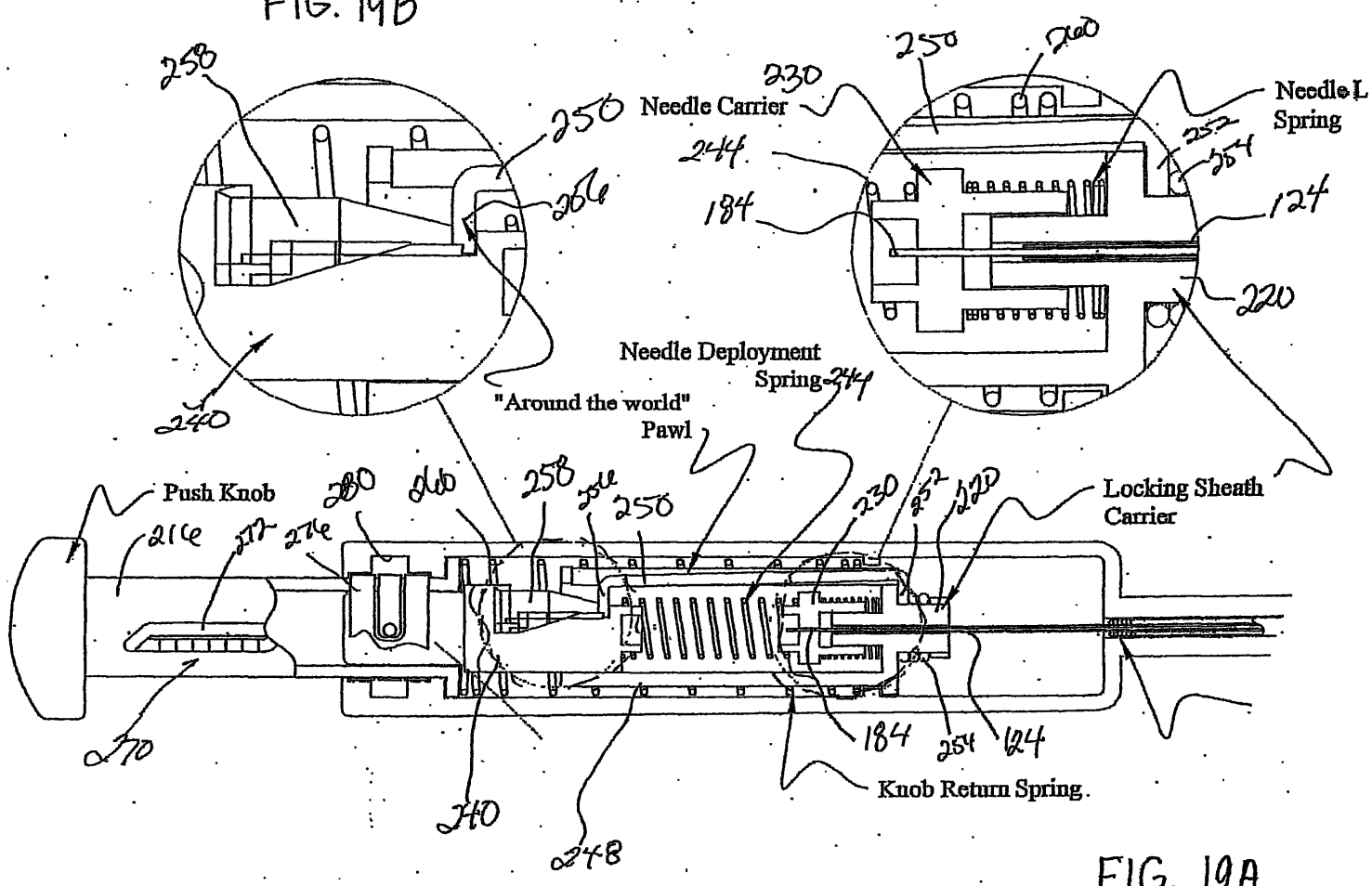


FIG. 19A

50

FIG. 21

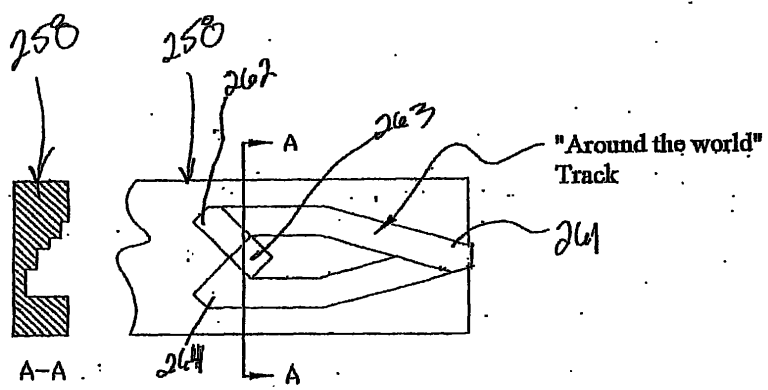


FIG. 20

FIG. 22

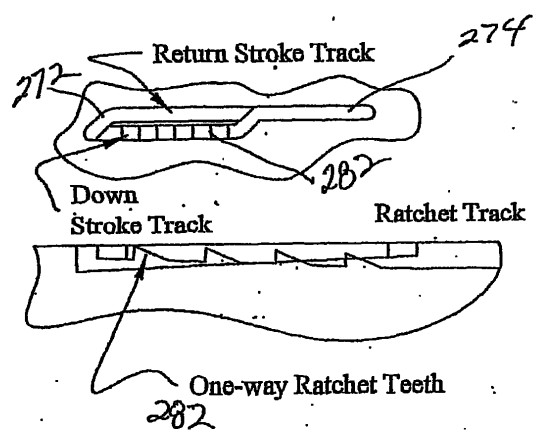


FIG. 23

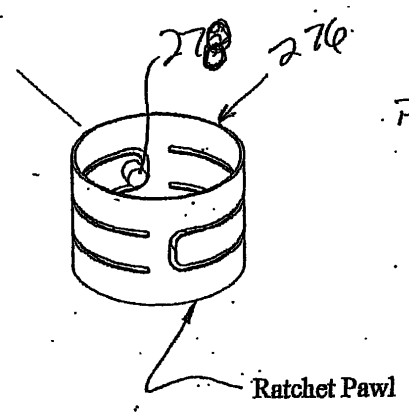


FIG. 24

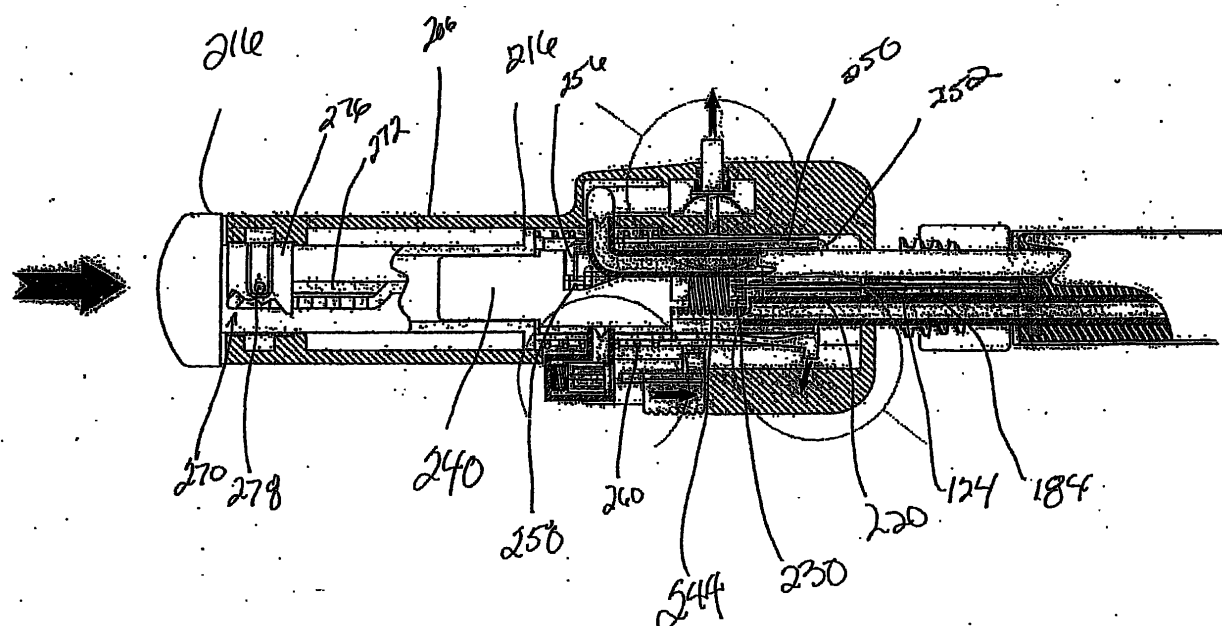
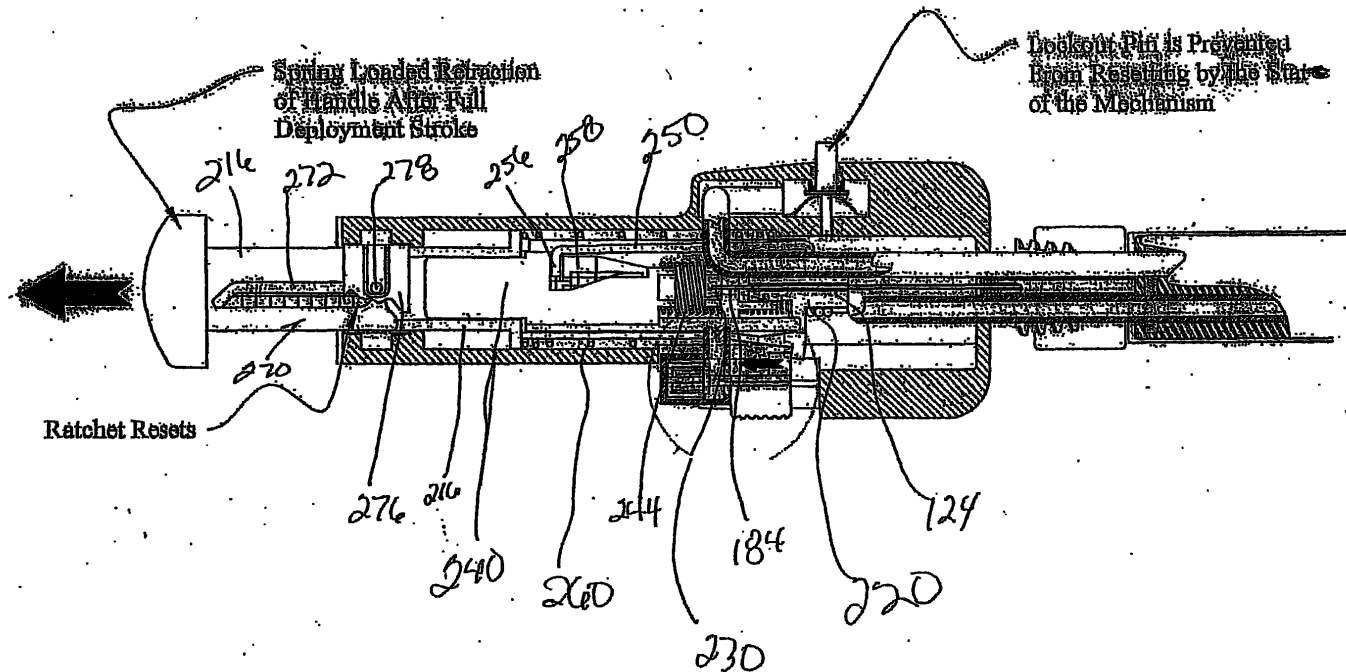


FIG. 25

WO 2004/103189

15/35

PCT/US2004/015670



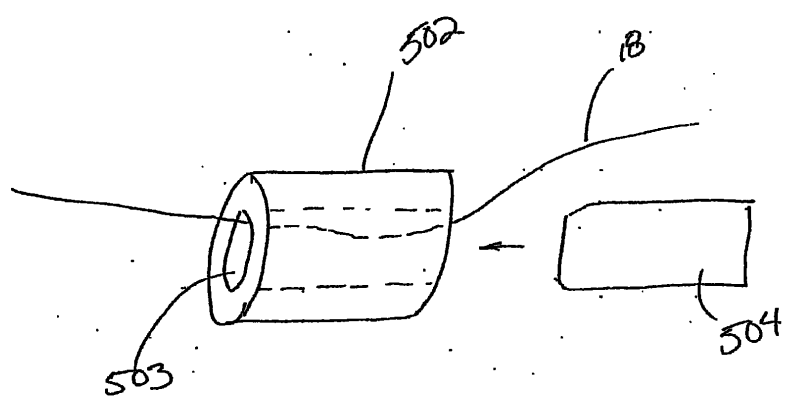


FIG. 26A

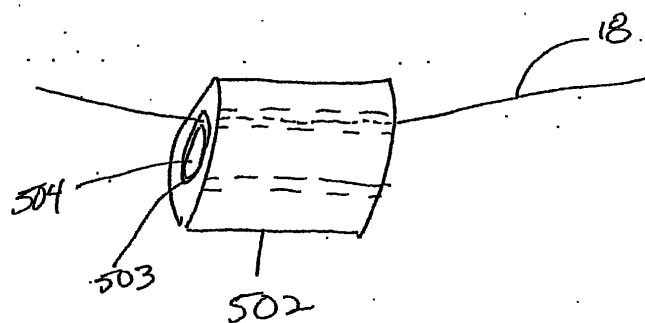


FIG. 26B

FIG. 27

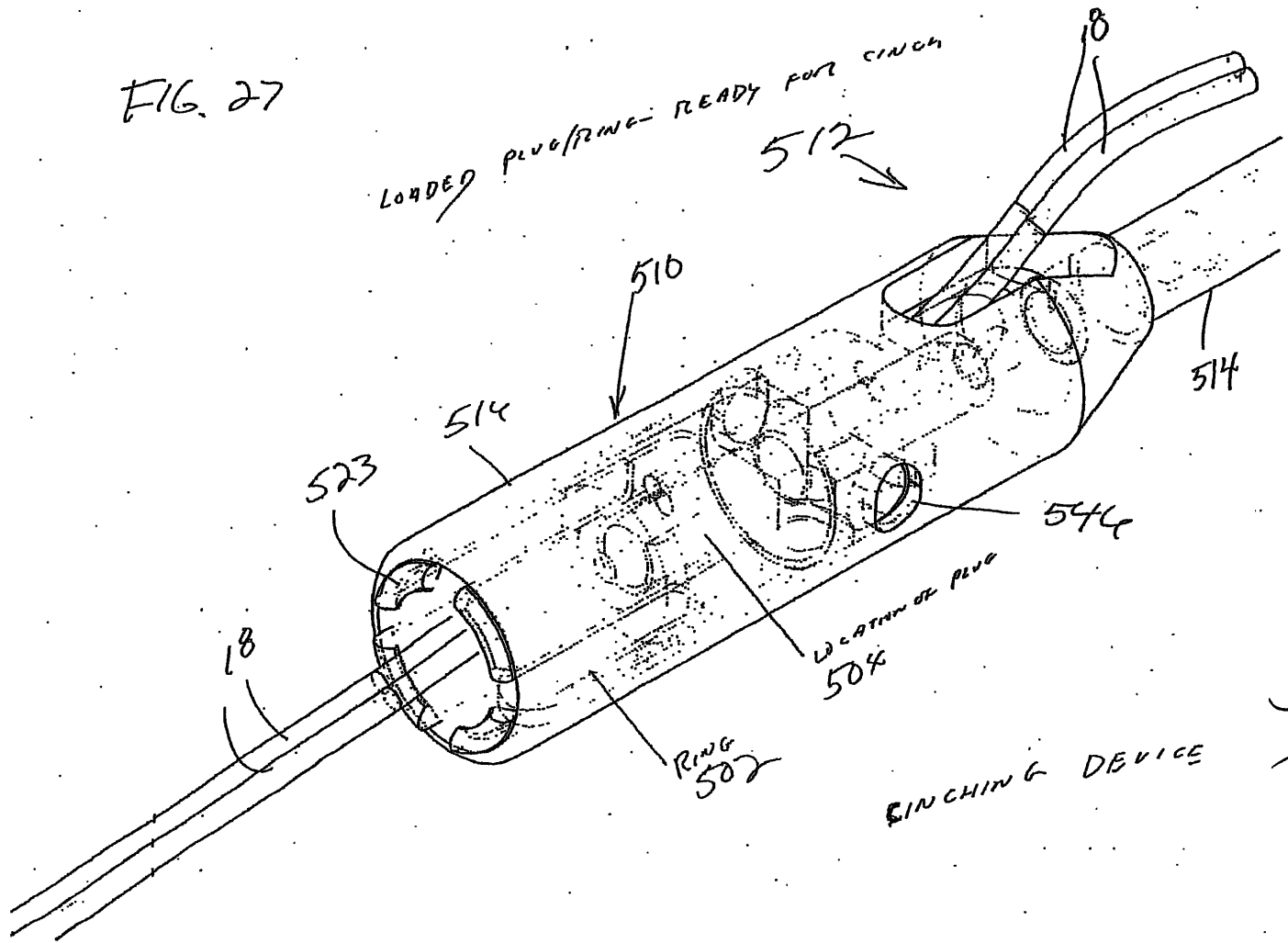
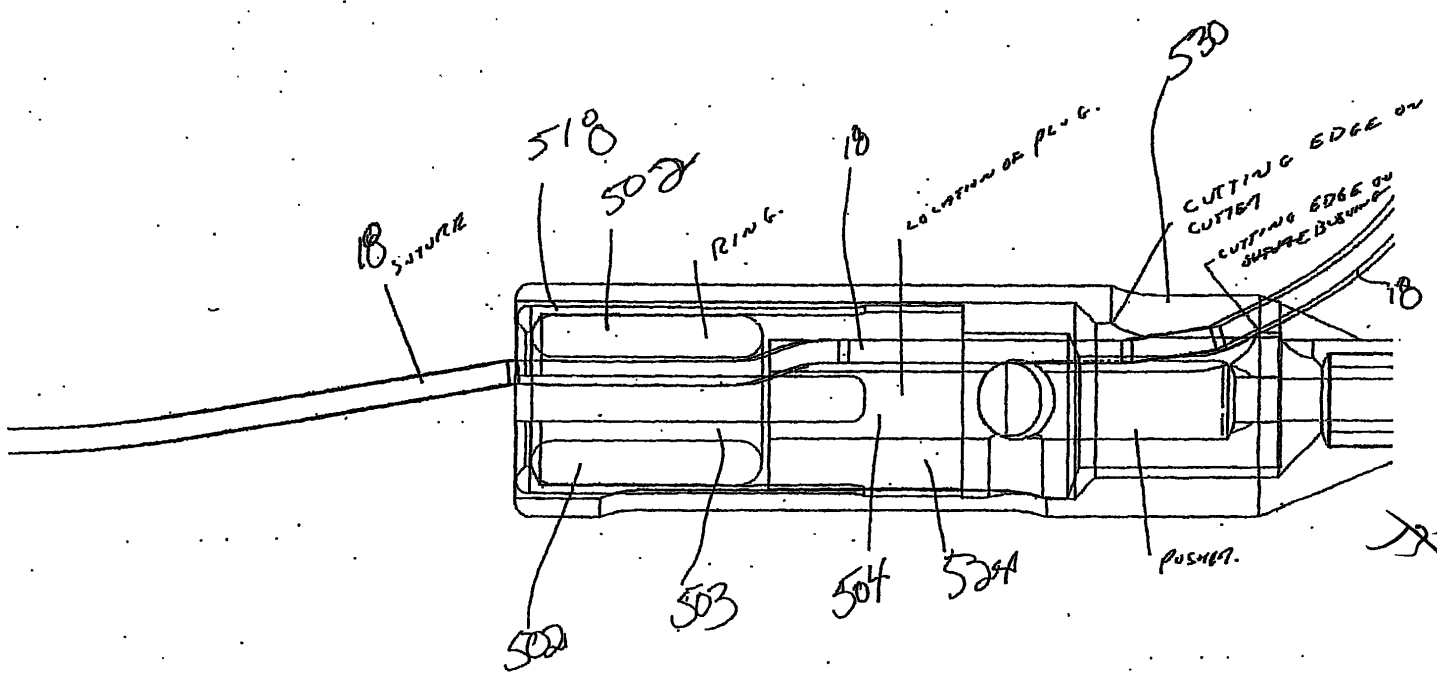


FIG. 28

55

WO 2004/103189



18/35

PCT/US2004/015670

~~50~~ 56

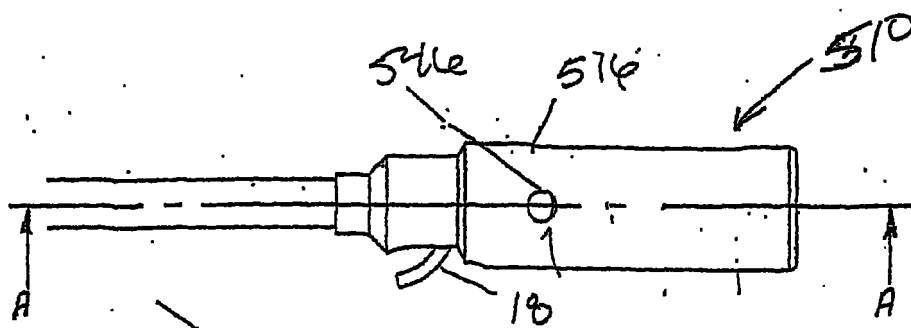


FIG. 29

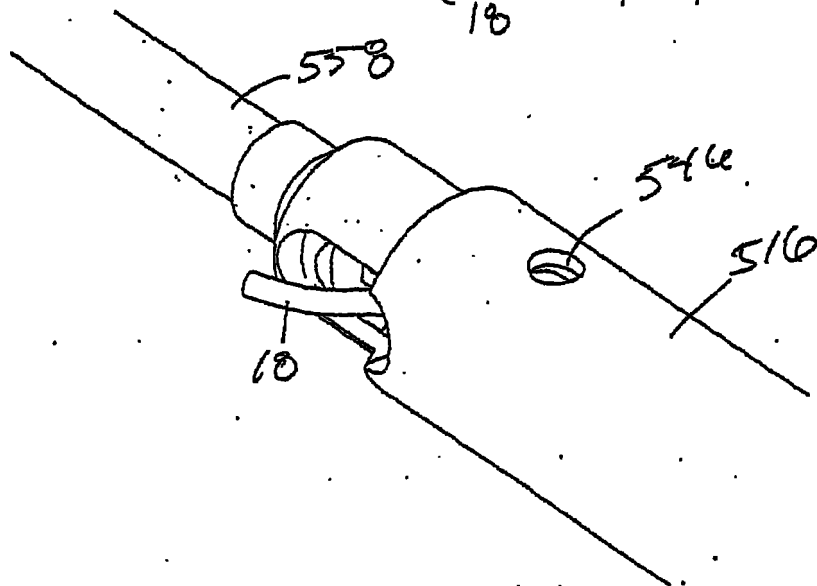


FIG. 30

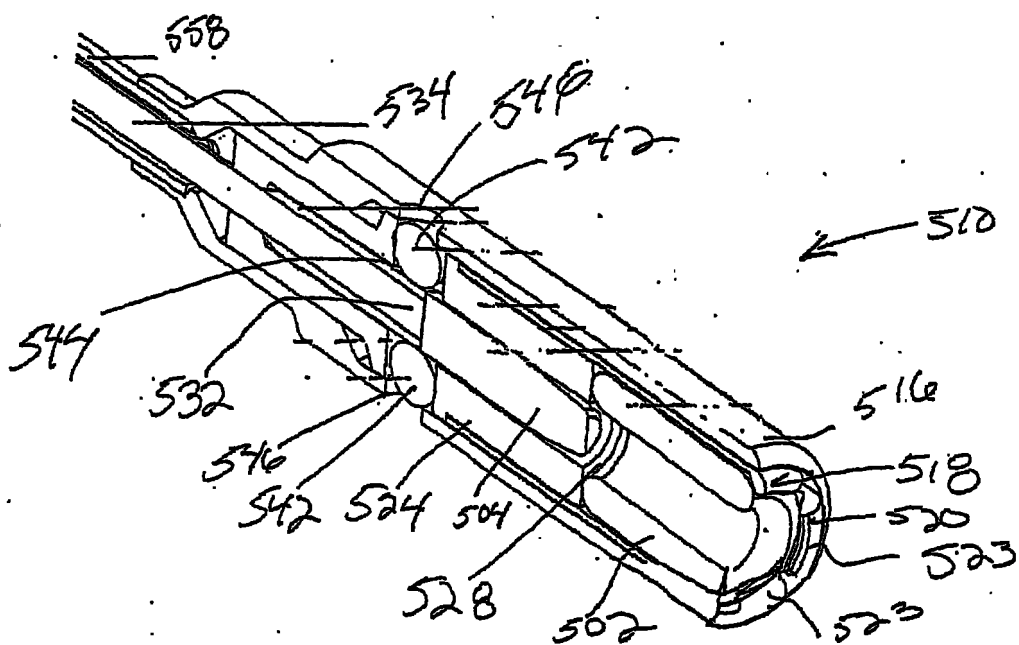


FIG. 31
SECTION A-A

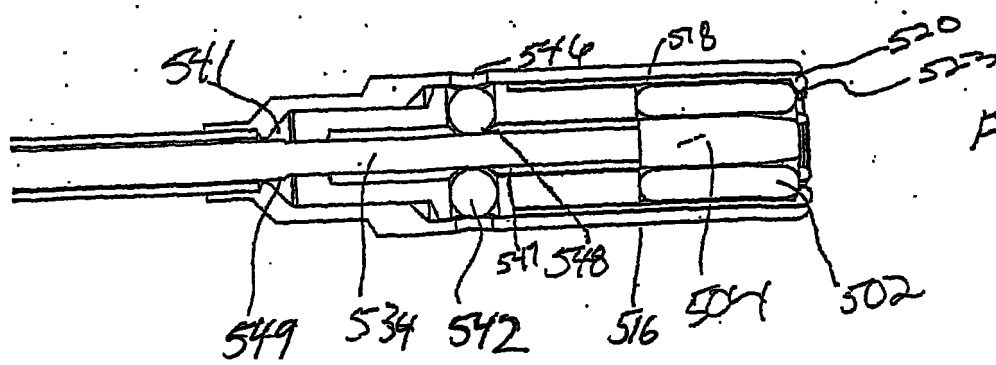


FIG. 32

20/35

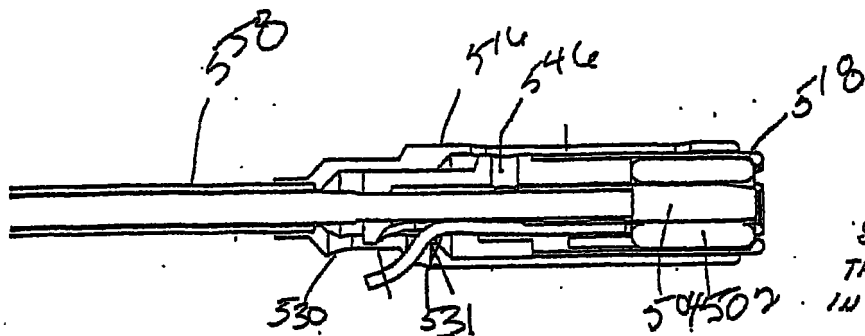


FIG 33
SECTION B-B
TAKEN FROM FIG 29
IN THE ORTHOGONAL PLANE

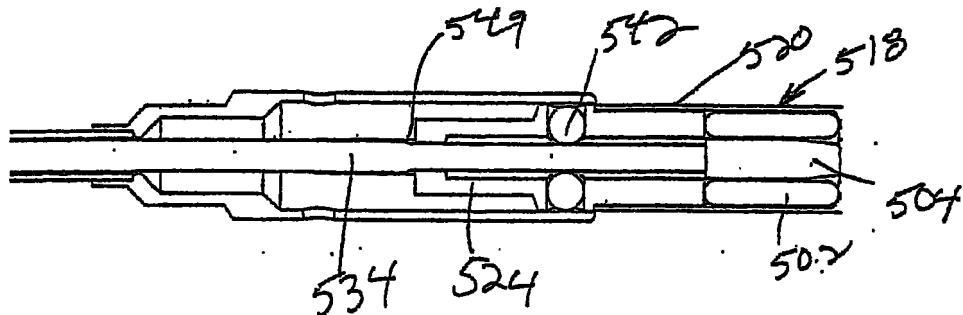


FIG 34

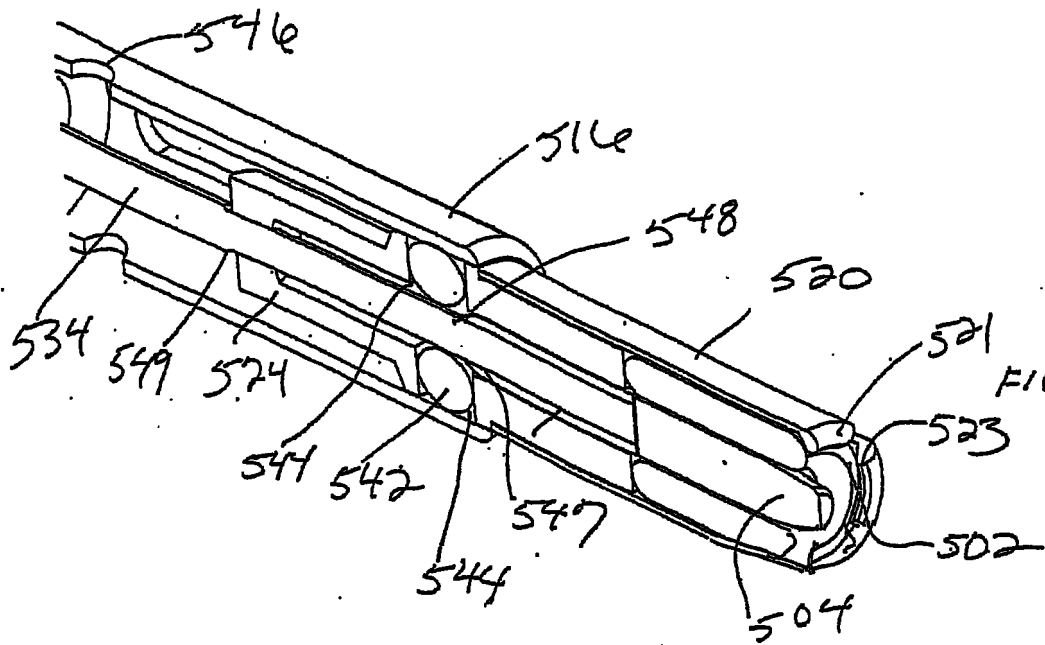


FIG 35

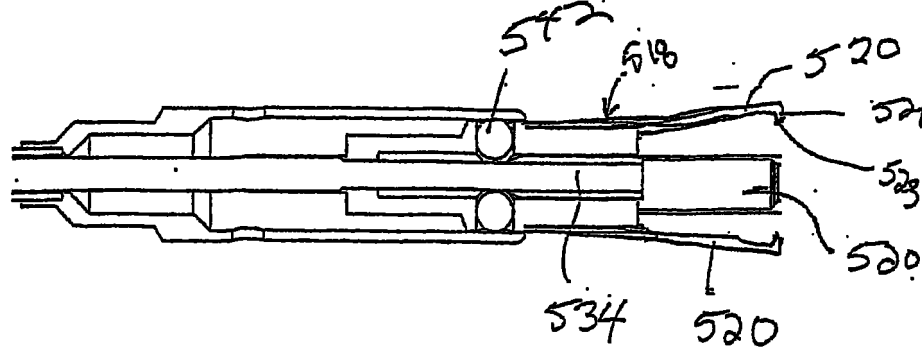


FIG 36

[Handwritten mark]

FIG. 37

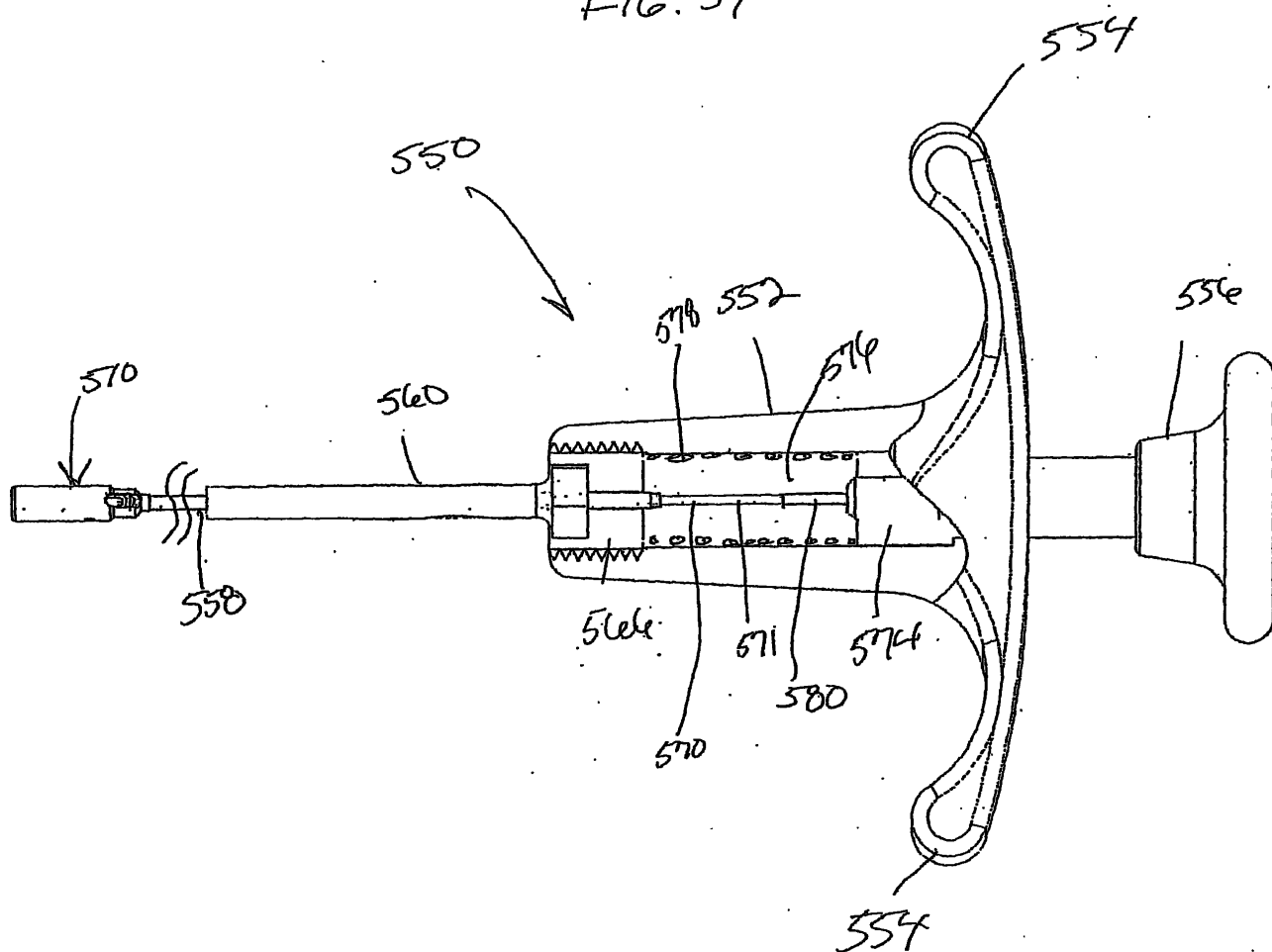
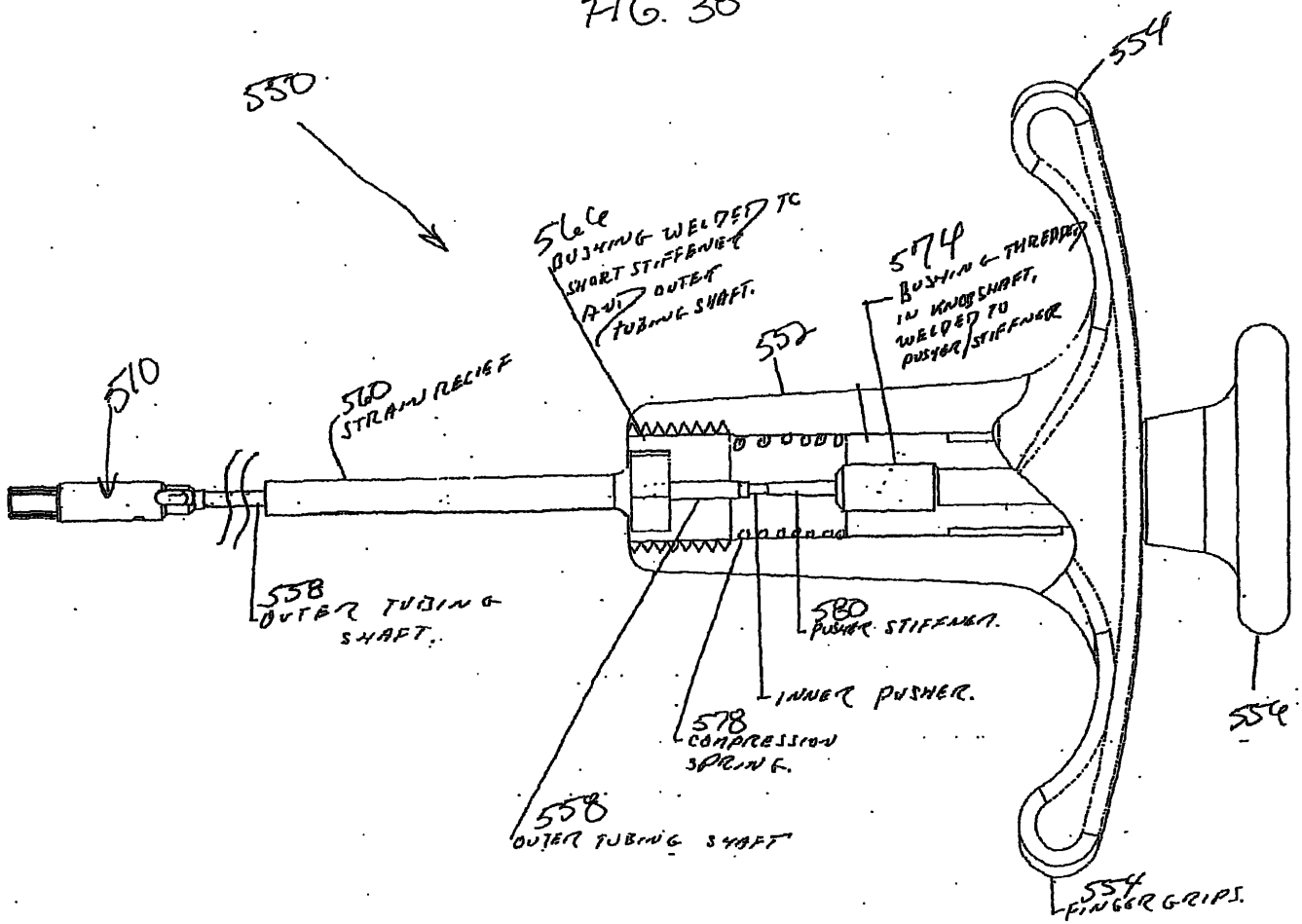


FIG. 38



60

FIG. 39

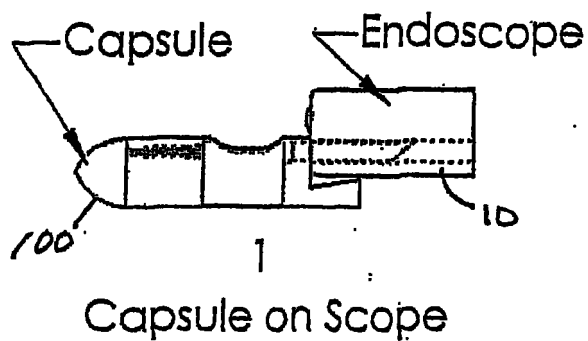


FIG. 40

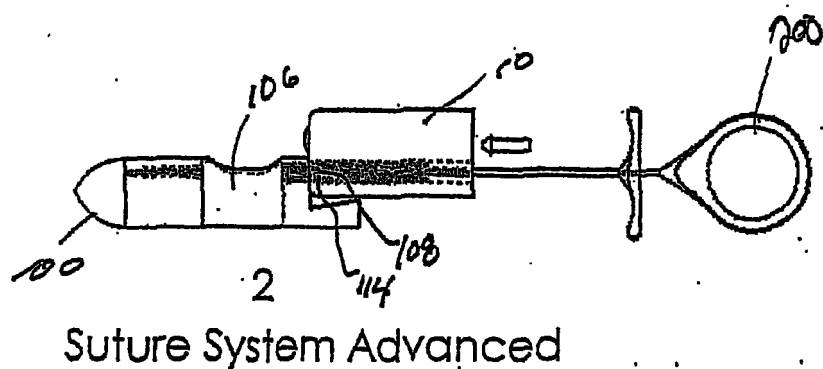


FIG. 41

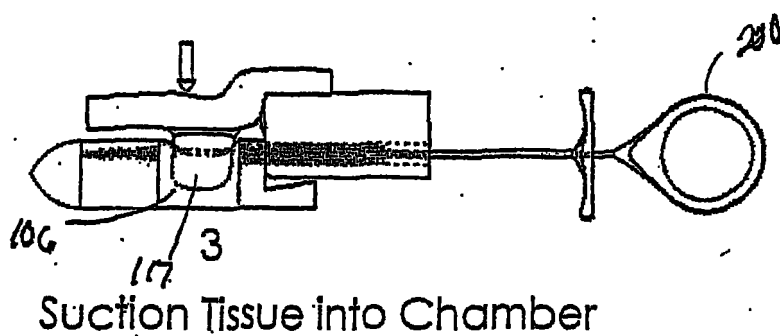
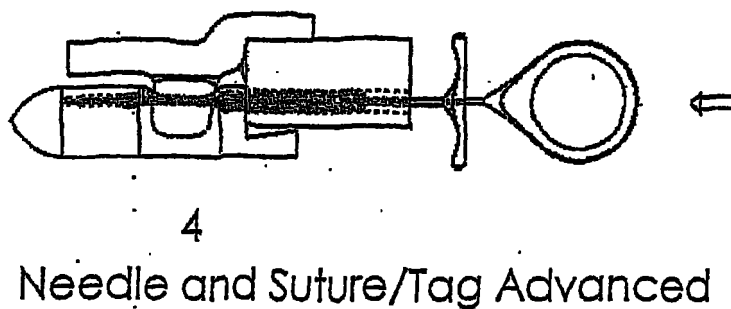
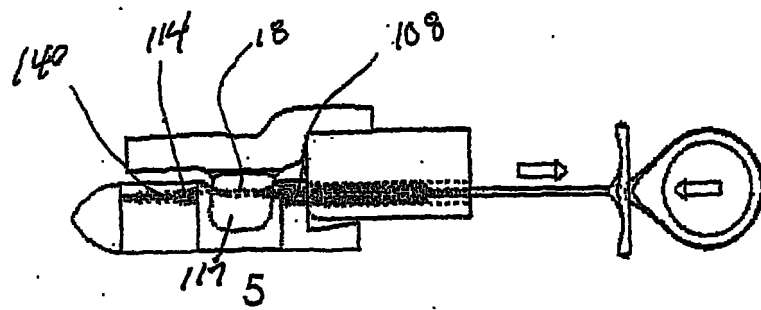


FIG. 42



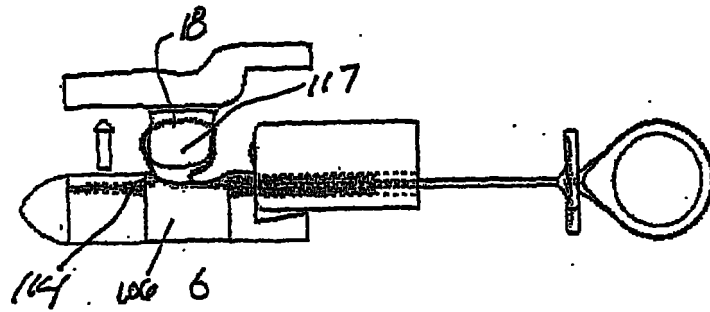
61

FIG. 43



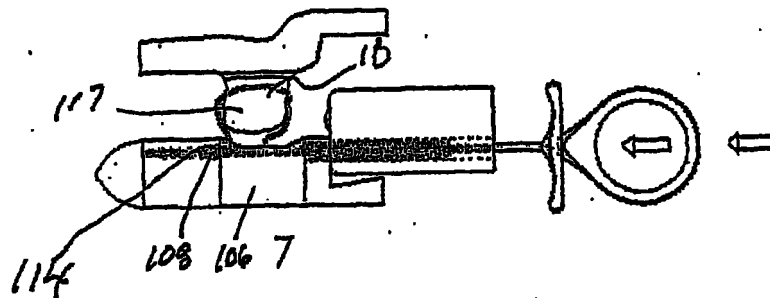
Tag Released / Needle Retracted

FIG. 44



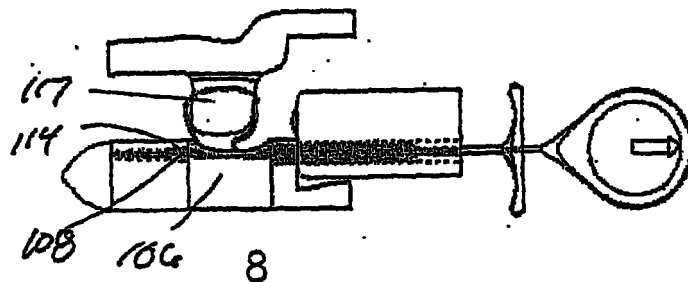
Tissue Released

FIG. 45



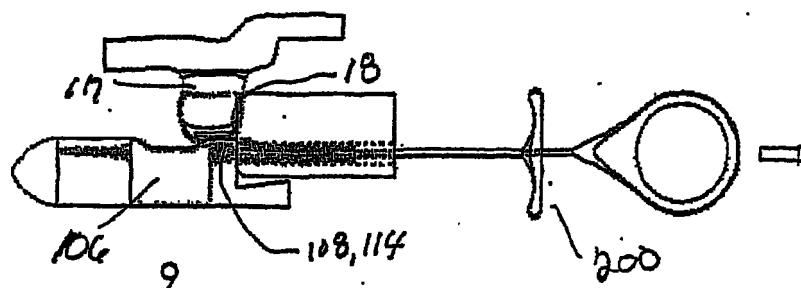
Needle Advanced

FIG. 46



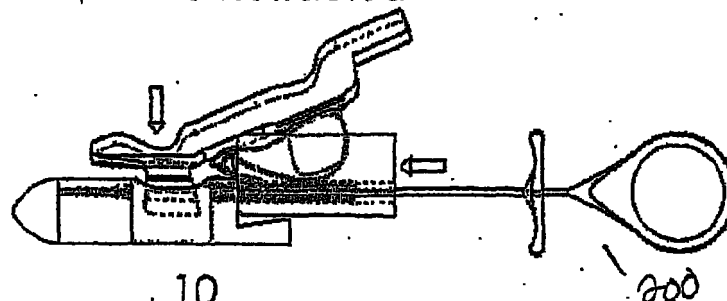
Suture Tag Recovered

FIG. 47



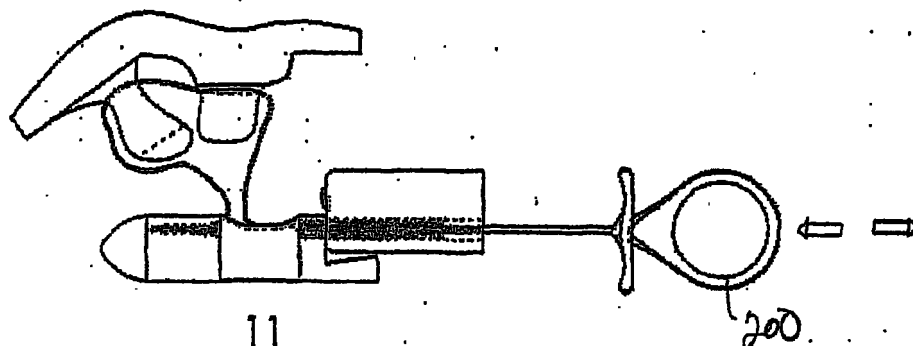
Needle Retracted

FIG. 48



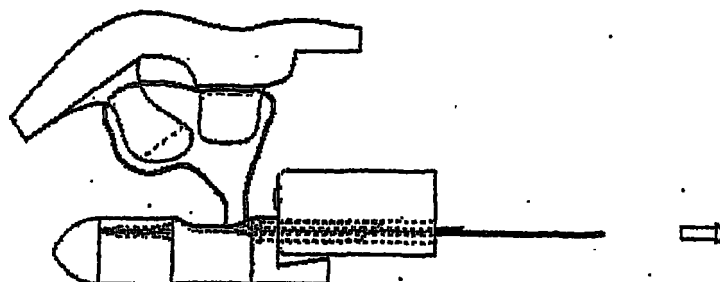
Capture Second Bite of Tissue

FIG. 49



Suture Second Bite of tissue

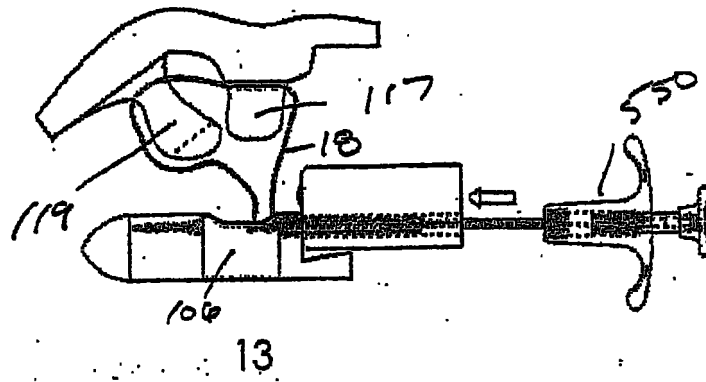
FIG. 50



Remove Suturing System

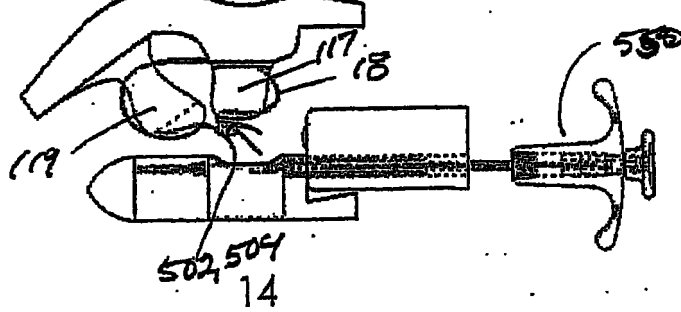
67

FIG. 51



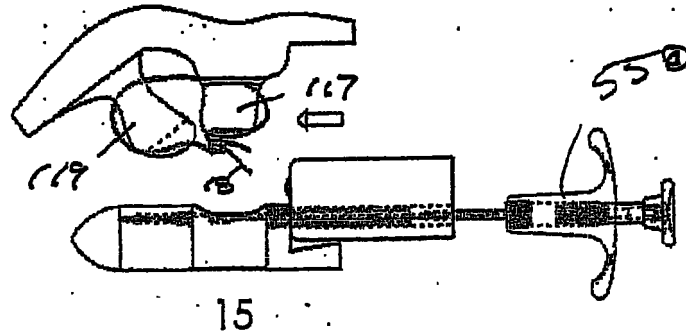
Advance Anchor Delivery Device

FIG. 52



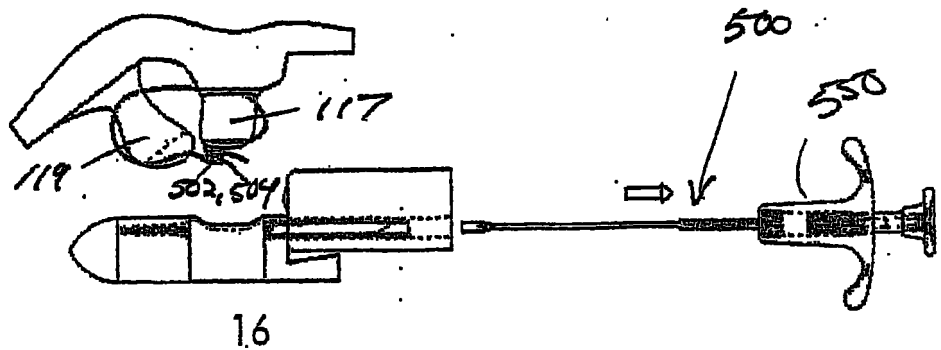
Cinch Cut & Release

FIG. 53



Plication Complete

FIG. 54



Remove Anchor Delivery Device

64

WO 2004/103189

27/35

PCT/US2004/015670

[Handwritten signature]

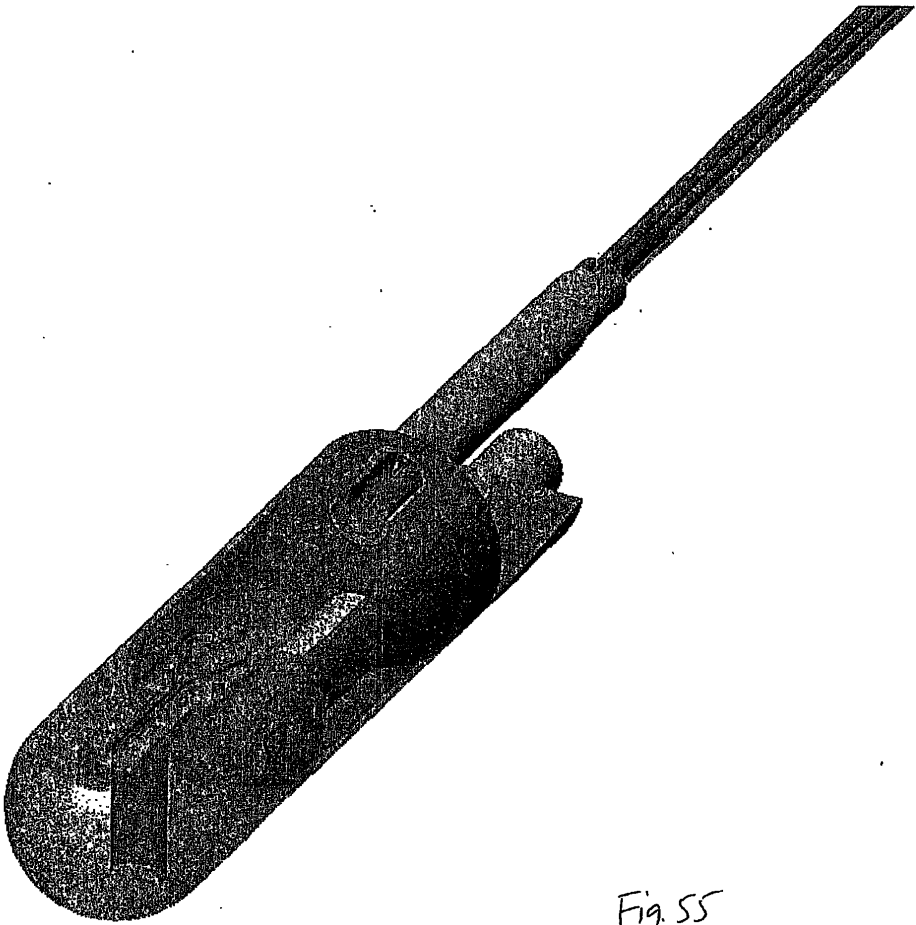


Fig. 55

57

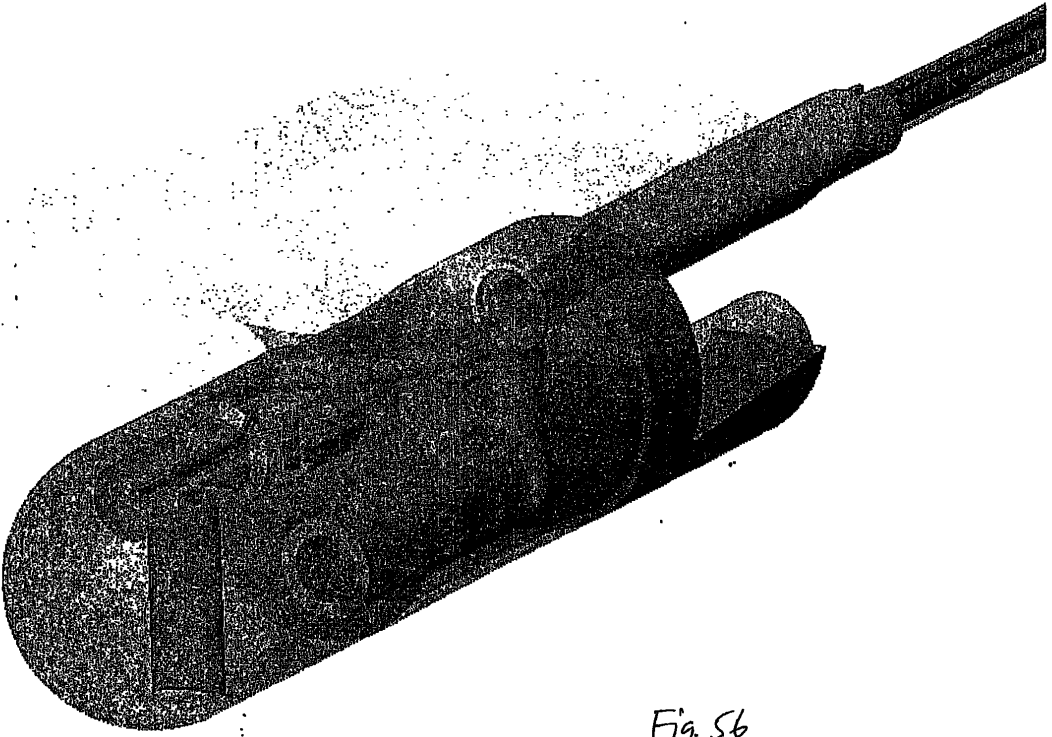


Fig. 56

66

[Handwritten signature]

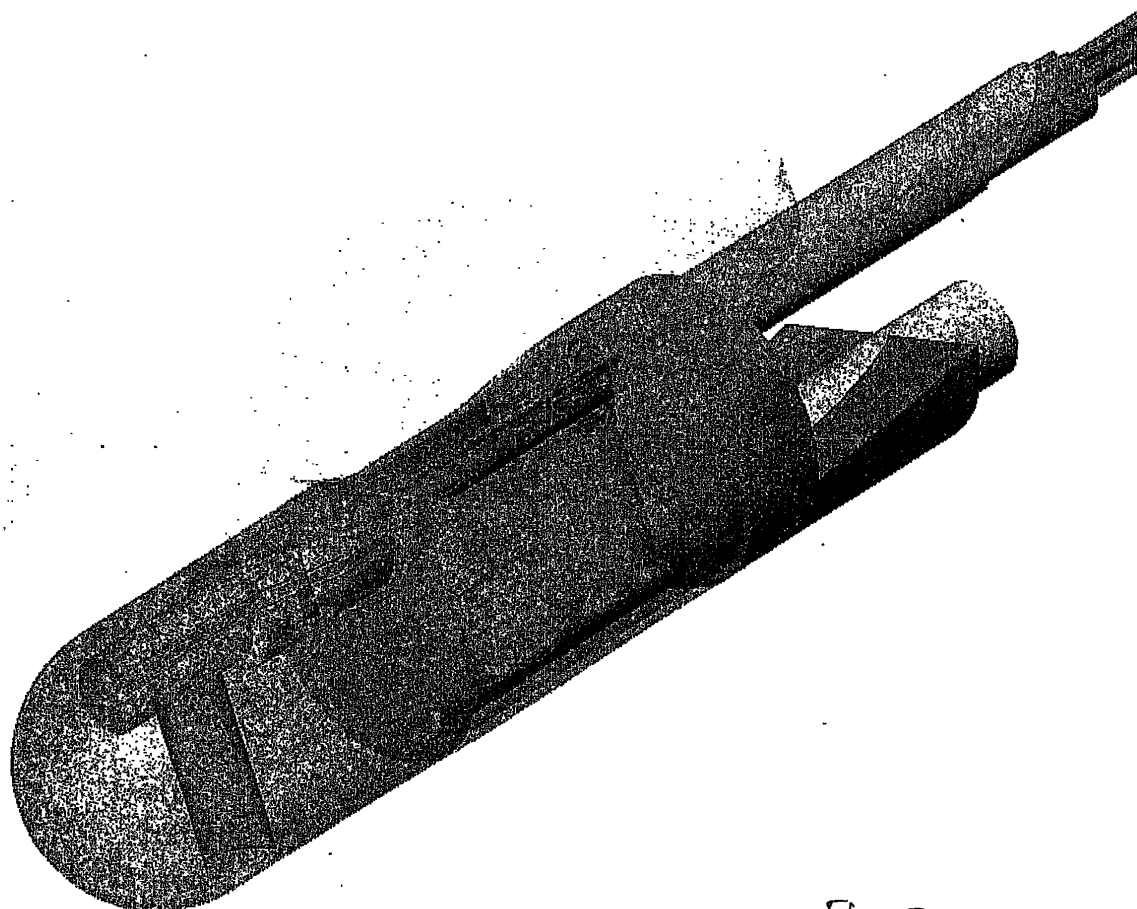
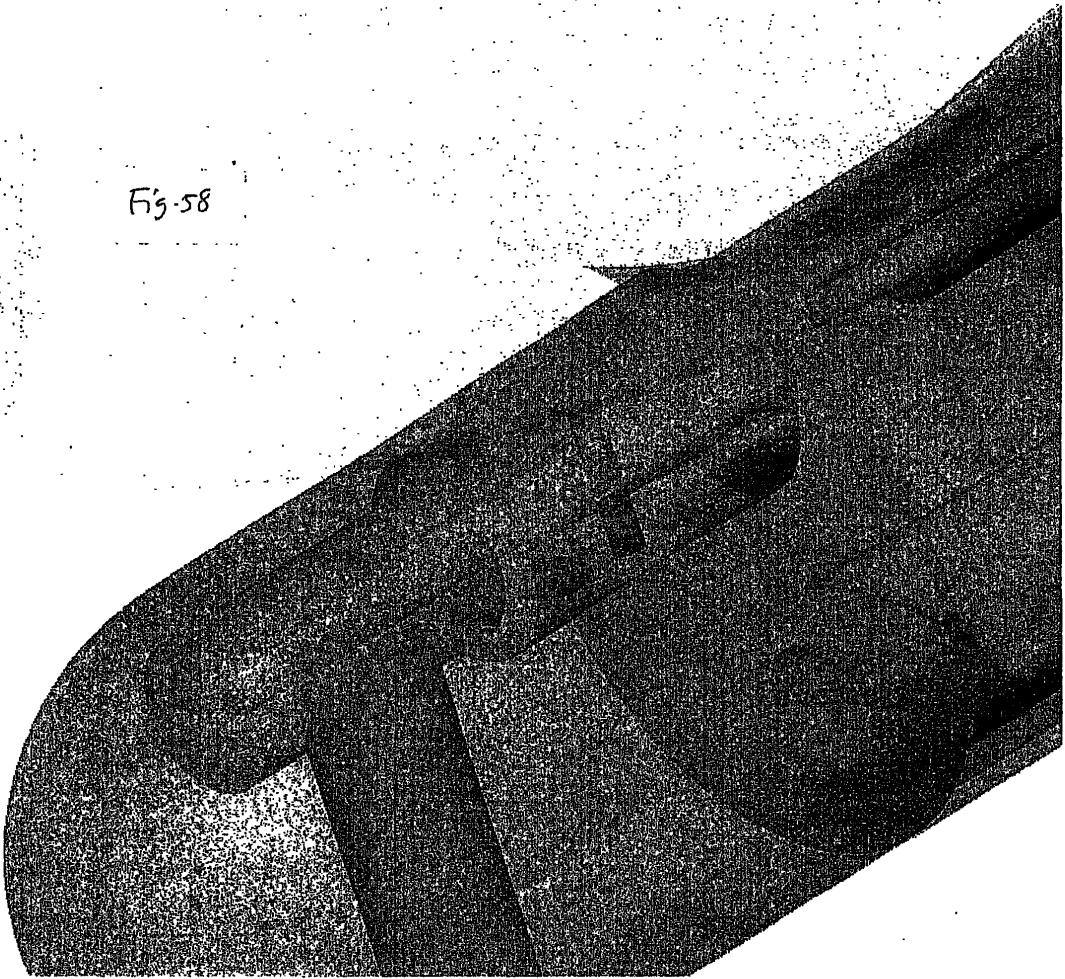


Fig. 57

~~10/1~~

Fig. 58



[Handwritten signature]

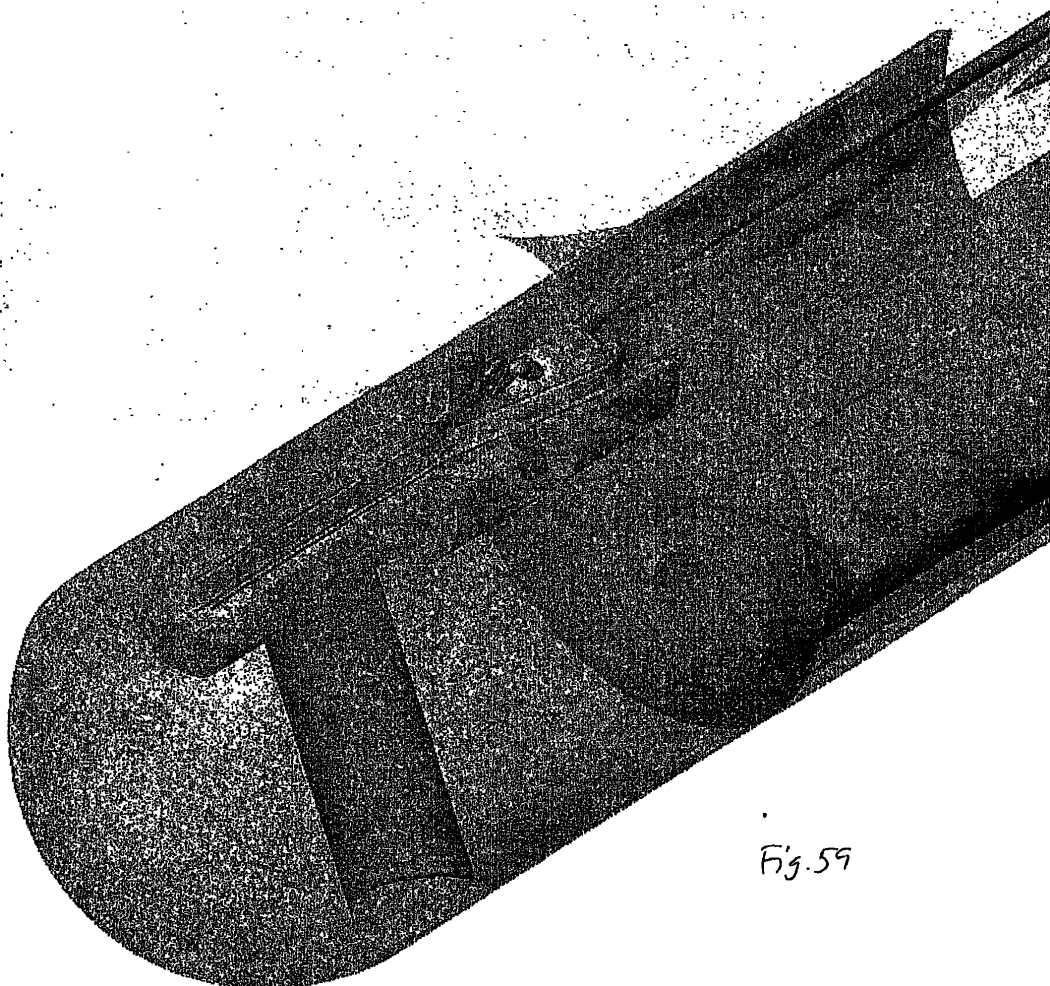


Fig. 59

69

69

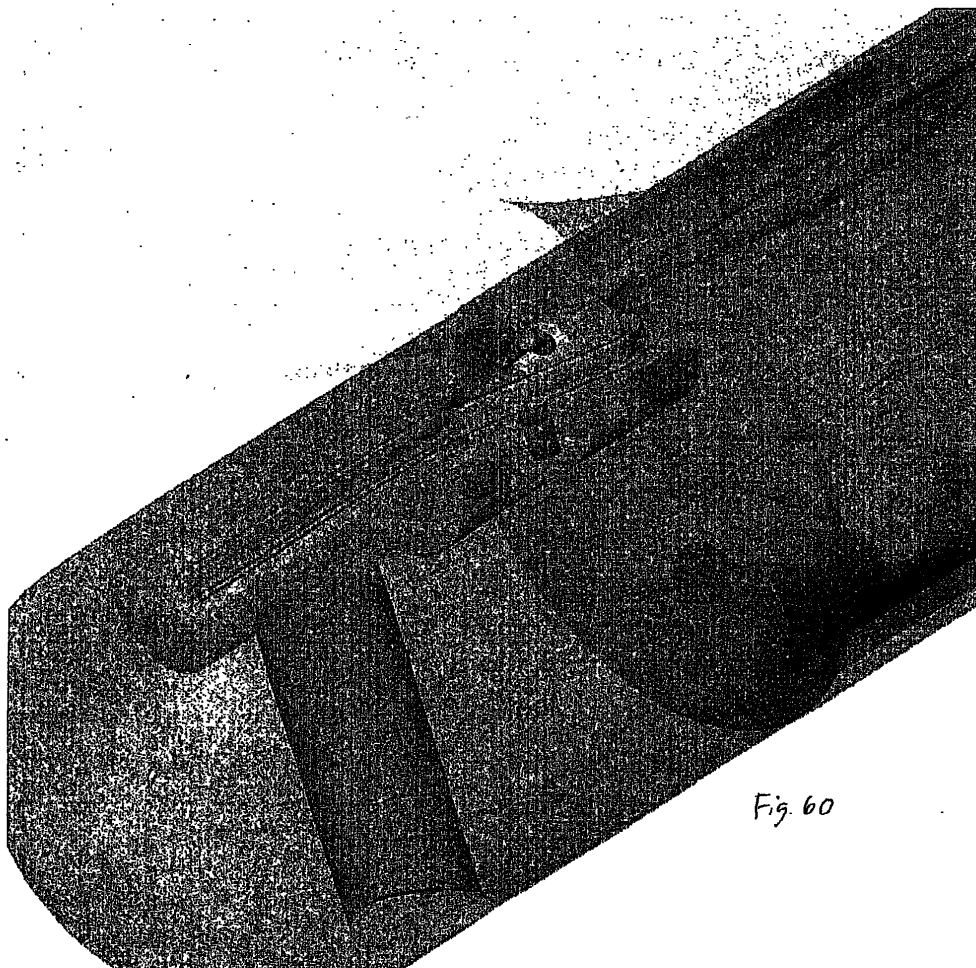


Fig. 60

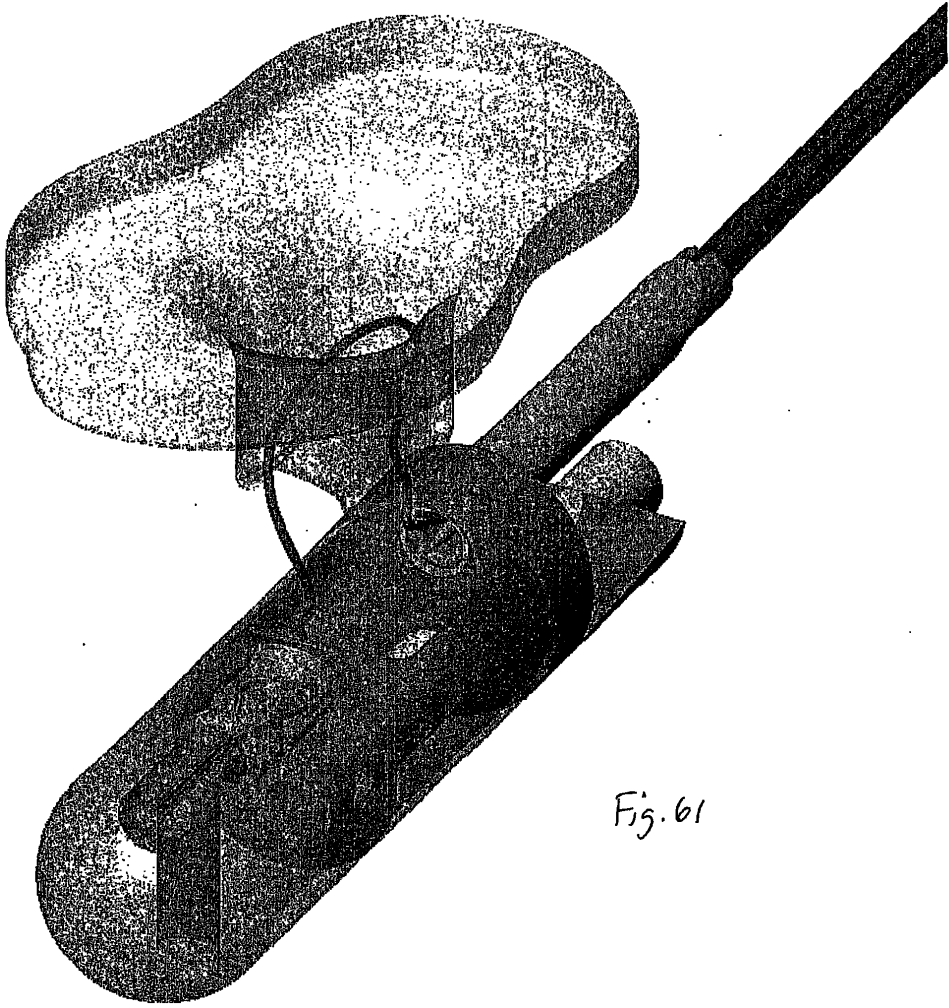


Fig. 61

70

WO 2004/103189

33/35

PCT/US2004/015670

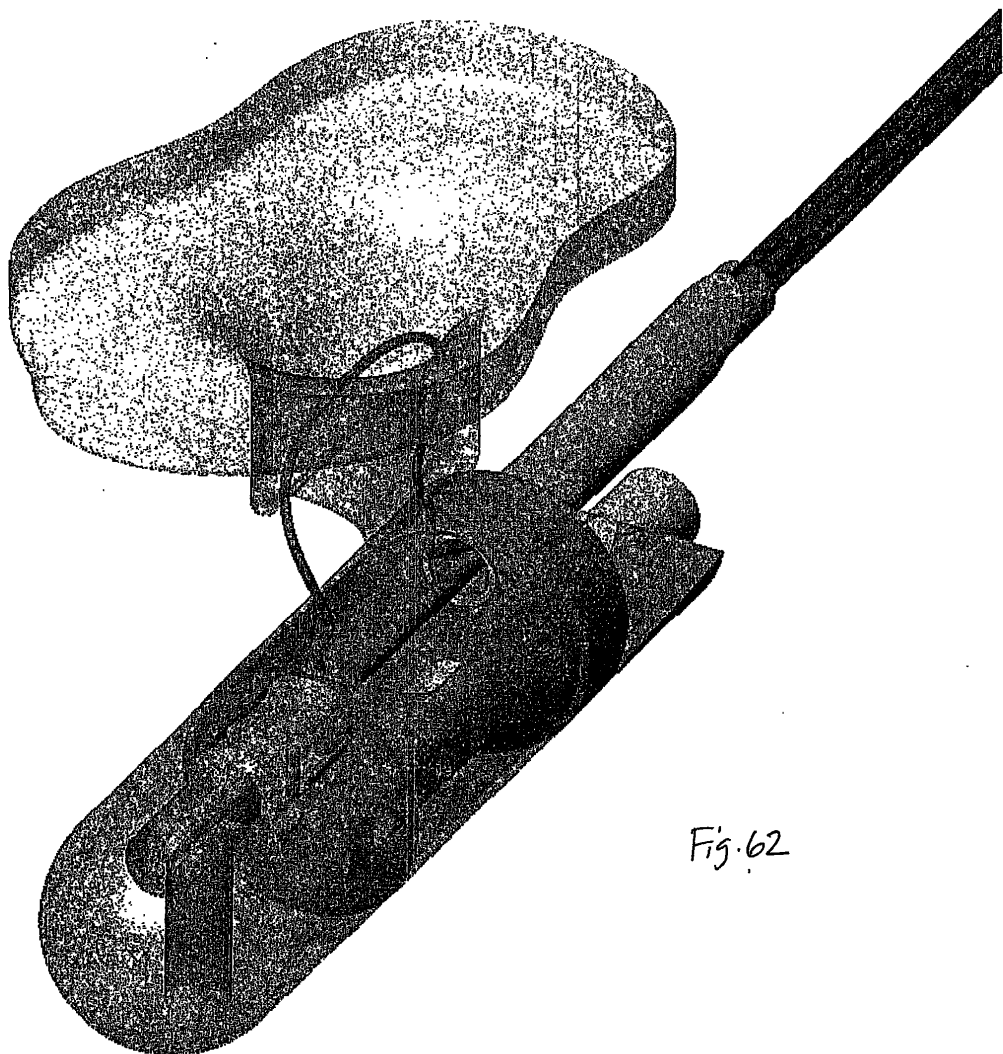


Fig. 62

71

[Handwritten signature]

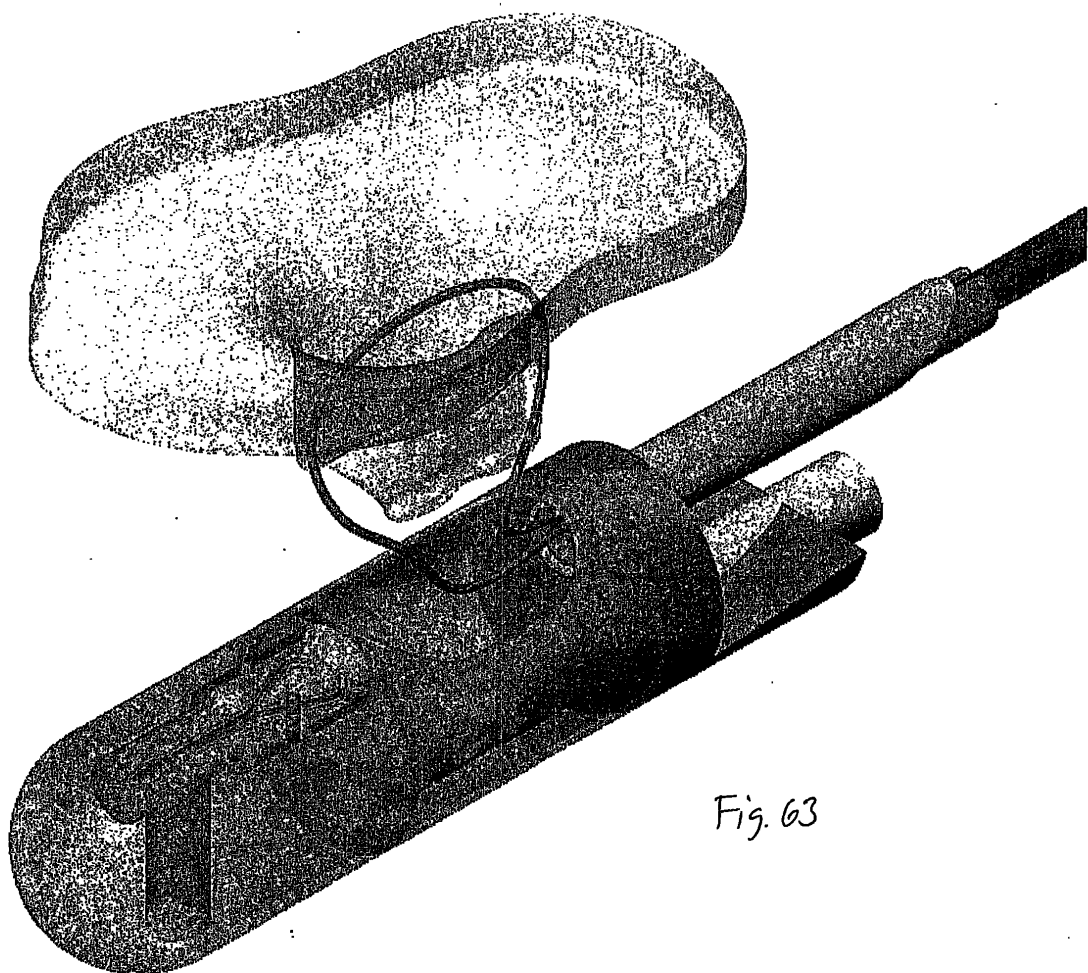


Fig. 63

(12) SOLICITUD INTERNACIONAL PUBLICADA SEGÚN EL TRATADO DE COOPERACIÓN INTERNACIONAL EN MATERIA DE PATENTES (PCT)

(19) Organización Mundial de Propiedad Intelectual
Oficina Internacional



(43) Fecha de Publicación Internacional
2 de Diciembre de 2004 (02.12.2004)

(10) Número de Publicación Internacional
WO 2004/103189 A1

(51) Clasificación Internacional de Patentes⁷: **A61B 17/10**

Jeffrey; Wallingford, CT (US). FERRIEERA, Danial; Milford, CT (US).

(21) No. Solicitud Internacional: **PCT/US2004/015670**

(74) Agente: **HERSH, Joyce, C; Kirkpatrick & Lockhart LLP, 75 State Street, Boston, MA 02109-1808 (US).**

(22) Fecha de Presentación Internacional:
17 de mayo de 2004 (17.05.2004)

(81) Países designados (a menos que se indique lo contrario para cada clase de protección disponible):
AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(25) Idioma de Presentación: **Inglés**

(26) Idioma de Publicación: **Inglés**

(30) Datos relativos a la Prioridad:
60/471,248 16 de mayo de 2003 (16.05.2003) US

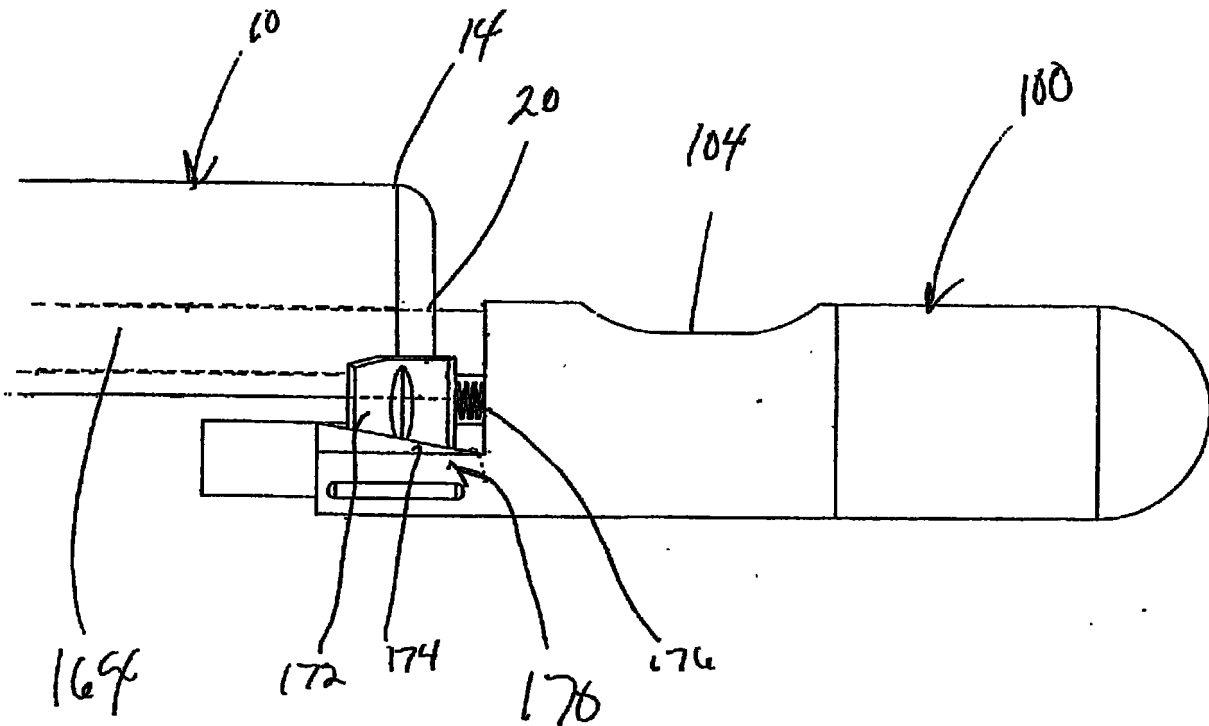
(71) Solicitante: **C.R. BARD, INC. [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).**

(72) Inventores: **GAMBALE, Richard, A.; 382 Dunstable Road, Tyngsboro, MA 01879 (US). LUKIN, Peter, J.; 28 Russell Lane, Lancaster, MA 01523 (US). DICESARE, Paul; Eastern Connecticut (US). BATTLES, Christopher; New Haven, CT (US). RADZIUNAS,**

(84) Países designados (a menos que se indique lo contrario para cada clase de protección disponible):
ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasiática (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), Europea (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU,

[Continúa en la página siguiente]

(54) Título: EQUIPO SUTURADOR ENDOSCÓPICO CON PUNTOS MÚLTIPLES E INTUBACIÓN ÚNICA



(57) Extract : Se provee un sistema suturador endoscópico para unir tejidos internos del cuerpo en una variedad de procedimientos. El sistema comprende una cápsula suturadora (100) que se puede montar en forma desenganchable en el extremo distal (14) de un endoscopio (10) y capaz de formar puntos múltiples en el tejido en una pluralidad de lugares sin

004/103189 A1

Para códigos de dos letras y otras abreviaturas, remítase a las "Notas Guía sobre Códigos y Abreviaturas" que aparece al comienzo de cada edición regular del Boletín Oficial PCT.

- con informe internacional de búsqueda
- antes de la expiración del límite de tiempo para corregir los reivindicaciones y para volverse a publicar en el caso de recibo de correcciones

EQUIPO SUTURADOR ENDOSCÓPICO CON PUNTOS MÚLTIPLES E INTUBACIÓN ÚNICA

SOLICITUDES RELACIONADAS

La solicitud reivindica el beneficio de la Solicitud Provisional de los Estados Unidos No. 60/471,248, presentada el 16 de mayo de 2003, cuyas enseñanzas completas se incorporan aquí por referencia.

CAMPO DE LA INVENCION

La presente invención se refiere a dispositivos y métodos para sujetar tejidos del cuerpo humano, unos con otros. En particular, la invención concierne a un sistema suturador endoscópico.

ANTECEDENTES DE LA INVENCION

Dispositivos de aposición endoscópicos son dispositivos que pueden usarse en el cuerpo de un paciente sin la necesidad de practicar una incisión externa en el paciente, controlándose el dispositivo fuera del paciente por medios endoscópicos. El dispositivo puede comprender un mecanismo cosedor o grapador para uso en endoscopia flexible, aunque es igualmente aplicable a dispositivos para uso en endoscopia rígida. Se ha descubierto que tales dispositivos son útiles en los tratamientos del sistema digestivo, insertándose el endoscopio a través del esófago del paciente. En particular, se ha descubierto que tales dispositivos son útiles en tratar la enfermedad de reflujo gastroesofágico (GERD). En un procedimiento para tratar GERD, los puntos se ponen para formar pliegues de tejido en la unión del esófago y el estómago. El menor cambio anatómico resultante de la formación de pliegues parece aliviar los síntomas de GERD en algunos pacientes.

Dispositivos cosedores de este tipo general se describen, por ejemplo, en las Patentes de los Estados Unidos Nos. 5,080,663 y 5,792,153, las cuales se incorporan aquí por referencia. Esas patentes divulgan un

está fuera de la porción de tejido, y una segunda posición, en la cual atraviesa la porción de tejido, y un porta-hilo adaptado para conectarse al hilo y que puede alojarse en la aguja hueca. El dispositivo cosedor comprende un cuerpo, que define una cavidad dentro de la cual la porción de tejido puede retenerse mediante succión, y la aguja hueca se monta para movimiento en el cuerpo entre las posiciones primera y segunda.

Se describen dos incorporaciones particulares: Un dispositivo cosedor de un solo punto y un dispositivo cosedor de puntos múltiples. En el dispositivo un solo punto, el porta-hilo se transporta por la aguja a través del tejido, a medida la última pasa de su primera posición a su segunda posición. Cuando la aguja regresa a su primera posición, el porta-hilo se deja atrás en el extremo distal de la cápsula cosedora. En el dispositivo de puntos múltiples, ocurre el mismo procedimiento, pero es seguido por un paso adicional en el cual la aguja hueca se desplaza de su primera posición a su segunda posición, recoge el porta-hilo, y lo devuelve. En el siguiente paso puede formarse un segundo punto. Toda la secuencia de pasos se repite tantas veces como se requiera para formar el número deseado de puntos.

Luego de la aplicación de las suturas a través del tejido, la sutura tiene que anclarse fuertemente mediante nudos o por un dispositivo de anclaje mecánico. Las Solicitudes de los Estados Unidos Nos. 10/220,413 ("Suture Clips, Delivery Devices and Methods", presentada el 13 de marzo de 2003) y 10/275,534 ("Tissue Capturing and Suturing Device and Method", presentada el 6 de noviembre de 2002), las cuales se incorporan aquí por referencia en su totalidad, divulgan dispositivos mecánicos de anclaje para sujetar una sutura en un lugar interno del cuerpo, que se aplican mediante un endoscopio. Estas solicitudes corresponden a las Publicaciones PCT Nos. WO 01/66001 y WO 01/89393, respectivamente. No obstante, debido a su gran tamaño, estos sistemas requieren que el endoscopio se retire del paciente con el fin de que el dispositivo de

intervención, durante el cual el paciente tiene que mantenerse bajo sedación consciente, son consideraciones importantes en cualquier procedimiento endoscópico. Los dispositivos suturadores del arte previo tienen que retirarse del paciente por cada punto sucesivo hecho con la incorporación de un solo punto. Por lo tanto, el uso de los dispositivos es intensivo en tiempo, engorroso y de algún riesgo para el paciente, debido a las intubaciones múltiples y al peligro de perforación del esófago. Sería deseable proveer un dispositivo endoscópico de aposición de tejido, que minimice el tiempo de la intervención y el número de intubaciones, haciendo y sujetando simultáneamente puntos múltiples durante la intervención.

SUMARIO DE LA INVENCION

La presente invención provee un dispositivo endoscópico de aposición de tejido, capaz de sujetar múltiples sitios de tejido con una sola intubación de un endoscopio, que porta una cápsula suturadora en su extremo distal, en el paciente. Para poner las suturas, el sistema provee una cápsula suturadora que puede fijarse en forma desmontable al extremo distal de una variedad de endoscopios usados comúnmente. La cápsula suturadora comprende una cámara de succión de tejido para capturar una sección de tejido, una aguja corrediza a lo largo de una pista de aguja que atraviesa la cámara de succión y un tambor de sutura unido a una sutura que se puede asegurar en forma desmontable a la aguja.

Para hacer puntos múltiples sin requerir el retiro del dispositivo para recargar el hilo de sutura, la cápsula incluye asimismo una pinza de sutura en su extremo distal, distal a la cámara de succión, para recibir de la aguja el tambor de sutura a medida que atraviesa el tejido capturado. Luego de transportar el tambor de sutura y la sutura desde un lado proximal de tejido capturado hasta el lado distal del tejido, el tambor puede dejarse atrás en la pinza del tambor de sutura y la aguja puede replegarse proximalmente.

tambor de sutura en la aguja, cuando ésta se lanza y recoge de la pinza del tambor de sutura en el extremo distal de la cápsula. Entonces el tejido puede liberarse de la cápsula y recapturarse el tambor por la aguja en disponibilidad para otro punto a través de una porción diferente de tejido capturado (aproximándose desde el lado proximal del tejido) o el tambor puede dejarse en su sitio y capturarse otra porción de tejido, de manera que cuando la aguja se avance distalmente para capturar el tambor, la aguja que se repliega proximalmente llevará la sutura a través del tejido en una dirección proximal. Llevando de un lado para otro el tambor y su sutura asociada a través de una serie de porciones de tejido capturado en esta forma, puede formarse una pluralidad de puntos, sin requerirse el retiro de la cápsula para recarga.

La aguja y el seguro del tambor de sutura se operan selectivamente desde el extremo proximal del endoscopio por un mango de control. El mango de control se puede fijar en forma desmontable al extremo proximal del endoscopio, de modo que esté en comunicación con el puerto del canal de maniobra del mango del endoscopio. Ejes de control acoplados al mango se extienden a través del canal de maniobra del endoscopio y controlan la operación de la aguja y el seguro del tambor de sutura mediante su movimiento longitudinal iniciado en el mango. El mango puede tener un miembro operativo longitudinal para controlar tanto el movimiento de la aguja como la liberación y sujeción del seguro del tambor de sutura.

Como hay cuatro fases de operación de la aguja durante la ida y vuelta del tambor a través de una porción de tejido, cuando sólo se provee un miembro longitudinal en el mango, se prefiere una operación segmentada del miembro de control longitudinal para indicar al usuario qué fase de operación de la aguja está ocurriendo. Por ejemplo, el miembro de control debe indicar al usuario una primera fase cuando el miembro longitudinal no esté oprimido y la aguja con el tambor cargado esté



longitudinal hacia el mango indica la segunda fase de la operación. El miembro longitudinal debe regresar automáticamente para recoger la aguja proximalmente, dejando al mismo tiempo el tambor atrás en la pinza del tambor de sutura (la tercera fase). El mango debe ofrecer una posición inactiva en la tercera fase, en la cual la aguja se retira proximalmente del tejido sin el tambor y queda en disponibilidad para accionarse distalmente de nuevo para recoger el tambor. Durante el regreso automático de la aguja proximalmente, tal como por un resorte de retorno, se puede descontinuar también el vacío automáticamente al final de la carrera de retorno, de modo que la porción de tejido se libere con el hilo de sutura pasando ahora a través de ella. La fase cuatro ocurre cuando la aguja se avanza distalmente de nuevo para recapturar el tambor de sutura (sea con tejido succionado en la cámara o sea para reposicionar el tambor antes de la captura del tejido). La pulsación, nuevamente, del miembro de operación longitudinal inicia la fase cuatro cuando la aguja ha alcanzado el extremo distal de su carrera y recapturado el tambor de sutura. La liberación del miembro de operación longitudinal de la fase cuatro devuelve el mango y la aguja de regreso a su estado inicial: fase uno.

El mango de control de la cápsula suturadora puede incluir también controles de vacío para succionar selectivamente tejido en la cámara de succión durante el ciclo de suturamiento. Mediante un interruptor en el mango, el usuario puede activar entonces convenientemente un suministro de vacío enrutado a través del mango. Opcionalmente, puede proveerse un mecanismo de enclavamiento de vacío que impida la operación del dispositivo, si no se obtiene una presión suficiente de línea negativa para garantizar que el tejido se succione completamente en la cámara, de modo que la aguja y la sutura consigan una profundidad de penetración suficiente. El control de vacío puede incluir asimismo un mecanismo que automáticamente suspenda el vacío hacia la cámara de succión, una vez que la aguja ha completado su carrera de enrollado proximal desde el tejido



tenso la sutura durante la intervención, de modo que se desplace proximal y distalmente con el movimiento de la aguja en lugar de sólo distalmente, lo cual puede llevar a que el material de sutura se apiñe en manojos en el área de la cámara de succión.

Una vez se han formado puntos a través de varios lugares seleccionados de tejido, los cabos de sutura tienen que sujetarse para retener la sutura fuertemente en posición a través del tejido. El presente sistema suturador ofrece además un anclaje de sutura que puede aplicarse a los cabos de sutura para sujetarlos con un dispositivo de aplicación, que puede pasarse a través del canal de maniobra del endoscopio, de modo que no se requiere el retiro del endoscopio con el fin de completar la intervención. El anclaje de sutura comprende un anillo y un tapón dimensionado para encajar por fricción la superficie interior del anillo, de manera que los cabos de sutura, que atraviesan el anillo, se capturen entre los dos componentes. Para sujetar una sutura, los cabos de sutura se guían a través del anillo, y se avanza al lugar de sutura, sitio en el cual puede insertarse el tapón en el anillo, manteniendo al mismo tiempo tenso la sutura, de modo que se capture en una condición apretada a través del tejido.

El anclaje de sutura puede aplicarse al lugar de tejido y sujetarse por un dispositivo de aplicación conformado por un eje y un extremo operativo distal, que se pueden pasar a través del canal de maniobra del endoscopio y un mango de control en el extremo proximal del eje para controlar el extremo operativo para ensamblar el anillo y el tapón. El extremo operativo distal del dispositivo de aplicación debe comprender un receptáculo para retener por lo menos un anillo y un tapón en la configuración desmontada, de modo que pueda guiarse al lugar de sutura con los cabos de sutura pasando a través del anillo abierto. El receptáculo puede configurarse como una jaula definida por cuatro brazos unidos en forma articulada únicamente en sus extremos proximales a un miembro de buje central para permitir que sus extremos distales se cierren o abran selectivamente para liberar un tapón

la fuerza del ensamble de insertar el anillo en el tapón, pero luego tienen que abrirse selectivamente para liberar el anclaje de sutura sujetado.

Para abrir y cerrar selectivamente los brazos de la jaula y cercenar el cabo de sutura una vez concluido el ensamble del anclaje de sutura, puede proveerse un manguito exterior deslizable sobre las lengüetas de la jaula. Cuando el miembro de la jaula está proximalmente dentro del manguito, de modo que el manguito esté sobre los extremos distales de las lengüetas, los extremos libres distales de las lengüetas permanecen agarrados radialmente hacia adentro en una configuración cerrada para retener el anillo y el tapón. Cuando la jaula se mueve distalmente en relación con el manguito, de modo que el manguito se ubique proximalmente sobre el área articulada de las lengüetas, se permite que los extremos libres distales de las lengüetas se abran radialmente para posibilitar la liberación del anillo y el tapón. Para ensamblar el anillo y el tapón mientras las lengüetas del tapón se mantienen cerradas, el tapón se presiona distalmente en el anillo por un eje impulsor que se desliza longitudinalmente en relación con la jaula, que impide el movimiento longitudinal del anillo durante el ensamble. Una vez insertado el tapón en el anillo y la jaula se ha movido distalmente en relación con el manguito, las lengüetas articuladas se abren elásticamente (los extremos distales se mueven radialmente hacia afuera) para liberar el ensamble del tapón y el anillo.

La jaula, el manguito exterior y el impulsor deben unirse a un mango de control en el extremo proximal del endoscopio por ejes de control, desplazables longitudinalmente a través del canal de maniobra del endoscopio para hacer que el movimiento de los componentes distales opere el extremo distal efectivamente; el mango puede incluir dos miembros de control a disponibilidad del usuario para lograr el movimiento relativo necesario para ensamblar y liberar el anillo y el tapón. El mango debe incluir por lo menos un miembro corredizo longitudinal, acoplado al impulsor con el fin de avanzar el tapón en el anillo y una funda exterior

manguito exterior para abrir las lengüetas de la jaula.

Es un objeto de la presente invención proveer un equipo suturador endoscópico que sea capaz de crear puntos en múltiples áreas diferentes de tejido interno requiriendo al mismo tiempo sólo una intubación del endoscopio o inserción de un laparoscopio.

Es otro objeto de la presente invención proveer una cápsula suturadora endoscópica, que ofrece una cámara de succión de tejido y una aguja deslizable a través del tejido capturado allí para aplicar un tambor portador de la sutura a través de porciones de tejido sucesivamente capturadas para formar un punto en cada porción separada.

Es otro objeto de la presente invención proveer un mango de control para una cápsula suturadora endoscópica, de puntos múltiples, que permite al usuario impartir únicamente un solo movimiento longitudinal de un mecanismo de control, con el fin de completar un punto de sutura a través de una porción de tejido y devolver el sistema a un estado de disponibilidad para un segundo punto.

Es otro objeto de la presente invención ofrecer un equipo suturador endoscópico que comprende una cápsula suturadora con una aguja y tambor de sutura capturable en la aguja por un bloqueo de sutura y una pinza de sutura en la cápsula, un mango de control para operar los componentes de la cápsula de sutura, un anclaje de sutura para sujetar los cabos de sutura aplicados al tejido y un dispositivo de aplicación del anclaje de sutura para ensamblar y liberar el anclaje de sutura en el lugar de tejido interno.

Es otro objeto de la presente invención proveer un anclaje de sutura que comprende un anillo y un tapón, acoplable por fricción en el anillo, para capturar los cabos de sutura entre ellos y un dispositivo de aplicación del anclaje de sutura con un eje y un miembro operativo distal y un receptáculo que puede pasarse a través del canal de maniobra de un endoscopio y un mango de control posicionable en el extremo proximal de un endoscopio para operar el miembro distal para aplicar ensamblar y

BREVE DESCRIPCIÓN DE LOS DIBUJOS

Los anteriores y otros objetos y ventajas de la invención se apreciarán más completamente a partir de la siguiente descripción adicional de la misma, con referencia a los dibujos esquemáticos acompañantes, en donde:

FIG. 1 es una representación esquemática de un endoscopio con el sistema suturador de la presente invención;

FIG. 2 es una representación esquemática del dispositivo de aplicación del anclaje de sutura de la presente invención;

FIGS. 3A y 3B son representaciones esquemáticas de un anclaje de sutura de anillo y tapón;

FIG. 4 es una vista transparente isométrica de una cápsula suturadora;

FIG. 5 es una vista transparente isométrica de un cilindro de una cápsula suturadora, acoplada al extremo distal de un endoscopio;

FIG. 6 es una vista lateral de una cápsula suturadora, acoplada al extremo distal de un endoscopio por un mecanismo de fijación de cuña inversa;

FIG. 7A es una vista lateral de una cápsula suturadora de la presente invención indicando un área A de detalle que se muestra en FIG. 7B;

FIG. 7B es una vista de detalle del área A mostrada en FIG. 7A;

FIG. 8 es una vista lateral de una aguja y un tambor de sutura bloqueado en la aguja por un dispositivo de seguro del tambor de sutura;

FIG. 9 es una vista lateral de una aguja que lleva un tambor de sutura con el seguro del tambor de sutura en la posición desbloqueada;

FIG. 10 es una vista isométrica transparente de la cápsula suturadora con la aguja y el tambor de sutura avanzando distalmente hacia la pinza de sutura;

FIGS. 11-14 ilustran varias fases del tambor de sutura y la aguja entrando a la pinza del tambor de sutura en la cápsula;

FIG. 15 es una vista superior de la pinza del tambor de sutura con un



suturadora;

FIG. 17 es una vista en corte de un mango de control de sutura;

FIG. 18 es una vista detallada en corte del mango de control de FIG.

17;

FIG. 19A es una vista en corte del mango de control de sutura;

FIGS. 19B y 19C son vistas detalladas de componentes mostrados en la vista en corte de FIG. 19A;

FIG. 20 es una vista superior de una pista de uña universal;

FIG. 21 es una vista en corte tomada a lo largo de la línea A-A mostrada en FIG. 20;

FIG. 22 es una ilustración de una pista de uña de trinquete;

FIG. 23 es una vista isométrica de una uña de trinquete cilíndrica;

FIG. 24 es una vista en corte del mango de control completamente avanzado en la dirección distal;

FIG. 25 es una vista en corte del mango de control en una fase intermedia, en la cual la aguja ha depositado el tambor de sutura en la pinza de sutura en el extremo distal de la cápsula;

FIGS. 26A y 26B son vistas laterales del anclaje de sutura de la presente invención;

FIG. 27 es una vista isométrica del dispositivo de aplicación del anclaje de sutura;

FIG. 28 es una vista en corte del dispositivo de aplicación del anclaje de sutura;

FIG. 29 es una vista lateral del dispositivo de aplicación del anclaje de sutura;

FIG. 30 es una vista isométrica del dispositivo de aplicación del anclaje de sutura;

FIG. 31 es una vista en corte, isométrica, del dispositivo de aplicación del anclaje de sutura, tomada a lo largo de la línea A-A mostrada en FIG. 20.

FIG. 33 es una vista en corte del dispositivo de aplicación del anclaje de sutura, tomada de FIG. 29 en el plano ortogonal;

FIG. 34 es una vista en corte del dispositivo de aplicación del anclaje de sutura con el buje y la jaula extendidos distalmente;

FIG. 35 es una vista en corte, isométrica, del dispositivo de aplicación del anclaje de sutura con el buje y la jaula extendidos distalmente;

FIG. 36 es una vista en corte del dispositivo de aplicación del anclaje de sutura con lengüetas extendidas radialmente hacia fuera para liberar un anillo y un tapón;

FIG. 37 es una vista lateral en corte del mango de control del dispositivo de aplicación del anclaje de sutura;

FIG. 38 es una vista lateral en corte del mango de control del dispositivo de aplicación del anclaje de sutura en la configuración pulsada/oprimida;

FIGS. 39-54 son ilustraciones esquemáticas de diferentes pasos del proceso suturador de la presente invención;

FIGS. 55-63 son diagramas que representan varias fases del proceso suturador de la presente invención.

DESCRIPCIÓN DE LAS INCORPORACIONES ILUSTRATIVAS

FIGS. 1-3B muestran los componentes de un sistema suturador endoscópico, de puntos múltiples, de intubación única. En FIG. 1 se muestra el dispositivo suturador endoscópico, que comprende una cápsula suturadora 100 acoplada en forma desmontable al extremo distal 14 de un endoscopio 10. La cápsula 100 se opera por un mango de control 200, montado en forma desacoplable al extremo proximal 12 del endoscopio 10 adyacente al mango de control del endoscopio 16. El sistema suturador opera para poner suturas a través del tejido en lugares internos en un paciente accesibles mediante un endoscopio.

para proyectarse a través del canal de maniobra de un endoscopio. Extendido a través de un endoscopio, el extremo operativo distal 540 del dispositivo de aplicación se prolonga fuera del extremo distal 14 de un endoscopio, mientras el mango de control 16 se prolonga desde el extremo proximal 12 de un endoscopio, de modo que pueda operarse por un usuario. El dispositivo de aplicación 500 se configura para aplicar dispositivos de anclaje de sutura, tales como los mostrados en FIGS. 3A y 3B. Los anclajes de sutura de FIGS. 3A y 3B comprenden un anillo 502 en el cual se inserta un tapón 504, dimensionado para encajar a fricción en el agujero del anillo. Como se muestra en FIG. 3B, cuando las suturas 18 se pasan a través del anillo 502, la inserción del tapón 504 hace que la sutura quede atrapada y anclada entre la superficie exterior del tapón y la superficie interior del anillo, sujetando efectivamente los cabos de sutura 18 en el tejido. Una discusión exhaustiva de dispositivos apropiados de anclaje de sutura, incluida la presentación de ejemplos alternativos apropiados de tales anclajes de sutura, se expone en las Solicitudes pendientes de los Estados Unidos Nos. 10/220,413 y 10/275,534, incorporadas aquí por referencia. Aunque cada uno de los componentes mostrados en FIGS. 1-3B pueden usarse separadamente en procedimientos suturadores endoscópicos y son de utilidad para el fin propuesto, el uso conjunto de los componentes posibilita el suturamiento endoscópico que proporciona puntos múltiples a una pluralidad de lugares internos y los sujeta, con la intubación única de un endoscopio en un paciente.

Cápsula Sutura

FIG. 4 es una vista transparente isométrica de la cápsula suturadora 100. La cápsula 100 comprende un cuerpo cilíndrico 102 con una forma no traumática para reducir el riesgo de trauma a los tejidos internos durante la operación. La cápsula es similar en configuración y operación a la divulgada en la Patente de los Estados Unidos 5.792.153 discutida

tejido a suturarse, mediante vacío introducido en la cámara. La cápsula se configura para recibir una aguja 108 corrediza a través de una pista de aguja 110 formada de un lado a otro de la cápsula. La aguja puede ser un eje sólido de acero inoxidable con una punta distal afilada 112 y acoplarse en su extremo proximal a un eje impulsor 184, que se proyecta proximalmente de la cápsula de sutura, a través del canal de maniobra del endoscopio. El eje del impulsor sale del extremo proximal del endoscopio donde puede empalmarse a, y manipularse por, un mango de control, como se discutirá más adelante. Cuando la aguja se mueve longitudinalmente a través de la pista de la aguja, atraviesa la cámara de succión 106, de modo que el tejido succionado en la cámara será penetrado por la aguja que avanza distalmente.

La aguja 108 lleva un tambor anular de sutura 114 que ajusta con precisión sobre la superficie exterior de la aguja. El tambor tiene extremos proximal y distal, y puede presentar un ahusamiento decreciente desde su extremo proximal a su extremo distal para crear un perfil bajo, a medida que la aguja y el tambor de sutura se avanzan distalmente a través del tejido. Empalmado al tambor de sutura se encuentra un extremo de una sutura 18 que se llevará a través de una porción de tejido succionado cuando la aguja, que porta el tambor de sutura 114, se avanza distalmente. La sutura puede empalmarse pasando a través de un agujero en el tambor y formando una punta ampliada o nudo en la sutura, de modo que sea demasiado grande para volver a pasar por el tambor. El tambor de sutura se fija en forma desacoplable y selectivamente a la superficie exterior de la aguja por un seguro del tambor de sutura 120. Igualmente, el seguro del tambor de sutura puede operarse a control remoto desde el extremo proximal del endoscopio por un eje de seguro del tambor de sutura 122, que es corredizo sobre el eje de control de la aguja y la aguja 108.

El avance distal completo de la aguja pone el tambor de sutura 114 en los confines de una pista de tambor de sutura 140. Luego de penetrar una

proximalmente dejando atrás el tambor de sutura 114 en un área de acoplamiento 142 de la pinza del tambor de sutura. La pinza del tambor de sutura comprende una estructura 144 en Y, con dos brazos elásticos 146. Los brazos elásticos se unen entre sí en la base del miembro 144 en forma de Y y se extienden longitudinalmente en una dirección proximal, que termina en un extremo libre con una uña curvada hacia adentro 148 para agarrar la superficie proximal opuesta 116, una vez que el tambor 114 ha ingresado en el acoplamiento 142. Luego de la captura y liberación del tambor de sutura en la pinza del tambor de sutura 140, la aguja puede retraerse proximalmente y liberarse el tejido de la cámara de succión 106 con una sutura 18 que se ha dejado atravesando el tejido, y con un extremo empalmado al tambor de sutura capturado en el extremo distal 103 de la cápsula y el otro extremo de la sutura proyectándose en la pista de la aguja 110, a través del canal de maniobra del endoscopio y saliendo del extremo proximal del endoscopio.

FIG. 5 muestra otra vista isométrica de un extremo distal suturador de un endoscopio 10, que tiene asegurado a él un cascarón de una cápsula suturadora 100, con los componentes internos retirados. El puerto de succión 104 se abre hacia la cámara de succión 106. Al fondo de la cámara de succión se encuentran varios puertos de aspiración 160, indicados en líneas imaginarias, a través de los cuales se introduce una presión negativa a la cámara de succión para capturar selectivamente una porción de tejido que se va a suturar. El vacío se introduce en los puertos de aspiración 160 a través de un tubo de vacío 162, que se proyecta proximalmente desde la cápsula 100 y se une a una línea de vacío separada (no mostrada), que se extiende a lo largo del exterior del endoscopio 10.

La vista recortada del extremo distal 14 del endoscopio 10, indicada en FIG. 5, muestra un canal de maniobra 20 y un canal de inspección 22. Por razones de claridad, se han omitido otros canales que pueden pasar a través del endoscopio, como los previstos para una fuente de luz o una

(indicado en líneas imaginarias) insertado en el canal de maniobra 20 del endoscopio. El tubo guía 164 es rígido y se proyecta proximalmente desde el extremo proximal de la cápsula 105 para sobresalir una distancia corta dentro del canal de maniobra 20 del endoscopio. El tubo guía 164 es abierto para recibir el ensamble de la pista de la aguja 110, a través de la cual se desplaza la aguja durante la operación.

Tal como se indica en FIGS. 5 y 6, la cápsula puede fijarse al extremo distal 14 del endoscopio por un mecanismo de fijación de cuña inversa 170. Una cuña inversa y un mecanismo de fijación accesorio, endoscópico, se describen completamente en la Solicitud pendiente de los Estados Unidos No. 10/275,226, presentada el 11 de febrero de 2003, y titulada "Endoscopic Accessory Attachment Mechanism", que se incorpora aquí por referencia en su totalidad. Se divulga igualmente en la Solicitud PCT, publicada WO 01/87144. Los elementos básicos del mecanismo de fijación de cuña inversa incluyen un componente de cuña 172 corredizo sobre una superficie de una rampa 174 para encajar a presión entre el extremo distal del endoscopio 14 y la superficie de la rampa 174, a medida que se desliza ascendiendo la rampa. El efecto de palanca contra el extremo distal del endoscopio se mantiene por la presencia del tubo guía 164 a través del canal de maniobra 20. El resorte de retorno 176 mantiene la fuerza contra el miembro de cuña 172, de modo que éste se desvíe hacia arriba a lo largo de la superficie de la rampa 174 para mantener el contacto de cuña con el endoscopio.

FIG. 7A es una vista lateral de la cápsula de sutura 100 no montada en un endoscopio e indicando un área de detalle de la pista de la aguja 110, presentado en FIG. 7B. La pista de la aguja 110 permanece en el tubo guía 164 que se proyecta proximalmente de la cápsula 100, como se muestra en FIG. 7B. El tubo guía 164 es la estructura tubular más externa de la pista de la aguja y, como ya se mencionó, provee una estructura de montaje para acoplar la superficie interna del canal de maniobra de un endosconio para

90

inoxidable. El extremo proximal del tubo guía 166 tiene un corte biselado a través de su orificio que se ahusa hacia abajo para permitir la alineación circunferencial de los componentes de control, incluidos otros componentes de la pista de la aguja, a medida que se avanzan desde el extremo proximal del endoscopio a través del canal de maniobra a la cápsula 100, como se explicará a continuación.

La mayoría de los componentes de la pista de la aguja se encuentran alojados en una funda exterior 180 que se proyecta en toda la longitud del canal de maniobra del endoscopio, desde el mango de control en el extremo proximal hasta el tubo guía 164 de la cápsula 100. La funda exterior 180 y los componentes de la pista de la aguja, asociados con ella, se avanzan a través del extremo proximal del endoscopio al tubo guía 164, una vez que la cápsula se ha montado ya al extremo distal del endoscopio. El tubo guía puede elaborarse de cualquier material fuerte pero flexible, tal como el polímero polieterecetona (PEEK). La funda exterior tiene una porción aplanada 182 a lo largo de su porción distal, que permanece en el tubo guía 164 luego del ensamble, para permitir el paso de la sutura 18, de modo que ésta pueda continuar proximalmente a través del canal de maniobra del endoscopio y fuera del extremo proximal, sin requerirse que se proyecte a través de la funda exterior 180.

El componente más interno de la pista de la aguja es la aguja 108. La aguja puede tener un extremo distal alargado en forma de lanza 109 para interactuar con el seguro del tambor de sutura, como se discutirá más tarde. La punta distal 112 de la aguja es afilada para perforar el tejido, y el extremo proximal de la aguja se acopla a un eje impulsor 184, que se proyecta hacia el mango de control montado en el extremo proximal del endoscopio.

Desplazable sobre el eje de la aguja 108 en toda su longitud hay un manguito de bloqueo 124 del sistema de seguro del tambor de sutura 120. El manguito de bloqueo 124 es un hipotubo de acero inoxidable de

mide aproximadamente 0.0155 pulgadas. El manguito de bloqueo se acopla también al mango de control en el extremo proximal del endoscopio. El extremo distal del manguito de bloqueo tiene dos muescas longitudinales que se extienden proximalmente desde la punta distal del manguito a una profundidad de aproximadamente 0.080 pulgadas para definir dos estrías de bloqueo 126. Como se describe con más detalle a continuación, cuando el manguito de bloqueo se avanza distalmente en relación con la aguja, las estrías de bloqueo se montan sobre la forma de lanza ampliada 109 de la aguja 108, se abren radialmente hacia fuera para crear superficies de bloqueo 128, lo cual impide el deslizamiento distal del tambor de sutura 114.

Por fuera del manguito de bloqueo se encuentra ubicado un manguito de refuerzo 130. El manguito de refuerzo, formado de un material rígido tal como hipotubo de acero inoxidable, se extiende sobre la aguja y el manguito de bloqueo sólo a lo largo de sus porciones distales, contenido dentro del tubo guía 164. El manguito de bloqueo ayuda a garantizar que la aguja permanezca paralela al eje longitudinal del endoscopio durante el movimiento deslizante longitudinal dentro de la cápsula 100.

Externa a la funda exterior 180 se adhiere una envoltura exterior 132, formada de un material polimérico semi-rígido tal como PEEK, que sirve para mantener aún más la alineación de la aguja y el ensamble de la pista de aguja 110 en el tubo guía 164 de la cápsula 100. La envoltura exterior 132 sirve a manera de buje para ocupar el espacio entre la funda exterior 180 y la superficie interior del tubo guía 164. La parte superior de la envoltura tiene una ranura longitudinal 133, que se extiende en toda la longitud de la envoltura para permitir el paso de la sutura 18 sin interferencia, a medida que se desliza con el tambor de sutura 114 y la aguja 108. El fondo de la envoltura 132 aloja un pasador de alineación insertado transversalmente 134, que sobresale ligeramente de la superficie exterior de la envoltura. La protrusión del pasador de alineación 134 interfiere con el corte de incisión

92
QX

de maniobra de un endoscopio durante el ensamble del sistema, el pasador guía atrapa el extremo distal 166 del tubo guía 164, y el avance distal adicional del manguito exterior y la envoltura hacen que el pasador de alineación sigan el corte de incisión y roten el ensamble según se necesite, de modo que el pasador de alineación alcance la profundidad total en la porción más distal del corte de incisión 167. Esta ubicación del pasador de alineación garantiza que el ensamble de pista de la aguja 110 se alinee circunferencialmente con el tubo guía 164 y la cápsula suturadora 100, de modo que la sutura no se tuerza o enmarañe durante la operación de la aguja y el tambor durante el suturamiento.

FIG. 8 muestra una vista lateral de la aguja 108 con un tambor de sutura 114 bloqueado contra movimiento deslizante distal por un seguro del tambor de sutura 120. El tambor de sutura 114 es anular, definiendo un agujero pasante que se dimensiona para ajustar con precisión sobre el manguito de bloqueo 124. El manguito de refuerzo 130, acoplado al manguito de bloqueo 124 termina justo antes del extremo distal del manguito de bloqueo dejando un espacio de apoyo ("*a carrying space*") sobre el cual puede descansar el tambor de sutura 114 durante la aplicación en la aguja 108. El diámetro del manguito de refuerzo 130 es ligeramente mayor que el del agujero pasante del tambor de sutura 114 para presentar un tope e impedir que el tambor de sutura se deslice proximalmente en relación con la aguja y el manguito de bloqueo 124.

Como ya se describió, el extremo distal de la aguja se forma para que tenga un perfil de lanza 109, formado por un ahusamiento de barril creciente proximal 111 que converge con un ahusamiento de barril creciente distal 113, para crear una porción de diámetro mayor 115 de la punta en forma de lanza 109.

Cuando la aguja se repliega proximalmente en el manguito de bloqueo 124 del seguro del tambor de sutura 120, las estrías de bloqueo 126 se montan sobre el ahusamiento de barril proximal de la aguja, haciendo

tambor de sutura no puede pasar sobre ellas, lo cual inmoviliza el tambor de sutura 114 sobre la aguja.

Para liberar el tambor de sutura, de modo que pueda deslizarse distalmente en relación con la aguja, como se desearía cuando se deja el tambor en la pinza del tambor de sutura 140 durante la intervención de suturamiento, la aguja 108 se mueve distalmente en relación con el manguito de bloqueo 124. El movimiento de la aguja distalmente en relación con el manguito de bloqueo desplaza el ahusamiento de barril proximal al diámetro reducido del eje de la aguja 107 y las estrías 126 se amoldan elásticamente al diámetro reducido, regresando radialmente hacia adentro para definir un perfil menor sobre el cual pueda pasar el agujero pasante 118 del tambor de sutura 114. La porción de diámetro ampliado 115 de la aguja, sin el espesor añadido de las dos estrías 126 del manguito de bloqueo 124, define igualmente un perfil sobre el cual puede pasar libremente el agujero pasante 118 del tambor de sutura 114.

En FIG. 10 se presenta una vista transparente isométrica de la cápsula 100, que muestra la pinza del tambor de sutura 140. En la Figura, la aguja se está aproximando a la pinza del tambor de sutura 140, mientras que el tambor de sutura 114 se inmoviliza en posición sobre la aguja por el seguro del tambor de sutura 120. La aguja atraviesa la cámara de succión 106 en su camino para entregar el tambor a la pinza del tambor de sutura 140, la cual se localiza en el lado distal de la cámara de succión 106. Por razones de claridad no se muestra tejido en la Figura. La pinza del tambor de sutura 140 comprende un miembro 144 en forma de Y con dos brazos elásticos 146, unidos entre sí en la base de la Y, y con dos extremos libres que terminan en uñas proyectadas hacia adentro 148 para agarrar la cara proximal 116 del tambor de sutura 114. El área alrededor de las lengüetas elásticas 146 se configura para ajustarse con precisión a la punta ahusada cilíndrica del tambor de sutura 114 para sujetarlo firmemente y define un acoplamiento 142 donde se mantendrá fuertemente durante su retención en

el tambor por los pasos descritos a continuación con referencias a las vistas en corte presentadas en FIGS. 11-14. En FIG. 11, la aguja se muestra avanzando hacia el miembro 144 en forma de Y, de modo que su punta distal 112 quede dentro del área del acoplamiento 142, pero el tambor de sutura 114 no ha pasado aún las uñas proyectadas hacia adentro 148 de los brazos 146. Como se muestra en las vistas en corte de FIGS. 11 y 12, a medida que la aguja avanza distalmente, la punta distal afilada 112 de la aguja penetra la base 147 del miembro 144 en forma de Y, haciendo que los brazos elásticos 146 se separen para permitir la entrada del tambor de sutura 114 en el acoplamiento 142 a lo largo de las uñas que se proyectan hacia adentro 148. Durante esta fase, la aguja avanza distalmente en relación con el manguito de bloqueo 124 del tambor de sutura 114 del seguro del tambor de sutura 120 para liberar el seguro del tambor de sutura y permitir que la aguja se deslice fuera del tambor de sutura durante su carrera de repliegue proximal.

Luego de sentar el tambor de sutura 114 en el acoplamiento 142, como se muestra en FIG. 12, el comienzo de la carrera de repliegue proximal puede encontrar los brazos elásticos 146 en la pinza del tambor de sutura todavía ligeramente abiertos, debido a la presencia de la punta afilada de la aguja 112 en la base 147 del miembro 144 en forma de Y. El repliegue proximal de la aguja en esta condición puede hacer que el tambor de sutura se adhiera firmemente a la aguja, debido a las fuerzas de fricción residuales y, así, no sea capturado por las uñas 148 contra la cara proximal 116 del tambor de sutura. Por consiguiente, adicionalmente puede disponerse una banda de rozamiento por fricción 149 a lo largo del área de acoplamiento 142 para proporcionar una superficie de fricción sobre la cápsula en el área de acoplamiento, que sirva para mantener el tambor en el acoplamiento incluso si los brazos elásticos 146 no se han disparado todavía para cerrarse alrededor de la cara proximal 116 del tambor (FIG. 12). La banda de rozamiento por fricción puede ser un inserto polimérico.

cerrarán alrededor del tambor de sutura 114, de modo que las uñas 148 agarren la cara proximal 116 del tambor (FIG. 14). Tal como se muestra en la vista superior de FIG. 14, luego que la aguja 108 se repliega proximalmente, el tambor permanece capturado por la pinza del tambor de sutura 140 dentro del acoplamiento 142. En la posición capturada, los brazos elásticos 146 regresan a la posición cerrada de modo que las uñas que se proyectan hacia adentro 148 agarran la cara proximal 116 del tambor de sutura 114, impidiéndole el movimiento proximal de salida del acoplamiento. El acoplamiento 142 sirve además para retener el tambor 114 en alineación, de manera que no se desplace distal o lateralmente durante el procedimiento de suturamiento, de modo que cuando la aguja regrese para recoger el tambor, éste estará en alineación con el agujero pasante 118 del tambor de sutura 114.

Los pasos de recuperación del tambor son sustancialmente los inversos de los pasos ilustrados para llevar el tambor a la pinza de sutura. Al regresar para recuperar el tambor, la aguja se avanza otra vez distalmente al área de la pinza del tambor de sutura mientras está en la posición no bloqueada (mostrada en FIG. 10). Una vez que la aguja ha salido completamente en la base 147 de la Y, la aguja puede deslizarse proximalmente en relación con el seguro del tambor de sutura 120, de manera que las estrías de bloqueo 126 se monten sobre el ahusamiento de barril proximal 111 de la aguja, creando la condición inmovilizada mostrada en FIG. 15. En la posición inmovilizada, un repliegue proximal para entrega a la aguja superará la fuerza limitante presentada por uñas 148 contra la cara proximal 116 del tambor, haciendo que los brazos elásticos 146 se deformen ligeramente y permitan el paso del tambor 114 junto con la aguja en su carrera de repliegue proximal.

Mango de Control de la Cápsula de Sutura

Una vista lateral de un mango adecuado de control de sutura 200 se

dx

configuraciones del mango de control pueden ser apropiadas para operar la cápsula de sutura, según se requiera. El mango de control tiene que facilitar medios que permitan al operador accionar el eje impulsor de la aguja y el manguito de bloqueo del tambor de sutura 124 longitudinalmente y en relación uno con otro para operar la cápsula a través de los pasos ya descritos. Adicionalmente, el mango debe poder asegurarse en forma desmontable al ensamble del mango proximal de un endoscopio 210 en el puerto de apertura al canal de maniobra del endoscopio, a través del cual se insertarán el eje impulsor de la aguja y el manguito de bloqueo del tambor de sutura. Adicionalmente, puede ser preferible enrutar la línea de fuente de vacío a través del mango de control, de modo que el operador pueda introducir selectivamente y suspender el vacío, según lo apropiado, para capturar y liberar tejido durante el procedimiento de suturamiento. Alternativamente, el mango de control puede comprender un interruptor de control de vacío, que incluya un mecanismo de enclavamiento para impedir el movimiento longitudinal de los miembros del mango de control hasta que se obtenga una presión de vacío pre-establecida en la cámara de succión.

El mango de control mostrado en FIG. 16 incluye una boquilla sujetadora ("*a collet*") 204 en su extremo distal 202 para conexión a un mango de control del endoscopio 210 en el extremo proximal 12 de un endoscopio 10. La boquilla sujetadora se atornilla al puerto previsto normalmente para el canal de maniobra de la mayoría de los endoscopios, dejando al mismo tiempo un agujero pasante a través del cual el eje impulsor de la aguja 184 y la funda del seguro del tambor de sutura 124 puedan pasar en forma corrediza.

El mango de control comprende también una caja del interruptor de vacío 208 unida a la boquilla sujetadora 204 y dirige el ensamble de la línea de vacío a través del cuerpo del mango 200. El mango comprende además una porción de cuerpo principal 206, que aloja los componentes que

de bloqueo del tambor de sutura 124. En el pistón pueden disponerse marcaciones visuales 218 (que enseñen barras restantes del marcador no insertadas en el cuerpo principal 206) para indicar al usuario en qué fase de despliegue se encuentra en un momento dado el mango de control.

FIG. 17 presenta una vista en corte del cuerpo principal 206 del mango de control, que muestra el mecanismo que convierte el movimiento longitudinal del pistón 216 en movimiento de la aguja y el ensamble de seguro del tambor de sutura. FIG. 18 es una vista detallada en corte del cuerpo principal 206, mostrado en FIG. 17. Se observa que la posición del mango mostrado en FIGS. 16-18 representa el estado inicial del sistema, en el cual la aguja y el tambor permanecen en la pista de la aguja 110 en el lado proximal de la cámara de succión 106 antes de la primera carrera de sutura.

FIGS. 17, 18 y 19A muestran una vista en corte del mango de control en su posición inicial. El pistón 216 se acopla con un porta-funda de bloqueo 220 que se empalma al manguito de bloqueo del tambor de sutura 124 y se acopla con un porta-aguja 230, que se une al eje impulsor de la aguja 184. El pistón engrana el porta-aguja 230 presionando contra el porta-pistón 240 que empuja contra el resorte de despliegue de la aguja 244, que se encuentra en acoplamiento con el porta-aguja 230, cuando el pistón se empuja distalmente en relación con el cuerpo principal 206 del mango. Cuando el porta-pistón 240 se desliza distalmente, se desplaza a través del transportador principal 248 para mantenerlo en alineación longitudinal en el mango.

El pistón 216 se encuentra asimismo en acoplamiento con el porta-funda de bloqueo 220 mediante el agarre de un brazo de uña 250. El extremo distal 252 del brazo de uña engrana el porta-funda de bloqueo 220 directamente por contacto con un pequeño resorte 254. El brazo de uña se extiende proximalmente sobre el resorte de despliegue de la aguja, de modo que su extremo proximal 256 engrane una pista de uña universal 258

vista en corte transversal que se presenta tomada a lo largo de la línea A-A, mostrada en FIG. 21. La pista universal es tridimensional, de modo que a medida que el brazo de uña proximal se desplaza en la pista, su elevación cambia para guiar la uña completamente a lo largo de la pista en una dirección, a pesar de la aplicación únicamente de movimiento longitudinal desde el pistón.

Un resorte de retorno del mango 260 rodea todo el ensamble del porta-pistón 240, el transportador de despliegue de la aguja y el brazo de la uña, de modo que siempre esté presente una fuerza elástica proximal contra el pistón 216 de principio a fin del despliegue. Una característica adicional puede agregarse al mango para garantizar que una aguja parcialmente desplegada no se repliegue proximalmente en forma prematura.

Un ensamble de trinquete del pistón 270 garantiza que el pistón se desplace únicamente en una dirección distal hasta que haya alcanzado su longitud máxima de carrera distal, antes de permitir el retorno proximal del pistón. Esta característica garantiza que el operador tiene que concluir la carrera de aplicación distal de la aguja para asegurarse que esté completamente liberada en la dirección proximal, de modo que no se haga ningún intento por replegar el ensamble de la cápsula de sutura mientras la aguja está parcial o completamente insertada a través de una porción de tejido succionado. El ensamble de trinquete 270 comprende una pista de trinquete 272, configurada como un paralelogramo con una porción de pista recta que se proyecta distalmente 274. Un ensamble cilíndrico de uña de trinquete 276 con un brazo de uña saliente 278 configurado para montarse en el trecho durante el movimiento longitudinal del pistón 216 se asegura en un receso de la uña de trinquete 280, formado en el cuerpo principal 206 de la caja. Dientes de trinquete 282 se forman a un lado de la pista de trinquete en el paralelogramo 272, de modo que la acción del trinquete ocurra únicamente durante el movimiento distal del pistón 216 en el período en el cual la aguja estará atravesando la cámara de succión de la cápsula.

alt

paralelogramo sin dientes de trinquete representa el desplazamiento por el brazo de uña del trinquete 278 durante la carrera de retorno proximal del pistón 216, que no necesita controlarse por la acción del trinquete por razones de seguridad.

La operación del mango de control y el movimiento correspondiente de los componentes de la cápsula suturadora se describirán en conexión con FIGS. 17, 18, 19A, 24 y 25. Desde la posición inicial mostrada en FIGS. 17, 18 y 19A, el usuario comienza la operación del mango de control activando primero el interruptor de suministro de vacío 224 (FIG. 16) para abrir la línea de entrada de vacío 214 (conectada a un suministro de vacío) a la línea de salida de vacío 212, que se extiende a lo largo del endoscopio a la cápsula suturadora 100. La introducción de vacío hace que se succione tejido en la cámara de succión 106, y el proceso de suturamiento puede iniciarse.

Desde la posición inicial del mango mostrada en FIGS. 17, 18 y 19A, el usuario presiona completamente el pistón 216, como se indica en FIG. 24, para impulsar la aguja distalmente, que atraviesa la cámara de succión 106 e impulsa el tambor de sutura 114 en el ensamble de la pinza de sutura 140 como se muestra en FIG. 14. La pulsación del pistón 216 sirve para presionar el porta-pistón 240 distalmente a través del mango, comprimiendo el resorte de despliegue de la aguja 244 y, luego de la compresión de ese resorte, moviendo el porta-aguja 230 distalmente en una longitud de carrera equivalente a la recorrida por el pistón 216. El porta-funda de bloqueo 220 se mueve también distalmente durante toda la carrera distal del pistón 216, si bien en una magnitud ligeramente menor que la lograda por el porta-aguja 230, debido al desplazamiento de la uña 256 y la pista de la uña 258 durante el movimiento distal del porta-pistón 240.

Como se muestra mejor en FIG. 20, la posición inicial del extremo proximal del brazo de uña 256 y la pista de la uña 258 se representa por el numeral de referencia 261. Cuando el porta-pistón 240 se mueve primero

brazo de uña 250. Luego de alcanzar la segunda posición en 262, el brazo de uña comienza entonces a desplazarse con el porta-pistón 240 durante el resto de la carrera distal inicial del pistón 216. El movimiento que sigue a la salida total del brazo de uña en la posición 262 sirve para desplazar el manguito de bloqueo distalmente, pero no tanto como el movimiento distal de la aguja. El avance distal adicional de la aguja, creado por el mecanismo de uña, produce el desenganche del seguro del tambor de sutura 120, como se muestra en FIG. 9, de modo que sea posible dejar atrás en la pinza del tambor de sutura 140 el tambor de sutura 114.

Cuando el usuario libera el pistón de su configuración totalmente presionada, indicada en FIG. 24, el pistón regresa a una posición intermedia mostrada en FIG. 25. En esta posición, la aguja se repliega proximalmente de la pinza del tambor de sutura a una posición que es proximal a la cámara de succión 106. El tambor 114 se deja atrás en la pinza del tambor de sutura 140. La aguja y el seguro del tambor de sutura permanecen en la misma posición desbloqueada relativa en esta fase. La aguja y el manguito de bloqueo del tambor de sutura 124 permanecen en la misma posición relativa debido al efecto de bloqueo de la pista de la uña 258. Como se muestra en FIG. 25 y FIG. 20, el brazo de uña 256 se mantiene ahora en la tercera posición mostrada en el numeral de referencia 263 de la pista de la uña, que sirve para mantener el porta-aguja 230 avanzado en relación con el porta-funda de bloqueo 220. Todo el ensamble se ha movido proximalmente por la fuerza de retorno del resorte de retorno del mango 260, que generó una carrera de retorno proximal automático para todos los componentes, incluidos el pistón 216, el porta-pistón 240 y, en virtud del brazo de uña 250, tanto el porta-aguja 230 como el porta-funda de bloqueo 220.

Para avanzar la aguja una segunda vez para recuperar el tambor de sutura, sea después de que una segunda porción de tejido se ha succionado en la cámara de succión 106 o sea antes de succionar otra área de tejido. el

todos los componentes al desplazamiento distal máximo, como se mostró previamente en FIG. 24. No obstante, como el brazo de uña 256 se guía a la ubicación identificada por el numeral de referencia 264 en la pista de la uña 258 mostrado en FIG. 20, la carrera de retorno proximal experimentada por el mango bajo la fuerza elástica del resorte del mango 260 hará que el brazo de uña 256 siga la pista de regreso a su posición inicial 261.

El brazo de uña 256 se guía a través de su patrón específico en la pista universal 258 debido al cambio de elevación de cada segmento del trayecto mostrado en el dibujo de corte transversal de FIG. 21. Como el brazo de uña se forma para tener un sesgo elástico hacia abajo, a medida que se desplaza a través de cada cambio de elevación segmentada, éste salta elásticamente hacia abajo al siguiente nivel, una vez se ha alcanzado. Como resultado, durante la carrera de retorno proximal final, la uña regresa a la posición original en 261, lo cual crea un movimiento relativo entre la funda de seguro del tambor de sutura 124 y la aguja 108, de modo que las estrías de bloqueo 126 se abran nuevamente hacia fuera por el extremo distal en forma de lanza 109 de la aguja para asegurar el tambor de sutura 114 en su sitio. El mecanismo de trinquete del pistón permite el retorno completo a su posición original mostrada en FIG. 17. Como el brazo de uña 278 sigue una ruta descendente en la pista tri-dimensional 272 para alejarse de los dientes de trinquete 282 al final de la carrera en 274, el resorte de despliegue de la aguja 244 se expande también elásticamente para impartir movimiento proximal para todo el ensamble de la aguja y la funda del seguro del tambor de sutura. La configuración resultante del mango es la mostrada en FIG. 17, y la cápsula se regresa a su estado inicial con la aguja y el tambor de sutura replegados al lado proximal de la cámara de succión 106.

Anclaje de Sutura y Dispositivo de Aplicación

El anclaje de sutura y el dispositivo de aplicación del anclaje de

102

tarea de amarrar los nudos; provee un retenedor de sutura mecánico que puede aplicarse a través del canal de maniobra del endoscopio, obviando la necesidad de re-intubar con otro instrumento para completar el procedimiento. El anclaje de sutura y el dispositivo de aplicación descritos aquí son similares a los divulgados en la Solicitud pendiente de Patente de los Estados Unidos No. 10/275,534, correspondiente a la Publicación PCT No. WO 01/89393. La totalidad de la Solicitud de Patente de los Estados Unidos se incorpora aquí por referencia.

El anclaje de sutura de la presente invención se muestra en FIGS. 26A y B. En FIG. 26A se muestra un anclaje de sutura desmontado, como se indica, que comprende un anillo 502 con un agujero pasante 503, dimensionado para recibir con encaje de fricción un tapón 504, para capturar una sutura 18 que se ha introducido por el agujero pasante 503. FIG. 26B muestra la configuración ensamblada del anclaje de sutura de anillo y tapón, con el tapón 504 insertado en el agujero pasante 503 del anillo 502 para capturar la sutura 18 entre las superficies del tapón y el anillo. Se anota que en FIG. 26B la holgura entre el tapón y el anillo se ha exagerado para ilustrar que la sutura 18 esté presente entre esos dos componentes, pero debe entenderse que la sutura está firmemente agarrada entre ellos, de modo que no pueda correrse.

FIG. 27 muestra el extremo distal operativo 510 de un dispositivo de aplicación del anclaje de sutura 512. El extremo distal operativo se acopla a un eje 514 que es de longitud suficiente para extenderse a través de la longitud total del canal de maniobra de un endoscopio y sobresalir en el extremo proximal para acoplamiento con un mango de control 550 (mostrado en FIGS. 27 y 28-36, que siguen); pueden verse los componentes del extremo operativo distal del dispositivo de aplicación del anclaje de sutura. El dispositivo comprende un manguito exterior 516 a través del cual se puede deslizar una jaula 518, definida por una pluralidad de lengüetas rígidas 520, acoplada en forma deslizante (*"inchedly"*



distal 526 del buje 524, de modo que cuando las lengüetas se proyectan más allá del manguito 516, éstas se abren elásticamente en sentido radial en sus extremos distales 521. En su configuración cerrada, las lengüetas definen una jaula que hace las veces de receptáculo 528 para los componentes desmontados de tapón y anillo, que tienen que dirigirse al lugar de sutura a través del canal de maniobra del endoscopio. El receptáculo definido por la jaula 518 sirve para mantener el tapón y el anillo en alineación, de modo que puedan ensamblarse fácilmente en la ubicación remota.

Como se muestra en FIG. 27, cuando se ha concluido la colocación de la sutura en el tejido, los componentes del ensamble de aguja y bloqueo de tambor de sutura, junto con el mango de control, se retiran del canal de maniobra del endoscopio en su totalidad. Aunque la cápsula permanece montada en el extremo distal del endoscopio, el canal de maniobra ofrece espacio adecuado para la introducción del dispositivo del sistema de aplicación del anclaje de sutura 512. El miembro operativo distal 510 tiene espacio suficiente para operar, a medida que sobresale del extremo distal del canal de maniobra del endoscopio en la cavidad de succión 106 de la cápsula. Cuando el miembro operativo distal del dispositivo de aplicación del anclaje de sutura se inserta en el extremo proximal del canal de maniobra del endoscopio, los cabos de la sutura 18, que se proyectan a través del canal de maniobra y a través del tejido, se insertan primero a través del anillo 502 por su extremo distal, saliendo de su extremo proximal y situándose alrededor del tapón 504, de modo que se proyecten a través de un agujero proximal 530 del manguito 516, de modo que puedan mantenerse apretados a medida que el dispositivo se avanza al lugar interno (FIG. 28-30).

Con la sutura enhebrada a través del dispositivo, el dispositivo se avanza al lugar de sutura; la sutura puede halarse fuertemente para juntar las porciones de tejido que se han suturado, y el dispositivo se opera para

104

operación de ensamblar el anillo y el tapón y liberar el componente ensamblado se realiza preferiblemente con una sola carrera distal de un accionador del mango de control.

FIGS. 37 y 38 muestran un mango de control que se configura para operar un dispositivo de aplicación con una sola carrera distal de un mecanismo de control. El mango de control 550 comprende una caja 552 con anillos formados para los dedos 554, con el fin de servir de palanca a la mano de los usuarios cuando presionen el pistón 556 distalmente. Proyectándose distalmente del mango de control 550 hay un eje exterior 558, protegido por una pieza corta de alivio de deformación 560 para impedir la torsión en el área adyacente al mango. El extremo proximal 562 del eje exterior se une al cuerpo 552 del mango. El extremo proximal 562 del eje exterior se asegura firmemente al cuerpo del mango uniéndose a un buje 566, que se suelda en el interior del cuerpo del mango 552. El extremo distal del eje exterior 564 se acopla al manguito exterior 516. Un eje interior 570 es visible a través del eje exterior 558 para operar un impulsor 534, que empuja el tapón 504 en el anillo 502 durante el ensamble en la jaula 518. El eje interior 570 se fija en su extremo proximal 571 al cuerpo del pistón 556. Cuando el pistón se presiona, el eje interior 570 se mueve distalmente para empujar el tapón en el anillo para ensamble. El eje del pistón 556 se acopla a un buje 574 que es deslizable con un ajuste estrecho dentro de un canal 576 en el cuerpo 552 del mango. Un resorte de retorno 578, montado en el canal 576 entre el buje del pistón 574 y el buje del tubo exterior 566, sirve para empujar elásticamente el pistón de regreso a su posición proximal después de haberse presionado completamente en sentido distal. Un reforzador del impulsor 580 puede agregarse al eje interior para aumentar su resistencia a ceder bajo la carga de compresión que ocurre durante el ensamble del tapón en el anillo.

Aunque el mango se provee con un solo control de impulsor longitudinal en la forma de un pistón 556, la capacidad de realizar varias

a través de su carrera de ensamble de anillo y tapón. Como se ve en FIGS. 31-36, el buje 524, el anillo 502 y tapón 504 se retienen en el receptáculo 528, definido por la jaula 518 antes del ensamble (FIG. 31). El anillo 502 se mantiene distalmente contra las puntas curvadas radialmente hacia adentro 523 de las lengüetas 520. Debido a que las puntas curvadas hacia adentro 523 definen un diámetro que es menor que el del anillo, el anillo no puede deslizarse a lo largo de las puntas hasta que las lengüetas se abran. El tapón 504 se mantiene en alineación con el agujero pasante 503 del anillo al situarse en el agujero del buje 524.

Como se ve en FIG. 31, inmediatamente proximal al tapón alineado 504 se encuentra el extremo distal 532 del impulsor 534. Cuando el pistón 556 del mango de control 550 se empuja distalmente, el eje interior 570 presiona el impulsor distalmente para insertar el tapón 504 en el anillo 502, como se muestra en FIG. 32. En esta fase, la sutura se ha capturado entre el tapón 504 y el anillo 502, pero el anillo y el tapón ensamblados tienen que liberarse del receptáculo 528 definido por la jaula 518. Para efectuar esto, el buje 524 y la caja 518 se fabrican deslizables en relación con el manguito exterior 516 hasta el punto donde el extremo proximal de las lengüetas se unen articuladamente al buje, de modo que los extremos distales de las lengüetas 521 puedan abrirse elásticamente para liberar el anillo y el tapón ensamblados.

Para mantener el buje y las lengüetas estacionarios dentro del manguito exterior durante el ensamble del anillo y el tapón, pero desencadenando la liberación del buje y la jaula para deslizarse distalmente en relación con el manguito luego del ensamble del anillo y el tapón, se emplean bolas de bloqueo 542 que ruedan en recesos 544 formados en el buje 524. El eje del impulsor 534 forma la superficie inferior del receso que retiene las bolas de bloqueo. El espacio de los recesos 544 fuerza a las bolas a acoplarse con huecos de bloqueo 546 formados en el manguito exterior 516. Cuando las bolas de bloqueo se fuerzan dentro de los huecos

106

Las bolas de bloqueo pueden dispararse para liberarlas de los huecos de bloqueo 546 en el momento en que el tapón se ha insertado completamente en el anillo 502, formando una porción de diámetro reducido a lo largo del eje del impulsor, que corresponde a la longitud de carrera requerida para completar la inserción del tapón en el anillo. Cuando la porción de diámetro reducido alcanza las bolas de bloqueo, el receso en el cuales éstas se encuentran se amplía, liberando inmediatamente su fuerza de acoplamiento contra los huecos de bloqueo 546 del manguito exterior 516. La superficie redondeada de las bolas permite inmediatamente el desacople de los huecos de bloqueo 546 y posibilita que el buje 524 con la jaula 518 y el anillo y el tapón ensamblados se muevan todos distalmente en relación con el manguito, si las fuerzas distales se mantienen en el eje del impulsor 534. La porción de diámetro reducido del impulsor se indica en 548 en FIG. 32, que alcanza las bolas de bloqueo 542 en el momento en que el impulsor se ha extendido suficientemente para insertar el tapón del impulsor 504 en el anillo 502. La fuerza distal se mantiene sobre el buje 524 por acoplamiento de una porción de diámetro ampliado del impulsor que comienza en 549 engranando el extremo proximal del buje 541 (FIG. 32).

Con el movimiento distal continuado del impulsor 534, el ensamble del buje y la jaula se deslizan distalmente en relación con el manguito exterior 516 como se muestra en FIGS. 34 y 35. Una vez que la jaula se ha expuesto completamente desde el manguito exterior, las lengüetas 520 se abren elásticamente en dirección radial para permitir la liberación del anillo y el tapón ensamblados como se muestra en FIG. 36. El exceso de los cabos de sutura es cercenado cuando el buje aplasta las suturas contra el borde afilado 531 de la abertura del manguito 530 durante el avance distal del buje y la jaula 518. Cuando se libera el pistón 556 en el mango de control 550, el resorte de retorno 578 hace que el pistón se mueva proximalmente lo cual repliega el impulsor proximalmente hasta que el

movimiento proximal continuado del impulsor 534.

Operación

La operación del sistema suturador de intubación única ya descrito se explicará ahora con referencia a ilustraciones esquemáticas mostradas en FIGS. 39-54, en conjunción con los dibujos presentados en FIGS. 55-63. En operación del dispositivo, la cápsula de suturadora 100 se monta primeramente en el extremo distal de un endoscopio 10 como se indica en FIG. 39. Con la aguja 108 y el tambor de sutura 114 ubicados proximalmente a la cámara de succión 106, el ensamble del endoscopio y la cápsula se avanzan a través de un lumen natural del cuerpo al sitio de tejido previsto. Esta configuración se muestra también en FIG. 55.

Luego de alcanzar el lugar de tejido previsto, se aplica vacío para arrastrar una porción de tejido 117 en la cámara de succión 106, como se indica en FIGS. 41 y 56.

Luego de succionado el tejido 117, la aguja 108 y el tambor de sutura 114 pueden avanzarse distalmente a través del tejido, de modo que la aguja y el tambor salgan y penetren la pinza del tambor de sutura 140 como se indica en FIGS. 42, 57 y 58. Seguidamente, el tambor de sutura 114 se libera y la pinza del tambor de sutura 140 y la aguja se repliegan proximalmente dejando la sutura 18 puesta a través de la porción de tejido como se muestra en FIGS. 43 y 59.

Como se indica en FIGS. 45, 60 y 61, se suspende el vacío y se libera el tejido de la cámara de succión 106 con la sutura 18 pasando a través del tejido. Luego de liberar el tejido, o bien puede succionarse otra porción de tejido en un lugar diferente a penetrarse por la aguja abierta y suturarse durante la carrera de repliegue proximal del tambor de sutura 114 a través del tejido o bien, antes de aplicar succión para capturar otra porción de tejido, la aguja puede avanzarse distalmente para recoger el tambor de sutura 114 y replugarlo proximalmente de modo que la sutura quede en la

recupera primeramente y se lleva de regreso proximalmente antes de la siguiente sutura.

En FIGS. 45 y 62, se muestra que luego de la liberación de la primera porción de tejido suturado 117, la aguja 108 se avanza distalmente para recapturar el tambor de sutura en la pinza del tambor de sutura 140. Una vez el tambor se asegura sobre la aguja por el seguro del tambor de sutura 120, el ensamble de aguja y tambor pueden replegarse proximalmente de regreso a la pista de la aguja 110 en el sitio proximal de la cámara de succión, como se indica en FIGS. 46, 47 y 63. Una vez la aguja se retrae proximalmente con el tambor de sutura, puede aspirarse una segunda porción de tejido 119 en la cámara de succión y repetirse el proceso anterior para poner otra sutura en un segundo lugar de tejido usando la misma sutura 18, como se muestra en FIGS. 48-50. Luego de que un número deseado de porciones de tejido se han suturado con el material de sutura 18, la aguja y los componentes del mango de control, relacionados con el dispositivo suturador, pueden retirarse del canal de maniobra del endoscopio, y el dispositivo de aplicación del anclaje de sutura 500 cargado con un anillo 502 y un tapón 504 puede insertarse a través del canal de maniobra del endoscopio, de modo que el extremo operativo distal 510 del dispositivo se proyecte en la cámara de succión 106 de la cápsula 100. Como se indica en FIGS. 52 y 53, un anillo 502 y un tapón 504 pueden aplicarse a los extremos de la sutura 18 para sujetar la sutura, con el fin de que retenga juntas fuertemente las porciones de tejido 117 y 119. Una vez aplicado el anclaje de sutura, el dispositivo de aplicación del anclaje de sutura 500 puede retirarse del canal de maniobra del endoscopio, como se muestra en FIG. 54 y sacarse el endoscopio del paciente.

Habiendo así descrito la invención, lo que deseamos reivindicar y asegurar por el certificado de patente es:

Reivindicaciones

1. Un dispositivo suturador de tejido, endoscópico, que comprende:
 - una cápsula suturadora con una cámara de succión de tejido, una pista de la aguja y un tambor de pinza de sutura, en donde la pinza del tambor de sutura se ubica distal a la cámara de succión del tejido,
 - una aguja corrediza en la pista de la aguja y a lo largo de una ruta que atraviesa la cámara de succión del tejido, un seguro del tambor de sutura en una superficie exterior de la aguja, y
 - un tambor de sutura capturable en la superficie exterior de la aguja por el seguro del tambor de sutura y que es desmontable de la aguja en la pinza del tambor de sutura, cuando se libera el seguro del tambor de sutura.
2. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 1, en donde el seguro del tambor de sutura cambia su posición en relación con la superficie exterior de la aguja para crear una superficie de bloqueo que engrana el tambor de sutura para prevenir el movimiento de desplazamiento distal del tambor en relación con la aguja.
3. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 2, en donde la superficie exterior de la aguja se configura para engranar el seguro del tambor de sutura cuando el seguro se mueve longitudinalmente en relación con la aguja para formar la superficie de bloqueo.
4. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 3, en donde el bloqueo de sutura comprende por lo menos dos estrías de bloqueo que se abren a medida que se deslizan sobre una superficie ampliada de la aguja para crear la superficie de bloqueo que frena el tambor de sutura contra movimiento longitudinal.



brazos elásticos unidos en un remate de sus extremos en una configuración en Y, cada uno con un extremo libre en forma de uña que presenta un borde que se proyecta hacia adentro, configurado para engranar una superficie del tambor de sutura.

6. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 5, en donde la cápsula de sutura comprende además una cavidad que se configura para ajustar con precisión alrededor de la superficie del tambor de sutura, permitiendo al mismo tiempo el movimiento de los brazos elásticos de la pinza del tambor de sutura.

7. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 1, en donde el tambor de sutura es anular y se desliza sobre una superficie exterior de la aguja.

8. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 7, en donde el tambor tiene extremos proximal y distal y es ahusado por lo menos en su extremo distal para presentar un perfil bajo a medida que la aguja se avanza distalmente a través del tejido.

9. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 4, en donde la aguja es sólida y tiene un extremo distal en forma de lanza con superficies rectas de barril ahusado proyectándose desde las direcciones proximal y distal que concurren en una sección central de diámetro aumentado para definir una forma ampliada.

10. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 1, que comprende además un mango de control acoplable en forma desmontable al extremo proximal de un endoscopio y que tiene por lo menos un miembro de control longitudinal acoplado a un eje que se



11. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 10, en donde el mango comprende además un mecanismo de control para accionar el seguro del tambor de sutura durante una porción de una carrera del miembro de control longitudinal, que opera la aguja.

12. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 11, en donde el miembro de control longitudinal del mango incluye un mecanismo de uña universal y pista orientado para hacer que el movimiento de un eje de control del seguro del tambor de sutura durante sólo una porción de la carrera longitudinal del mecanismo de control, que opera la aguja.

13. Un dispositivo suturador de tejido, endoscópico, como se define en la reivindicación 10, en donde el mango de control incluye además un interruptor de control de vacío que incluye un mecanismo de enclavamiento que impide el movimiento longitudinal de los miembros de control del mango hasta que se logra una presión de vacío pre-establecida a la cámara de succión de la cápsula.

14. Un dispositivo suturador de tejido, endoscópico, de puntos múltiples, de intubación única, que comprende:

- una cápsula suturadora acoplable en forma desmontable a un extremo distal de un endoscopio y que tiene una aguja deslizable en una pista de aguja;

- una cámara de succión para recibir tejido;

- un tambor de sutura unido a una sutura y deslizable sobre la aguja;

- un seguro del tambor de sutura desmontable selectivamente en la aguja;

- una pinza del tambor de sutura distal a la cámara de succión y

desmontable a un extremo proximal de un endoscopio y que comprende por lo menos un miembro de control longitudinal empalmado a un extremo de un eje de control que presenta en su otro extremo una conexión a la aguja, de modo que el movimiento longitudinal del miembro de control resulta en el movimiento correspondiente de la aguja;

un anclaje de sutura que comprende un tapón insertable por fricción dentro de un anillo para capturar una sutura entre ellos;

un dispositivo de aplicación del anclaje de sutura que comprende un eje con extremos distal y proximal y que presenta un diámetro suficientemente pequeño para poder alojarse en forma deslizable a través de un canal de maniobra de un endoscopio y suficiente longitud para proyectarse por lo menos en la longitud del endoscopio;

un porta-anclaje de sutura en su extremo distal que comprende una jaula definida por una pluralidad de brazos dispuestos longitudinalmente y articulados en sus extremos proximales;

una cuchilla de sutura deslizable en la jaula;

un mango de control del dispositivo de aplicación del anclaje de sutura que comprende una corredera longitudinal para accionar un impulsor que se proyecta a través del eje para empujar el tapón en el anillo y avanzar la jaula distalmente en relación con el manguito para abrir las lengüetas y liberar el anillo y el tapón ensamblados.

15. Un método de suturar una pluralidad de pliegues de tejido, que comprende proveer:

una cápsula suturadora con una cámara de succión de tejido, una pista de aguja y una pinza del tambor de sutura, donde la pinza del tambor de sutura se ubica distal a la cámara de succión del tejido;

una aguja deslizable en la pista de la aguja y a lo largo de una ruta que atraviesa la cámara de succión del tejido, un seguro del tambor de sutura en una superficie exterior de la aguja.

en la pinza del tambor de sutura, cuando se libera el seguro del tambor de sutura; y

una sutura fijada al tambor de sutura;

succionar un pliegue del tejido en la cámara de succión del tejido;

avanzar la aguja, el tambor de sutura y la sutura en y a través del pliegue de tejido;

capturar el tambor de sutura en la pinza del tambor de sutura;

liberar el tambor de sutura de la aguja;

retraer la aguja a través y fuera del pliegue de tejido;

liberar el pliegue de tejido de la cámara de succión del tejido;

avanzar la aguja a la pinza del tambor de sutura y dentro del tambor de sutura;

capturar el tambor de sutura en la aguja;

liberar el tambor de sutura de la pinza del tambor de sutura;

retraer la aguja y el tambor de sutura acoplado a una posición proximal a la cámara de succión del tejido;

avanzar la cápsula suturadora a otra área de tejido;

succionar un pliegue de tejido en la cámara de succión del tejido;

avanzar la aguja, el tambor de sutura y la sutura en y a través del pliegue de tejido;

capturar el tambor de sutura en la pinza del tambor de sutura;

liberar el tambor de sutura de la aguja;

retraer la aguja a través y fuera del pliegue de tejido;

liberar el pliegue de tejido de la cámara de succión del tejido; y

asegurar los extremos de la sutura con una grapa de sutura; suturando así los pliegues de tejido.

FIG. 1

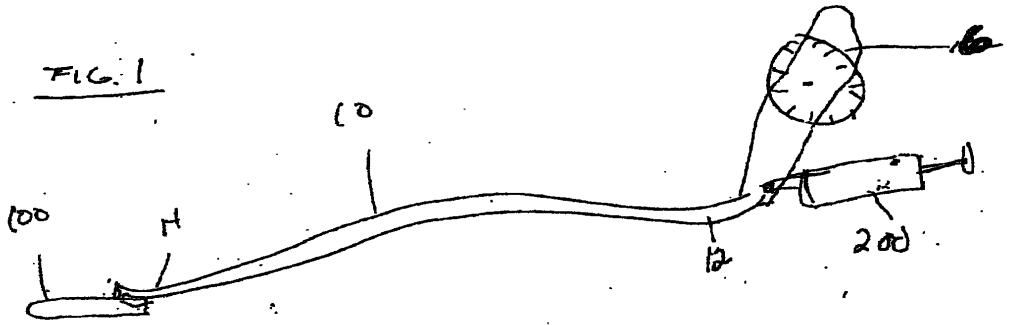


FIG. 2

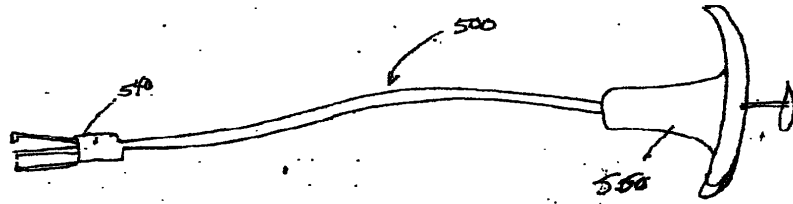


FIG. 3A

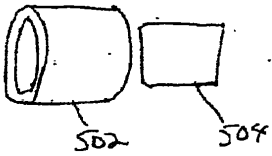
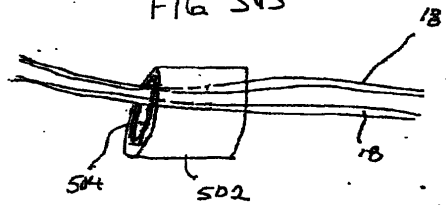


FIG. 3B



114

FIG. 4.

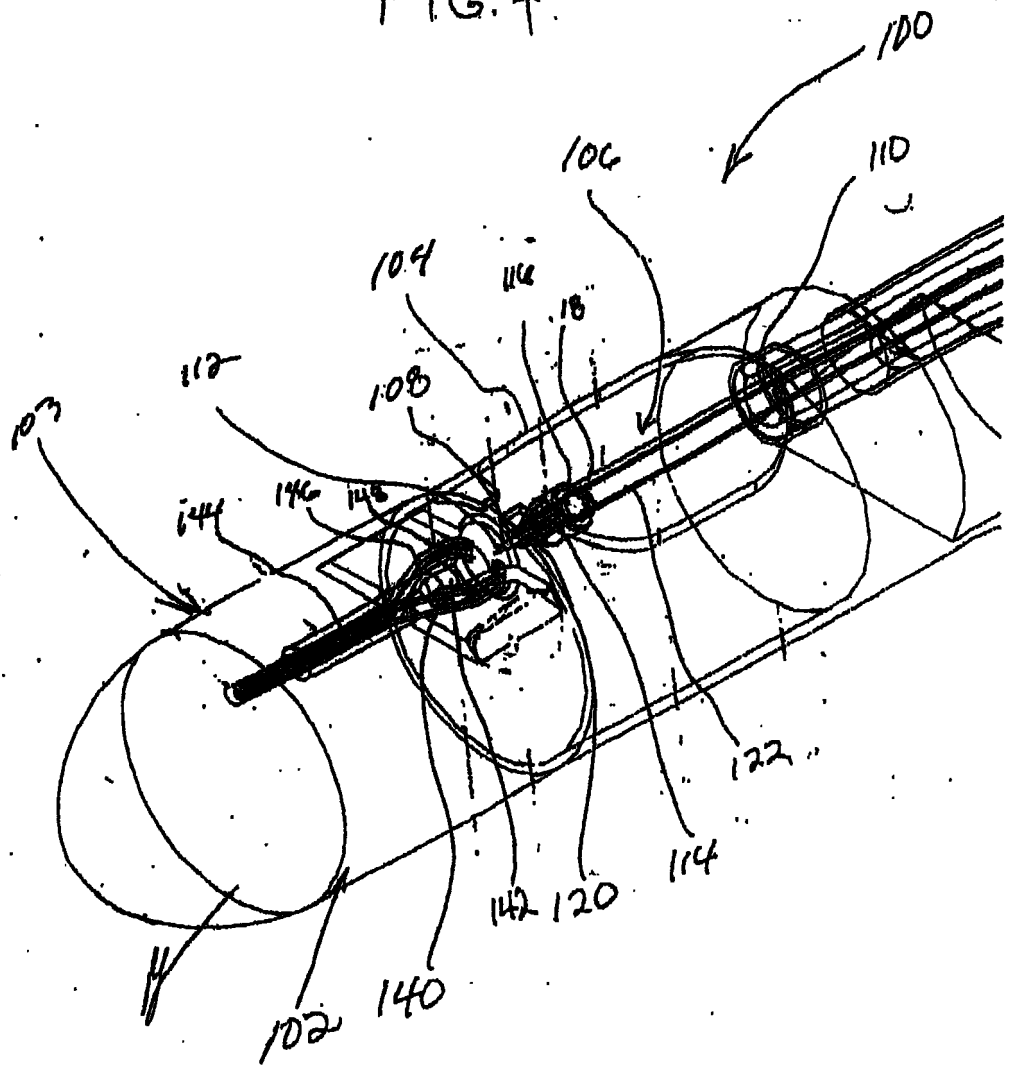


FIG. 5

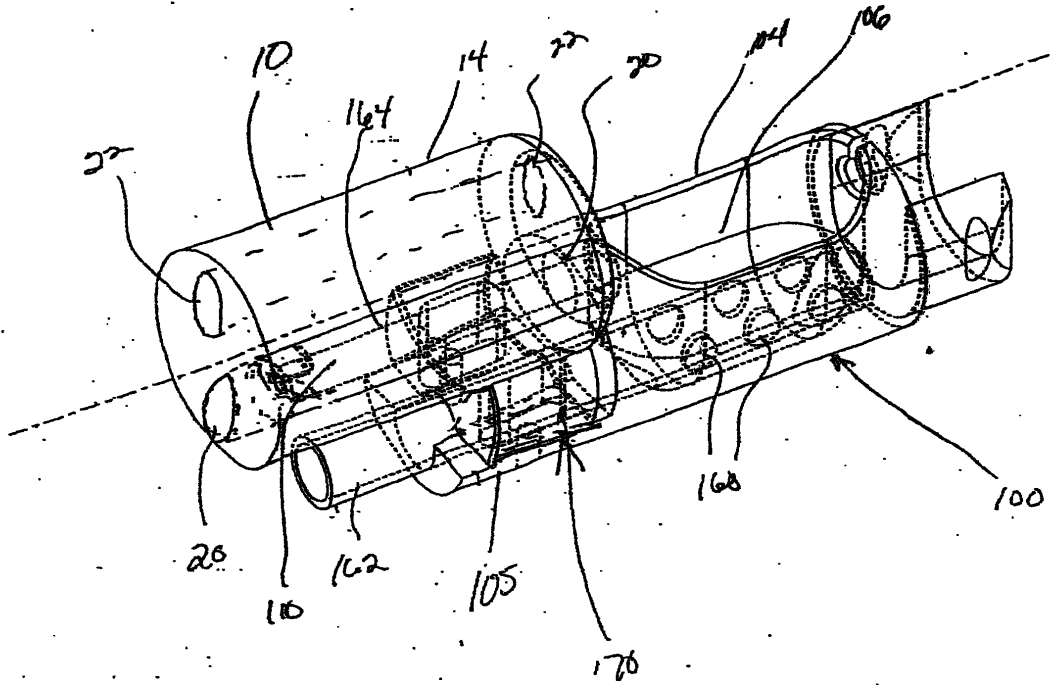
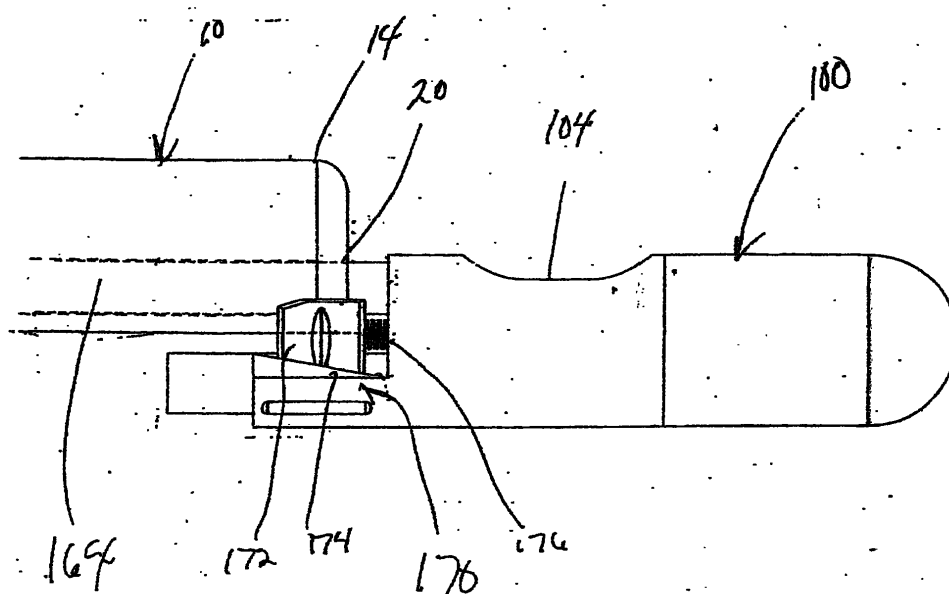


FIG. 6



~~117~~

FIG. 7B.

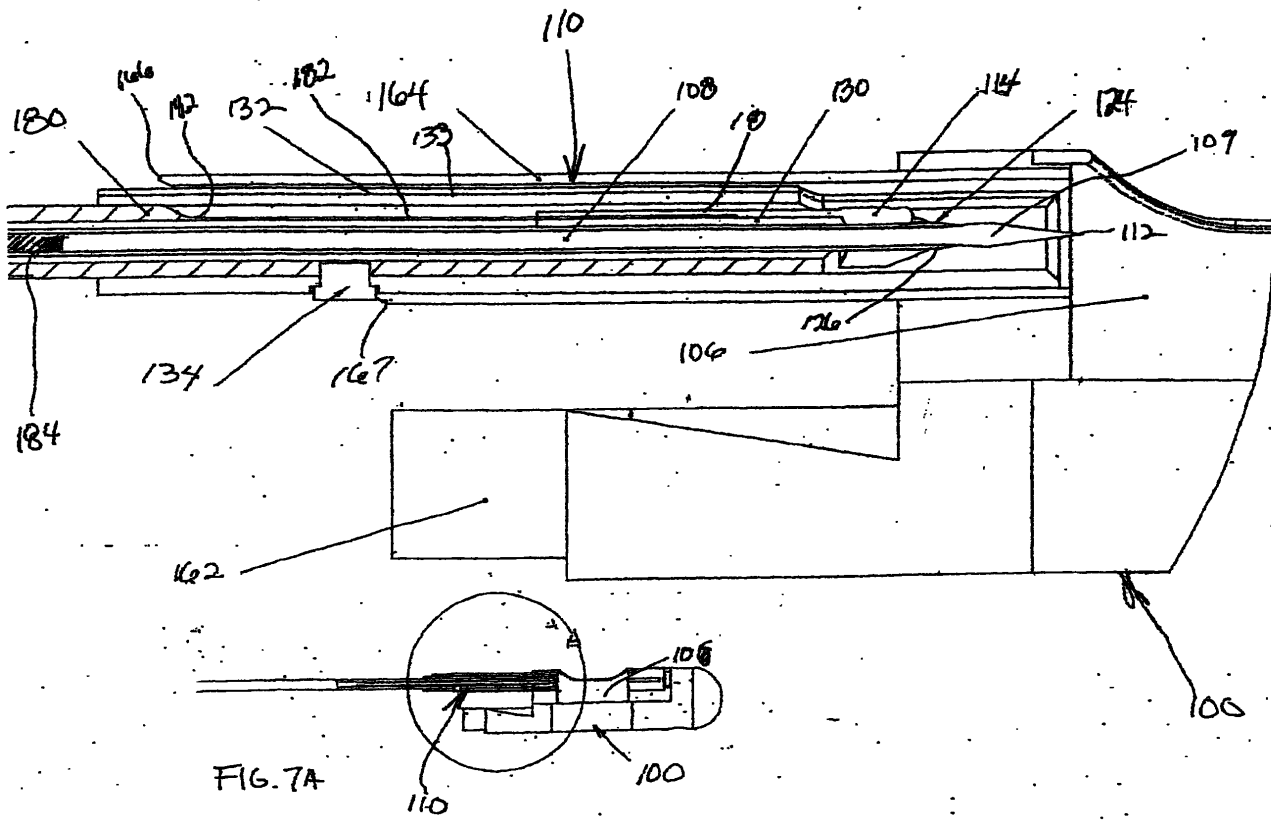
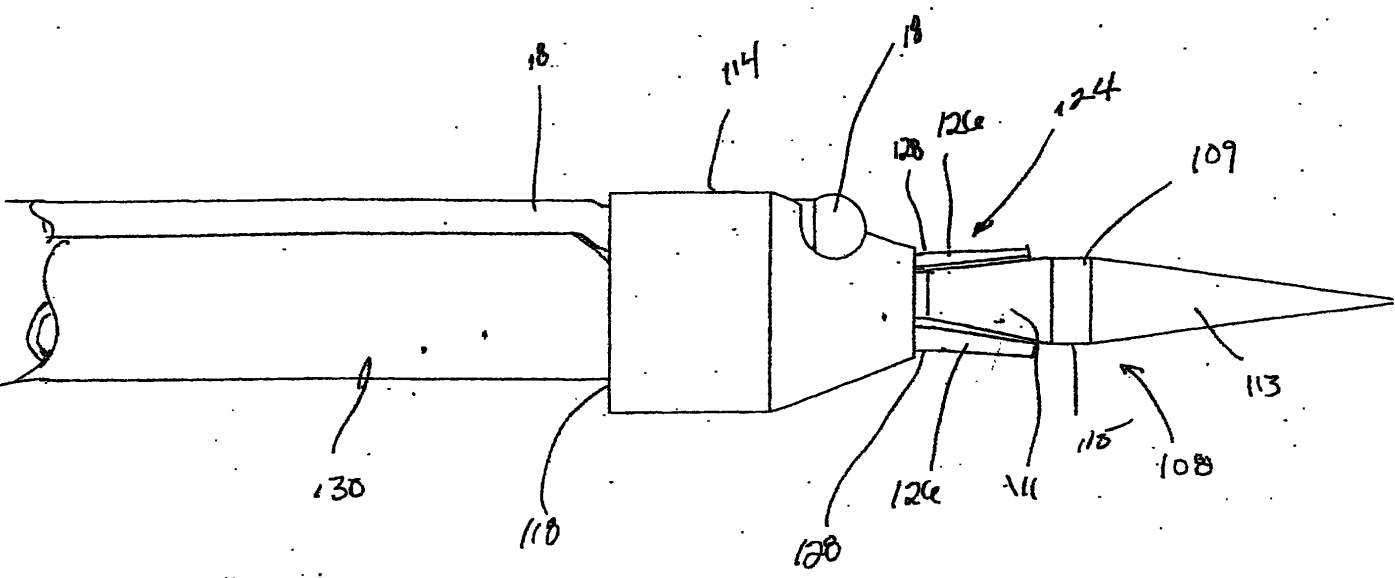


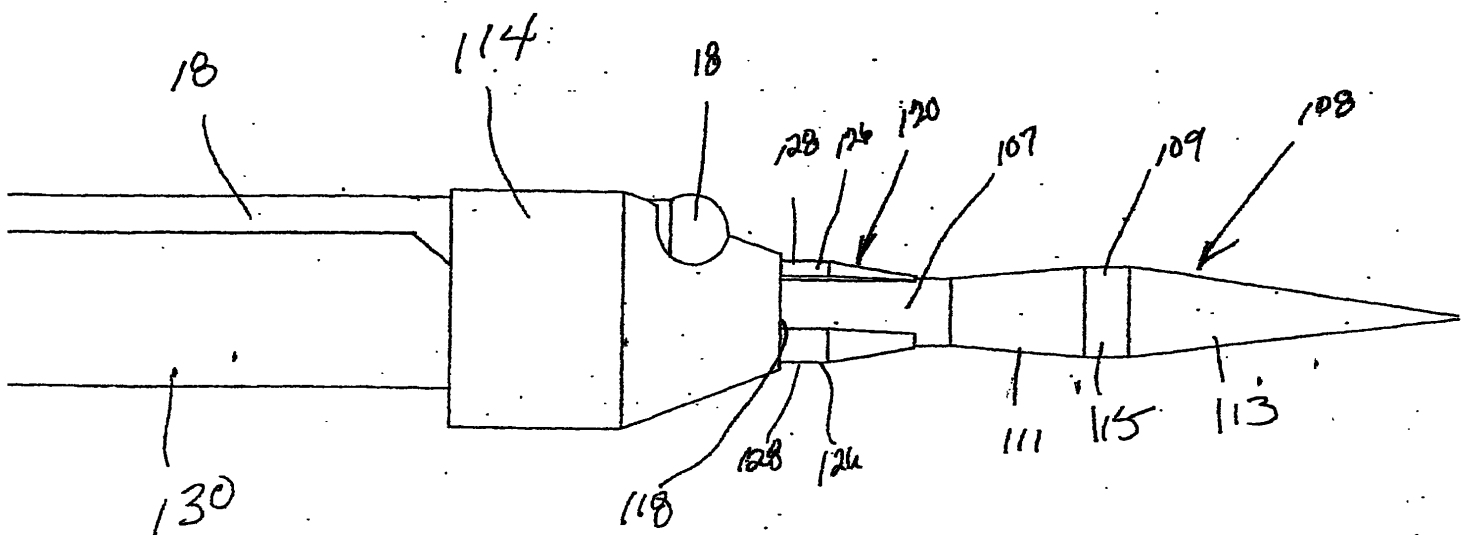
FIG. 8



6/30

~~119~~

FIG. 9

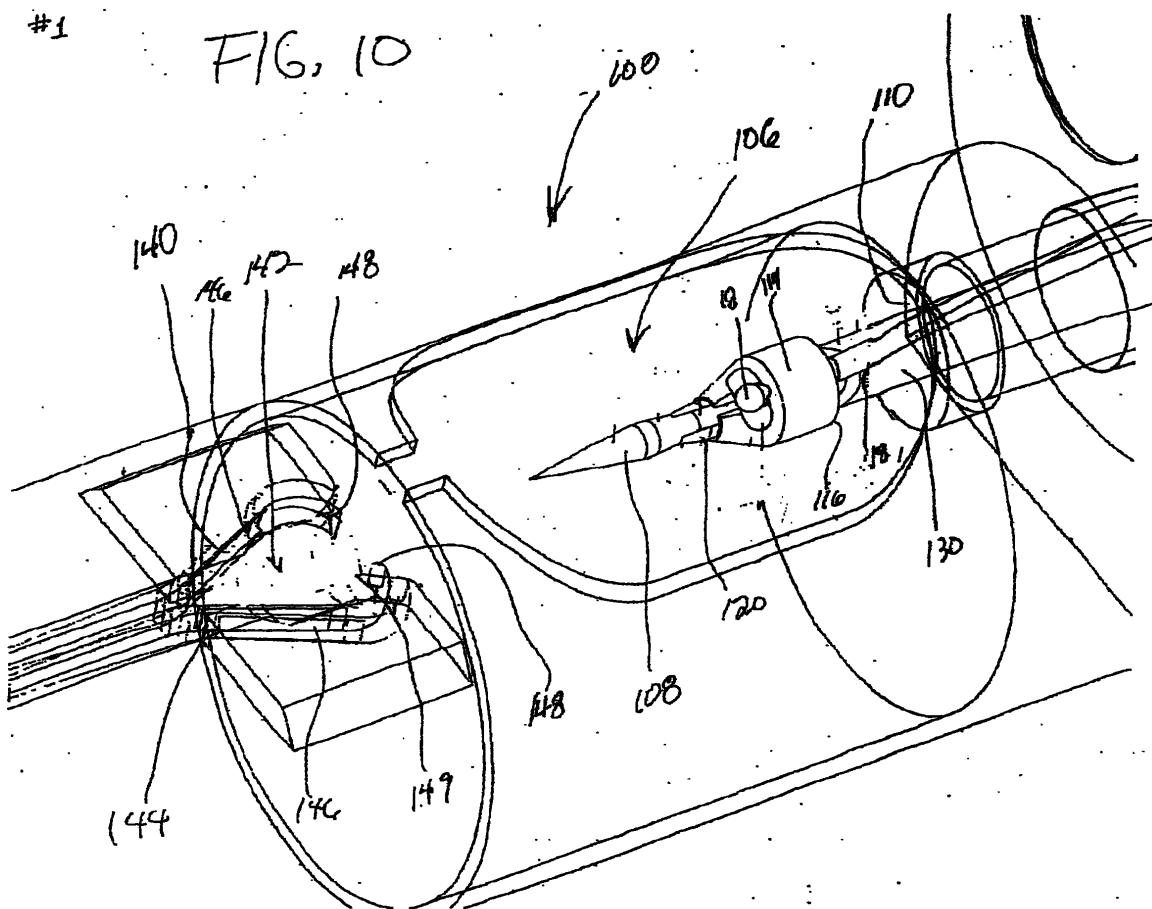


7/38

7/38

#1

FIG. 10



8/38

121

FIG. 11

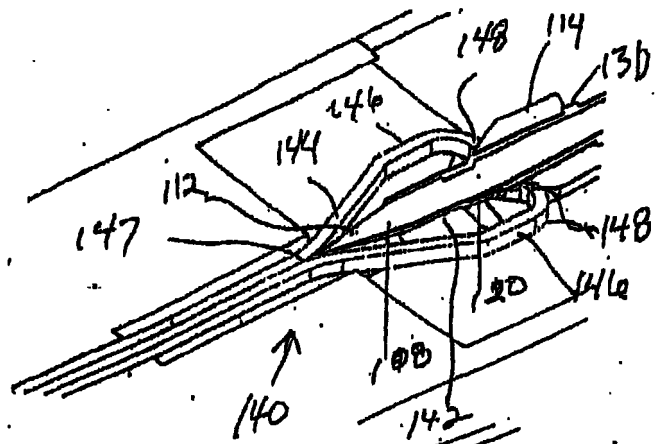


FIG. 12

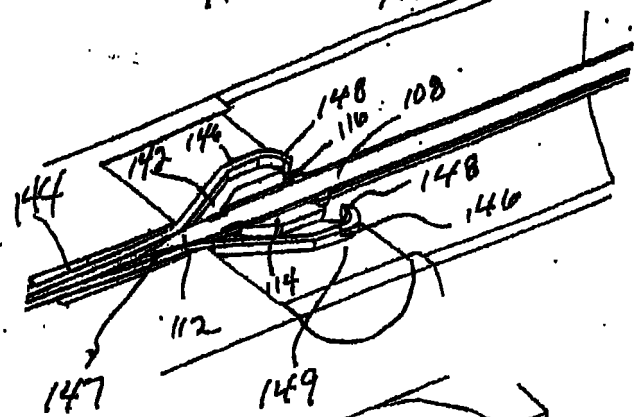


FIG. 13

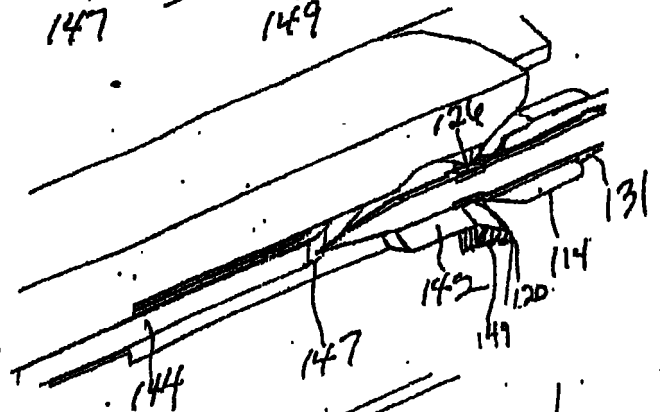
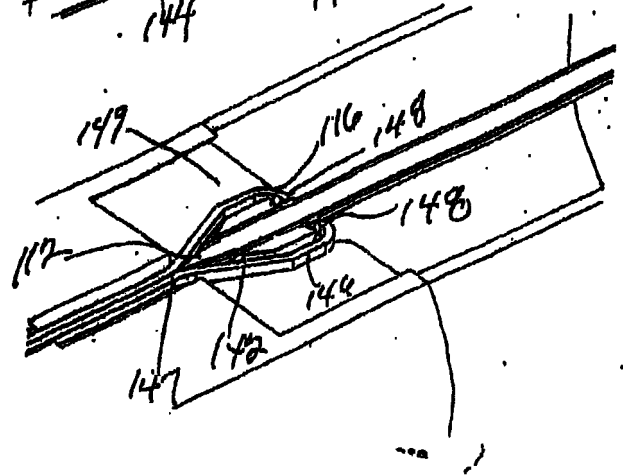


FIG. 14



Tambor Capturado por las Uñas de Bloqueo

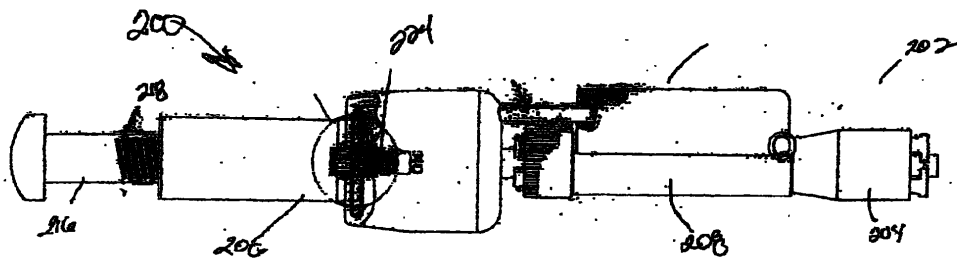


FIG. 16

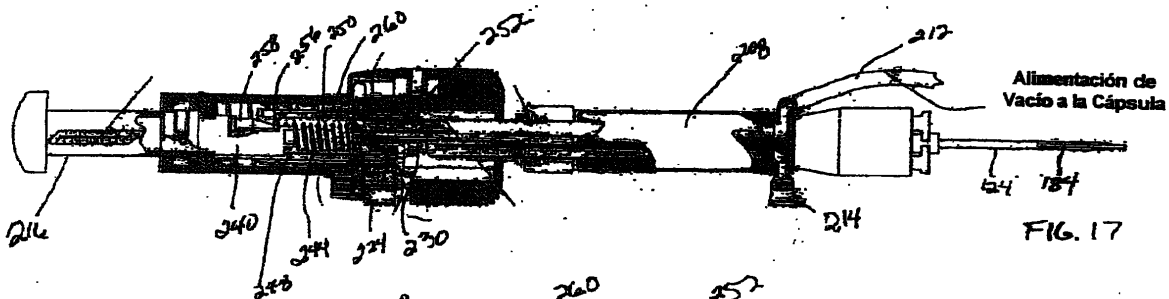


FIG. 17

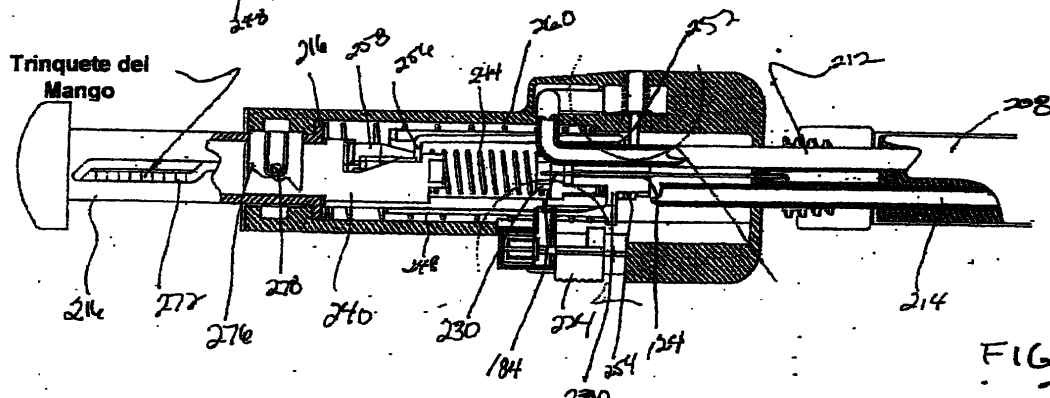
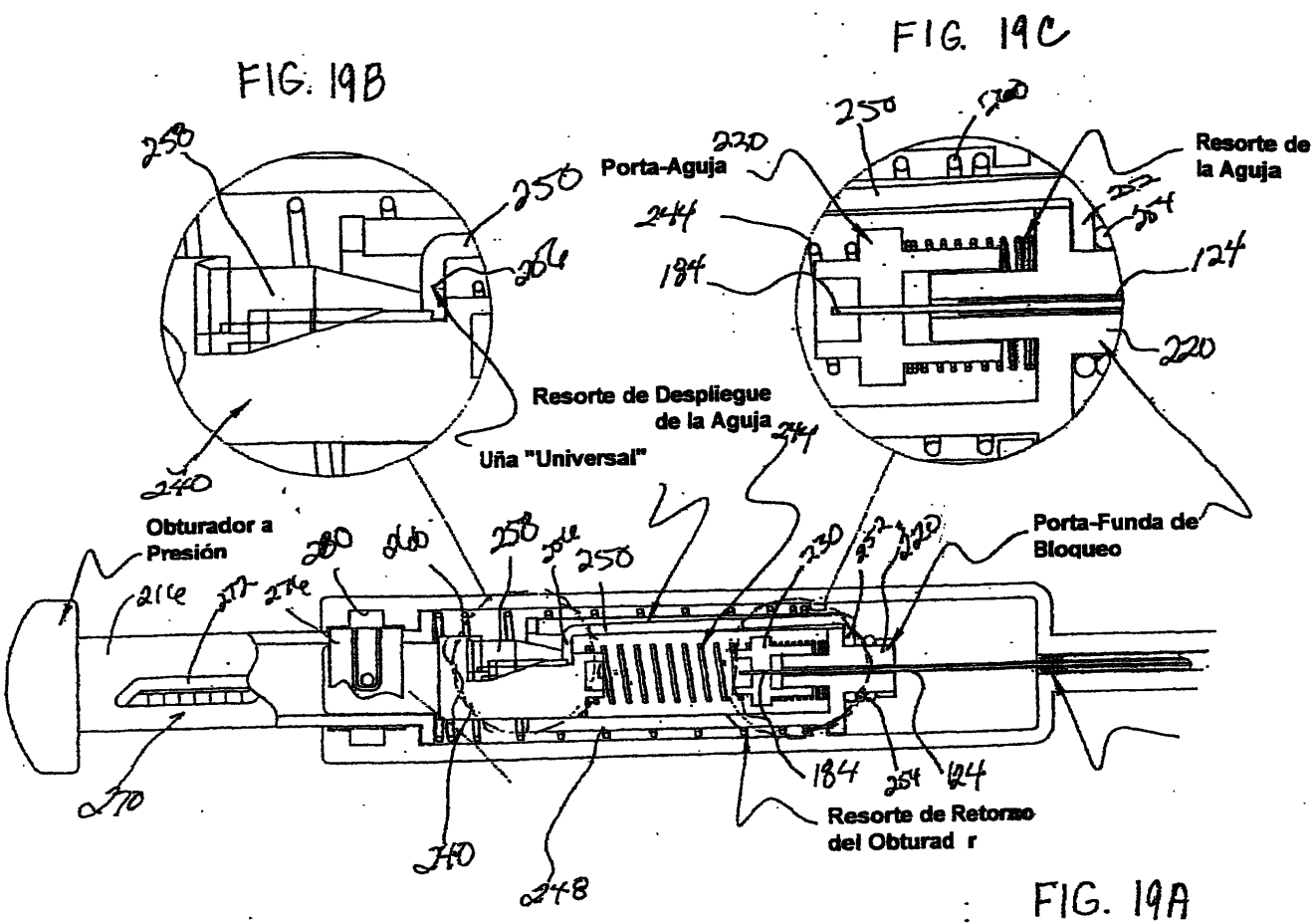


FIG. 18

27



12/36

35

FIG. 21

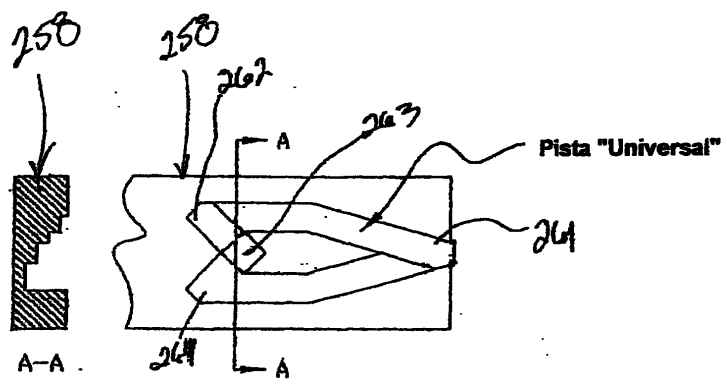


FIG. 20

FIG. 22

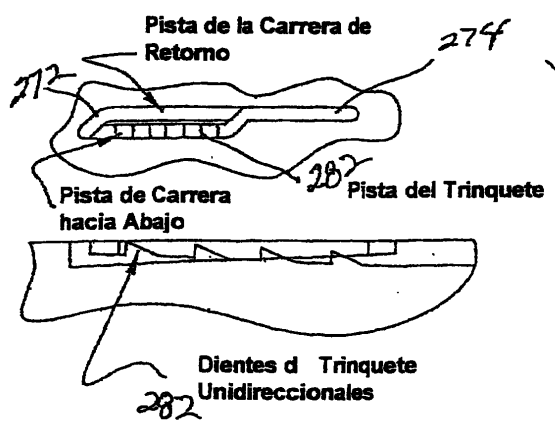
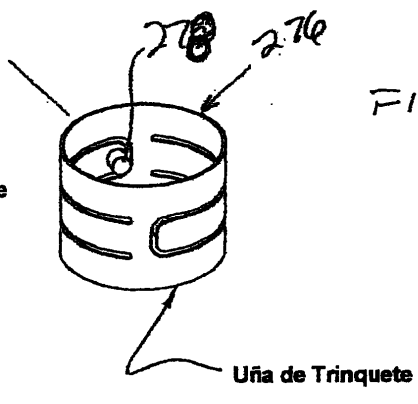


FIG. 23



[Handwritten signature]

FIG. 24

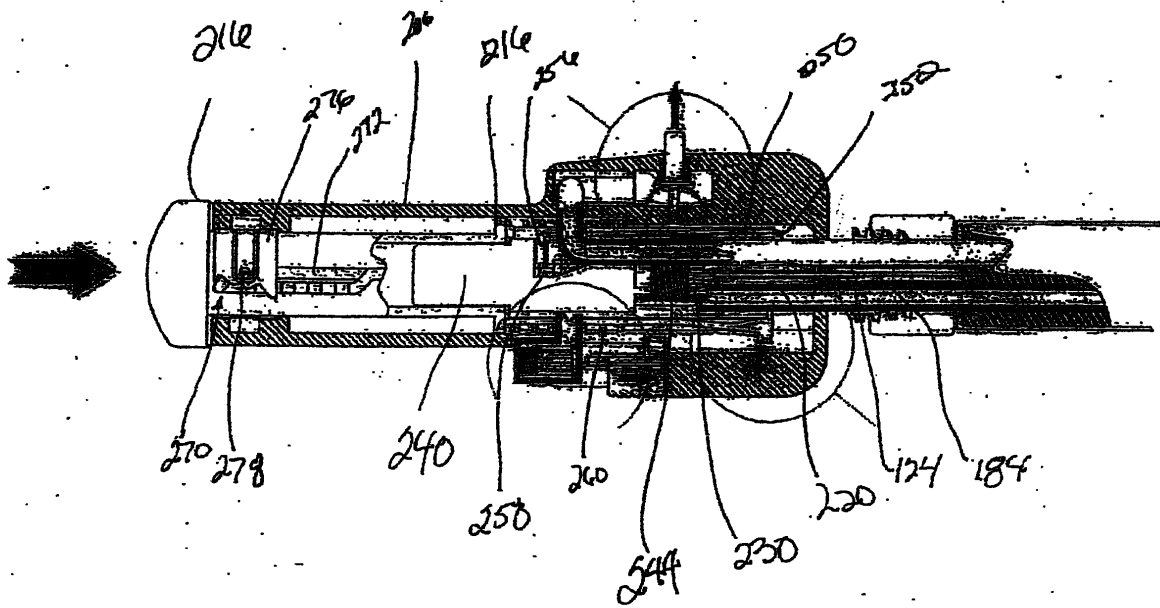
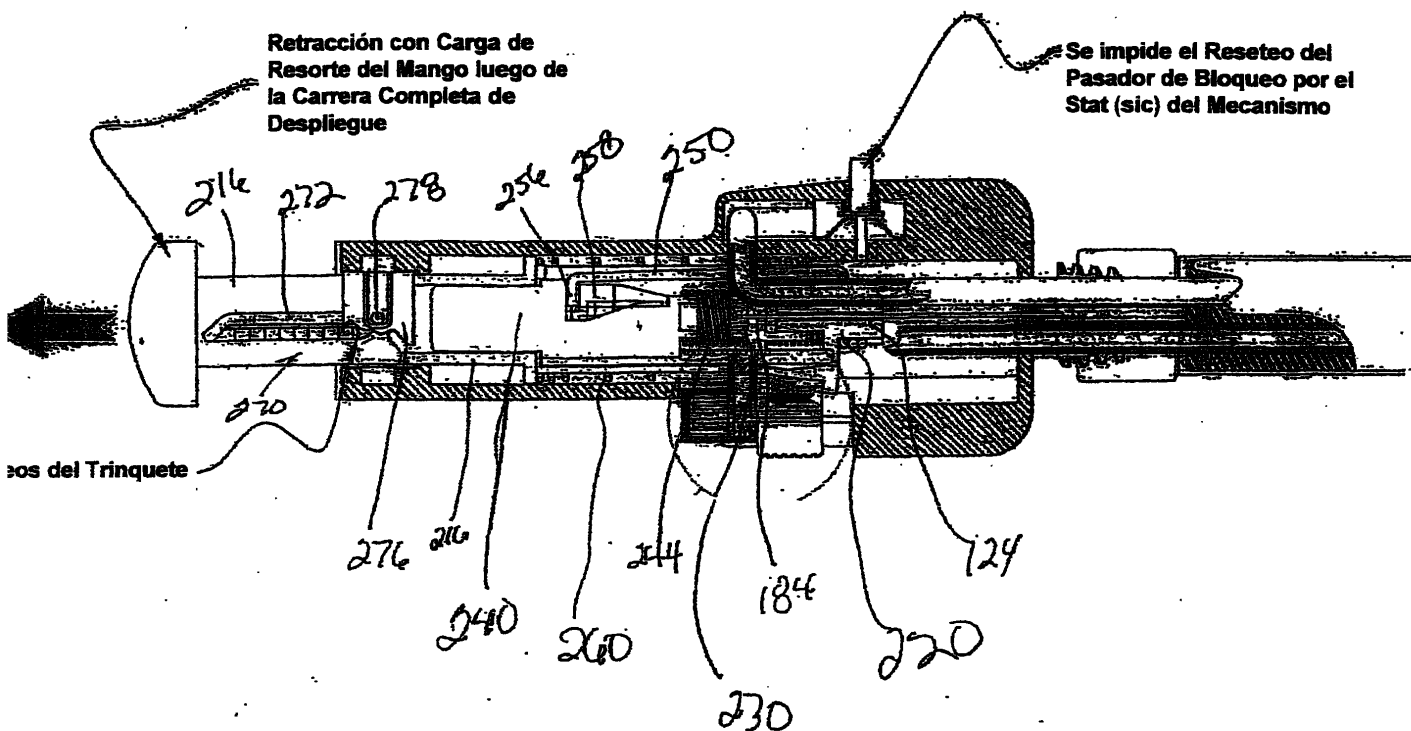
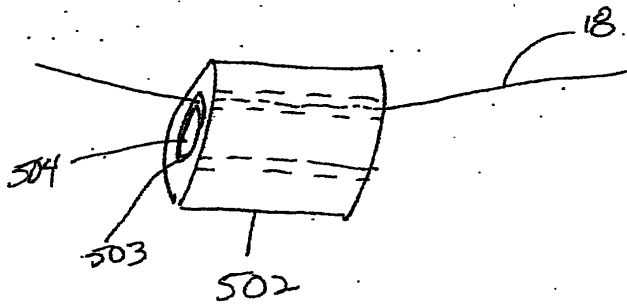
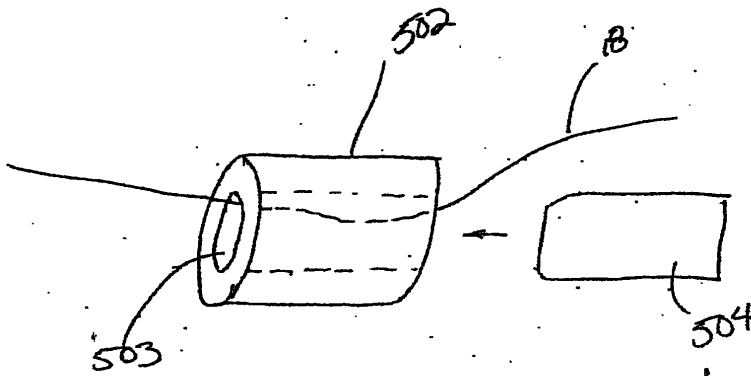


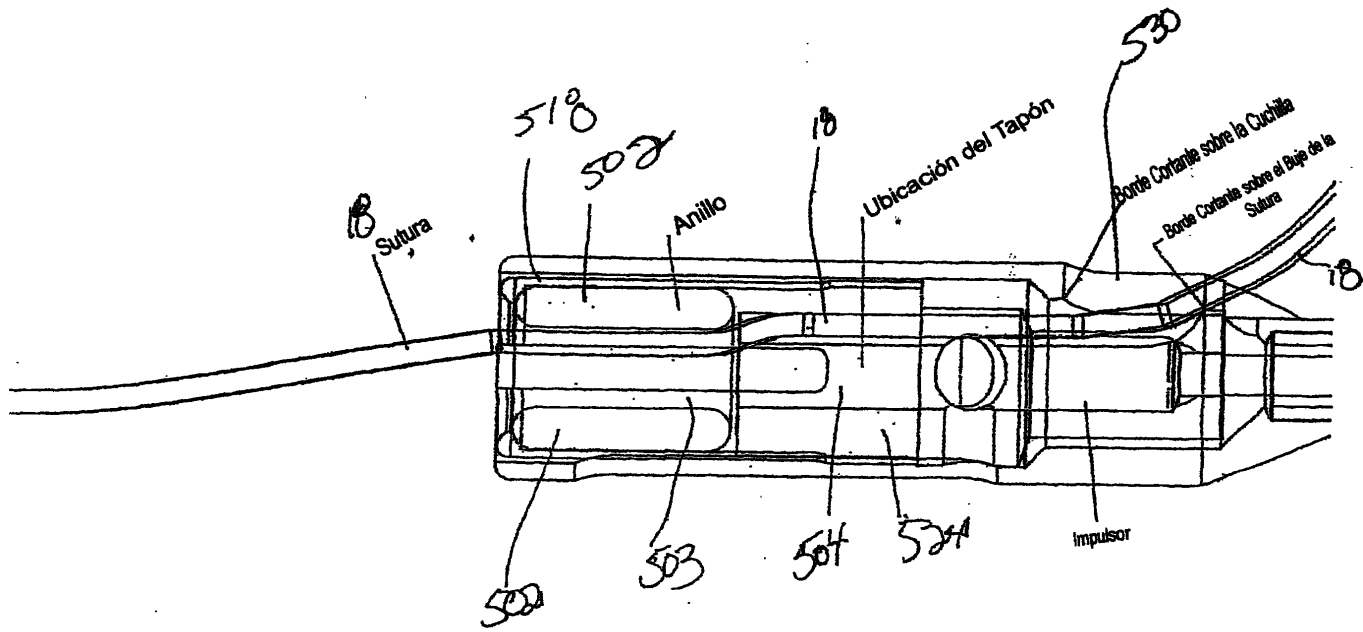
FIG. 25





729

FIG. 28



25

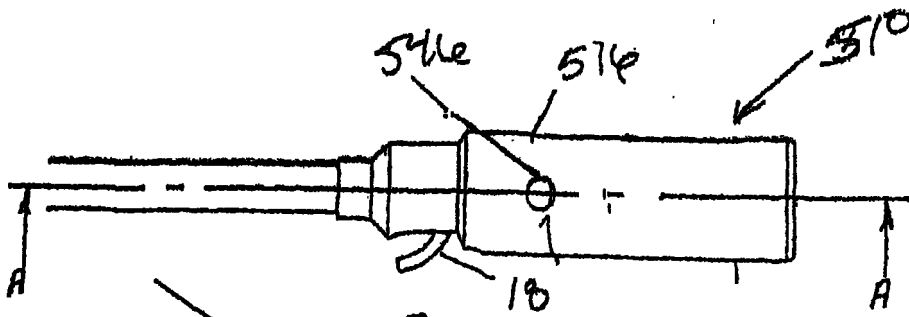


FIG. 29

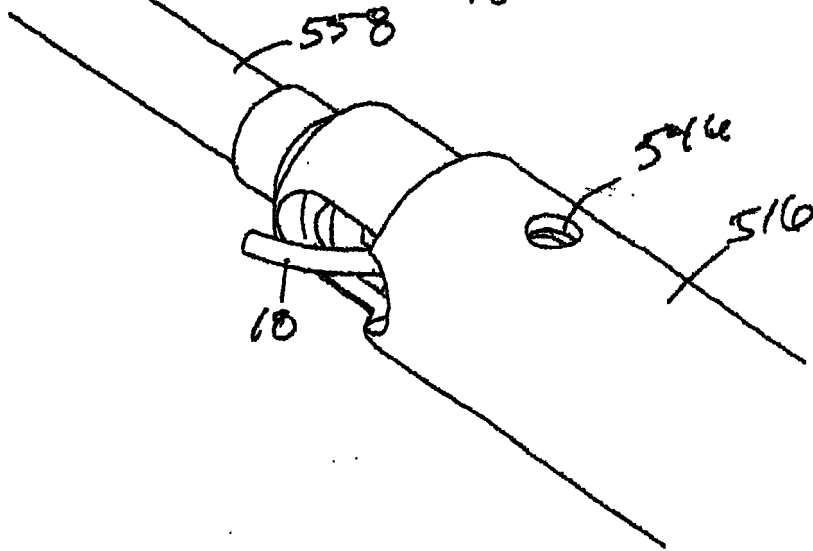


FIG. 30

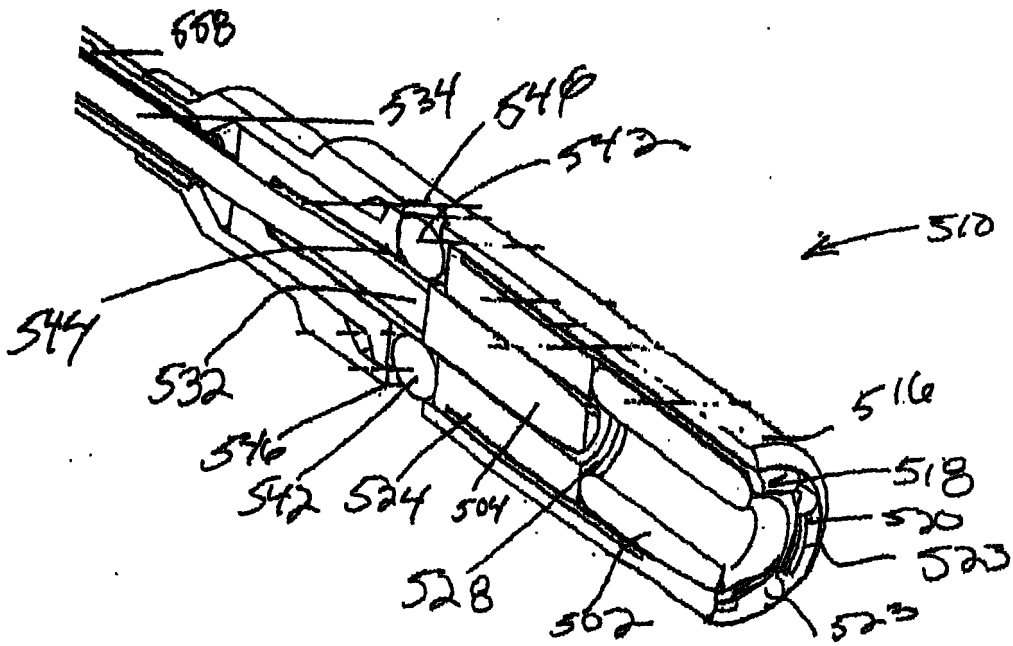


FIG. 31
Sección A-A

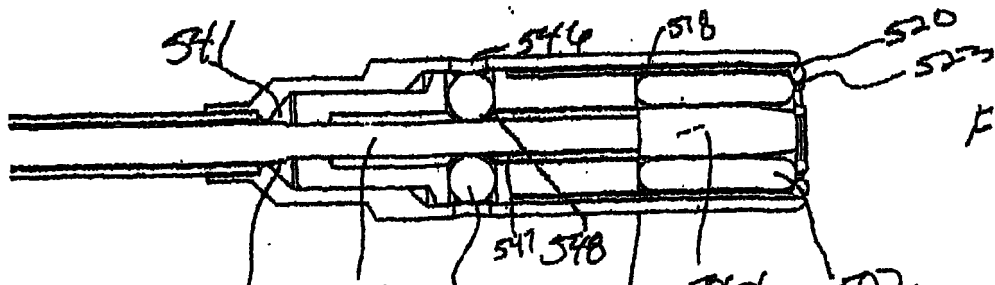


FIG. 32

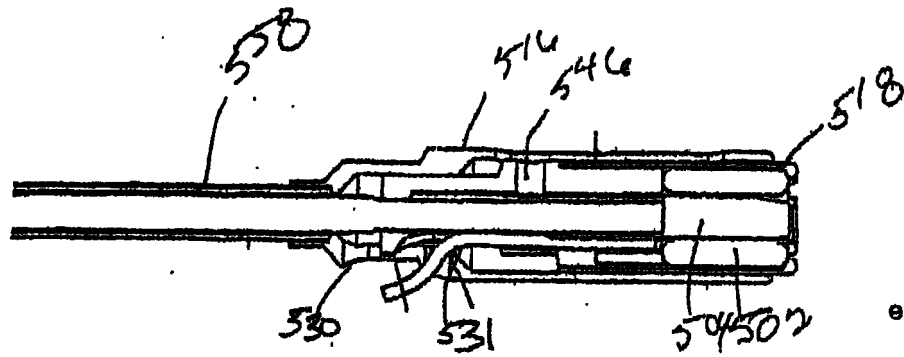


FIG 33
Sección B-B
Tomada de FIG. 29
en el Plano Ortogonal

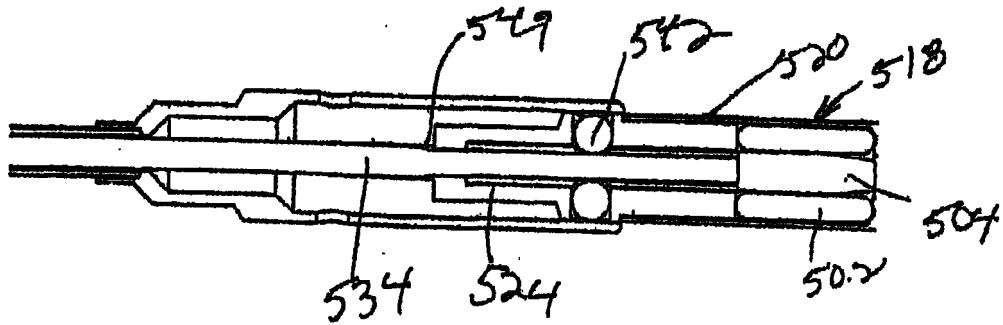


FIG 34

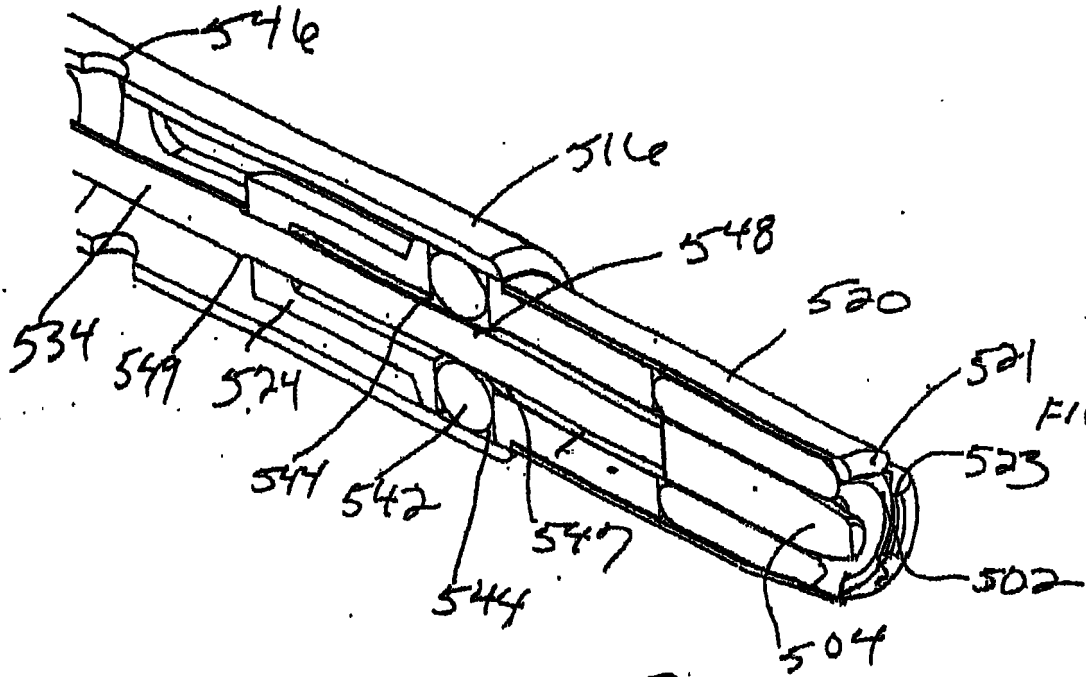


FIG 35

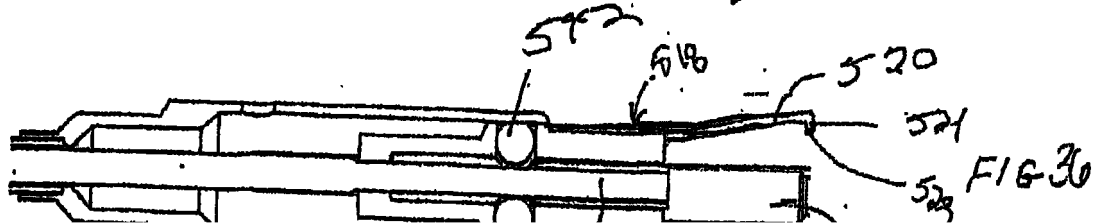
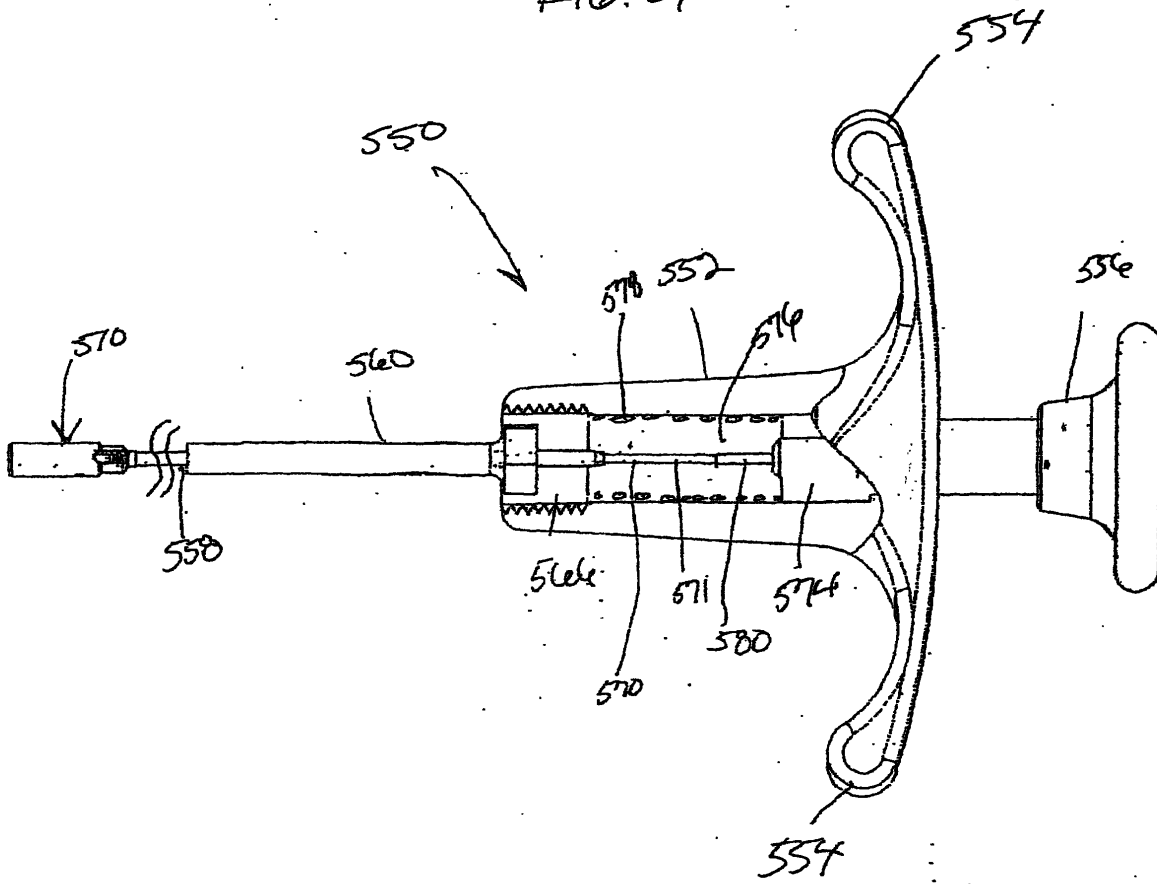


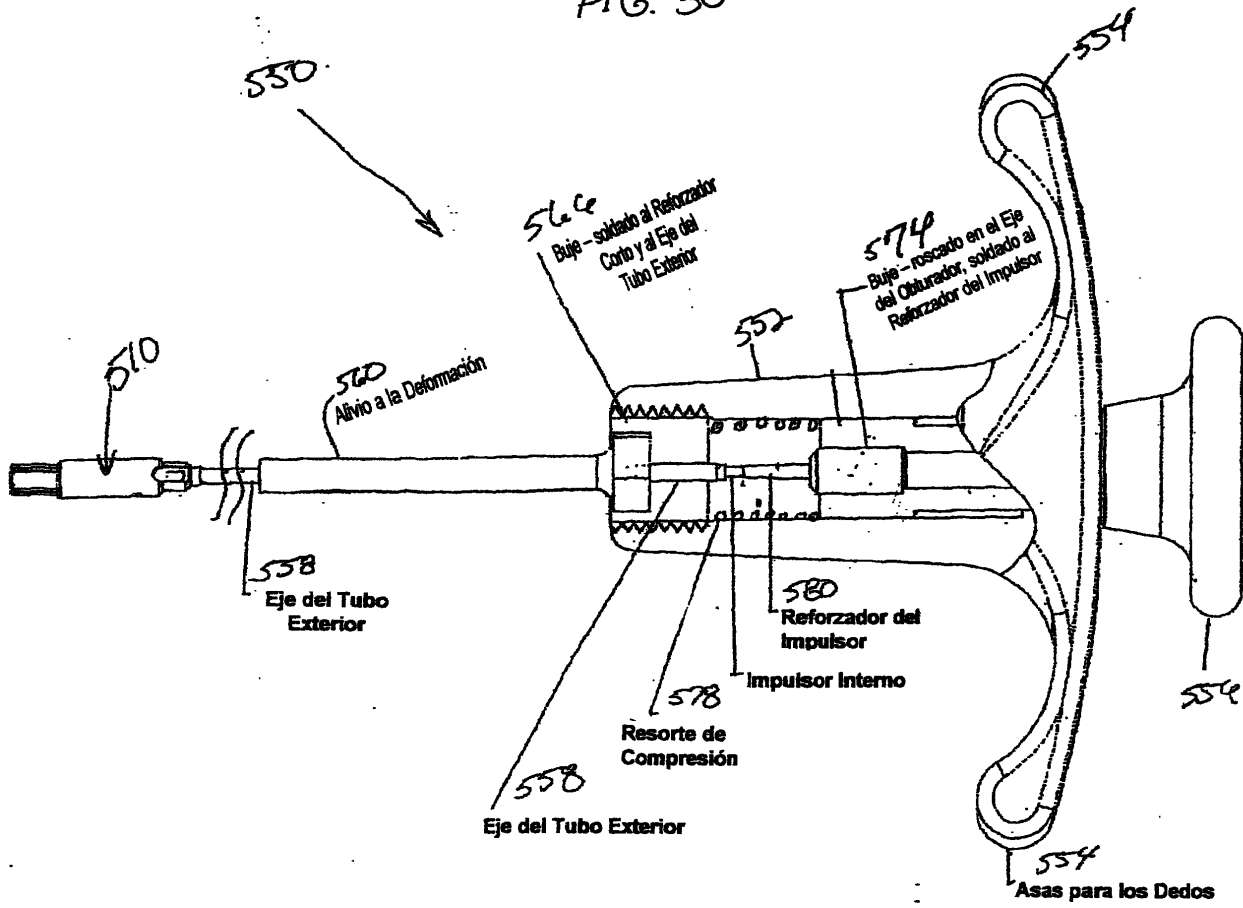
FIG 36

FIG. 37



134

FIG. 38



157

FIG. 39

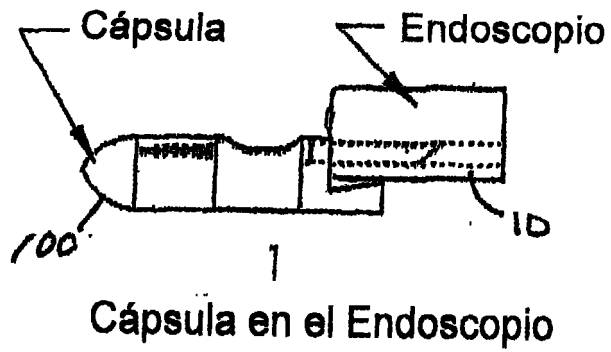


FIG. 40

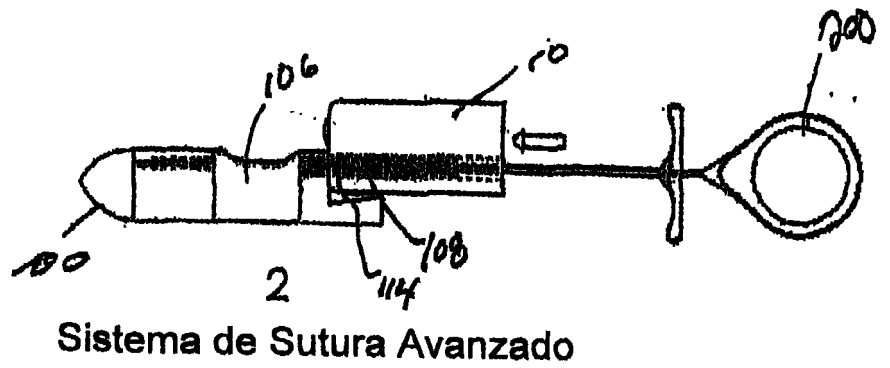


FIG. 41

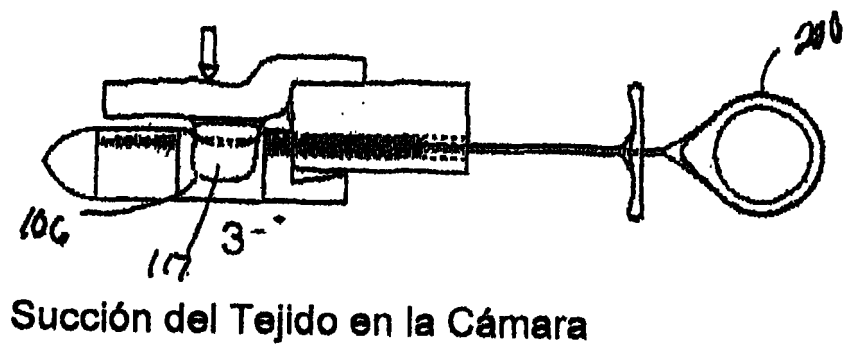
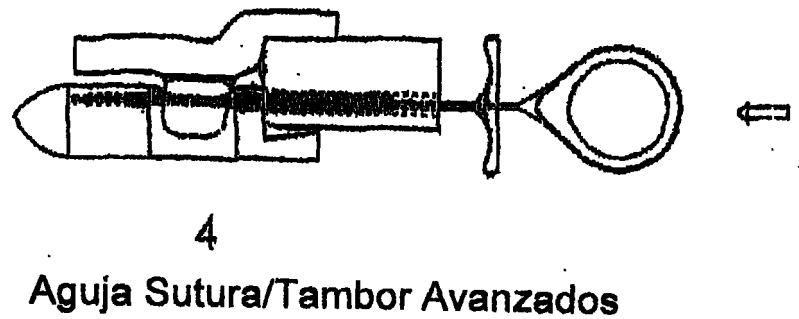
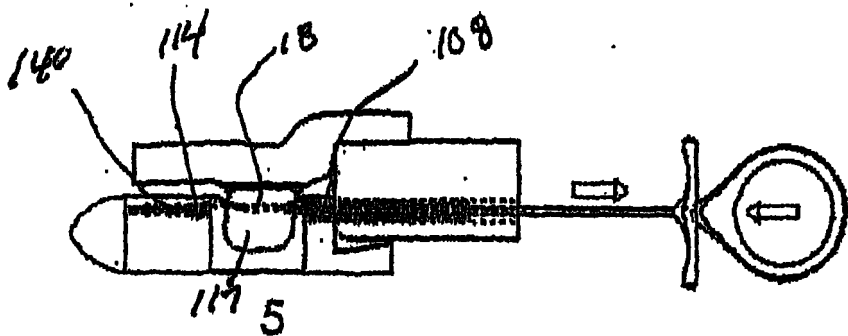


FIG. 42



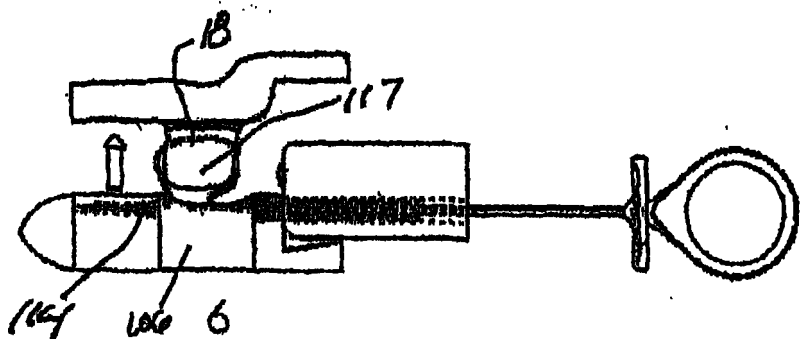
137

FIG. 43



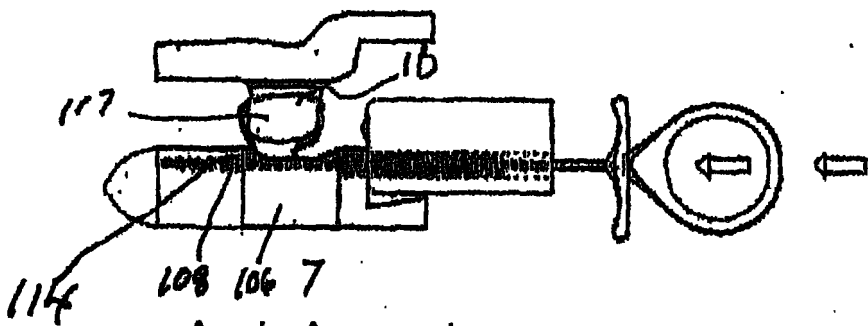
Tambor Liberado / Aguja Retraida

FIG. 44



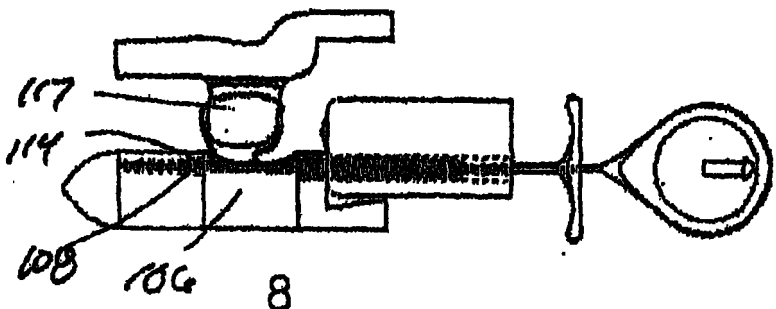
Tejido Liberado

FIG. 45



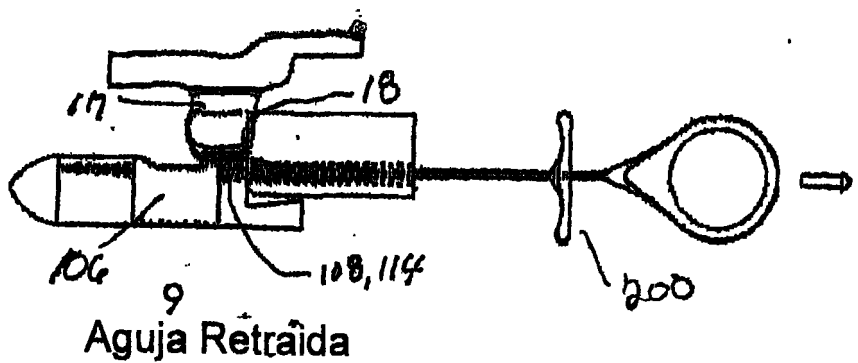
Aguja Avanzada

FIG. 46



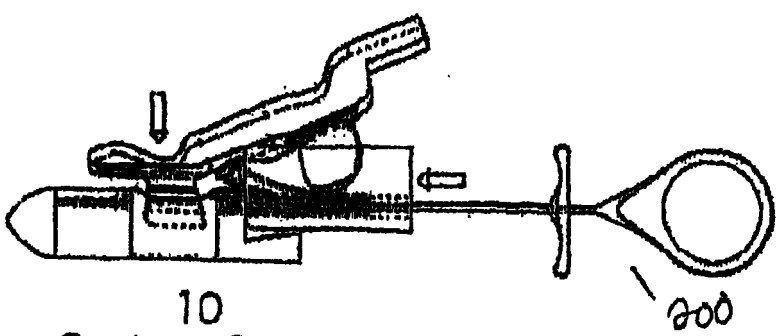
Tambor de Sutura Recuperado

FIG. 47



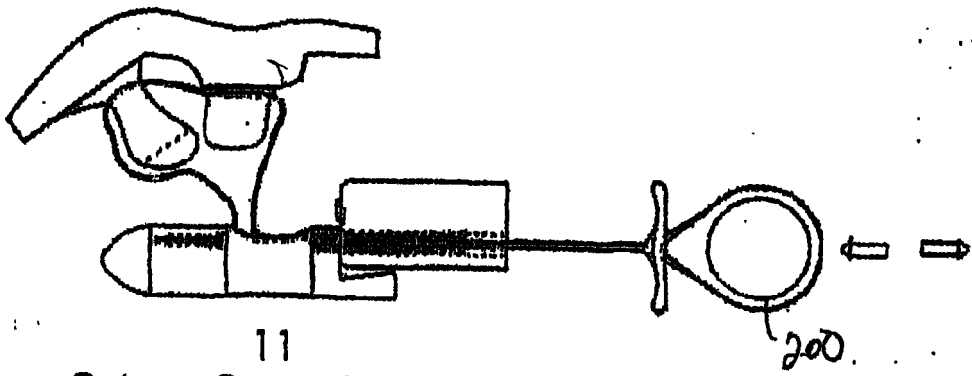
Aguja Retráida

FIG. 48



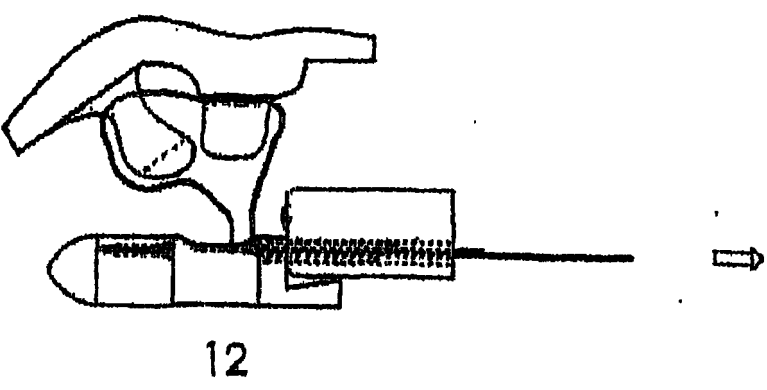
Capturar Segunda Porción de Tejido

FIG. 49



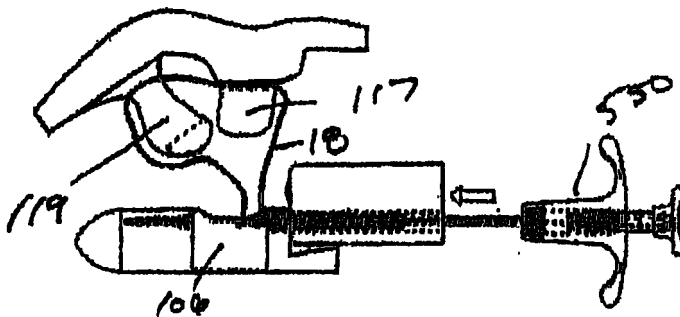
Suturar Segunda Porción de Tejido

FIG. 50



R tirar Sist ma Suturador

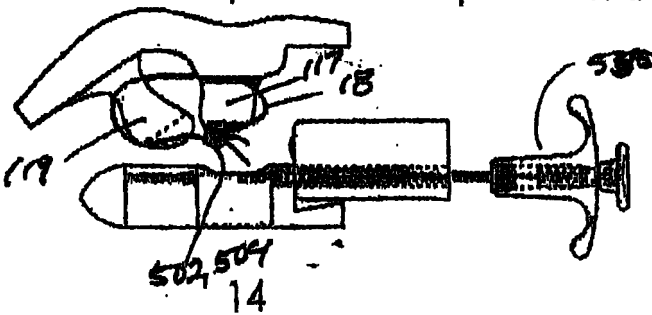
FIG. 51



13

Avanzar Dispositivo de Aplicación del Anclaje

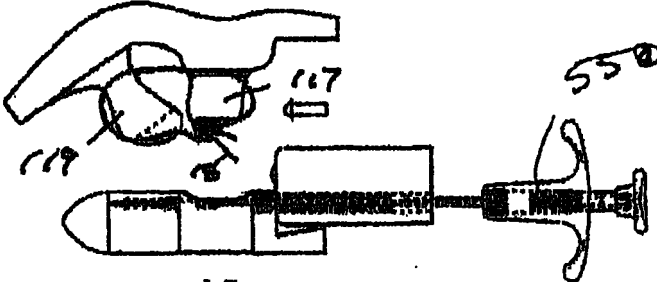
FIG. 52



14

Sujetar, Cortar & Liberar

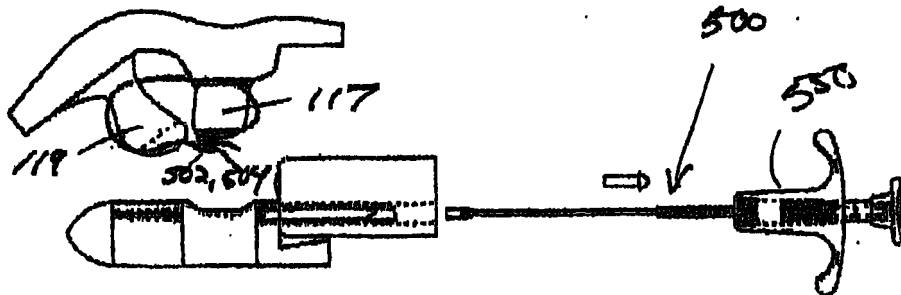
FIG. 53



15

Pliegue Completo

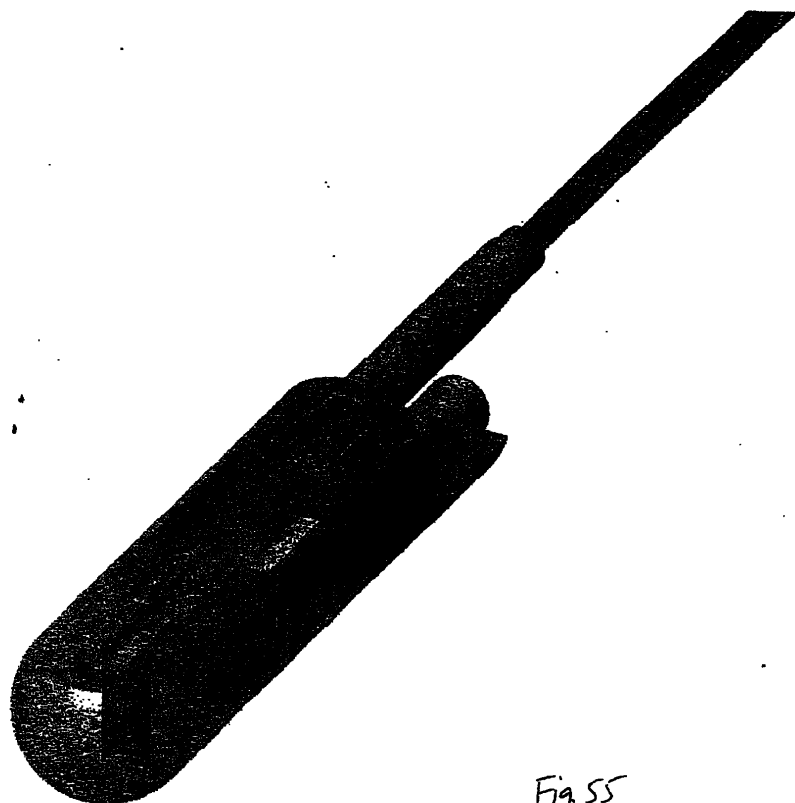
FIG. 54



16

Retirar el Dispositivo de Aplicación del Anclaje

140



27 / 36

Fig. 55

[Handwritten signature]

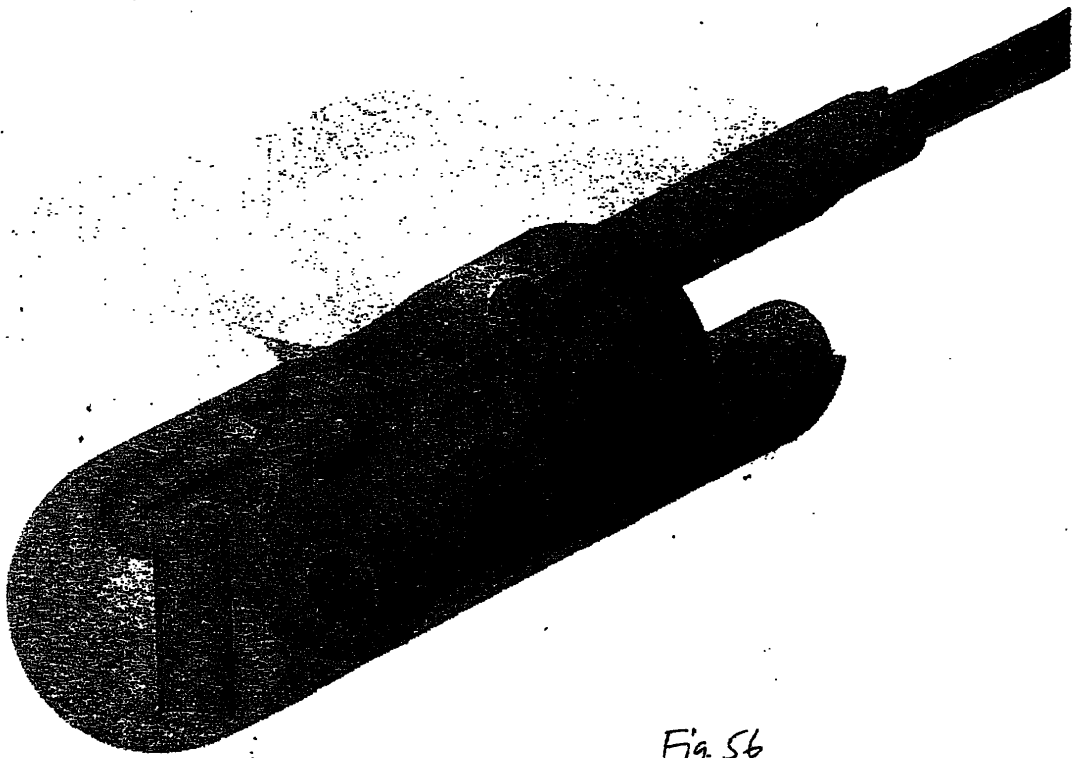
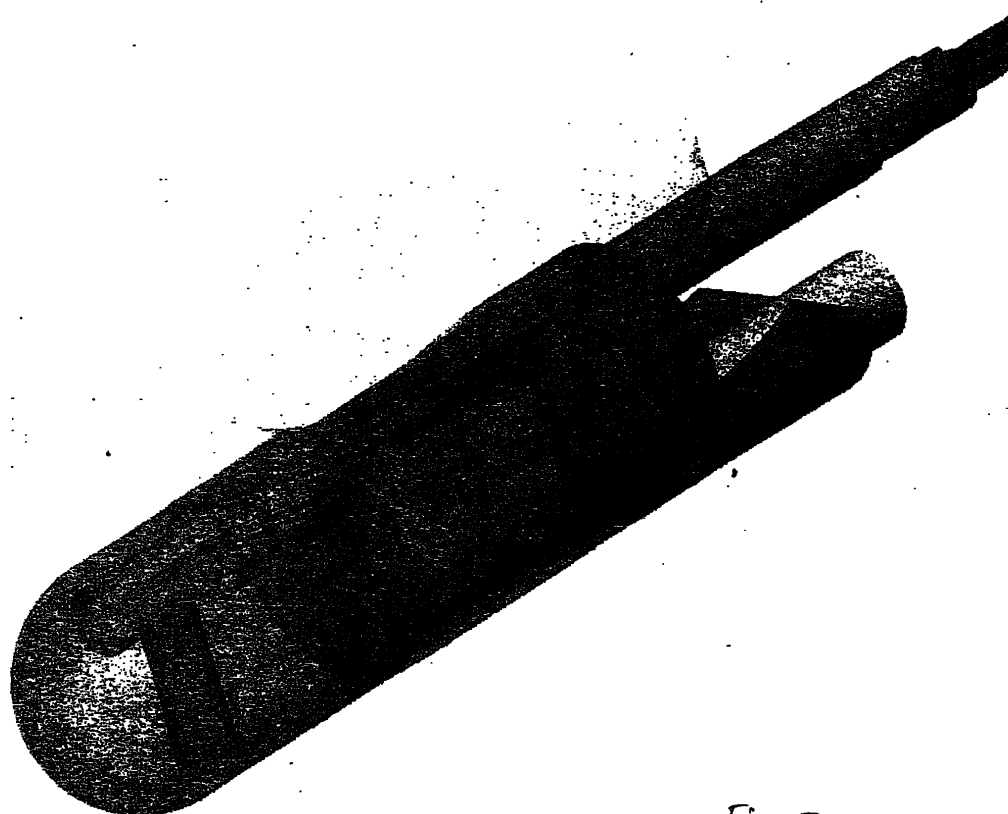


Fig. 56

[Handwritten signature]

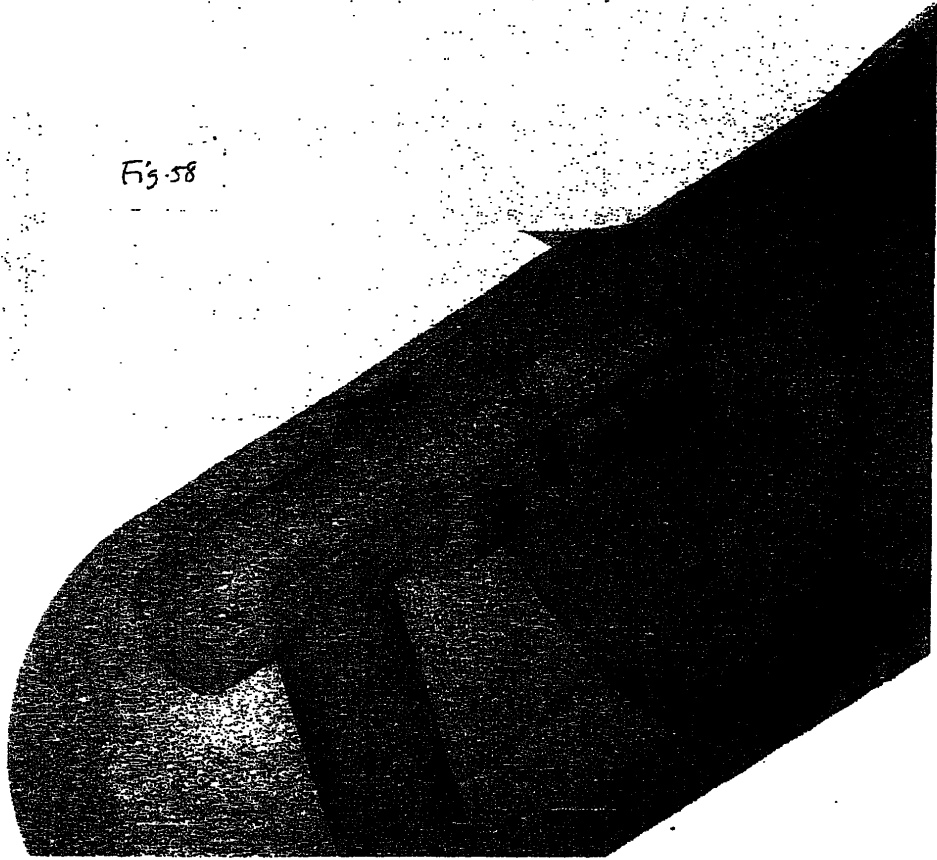


28/36

Fig. 57

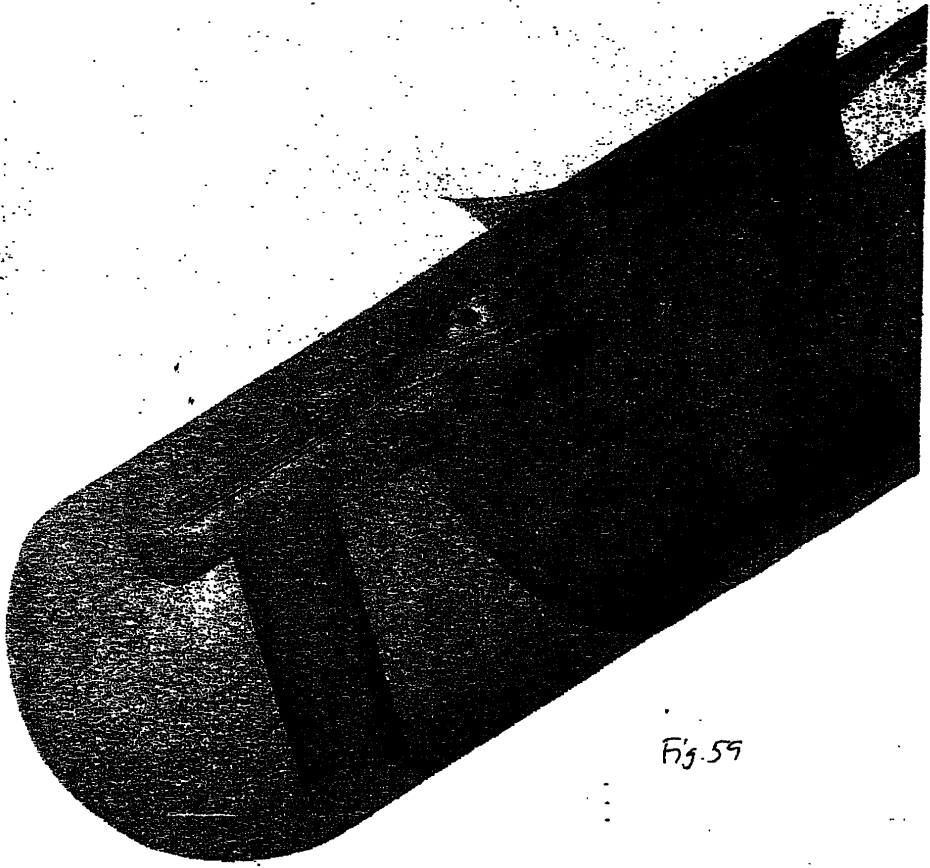
1/2

Fig. 58



30 / 36

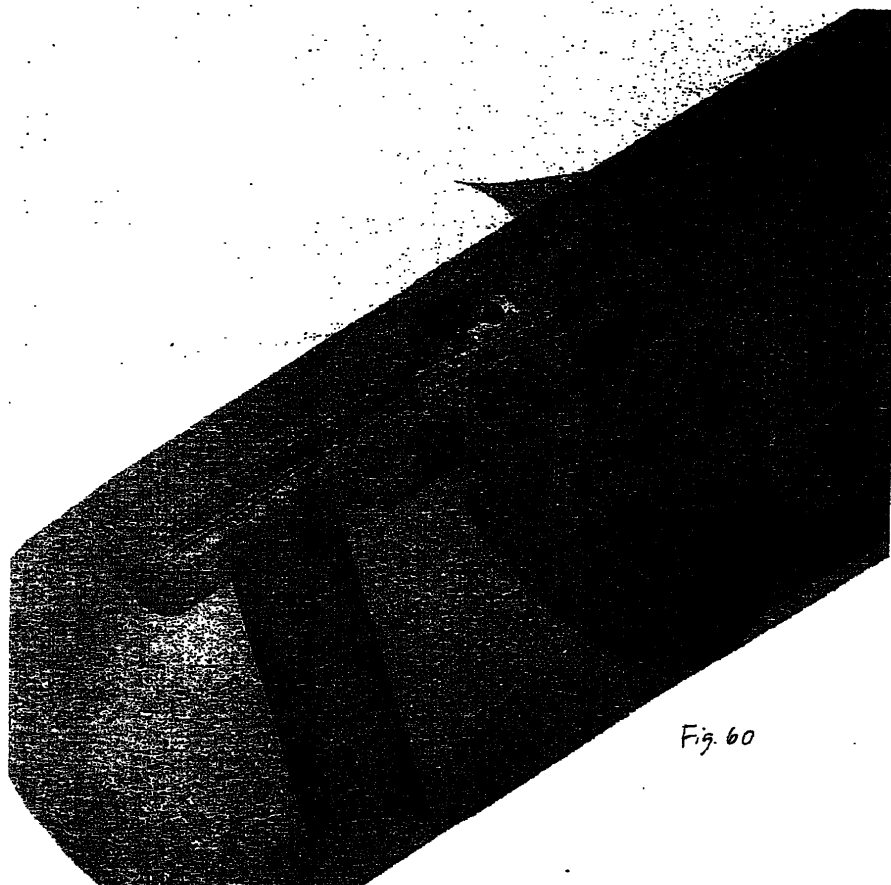
~~143~~



31/35

Fig. 59

~~144~~



32/36

Fig. 60

~~145~~

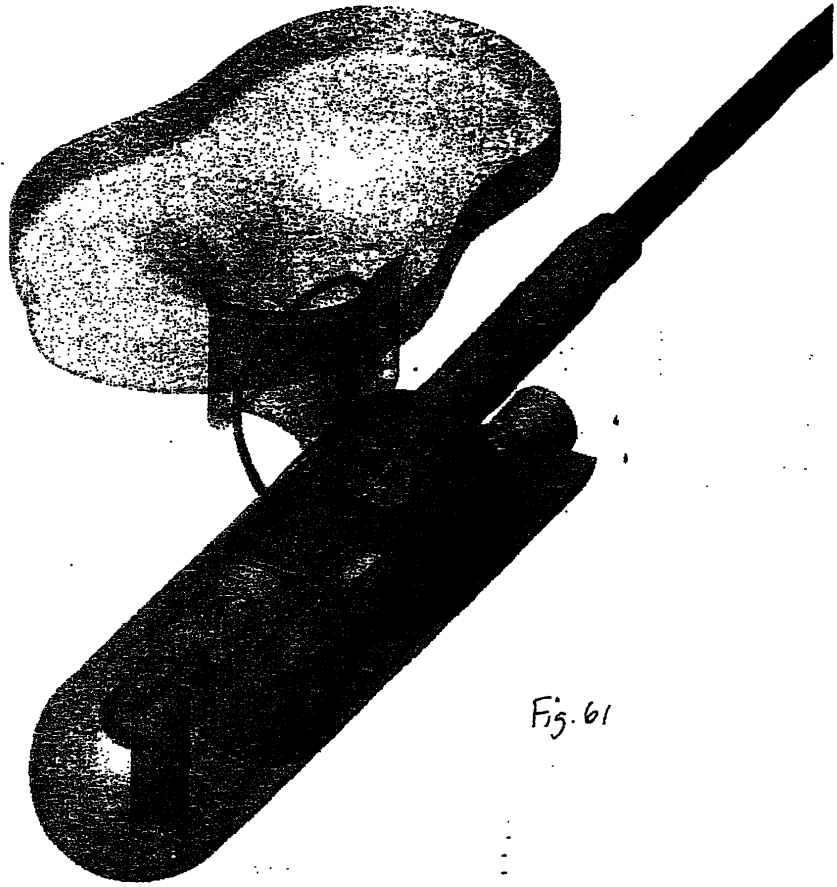
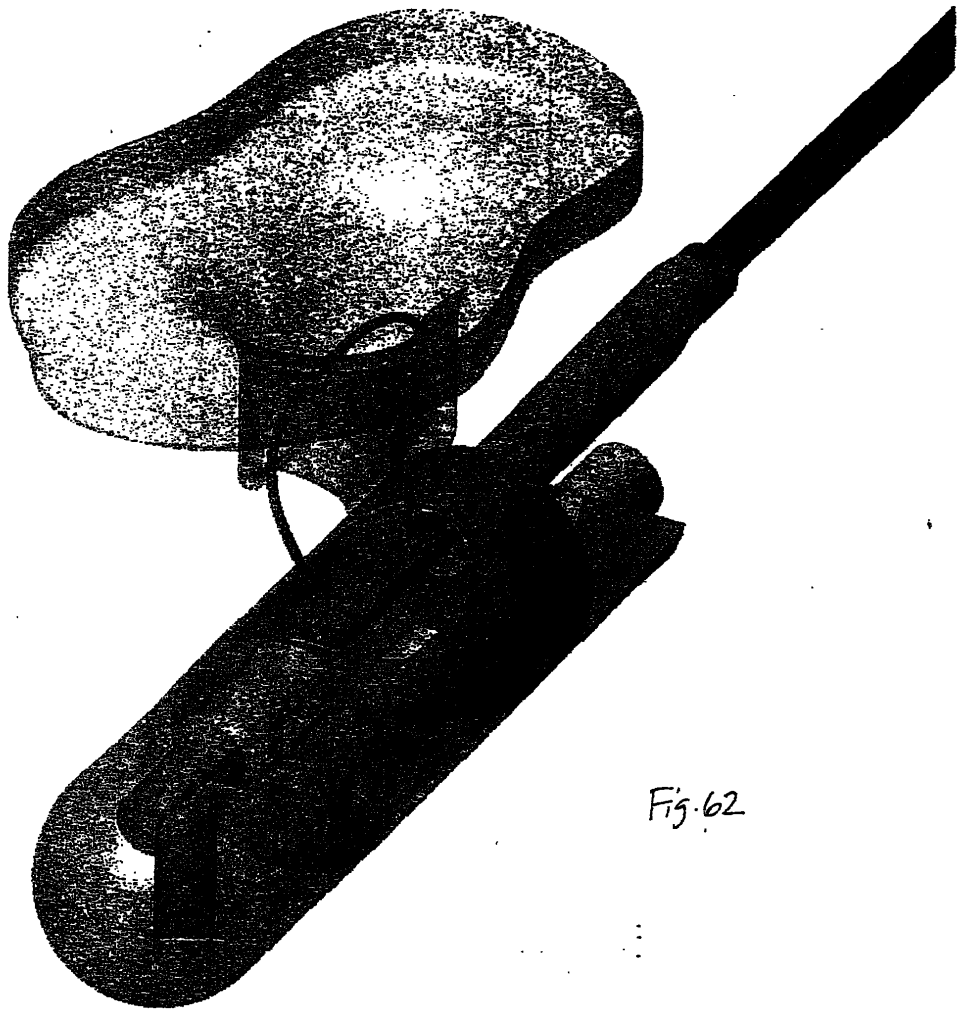


Fig. 61

33/35

~~746~~

747



34/36

Fig. 62

~~747~~

—

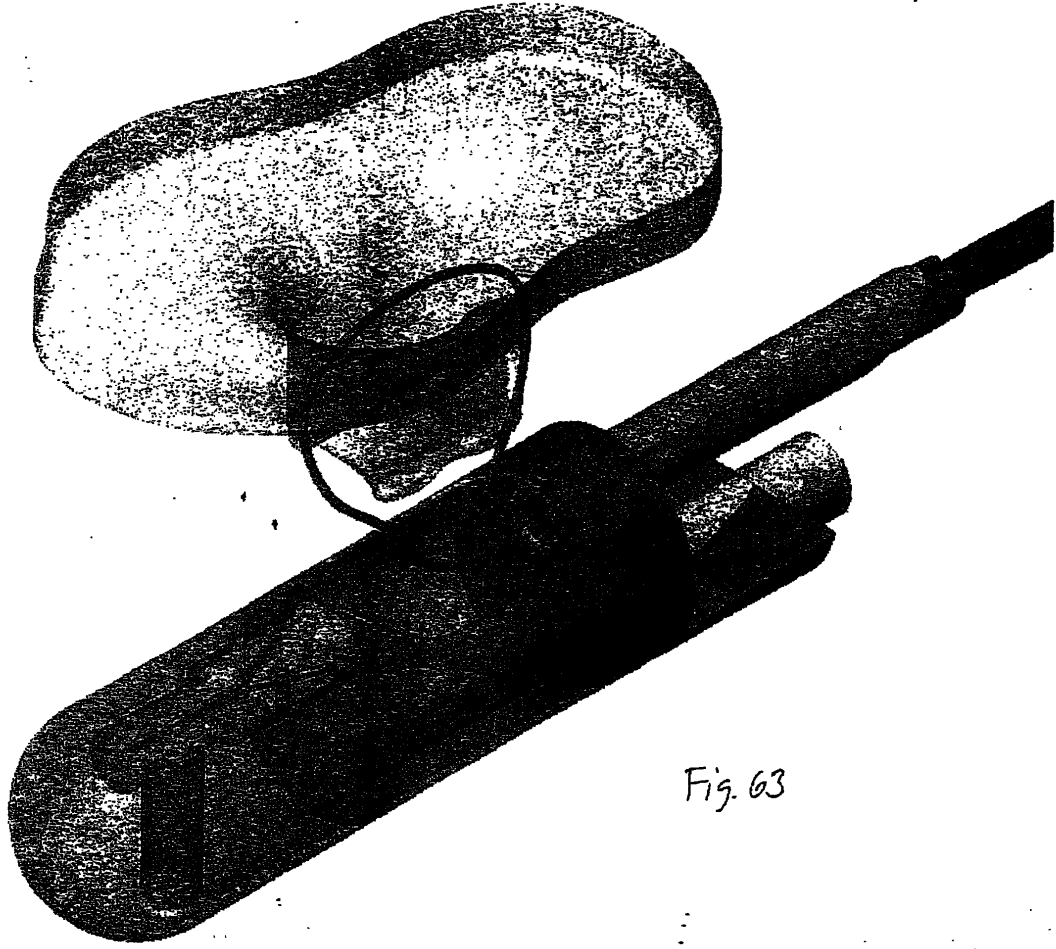


Fig. 63

36 / 36

FF

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/15670

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/10, 17/04, 17/12, 17/06

US CL : 606/139, 144, 145, 148, 222, 223, 224, 225, 227, 228

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. : 606/139, 144, 145, 148, 222, 223, 224, 225, 227, 228

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,792,153 A (SWAIN et al) 11 August 1998 (11.08.1998), see entire document.	1, 2
Y		10-13
Y	US 5,910,105 A (SWAIN et al) 08 June 1999 (08.06.1999), see entire document.	10-13

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

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"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)

"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

"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

"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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

02 August 2004 (02.08.2004)

Date of mailing of the international search report

21 OCT 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Anh Tuan Nguyen

Telephone No. (703) 308-0858

PATENT COOPERATION TREATY

150

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
JOYCE C. HERSH
KIRKPATRICK & LOCKHART LLP
75 STATE STREET
BOSTON, MA 02109-1808

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 21 OCT 2004	
Applicant's or agent's file reference B0751/7037WO	
FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US04/15670	International filing date (day/month/year) 17 May 2004 (17.05.2004)
Priority date (day/month/year) 16 May 2003 (16.05.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 17/10, 17/04, 17/12, 17/06 and US Cl.: 606/139, 144, 145, 148, 222, 223, 224, 225, 227, 228	
Applicant	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Anh Tuan Nguyen Telephone No. (703) 308-0858
--	---

Form PCT/ISA/237 (cover sheet) (January 2004)

DC
Action Code: Written Opinion
Base Date: 10/21/04
Due Date: 1/21/05
Deadline: 1/21/05
Info:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/15670

151
X

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/15670

26/52
Y

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 3-15	YES
	Claims 1, 2	NO
Inventive step (IS)	Claims 3-9, 14, 15	YES
	Claims 1, 2, 10-13	NO
Industrial applicability (IA)	Claims 1-15	YES
	Claims	NO

2. Citations and explanations:

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by SWAIN et al. '153.

Swain et al. teaches an endoscopic tissue suturing device comprising: a suturing capsule 2 having a tissue suction chamber 7, needle track 3 and a suture tag catch 65, a needle 8, suture tag lock 63, and a suture tag 42; wherein the suture tag lock changes its position relative to the exterior surface of the needle.

Claims 10-13 lack an inventive step under PCT Article 33(3) as being obvious over SWAIN et al. '153 in view of SWAIN et al. '105.

Swain et al teaches an endoscopic tissue suturing device as defined in claim 1. It should be noted that Swain et al. fails to teach a control handle having at least one longitudinally control member joined to a shaft. However, Swain et al. ('105) teaches a control handle for use with a medical endoscope for advancing instrumentalities through the instrument channel of the endoscope. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the control member of Swain et al. ('105) to control the sequential functioning of a sewing device mounted to the distal end of an endoscope (col. 2, line 39-42).

Claims 3-9, 14 and 15 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an exterior surface of a needle is shaped to engage the suture tag lock when a lock is moved longitudinally relative to the needle to form a lock surface; a suture tag catch comprising two resilient arms bound together at one end of their ends in a Y-configuration each with a prong-shaped free end having an inwardly projecting edge configured to engage a surface of the suture tag; and a suture tag that is annular and slides over an exterior surface of a needle.

Claims 1-15 meet the criteria set out in PCT Article 33(4), and thus meets industrial applicability because the subject matter claimed can be made or used in industry.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/15670

153
57

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Atty. Docket No.: B0751/7037WO

154
PATENT

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY (IPEA)

International Application No.: PCT/US04/15670
International Filing Date: 17 May 2004
Applicant: C.R. Bard, Inc.
Receiving Office: RO/US
Priority Date Claimed: 16 May 2003
Attorney's Docket No.: B0751/7037WO

REPLY TO WRITTEN OPINION

VIA U.S. POSTAL SERVICE EXPRESS MAIL INTERNATIONAL

Express Mail No. EV340040553US

Date of Deposit: November 30, 2004

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This IS A Reply to the Written Opinion mailed from the International Preliminary Examining Authority on 21 October 2004 for the subject application. For convenience, the remainder of the response is set forth in the order in which each issue was raised in the Written Opinion, and is divided into sections, each with an appropriate heading.

RE Item V - Reasoned Statement With Regard to Novelty, Inventive Step or Industrial Applicability

Negative Statement In Regard to Novelty

The Examiner has asserted that claims 1 and 2 do not satisfy the criteria set forth in Article 33(2) PCT in vie of Swain *et al.* (U.S. Pat. No. 5,792,153; "Swain '153"). The Examiner states that Swain '153 teaches an endoscopic tissue suturing device comprising a suturing capsule 2 having a tissue suction chamber 7, needle track 3 and suture tag catch 65, a

needle 8 suture tag lock 63 and a suture tag 42, and that the suture tag lock changes its position relative to the exterior surface of the needle.

Applicants respectfully disagree with the Examiner's interpretation of Swain '153. Swain '153 shows the hollow needle 38 in cross-sectional view, and having a beveled leading edge and a passage 39 within the needle. Thread carrier 42 is situated inside the needle 38. The needle 38 and thread carrier 42 are pushed forward through the tissue by the wire 41. The forward end of wire 41 has a pin 60, which has a barb 61, which fits into aperture 62 on the thread carrier 42. As the wire 41 pushes forward, the barb become disengaged from aperture 62, and once the needle has passed through the tissue, catch member 65 engages recess 63 on the thread carrier 42. Rotation of the wire and pin place the barb in a position where it can no longer engage the aperture. The wire 41, pin 60 and needle 38 are then drawn backwards through the tissue, leaving the thread carrier 42 engaged on the catch member 65.

The thread carrier 42 and its recess 63, and the wire 41 and pin 60 and barb 61 are all within the hollow needle 38. Claim 1, in contrast, clearly states that the suture tag lock is on an exterior surface of the needle, and that the suture tag is capturable on the exterior surface of the needle. This is not taught or suggested by Swain '153.

Claim 1, and dependent claims 2-13 are therefore novel in view of the cited reference.

Negative Statement In Regard to Inventive Step

The Examiner has asserted that claims 10-13 do not satisfy the criteria set forth in Article 33(3) PCT because the subject matter lacks an inventive step over Swain '153 and Swain *et al.* (U.S. Pat. No. 5,910,105; "Swain '105"). The Examiner states that Swain '153 fails to teach a control handle having at least one longitudinal control member joined to a shaft, but that Swain '105 teaches a control handle for use with a medical endoscope for advancing instrumentalities through the instrument channel of the endoscope, and that it would have been obvious to use the control member of Swain '105 to control the sequential functioning of a sewing device mounted to the distal end of an endoscope, as discussed on col. 2, lines 39-42.

As stated above, Swain '153 does not teach or suggest that the suture tag lock is on an exterior surface of the needle, and that the suture tag is capturable on the exterior surface of the needle, as is disclosed in claim 1. Instead, the thread carrier 42, wire 41 and pin 60 are

Attorney Docket No.: B 1/7037WO
Int'l Filing Date: 17 May 2004
Reply to Written Opinion

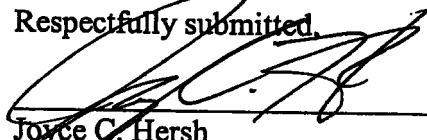
20/156
In. App. No. PCT/US04/15670
Applicant: C.R. Bard, Inc.
Page 3

located within hollow needle 38. Swain '105 likewise fails to disclose that either the suture tag lock or the suture tag are exterior to the needle.

Applicant therefore maintains that the claims are inventive over the cited references.

In view of the above remarks, favorable consideration of the application is respectfully requested.

Respectfully submitted,


Joyce C. Hersh
Reg. No. 42,890
Attorney for Applicant
KIRKPATRICK & LOCKHART LLP
75 State Street
Boston, MA 02109-1808
Tel: 617-261-3100
Fax: 617-261-3175

Date: November 30, 2004

PATENT COOPERATION TREATY

17/157

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

HERSH, Joyce, C.
Kirkpatrick & Lockhart LLP
75 State Street
Boston, MA 02109-1808
United States of America

Date of mailing (day/month/year) 28 July 2004 (28.07.2004)	
Applicant's or agent's file reference B0751/7037WO	IMPORTANT NOTIFICATION
International application No. PCT/US2004/015670	International filing date (day/month/year) 17 May 2004 (17.05.2004)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 16 May 2003 (16.05.2003)
Applicant C.R. BARD, INC.	

- By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- (If applicable) The letters "NR" appearing in the right-hand column denote a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- (If applicable) An asterisk(*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b) (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

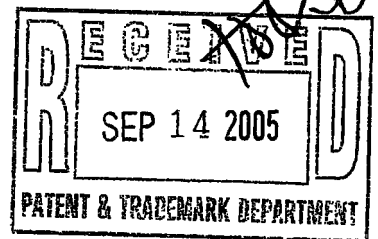
<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
16 May 2003 (16.05.2003)	60/471,248	US	09 July 2004 (09.07.2004)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 338.89.75	Authorized officer Rosana REYES (Fax : 338 89 75) Telephone No. (41-22) 338 8471
--	--

PATENT COOPERATION TREATY

From the RECEIVING OFFICE

PCT



COMMUNICATION IN CASES FOR WHICH
NO OTHER FORM IS APPLICABLE

To:

JOYCE C. HERSH
KIRKPATRICK & LOCKHART LLP
75 STATE STREET
BOSTON, MASSACHUSETTS 02109-1808

Date of mailing
(day/month/year) **01 SEP 2005**

Applicant's or agent's file reference B0751/7037WO	REPLY DUE See paragraph 1 below
International application No. PCT/LIS2004/015670	International filing date (day/month/year) 17 May 2004
Applicant C.R. BARD, INC.	

1. ☐ REPLY DUE within _____ months/days from the above date of mailing
- ☐ NO REPLY DUE, however, see below _____
- ☒ IMPORTANT COMMUNICATION
- ☐ INFORMATION ONLY

2. COMMUNICATION:

Regarding the above mentioned application, please send corrected title for this application. Title on Request does not correspond with title on Demand.

Thank you.

*Resp. to Comm in Case for which No
Other Form is Applicable*

DOCKETED

Correct title

Base Date: 01 Sep 2005

Due Date: 01 Oct 2005

Statutory Period: 01 Oct 2005

Administrator: 89

Date: 15 Sep 2005

Reviewed & Approved:

Resp. Atty: _____ Date: _____

Name and mailing address of the receiving Office Mail Stop PCT, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 703-305-3230	Authorized officer Dian Gordon Telephone No. 703-308-9290 EX 125
---	---

Form PCT/RO/132 (July 1992; reprint January 2004)

PCT

NOTIFICATION OF DEFECTS IN
THE INTERNATIONAL APPLICATION

(PCT Articles 3(4)(i) and 14(1) and Rule 28.1)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office,
PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as receiving Office

Date of mailing

(day/month/year) 28 July 2004 (28.07.2004)

International application No.

PCT/US2004/015670

International filing date

(day/month/year) 17 May 2004 (17.05.2004)

Applicant

C.R. BARD, INC.

- 1.
- ☒
- The International Bureau hereby calls the attention of the receiving Office to the defects in the international application as filed, which are specified on the attached

☒ Annex A☐ Annex B1 (text matter of the international application as filed)☐ Annex C1 (drawings of the international application as filed)

- 2.
- ☐
- The International Bureau hereby calls the attention of the receiving Office to the defects in the translation of the international application furnished under Rule 12.3, which are specified on the attached

☐ Annex A☐ Annex B2 (text matter of the translation of the international application)☐ Annex C2 (drawings of the translation of the international application)

Additional observations (if necessary):

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 338.89.75

Authorized officer

Rosana REYES (Fax : 338 89 75)

Telephone No. (41-22) 338.84.71

The International Bureau has found the following defects in the international application as filed:

1. As to signature* of the international application (Rules 4.15, 26.2bis(a) and 90.4), the request:
 - a. ☐ is not signed* by the applicant or, if there is more than one applicant, by at least one of them
 - b. ☐ is not accompanied by the statement referred to in the check list in Box No. IX of the request explaining the lack of the signature of an applicant for the designation of the United States of America
 - c. ☐ is signed by what appears to be an agent/common representative but:
 - ☐ the international application is not accompanied by a power of attorney appointing him
 - ☐ the power of attorney accompanying the international application was not signed by all the applicants
 - d. ☐ other (specify):

* Although Rule 4.15 requires that all applicants must sign the request (e.g. including all inventors/applicants for the designation of the United States of America), for the purposes of Article 14(1)(a)(i), if there is more than one applicant, it shall be sufficient that the request be signed by one of them (Rule 26.2bis(a)).
However, the applicant's attention is drawn to the fact that the national law applied by each designated Office may require, in connection with the processing of the international application in the national phase, that the applicant furnish the confirmation of the international application by the signature of any applicant for the designated State who has not signed the request (Rule 51bis.1(a)(vi)).
2. As to indications concerning the applicant* who is entitled, according to Rule 19.1, to file the international application with the receiving Office, the request (Rules 4.4, 4.5 and 26.2bis(b)):
 - a. ☐ does not properly indicate the applicant's name (specify):
 - b. ☐ does not indicate the applicant's address
 - c. ☐ does not properly indicate the applicant's address (specify):
 - d. ☐ does not indicate the applicant's nationality.
 - e. ☐ does not indicate the applicant's residence.
 - f. ☐ further observations about indications concerning other applicants (if applicable):

* Although Rules 4.4 and 4.5 require indications concerning the applicant, or if there are several applicants, of each of them, for the purposes of Article 14(1)(a)(ii), if there is more than one applicant, it shall be sufficient that the indications required under Rule 4.5(a)(ii) and (iii) be provided in respect of one of them who is entitled according to Rule 19.1 to file the international application with the receiving Office (Rule 26.2bis(b)).
However, the applicant's attention is drawn to the fact that the national law applied by each designated Office may require, in connection with the processing of the international application in the national phase, that the applicant furnish any missing indication required under Rule 4.5(a)(ii) and (iii) in respect of any applicant for the designated State (Rule 51bis.1(a)(vii)).
3. As to the language of certain elements of the international application, other than the description and claims (Rules 12.1(c) and 26.3ter(a) and (c)):
 - a. ☐ the request is not in a language of publication accepted by this receiving Office; (the) language(s) accepted by this receiving Office is/are:
 - b. ☐ the text matter of the drawings is not in the language in which the international application is to be published, which is: english
 - c. ☐ the abstract is not in the language in which the international application is to be published, which is: english
4. The title of the invention:
 - a. ☐ is not indicated in Box No. I of the request (Rule 4.1(a)).
 - b. ☐ is not indicated at the top of the first sheet of the description (Rule 5.1(a)).
 - c. ☒ as appearing in Box No. I of the request is not identical with the title heading the description (Rule 5.1(a)).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : C. R. BARD, INC.
International Application No.: PCT/US2004/015670
International Filing Date : 17 May 2004 (17.05.2004)
Earliest Priority Date : 16 May 2003 (16.05.2003)
For : SINGLE INTUBATION, MULTI-STITCH
ENDOSCOPIC SUTURING SYSTEM

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence, and any document(s) referred to as attached hereto, is/are being transmitted to the United States Patent and Trademark Office, Facsimile No. (703) 305-3230 on this 15th day of September, 2005.

Debra M. Doherty
(Typed or printed name of person mailing paper or fee)

[Signature]
(Signature)

MAIL STOP PCT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO COMMUNICATION IN CASES FOR WHICH
NO OTHER FORM IS APPLICABLE**

Sir:

This is in response to the Communication in Cases for Which No Other Form is Applicable mailed 01 September 2005. Enclosed is a corrected page 1 of the PCT Request correcting the spelling of "MULTISTITCH" to "MULTI-STITCH". If anything further is required please contact the undersigned.

Respectfully submitted,

[Signature]
Joyce G. Hersh
Reg. No. 42,890
KIRKPATRICK & LOCKHART LLP
75 State Street
Boston, Massachusetts 02109-1808
United States of America
Telephone: (617) 261-3100

Date:

September 15, 2005

Attorney Docket No.: B0751/7037WO

PCF

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) B0751/7037WO

Box No. I TITLE OF INVENTION SINGLE INTUBATION, MULTI-STITCH ENDOSCOPIC SUTURING SYSTEM	
Box No. II APPLICANT ☐ This person is also inventor	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) C.R. BARD, INC. 730 Central Avenue Murray Hill, NJ 07974 US	Telephone No. 908-277-8000 Facsimile No. 908-277-8025 Teleprinter No. Applicant's registration No. with the Office
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: ☒ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) GAMBALE, Richard A. 382 Dunstable Road Tyngsboro, MA 01879 US	This person is: ☐ applicant only ☐ applicant and inventor ☒ inventor only (If this check-box is marked, do not fill in below.) Applicant's registration No. with the Office
State (that is, country) of nationality: US	State (that is, country) of residence: US
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☐ agent ☐ common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) HERSH, Joyce C. Kirkpatrick & Lockhart LLP 75 State Street Boston, MA 02109-1808	Telephone No. 617-261-3100 Facsimile No. 617-261-3175 Teleprinter No. Agent's registration No. with the Office 42,890
☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.	

PC₁

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) B0751/7037WO

Box No. I TITLE OF INVENTION	
SINGLE INTUBATION, MULTISTITCH ENDOSCOPIC SUTURING SYSTEM	
Box No. II APPLICANT ☐ This person is also inventor	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
C.R. BARD, INC. 730 Central Avenue Murray Hill, NJ 07974 US	
Telephone No. 908-277-8000	
Facsimile No. 908-277-8025	
Teleprinter No.	
Applicant's registration No. with the Office	
State (that is, country) of nationality: US	
State (that is, country) of residence: US	
This person is applicant for the purposes of: ☒ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
GAMBALE, Richard A. 382 Dunstable Road Tyngsboro, MA 01879 US	
This person is: ☐ applicant only ☐ applicant and inventor ☒ inventor only (If this check-box is marked, do not fill in below.)	
Applicant's registration No. with the Office	
State (that is, country) of nationality: US	
State (that is, country) of residence: US	
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box	
☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☐ agent ☐ common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
HERSH, Joyce C. Kirkpatrick & Lockhart LLP 75 State Street Boston, MA 02109-1808	
Telephone No. 617-261-3100	
Facsimile No. 617-261-3175	
Teleprinter No.	
Agent's registration No. with the Office 42,890	
☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.	

164

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)			
<i>If none of the following sub-boxes is used, this sheet should not be included in the request.</i>			
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i> LUKIN, Peter J. 28 Russell Lane Lancaster, MA 01523 US		This person is: ☐ applicant only ☐ applicant and inventor ☒ inventor only <i>(If this check-box is marked, do not fill in below.)</i>	
State <i>(that is, country)</i> of nationality: US		State <i>(that is, country)</i> of residence: US	
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box			
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i> DICESARE, Paul Eastern Connecticut US		This person is: ☐ applicant only ☐ applicant and inventor ☒ inventor only <i>(If this check-box is marked, do not fill in below.)</i>	
State <i>(that is, country)</i> of nationality: US		State <i>(that is, country)</i> of residence: US	
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box			
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i> BATTLES, Christopher New Haven, Connecticut US		This person is: ☐ applicant only ☐ applicant and inventor ☒ inventor only <i>(If this check-box is marked, do not fill in below.)</i>	
State <i>(that is, country)</i> of nationality: US		State <i>(that is, country)</i> of residence: US	
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box			
Name and address: <i>(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)</i> RADZIUNAS, Jeffrey Wallingford, Connecticut US		This person is: ☐ applicant only ☐ applicant and inventor ☒ inventor only <i>(If this check-box is marked, do not fill in below.)</i>	
State <i>(that is, country)</i> of nationality: US		State <i>(that is, country)</i> of residence: US	
This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box			
☒ Further applicants and/or (further) inventors are indicated on another continuation sheet.			

165

Supplemental Box

If the Supplemental Box is not used, this sheet should not be included in the request.

1. If, in any of the Boxes, except Boxes Nos. VIII(i) to (v) for which a special continuation box is provided, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No." (indicate the number of the Box) and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:
- (i) if more than two persons are to be indicated as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;
 - (ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;
 - (iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;
 - (iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;
 - (v) if, in Box No. VI, there are more than three earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.
2. If the applicant intends to make an indication of the wish that the international application be treated, in certain designated States, as an application for a patent of addition, certificate of addition, inventor's certificate of addition or utility certificate of addition: in such a case, write the name or two-letter code of each designated State concerned and the indication "patent of addition," "certificate of addition," "inventor's certificate of addition" or "utility certificate of addition," the number of the parent application or parent patent or other parent grant and the date of grant of the parent patent or other patent grant or the date of filing of the parent application (Rules 4.11(a)(iii) and 49bis.1(a) or (b)).
3. If the applicant intends to make an indication of the wish that the international application be treated, in the United States of America, as a continuation or continuation-in-part of an earlier application: in such a case, write "United States of America" or "US" and the indication "continuation" or "continuation-in-part" and the number and the filing date of the parent application (Rules 4.11(a)(iv) and 49bis.1(d)).

FERRIERA, Danial
Milford, Connecticut
US

Box No. V DESIGNATIONS

The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.

However,

- ☐ DE Germany is not designated for any kind of national protection
- ☐ KR Republic of Korea is not designated for any kind of national protection
- ☐ RU Russian Federation is not designated for any kind of national protection

(The check-boxes above may be used to exclude (irrevocably) the designations concerned in order to avoid the ceasing of the effect, under the national law, of an earlier national application from which priority is claimed. See the Notes to Box No. V as to the consequences of such national law provisions in these and certain other States.)

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country or Member of WTO	regional application:* regional Office	international application: receiving Office
item (1) 16 May 2003 16.5.2003	60/471,248			
item (2)				
item (3)				

- ☐ Further priority claims are indicated in the Supplemental Box.

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office) identified above as:

- ☐ all items ☒ item (1) ☐ item (2) ☐ item (3) ☐ other, see Supplemental Box

* Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) (if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

ISA / US

Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):

Date (day/month/year)

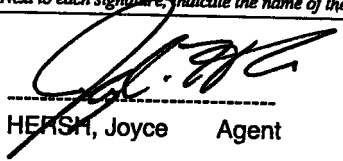
Number

Country (or regional Office)

Box No. VIII DECLARATIONS

The following declarations are contained in Boxes Nos. VIII (i) to (v) (mark the applicable check-boxes below and indicate in the right column the number of each type of declaration):

		Number of declarations
☐ Box No. VIII (i)	Declaration as to the identity of the inventor	:
☐ Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	:
☐ Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	:
☐ Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America)	:
☐ Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	:

Box No. IX CHECK LIST; LANGUAGE OF FILING		Number of items
This international application contains: (a) in paper form, the following number of sheets: request (including declaration sheets) : 5 description (excluding sequence listing and/or tables related thereto) : 27 claims : 4 abstract : 1 drawings : 35 Sub-total number of sheets : 72 sequence listing : tables related thereto : <i>(for both, actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (c) below)</i> Total number of sheets : 72 (b) ☐ only in computer readable form (Section 801(a)(i)) (i) ☐ sequence listing (ii) ☐ tables related thereto (c) ☐ also in computer readable form (Section 801(a)(ii)) (i) ☐ sequence listing (ii) ☐ tables related thereto Type and number of carriers (diskette, CD-ROM, CD-R or other) on which are contained the ☐ sequence listing: ☐ tables related thereto: <i>(additional copies to be indicated under items 9(ii) and/or 10(ii), in right column)</i>	This international application is accompanied by the following item(s) (mark the applicable check-boxes below and indicate in right column the number of each item): 1. ☒ fee calculation sheet : 2. ☐ original separate power of attorney : 3. ☐ original general power of attorney : 4. ☐ copy of general power of attorney; reference number, if any: : 5. ☐ statement explaining lack of signature : 6. ☐ priority document(s) identified in Box No. VI as item(s): : 7. ☐ translation of international application into (language): : 8. ☐ separate indications concerning deposited microorganism or other biological material : 9. ☐ sequence listing in computer readable form (indicate type and number of carriers) (i) ☐ copy submitted for the purposes of international search under Rule 13ter only (and not as part of the international application) : (ii) ☐ (only where check-box (b)(i) or (c)(i) is marked in left column) additional copies including, where applicable, the copy for the purposes of international search under Rule 13ter : (iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing mentioned in left column : 10. ☐ tables in computer readable form related to sequence listing (indicate type and number of carriers) (i) ☐ copy submitted for the purposes of international search under Section 802(b-quater) only (and not as part of the international application) : (ii) ☐ (only where check-box (b)(ii) or (c)(ii) is marked in left column) additional copies including, where applicable, the copy for the purposes of international search under Section 802(b-quater) : (iii) ☐ together with relevant statement as to the identity of the copy or copies with the tables mentioned in left column : 11. ☐ other (specify): :	
Figure of the drawings which should accompany the abstract:	Language of filing of the international application:	
Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE <i>Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).</i>		
 HERSH, Joyce Agent		

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA /	6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only
Date of receipt of the record copy by the International Bureau:

167/168

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

For International Preliminary Examining Authority use only	
Identification of IPEA	Date of receipt of DEMAND
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION	
Applicant's or agent's file reference B0751/7037WO	
International application No. PCT/US/2004/015670	International filing date (day/month/year) 17 May 2004 (17.05.2004)
(Earliest) Priority date (day/month/year) 16 May 2003 (16.05.2003)	
Title of invention SINGLE INTUBATION, MULTI-STITCH ENDOSCOPIC SUTURING SYSTEM	
Box No. II APPLICANT(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) C. R. BARD, INC. 730 Central Avenue Murray Hill, NJ 07974 US	Telephone No. 908-277-8000
	Facsimile No. 908-277-8025
	Teleprinter No.
	Applicant's registration No. with the Office
State (that is, country) of nationality: US	State (that is, country) of residence: US
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
State (that is, country) of nationality:	State (that is, country) of residence:
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
State (that is, country) of nationality:	State (that is, country) of residence:
☐ Further applicants are indicated on a continuation sheet.	

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCEThe following person is ☒ agent ☐ common representativeand ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.Name and address: (Family name followed by given name; for a legal entity, full official designation.
The address must include postal code and name of country.)HERSH, Joyce C.
Kirkpatrick & Lockhart LLP
75 State Street
Boston, MA 02109-1808
US

Telephone No.

617-261-3100

Facsimile No.

617-261-3175

Teleprinter No.

Agent's registration No. with the Office

42,890

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.**Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION****Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

☒ the international application as originally filedthe description ☒ as originally filed☐ as amended under Article 34the claims ☒ as originally filed☐ as amended under Article 19 (together with any accompanying statement)☐ as amended under Article 34the drawings ☒ as originally filed☐ as amended under Article 342. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.3. ☐ The applicant wishes the start of the international preliminary examination to be postponed until the expiration of the applicable time limit under Rule 69.1(d).4. ☐ The applicant expressly wishes the international preliminary examination to start earlier than at the expiration of the applicable time limit under Rule 54bis.1(a).

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

☒ which is the language in which the international application was filed.☐ which is the language of a translation furnished for the purposes of international search.☐ which is the language of publication of the international application.☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination.**Box No. V ELECTION OF STATES**

The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the PCT.

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | |
|--|---|--------|
| 1. translation of international application | : | sheets |
| 2. amendments under Article 34 | : | sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | sheets |
| 4. copy (or, where required, translation) of statement under Article 19 | : | sheets |
| 5. letter | : | sheets |
| 6. other (<i>specify</i>) | : | sheets |

For International Preliminary
Examining Authority use only

- | received | not received |
|--------------------------|--------------------------|
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |
| ☐ | ☐ |

The demand is also accompanied by the item(s) marked below:

- | | |
|--|--|
| 1. ☒ fee calculation sheet | 5. ☐ statement explaining lack of signature |
| 2. ☐ original separate power of attorney | 6. ☐ sequence listing in computer readable form |
| 3. ☐ original general power of attorney | 7. ☐ tables in computer readable form related to a sequence listing |
| 4. ☐ copy of general power of attorney; reference number, if any: | 8. ☒ other (<i>specify</i>): Transmittal letter |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).


HERSH, Joyce C., Agent

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

- | | |
|--|--|
| 3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.
☐ The applicant has been informed accordingly. | 6. ☐ The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54bis.1(a) and item 7 or 8, below, does not apply. |
| 4. ☐ The date of receipt of the demand is WITHIN the time limit of 19 months from the priority date as extended by virtue of Rule 80.5. | 7. ☐ The date of receipt of the demand is WITHIN the time limit under Rule 54bis.1(a) as extended by virtue of Rule 80.5. |
| 5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82. | 8. ☐ Although the date of receipt of the demand is after the expiration of the time limit under Rule 54bis.1(a), the delay in arrival is EXCUSED pursuant to Rule 82. |

For International Bureau use only

Demand received from IPEA on:

121

REQUISITOS NECESARIOS PARA PRESENTACION Y AGILIZACION DEL TRAMITE

PATENTE DE INVENCION

MODELO DE UTILIDAD

USUARIO RADICADOR

- Indicación de que se solicita la concesión de una patente.
- Datos de identificación del solicitante o de la persona que se presenta la solicitud.
- Descripción de la invención.
- Dibujos de ser estos pertinentes.
- Comprobante de Pago de las tasas establecidas.

() ()
() ()
() ()
() ()
() ()

COMPLETA

()

INCOMPLETA

() ()

DISEÑO INDUSTRIAL

- Indicación de que se solicita el registro de Diseño Industrial
- Datos de identificación del solicitante o de la persona que presenta la solicitud.
- Representación gráfica o fotográfica del Diseño Industrial o muestra del Material que incorpora el diseño.
- Comprobante de pago de las tasas establecidas

() ()
() ()
() ()
() ()

COMPLETA

()

INCOMPLETA

() ()

ESQUEMA DE TRAZADO

- Indicación de que solicita el registro de un Esquema de trazado.
- Datos de identificación del solicitante o de la persona que presenta La solicitud.
- Representación gráfica del esquema de trazado
- Comprobante de pago de las tasas establecidas.

() ()
() ()
() ()
() ()

COMPLETA

()

INCOMPLETA

() ()

Firma Responsable:

Fecha:

_____ 05

172

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Bogotá,
2020

Doctor(a)
CADENA SARMIENTO JUAN PABLO

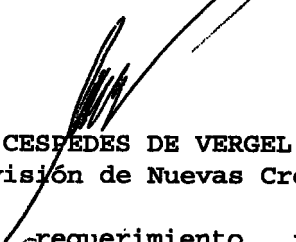
REFERENCIA	Radicación No.	5 122677
	Solicitud internacional	US2004/015670
	Fecha inicio fase nacional	16/12/2005
	Trámite	11
	Evento	379
	Actuación	430
	Oficio No.	780

Como resultado del examen de forma, realizado con fundamento en el artículo 38 de la Decisión 486 de la Comisión de la Comunidad Andina, artículo 27 del Tratado de Cooperación en Materia de Patentes (PCT), regla 51 bis del Reglamento y Circular Única de la Superintendencia de Industria y Comercio, se le comunica que:

1. Si fuere el caso, el solicitante debe adjuntar la traducción de los anexos del reporte de examen preliminar internacional (Art. 36.2.b) del tratado PCT.
2. La solicitud no contiene la copia del documento en que consta la cesión del derecho a la patente del inventor al solicitante o a su causante. (Art. 26-k) Decisión 486.
3. La solicitud no contiene el poder debidamente otorgado, con el lleno de los requisitos exigidos por los artículos 63 y subsiguientes del Código de Procedimiento Civil. Adicionalmente, deberá presentar el documento que acredita la existencia y representación legal de la sociedad solicitante, cuando ésta fuere persona jurídica.

En cumplimiento de lo dispuesto por el artículo 39 de la Decisión 486, se le requiere para que dentro del término de dos meses siguientes a la fecha de notificación del presente oficio, complete los requisitos anteriormente enunciados. En caso de no dar cumplimiento al presente requerimiento, la solicitud se considerará abandonada y perderá su prelación.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Unica No.10 de 2001.


ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la división de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista de fecha 27 ENE. 2006
adpa11