

ALVARO CASTELLANOS M. & CIA.
ABOGADOS
AGENTES DE LA PROPIEDAD INTELECTUAL
Carrera 9 No. 83-08
Bogotá-Colombia

107
SUPERINDUSTRIA Y COMERCIO
Radicación : 04056189 00000003 Folios: 69
Fecha (AND): 2004-11-16 14:56:33
Trámite : 011 PCT-PATENT 379 FASE NACI 444 REPUESTA
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Señora

Jefe de la División de Nuevas Creaciones

Superintendencia de Industria y Comercio

Ministerio de Comercio, Desarrollo Industria y Turismo

E. S. D.

Ref.: Expediente No. 04.058.189

Solicitud de Patente PCT Entrada en Fase Nacional para:

**"TUBO ENDOTRAQUEAL CON CONTROL DE LA DIRECCION DE LA PUNTA Y
MECANISMO PARA MANTENER LA POSICION"**

Solicitante: MERLYN ASSOCIATES, INC.

RESPUESTA AL EXAMEN DE FORMA

Yo, MARGARITA CASTELLANOS ABONDANO, mayor de edad, identificada y domiciliada como aparece al pie de mi firma, en atención a su oficio No. 06637 notificado el 16 de Julio de 2004 y estando dentro del término adicional que solicité mediante memorial radicado el 26 de Agosto de 2004, atentamente me permito dar repuesta al mismo de la siguiente manera :

Establece el funcionario examinador lo siguiente:

-"la solicitud no contiene la copia del documento en que consta la cesión del derecho de patente del inventor al solicitante o a su causante".

-"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".

Con el objeto de atender a las anteriores observaciones, me permito presentar los siguientes documentos:

- Copia auténtica del documento de poder otorgado por la sociedad solicitante junto con la certificación notarial en el que consta la existencia y representación de la sociedad debidamente legalizado por Apostilla, junto con su traducción.
- Sustitución de poder a nombre de **MARGARITA CASTELLANOS**.
- Copia auténtica de la copia certificada de la cesión de los inventores, junto con su traducción.
- Copia auténtica de la copia certificada de un documento de corrección de cesión de los inventores, junto con su traducción. Mediante éste documento se corrige el documento de cesión anterior, el cual se registró de manera incorrecta.
- Copia certificada por la Oficina de Patentes de los Estados Unidos de América de la solicitud de patente No. 09/405,750 presentada ante dicha oficina el día 27 de septiembre de 1999, para una invención titulada "Tubo endotraqueal con control de la dirección de la punta y mecanismo para mantener la posición.

Cumplido así con lo dispuesto, atentamente solicito a Ud. se continúe con el trámite correspondiente a esta solicitud de Patente de Invención.

Señor Jefe,


Margarita Castellanos Abondano
C.C. No. 39.779.654 de Usaquén
T.P.A. No. 70.819 del Consejo Superior de la Judicatura
Carrera 9 No. 93-09 – Bogotá, D.C.
Teléfono: 6107420 – 6107480

Bogotá, D.C. **16 NOV. 2004**
MCA/ gcb/4924-FNPCT

Señor

Jefe de la División de Nuevas Creaciones

Superintendencia de Industria y Comercio

Ministerio de Comercio, Desarrollo, Industria y Turismo

E. S. D.

Ref.: PODER conferido por la sociedad MERLYN ASSOCIATES, INC.

Yo, XIMENA CASTELLANOS ABONDANO, mayor de edad, identificada y domiciliada como aparece al pie de mi firma, atentamente manifiesto a Uds. que sustituyo en la Dra. MARGARITA CASTELLANOS ABONDANO, el poder que me confirió la sociedad MERLYN ASSOCIATES, INC., con domicilio en 11 Bayleaf Lane, Irvine, California 92620, ESTADOS UNIDOS DE AMERICA, debidamente legalizado por Apostilla, bajo el No. 213063 el día 21 de Octubre de 2004, con las mismas facultades que me fueron conferidas, para tramitar la solicitud de Patente de Invención, en Colombia, para: "TUBO ENDOTRAQUEAL CON CONTROL DE LA DIRECCIÓN DE LA PUNTA Y MECANISMO PARA MANTENER LA POSICION", que se tramita bajo el Expediente No. 04.058.189.

Del Señor Jefe,

Acepto


Ximena Castellanos Abondano
C.C. No. 39.773.330 de Usaquén
T.P.A. No. 58.236 del C.S.J.
Carrera 9 No. 93-09 - Bogotá, D.C.
Teléfonos: 6107420 - 6107480


Margarita Castellanos Abondano
C.C. No. 39.779.654 de Usaquén
T.P.A. No. 70.819 del C.S.J.
Carrera 9 No. 93-09 - Bogotá, D.C.
Teléfonos: 6107420 - 6107480

Bogotá, D.C.
XCAMCA/4924-FNPCT

GAUSER/PATENTES/49/4924-FNPCT/MEMOSUSTITUCION

**AUTENTICACION DE FIRMA
MEDIANTE COMPARECENCIA PERSONAL**
(Art. 84 C.R.C. mod. Decr. 2282 de 1989, art. 1 mod. 38)

Ante el Notario Cuarenta y Uno (41) del círculo de esta ciudad compareció personalmente:
Miguel Ángel Castañeda
 identificado con C.C. **29.973.1350**
 expedida en: **Medellín** y tarjeta profesio-
 nal de abogado(a) No. **558.856** del Consejo
 Superior de la Judicatura, con documento di-
 rigido a: **Superintendencia**
 y declaró que la firma puesta en este escrito es
 suya.

[Firma manuscrita]
 Firma del declarante

6 NOV. 2004

En Bogotá D.C. a **6 de Noviembre de 2004**
 AUTORIZO ESTA DILIGENCIA EL SUSCRITO NOTARIO



**AUTENTICACION DE FIRMA
MEDIANTE COMPARECENCIA PERSONAL**
(Art. 84 C.R.C. mod. Decr. 2282 de 1989, art. 1 mod. 38)

Ante el Notario Cuarenta y Uno (41) del círculo de esta ciudad compareció personalmente:
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 y declaró que la firma puesta en este escrito es
 suya.

[Firma manuscrita]
 Firma del declarante

6 NOV. 2004

En Bogotá D.C. a **6 de Noviembre de 2004**
 AUTORIZO ESTA DILIGENCIA EL SUSCRITO NOTARIO



PODER

El (los) Jay Kotin, en representación de
MERLYN ASSOCIATES, INC.

Domiciliados en 11 Bayleaf Lane, Irvine,
California 92620, ESTADOS UNIDOS DE
AMERICA

Nombran por el presente a XIMENA CASTELLANOS A. y/o
MARGARITA CASTELLANOS A. abogadas con oficinas en la
Carrera 9 No. 93-09, Bogotá-Colombia para

y para obtener la protección de mi (nuestra) propiedad
industrial y con este fin autorizamos a dichos apoderados para
que nos representen ante cualesquiera autoridades o personas
de los órdenes administrativo, contencioso-administrativo y
judicial en todo lo relacionado con los siguientes actos y
gestiones:

- Obtención de patentes de invención, modelos y dibujos
industriales; registro de marcas de fábrica, de servicio,
colectivas o defensivas y de denominaciones de origen,
depósito de nombres y enseñas comerciales; su
renovación, prórroga, inscripción de traspaso y cambio de
nombre o domicilio, cancelación voluntaria y el registro de
licencias de uso de esos derechos;
- Para la obtención de registros sanitarios;
- Acciones de oposición, observación, cancelación, nulidad,
medidas cautelares y en general los juicios civiles, penales,
administrativos o contencioso-administrativos que
promovamos o se nos promuevan.

Pudiendo en todos los actos y gestiones arriba mencionados
sustituir éste mandato, transigir, desistirse, recibir, cancelar,
renunciar, aceptar notificaciones y nombrar apoderados
judiciales y extrajudiciales.

Dado y firmado hoy 15 de Octubre de 2004

en Irvine, California, ESTADOS UNIDOS
DE AMERICA

por Jay Kotin, Presidente de MERLYN ASSOCIATES,
(El notario debe suscribir el documento en la página siguiente)

(Se requiere legalización consular o mediante apostilla)

CERTIFICADO NOTARIAL (Sociedad)

POWER OF ATTORNEY

I (we) the undersigned Jay Kotin

Of Merlyn Associates, Inc.
Of 11 Bayleaf Lane, Irvine, California
92620, USA

hereby grant(s) Power of Attorney to XIMENA
CASTELLANOS A. and for MARGARITA CASTELLANOS
a. attorneys residing at Carrera 9 No. 93-09, Bogotá-
Colombia, to

and to obtain the protection of my (our) Industrial Property, for
which purpose we authorize the said attorneys to represent us
before any authorities, or persons, specially those,
administrative, contentious and judicial, in all matters
concerning the following:

- Obtainment of patents, models and designs, registration of
trademarks, service, collective and defensive marks, and of
designations of origin; the deposit of trade names and
ensigns; its renewal, extension, recordal of assignments,
change of name or domicile, voluntary cancellation, and the
registration of licenses of use of the above rights;
- For the obtainment of Sanitary registrations;
- Actions of opposition, cancellation, nullity, infringement,
granting of licenses; and in general the civil, criminal and
administrative suits related to those rights; actions and
suits instituted by us or against us;

In all the above matters they may substitute this power of
attorney, compromise, desist, cancel, receive, renounce,
accept notifications and appoint attorneys in fact, in or out of
court.

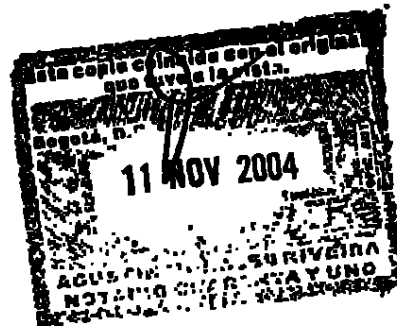
Given and signed this 15th day of October 2004

In Irvine, California USA

by Jay Kotin, President of Merlyn Associates, Inc.
(Notary shall execute on the other side)

(Consular legalization or apostille is required)

NOTARIAL CERTIFICATION (Corporation)



COLOMBIA

Hoy 15 de Octubre de 2004
compareció (eron) personalmente
Jay Kotin

a quienes conozco como la(s) personas que firma(n) en
representación de la Sociedad (Compañía) denominada

MERLYN ASSOCIATES, INC.

Certifico:

a) Que MERLYN ASSOCIATES, INC.

es una sociedad/Compañía legalmente constituida y
existente de acuerdo con las leyes de California

b) Que el domicilio de dicha Sociedad/Compañía es
11 Bayleaf Lane, Irvine, California 92620, USA
c) Que el objeto u objetos para los cuales se otorga el
presente poder están comprendidos dentro del objeto
social de la mencionada Sociedad /Compañía.

d) Que el Sr. Jay Kotin
esta autorizado para otorgar el presente poder. Lo anterior
esta probado por medio de los siguientes documentos, que
certifico he visto*

Los Estatutos de la Sociedad de fecha
26 de Junio de 1998
(Ciudad) Irvine

(Estado) California

Hoy 15 de Octubre de 2004

(Notario Público)

*Los documentos debe identificarse con fecha y origen.

On this 15th day of October 2004
personally appeared Jay Kotin

whom I know to be the person(s) who signed this document
as representative(s) of the Corporation /Company named

I certify: Merlyn Associates, Inc.

a) That

is a corporation (Company legally constituted and in
existence in accordance with the laws of California

b) That the domicile of said Corporation/Company is

11 Bayleaf, Irvine, California 92620 USA

c) That the purpose or purposes for which the present
Power of Attorney is granted are comprised within the
object set forth in the charter of the mentioned
Corporation/Company.

d) That Mr. Jay Kotin

is ~~has~~ authorized to grant the present Power of Attorney. The
aforementioned was duly proven through the following
documents and I duly certify having seen them*:

(City) Irvine

(State) California

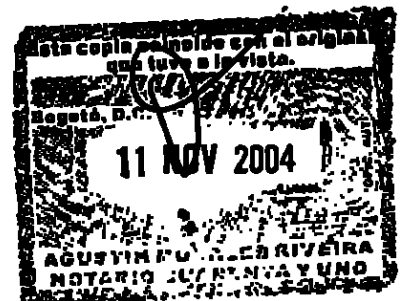
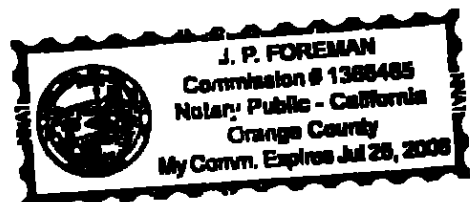
this 15 day of ~~October~~ October 2004

(Notary Public)

J. P. Foreman

*Documents must be identified with date and origin

Corporation Bylaws dated June 26, 1998 in
Huntington Beach, California USA



State of California

SECRETARY OF STATE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America
This public document
2. has been signed by J. P. FOREMAN
3. acting in the capacity of Notary Public, State of California
4. bears the seal/stamp of J. P. FOREMAN, Notary Public,
State of California

CERTIFIED

5. At Sacramento, California
6. the 21st day of October 2004
7. by Deputy Secretary of State, State of California
8. No. 213063
9. Seal/Stamp:

10. Signature

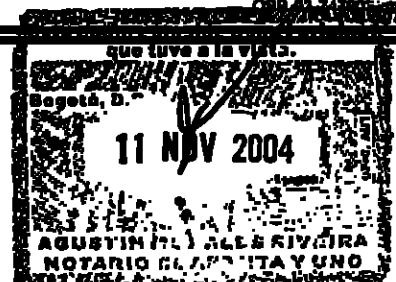


Kevin Shelley

KEVIN SHELLEY
Secretary of State

BY

[Signature]



State of CaliforniaCounty of OrangeOn October 15, 2004 before me, J.P. Foreman

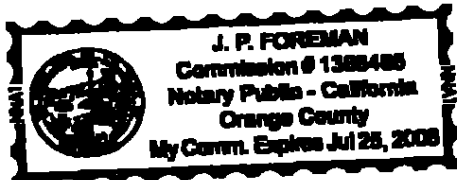
DATE

NAME, TITLE OF OFFICER - E.G., "JANE DOE, NOTARY PUBLIC"

personally appeared Jay Kotin

NAME(S) OF SIGNER(S)

☒ personally known to me - OR ☐ ~~proved to me on the basis of satisfactory evidence~~
 to be the person(s) whose name(s) is/are
 subscribed to the within instrument and ac-
 knowledged to me that he/~~she/they~~ executed
 the same in his/~~her/their~~ authorized
 capacity(~~ies~~), and that by his/~~her/their~~
 signature(s) on the instrument the person(s);
 or the entity upon behalf of which the
 person(s) acted, executed the instrument.



WITNESS my hand and official seal.

J. P. Foreman
 SIGNATURE OF NOTARY

OPTIONAL

Though the data below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent reattachment of this form.

CAPACITY CLAIMED BY SIGNER

- ☐ INDIVIDUAL
☒ CORPORATE OFFICER

President

TITLE(S)

- ☐ PARTNER(S) ☐ LIMITED
☐ GENERAL
☐ ATTORNEY-IN-FACT
☐ TRUSTEE(S)
☐ GUARDIAN/CONSERVATOR
☐ OTHER: _____

SIGNER IS REPRESENTING:

NAME OF PERSON(S) OR ENTITY(IES)

Merlyn Associates, Inc.

DESCRIPTION OF ATTACHED DOCUMENT

Power of Attorney

TITLE OR TYPE OF DOCUMENT

2

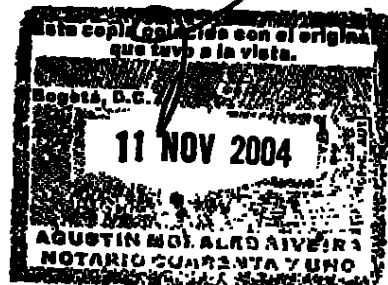
NUMBER OF PAGES

October 15, 2004

DATE OF DOCUMENT

• None

SIGNER(S) OTHER THAN NAMED ABOVE



_____**TRADUCCION OFICIAL No. 04-1108**_____

de un documento escrito en INGLES, el cual para su identificación lleva el sello de la Traductora e Intérprete Oficial, Res. 2755/68 y 01144/97 de Minjusticia, al igual que la presente._____

(Anexos a un documento de Poder de Merlyn Associates, Inc.)

Estatutos de la Sociedad de fecha Junio 26, 1998 en Huntington Beach, California, USA

(Sello): J. P. FOREMAN – Comisión No. 1166485

Notario Público – California -- Condado de Orange

Mi comisión vence Julio 25, 2006

CALIFORNIA - RECONOCIMIENTO PARA FINES GENERALES

ESTADO DE CALIFORNIA

CONDADO DE ORANGE

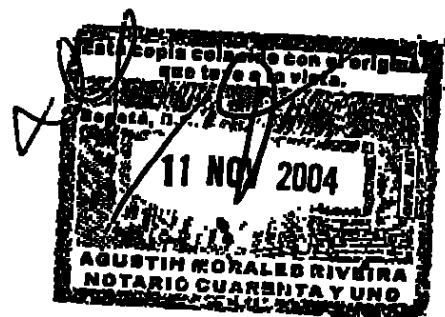
Hoy día 15 de Octubre de 2004, ante mí J.P. Foreman, compareció personalmente Jay Kotin a quien conozco personalmente o (x) quienes probaron ante mí con base en prueba satisfactoria ser la persona(s) cuyo nombre(s) está(n) suscrito(s) en el instrumento adjunto y reconocieron ante mí que habían otorgado el mismo en su calidad autorizada y que con su firma en el instrumento, la persona o entidad en nombre de la cual actuó dicha persona, otorgó el instrumento.

DA FE mi firma y sello oficial.

(fdo) J. P. Foreman

Firma del Notario

(Sello): J. P. FOREMAN – Comisión No. 1166485



Notario Público – California – Condado de Orange

Mi comisión vence Julio 25, 2006

OPCIONAL

Aunque los datos siguientes no los exige la ley, pueden ser útiles a personas que confían en el documento y puede evitar que se anexen otros fraudulentamente.

Capacidad que dice tener el firmante Descripción del documento adjunto:

☐ Persona

Título o tipo de documento: Poder

☒ Funcionario corporativo

Cargo: Presidente

No. de páginas: 2

☐ Apoderado

☐ Síndico

Fecha documento: Octubre 15, 2004

☐ Tutor / guardián

☐ Otro _____

Otros firmantes: ninguno

Firmante representa a: Marlyn Associates, Inc.

ESTADO DE CALIFORNIA

SECRETARIO DE ESTADO

APOSTILLA

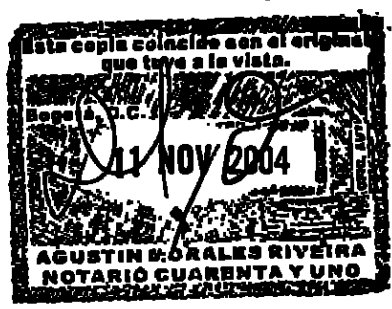
(Convención de La Haya del 5 de Octubre 1961)

1. País: Estados Unidos de América

Este documento público

2. Ha sido firmado por J. P. Foreman

3. Actuando en su carácter de Notario Público, Estado de California



4. Lleva el sello de J.P. Foreman, Notario Público, Estado de California

CERTIFICADO

5. EN Sacramento, California

6. El día 21 de Octubre de 2004

7. por el Secretario de Estado Delegado, Estado de California

8. No. 213063

9. Sello: (sello)

10. Firma

(fdo) Kevin Shelley

KEVIN SHELLEY

Secretario de Estado

Por (fdo) ilegible

ES TRADUCCION FIEL Y COMPLETA, A LA CUAL ME REMITO,

Bogotá, Noviembre 4, 2004.

DORA DUQUE DE BENJAL

TRADUCTORA E INTERPRETE OFICIAL

RES. 02755/00 Y 01114/97 - MINISTERIO DE JUSTICIA

REP. DE COLOMBIA

NO SE ASUME
RESPONSABILIDAD DEL TEXTO

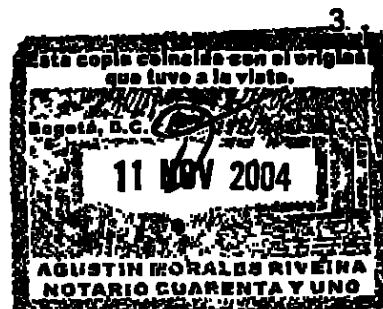
2004 NOV -5 P 12: 04

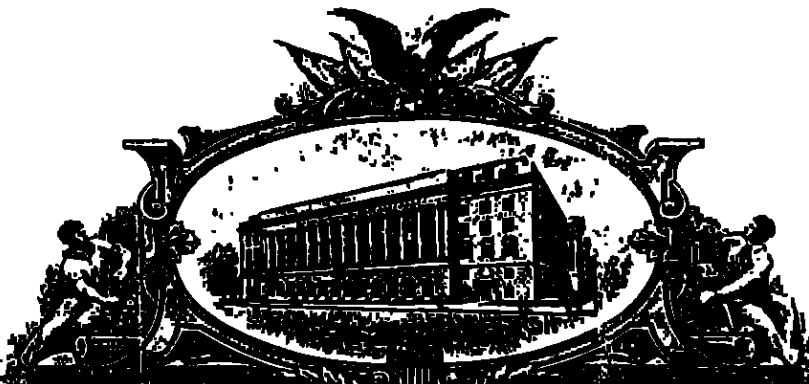
JEFE DE LEGALIZACIONES
SANTAFE DE BOGOTA D.C.

MINISTERIO DE RELACIONES
EXTERIORES

658792

Don Duque
CUYA FIRMA APARECE EN EL
DOCUMENTO DESEMPENA
LAS FUNCIONES INDICADAS





THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

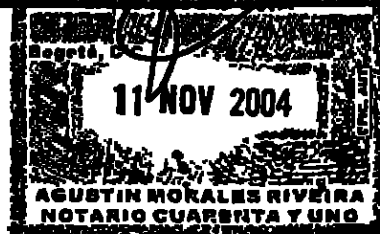
October 22, 2004

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE
RECORDS OF THIS OFFICE OF A DOCUMENT RECORDED ON
February 06, 2002.

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS



E. Barnett
E. BORNETT
Certifying Officer



01-06-2000

Form PTO-1000
1-3-82

RE



ITER

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

MAD 12.6.99

101238663

Attorney Docket No.: 200106-20001

To the Assistant Commissioner for Patents: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies): Andrew J. TOTI, Michael H. WONG and Jay KOTIN Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No	2. Name and address of receiving party(ies): Mady Associates, Inc. 10800 Culbert Street Unit 40 Huntington Beach, CA 92647 11 BAYLEAF LANE IRVINE, CA 92610 DATE 01/23/02 JAY KOTIN
3. Nature of conveyance: ☒ Assignment ☐ Mortgage ☐ Security Agreement ☐ Change of Name ☐ Other _____ Execution Date: Andrew J. TOTI, 11/17/99; Michael H. WONG, 11/19/99; Jay KOTIN, 11/24/99	Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):
If this document is being filed together with a new application, the execution date of the application is: _____
A. Patent Application No.(s) 08/408,700 B. Patent No.(s) _____
Additional numbers attached? ☐ Yes ☒ No

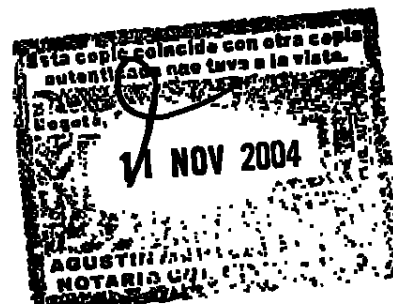
5. Name and address of party to whom correspondence concerning document should be mailed: Louis A. Mok, Esq. LOES & LOES LLP 10100 Santa Monica Blvd., 22nd Floor Los Angeles, CA 90067-4164	6. Total number of applications and patents involved: [1] 7. Total fee (27 CFR 3.41) \$ <u>40.00</u> ☒ Enclosed ☐ Authorized to be charged to deposit account 8. Deposit account number: 12-1520 (Attach duplicate copy of this page if paying by deposit account)
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DO NOT USE THIS SPACE

9. Statement and signature:
To the best of my knowledge and belief the foregoing is true and correct and any attached copy is a true copy of the original document.

Louis A. Mok, Reg. No. 22,685 Date: December 2, 1999

OMB No. 0581-0011 Rev. 4/99
Mail documents to be recorded with required cover sheet information to:
01/13/2000 09:00:10 01/13/00
01. FC&BI 44.00 IP
Assistant Commissioner for Patents
Box Assignments
Washington, D.C. 20231

DC234821.1
20010620001
11/06/1996 10PATENT
REEL: 012386 FRAME: 0240

12

Attorney Docket No. 200190-20001

ASSIGNMENT

(1-8) Insert Name(s) of Inventor(s)

(1) Andrew J. TOTI (8)
 (2) Michael H. WONG (9)
 (3) Jay KOTIN (7)
 (4) (8)

In consideration of the sum of one dollar (\$1.00) and other good and valuable considerations paid to each of the undersigned, the undersigned agree(s) to assign, and hereby does assign, transfer and let over to

(9) Insert name of Assignee. (9) Marilyn Associates, Inc.
 (10) Insert state of Incorporation of Assignee. (10) California
 11 BAYLEAF LANE, IRVINE, CA 92610
 (11) Insert address of Assignee. (11) of 48885-Gothard Street Unit #9, Huntington Beach, CA 92647-
 (hereinafter designated as the Assignee) the entire worldwide right, title and interest in the invention known as
 (12) Insert identification of invention, such as Title, Case Number or Foreign Application Number. (12) ENDOTRACHEAL TUBE WITH TIP DIRECTIONAL CONTROL AND POSITION PRESERVING MECHANISM, 08408,700
 for which the undersigned has (have) executed an application for patent in the United States of America and all patent applications in foreign countries corresponding thereto or based thereon.
 (13) Insert Date of Signing of Application. (13) on

1) The undersigned agree(s) to execute all papers necessary in connection with any original, renewal, divisional and continuing United States and foreign applications for the above-identified invention and also to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.

2) The undersigned agree(s) to execute all papers necessary in connection with any interference which may be declared concerning this application or continuation or division thereof and to cooperate with the Assignee in every way possible in obtaining evidence and going forward with such interference.

3) The undersigned agree(s) to execute all papers and documents and perform any act which may be necessary in connection with claims or provisions of the International Convention for Protection of Industrial Property or similar agreements.

4) The undersigned agree(s) to perform all affirmative acts which may be necessary to obtain a grant of a valid United States patent to the Assignee.

5) The undersigned hereby authorize(s) and request(s) the Commissioner of Patents to issue any and all Letters Patents of the United States resulting from said application or any division or divisions or continuing applications thereof to the said Assignee, as Assignee of the entire interest, and hereby covenants that he has (they have) full right to convey the entire interest herein assigned, and that he has (they have) not executed any agreement in conflict herewith.

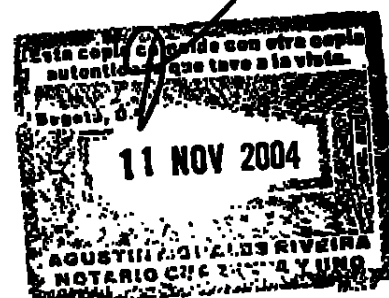
6) The undersigned hereby appoints STUART LUBITZ, Reg. No. 20,680; LOUIS A. MOK, Reg. No. 22,585; JOHN P. SCHERLACHER, Reg. No. 23, 009; HIDEO KODA, Reg. No. 27,729; WILLIAM H. WRIGHT, Reg. No. 30,312; DAVID L. LUBITZ, Reg. No. 38,229; WEI-NING YANG, Reg. No. 38,680; KARLTON BUTTS, Reg. No. 38,128; F. JASON FARHADIAN, Reg. 42,823 the power to insert on this assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

Date: 11/17/99 Signature of Inventor [Signature]
 Date: 11/19/99 Signature of Inventor [Signature]
 Date: 11/24/99 Signature of Inventor [Signature]
 Date: _____ Signature of Inventor _____

th
 20019020001
 CC2243121

RECORDED: 02/06/2002

PATENT
 REEL: 012385 FRAME: 0241



_____**TRADUCCION DE DOCUMENTO EN INGLES**_____

ESTADOS UNIDOS DE AMERICA
A TODOS A QUIENES LOS PRESENTES LLEGAREN
DEPARTAMENTO DE COMERCIO DE ESTADOS UNIDOS
Oficina de Patentes y Marcas de Estados Unidos

Octubre 22, 2004

POR LA PRESENTE CERTIFICAMOS QUE LA ANEXA ES COPIA
AUTENTICA DE LOS ARCHIVOS DE ESTA OFICINA DE UN DOCUMENTO
REGISTRADO EL
6 de Febrero de 2002

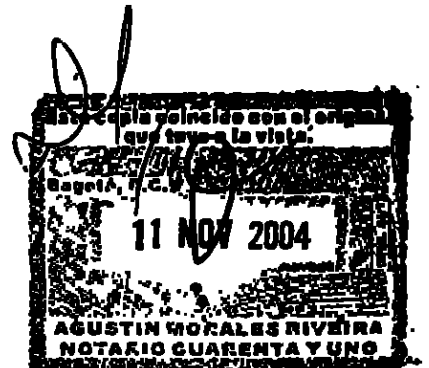
Por autoridad del
COMISIONADO DE PATENTES Y MARCAS
(FDO) ilegible
E. Bornett
Funcionario de Certificación

(Sello)

Depto. de Comercio
Oficina de Marcas y Patentes

CARATULA DE FORMATO DE REGISTRO
UNICAMENTE PATENTES

Al Comisionado de Patentes y Marcas: Favor registrar los documentos
originales adjuntos o copias de los mismos.



1. Nombre de las partes cedentes:

Andrew J. Toti, Michael H. Wong y Jay Kotin

Nombres adicionales de partes cedentes? Si () No (x)

2. Nombre y dirección de la parte receptora

Nombre: MERLYN ASSOCIATES, INC.

Dirección Interna: (en blanco)

Dirección postal: 11 Bayleaf Lane

Ciudad: Irvine, Estado: CA ZIP: 92620

Nombres y direcciones adicionales adjuntos? Si () No (x)

3. Naturaleza del Traspaso

(x) Cesión

() Fusión

() Contrato Garantía

() Cambio de nombre

(x) Otro DOCUMENTO DE CORRECCION de documento de cesión registrado

incorrectamente en riel/marco 010485/0442

Fecha otorgamiento: Enero 23, 2002

4. Solicitud #. O Patente #

Si este documento se está presentando junto con una solicitud nueva, la fecha de firma de la solicitud es: _____

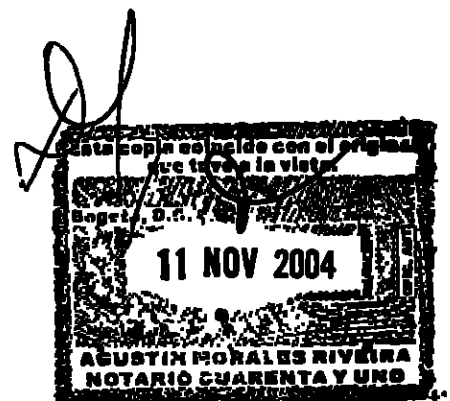
A. Solicitud de Patente No. 10/270,724

B. Patente No... 6,321.749

Números adicionales adjuntos? Si () No (x)

5. Nombre y dirección de la parte a quien debe dirigirse la correspondencia relacionada con este documento:

Nombre: Marc Bobys, Esq.



Dirección interna: Oppenheimer Wolf & Donnelly LLP

Dirección postal: 2029 Century Park East Suite 3800

Ciudad: Los Angeles, Estado: CA ZIP 90067

6. Número total de solicitudes y patentes involucradas: 1

7. Derechos totales (37 CFR 3.41) \$40.00

☐ Adjunto

☒ Se autoriza cargar a la cuenta de depósito

8. Cuenta de depósito número - 16-2230

9. Declaración y firma – De acuerdo con mi conocimiento y entendimiento, la anterior información es auténtica y correcta y cualquier copia adjunta a la misma es copia auténtica del documento original,

Marc Bobys, Reg. No. 45,267 Firma: (fdo) ilegible Fecha: Enero 30. 2002

Número total de hojas incluyendo adjuntos y el documento: 7

Depto. de Comercio

Oficina de Marcas y Patentes

01-06-2000 - 101238663

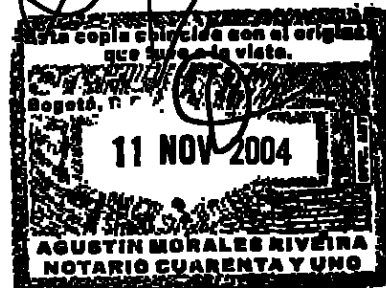
Al Comisionado de Patentes y Marcas: Favor registrar los documentos originales adjuntos o copias de los mismos.

1. Nombre de las partes cedentes:

Andrew J. Toti, Michael H. Wong y Jay Kotin

Nombres adicionales de partes cedentes? Si ☐ No ☒

2. Nombre y dirección de la parte receptora



Nombre: MERLYN ASSOCIATES, INC.

Dirección interna: (en blanco)

Dirección postal: 11 Bayleaf Lane

Ciudad: Irvine, Estado: CA ZIP: 92620 Jay Kotin Fecha 01/23/02

Nombres y direcciones adicionales adjuntos? Si () No (x)

3. Naturaleza del Traspaso

(x) Cesión

() Fusión

() Contrato Garantía

() Cambio de nombre

() Otro

Fecha de otorgamiento: Andrew J. Totl 11/17/99; Michael H. Wong 11/19/99;

Jay Kotin 11/24/99

4. Solicitud #. O Patente #

Si este documento se está presentando junto con una solicitud nueva, la fecha de firma de la solicitud es:-

A. Solicitud de Patente No. 08/405.760

B. Patente No.....

Números adicionales adjuntos? Si () No (x)

5. Nombre y dirección de la parte a quien debe dirigirse la correspondencia relacionada con este documento:

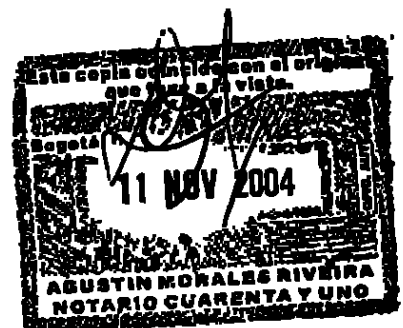
Nombre: Louis A. Mock, Esq.

LOEB & LOEB LLP

10100 Santa Monica Blvd., plso 22

Los Angeles, CA 90067-4164

6. Número total de solicitudes y patentes involucradas: 1



7. Derechos totales (37 CFR 3.41) \$40.00

(x) Adjunto

() Se autoriza cargar a la cuenta de depósito

8. Cuenta de depósito número - 12-1820

9. Declaración y firma – De acuerdo con mi conocimiento y entendimiento, la anterior información es auténtica y correcta y cualquier copia adjunta a la misma es copia auténtica del documento original.

Louis A. Mock, Reg. No. 22,588 Firma: (fdo) ilegible Fecha: Dic. 2, 1999

Envíe documentos para ser registrados con la información de la carátula a:

Comisionado Asistente de Patentes

Casilla de Ceslones

Washington, D. C., 20231

Archivo Apoderado No. 200199-

2001

CESION

(Inserte nombre de Inventores): (1) Andrew J. TOTI

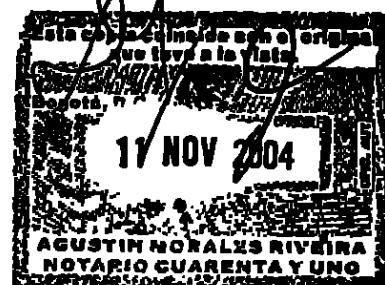
(2) Michal H. WONG

(3) Jay KOTIN

En consideración a la suma de un dólar (\$1.00) y otra compensación positiva y de valor pagada a cada uno de los suscritos, acordamos ceder y por medio del presente cedemos, traspasamos y enajenamos a:

Marlyn Associates, Inc.

California - 11 Bayleaf Lane, Irvine, CA -



En adelante llamada la cesionaria, todos los derechos, títulos e intereses sobre la invención conocida como:

TUBO ENDOTRAQUEAL CON MECANISMO PRESERVATIVO DE CONTROL DE PUNTA DIRECCIONAL Y COLOCACION , 09/406,750

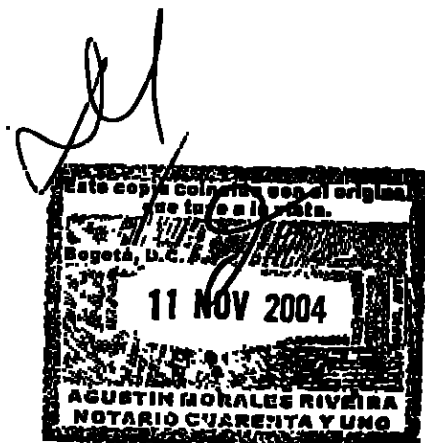
Para lo cual los suscritos hemos firmado una solicitud de patente en los Estados Unidos de América y todas las solicitudes en países extranjeros correspondientes a la misma y sobre la misma.

(1) Los suscritos nos obligamos a firmar todos los documentos necesarios relacionados con cualquier solicitud original, re-expedición, división y continuación para la invención antes mencionada y también a otorgar cesiones separadas en relación con tales solicitudes cuando el cesionario lo considere necesario o conveniente.

(2) El suscrito se obliga a otorgar todos los documentos necesarios en relación con cualquier interferencia que pueda ser declarada en relación con esta solicitud o continuación o división de la misma y a cooperar con el cesionario de cualquier forma posible para obtener prueba y perseguir tal interferencia.

(3) Los suscritos nos obligamos a otorgar todos los papeles y documentos y ejecutar cualquier acto que pueda ser necesario en relación con reivindicaciones o normas de la Convención Internacional para la Protección de la Propiedad Industrial o acuerdos similares.

(4) Los suscritos nos obligamos a ejecutar todos los actos afirmativos que puedan ser necesarios para obtener la concesión de un Patente de los Estados Unidos al cesionario.



(5) Los suscritos por medio del presente autorizamos y solicitamos al Comisionado de Patentes expedir toda Patente de los Estados Unidos que resulte de dicha solicitud o cualquier división o divisiones o solicitudes de continuación de la misma a dicho cesionario, como cesionario de todo interes, y por medio del presente manifestamos que tenemos pleno derecho a traspasar todo interes aquí cedido y que no hemos otorgado ningún otro contrato que esté en conflicto con el presente.

(6) Los suscritos por medio del presente nombramos a STUART LUBITZ, reg. No. 20.680, LOUIS A. MOCK Reg. 22,586; JOHN P. SCHERLACHER, reg. No. 23,009; HIDEO KODA, Reg. No. 27.729, WILLIAM H. WRIGHT, reg. No. 36.312; DAVID L. LUBITZ, Reg. No. 38.229; WEI-NING YANG Reg. No. 36.690; KARLTON BUTTS Reg. No. 39.126, F. JASON PAR-HADAN Reg. No. 42.523 el poder para insertar en esta cesión cualquier identificación posterior que pueda ser necesaria o deseable con el fin de cumplir las reglas de la Oficina de Patentes y Marcas de Estados Unidos para el registro de este documento.

Fecha: 11/17/99 Firma del inventor (fdo) ilegible

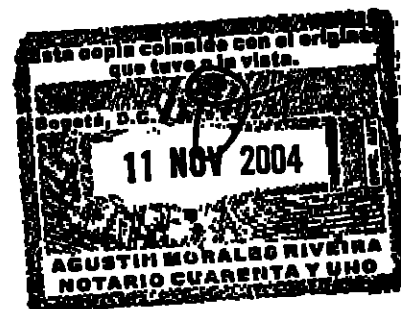
Fecha: 11/19/99 Firma del inventor (FDO) ILEGIBLE

Fecha: 11/24/99 Firma del inventor (fdo) ilegible

ES TRADUCCION FIEL Y COMPLETA, a la cual me remito,

Bogotá, Noviembre 5, 2004.

Am. D. de Brul



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THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

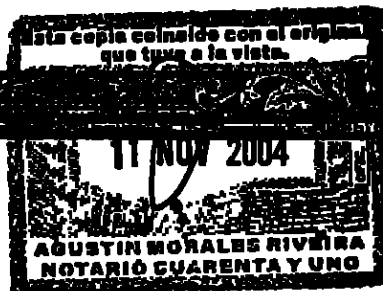
October 22, 2004

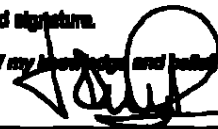
THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE
RECORDS OF THIS OFFICE OF A DOCUMENT RECORDED ON
December 06, 1999.

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS



E. Bornett
E. BORNETT
Certifying Officer



01-06-2000 RE		U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office
12-6-99		101238663
To the Assistant Commissioner for Patents: Please record the attached original documents or copy thereof.		
1. Name of conveying party(ies): Andrew J. TOTI, Michael H. WONG and Jay NOTIN Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No	2. Name and address of receiving party(ies): Merlyn Associates, Inc. 18032 Gothard Street Unit #C Huntington Beach, CA 92647 Additional name(s) & address(es) attached? ☐ Yes ☒ No	
3. Nature of conveyance: ☒ Assignment ☐ Merger ☐ Security Agreement ☐ Change of Name ☐ Other _____ Execution Date: Andrew J. TOTI, 11/17/99; Michael H. WONG, 11/19/99; Jay NOTIN, 11/24/99	RECEIVED OPR/FINANCE 899 DEC -6 AM 9:36	
4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date of the application is: _____ A. Patent Application No.(s) <u>08/506,782</u> B. Patent No.(s) _____ Additional numbers attached? ☐ Yes ☒ No		
5. Name and address of party to whom correspondence concerning document should be mailed: Louis A. Mok, Esq. LOEB & LOEB LLP 10100 Santa Monica Blvd., 22nd Floor Los Angeles, CA 90067-4164	6. Total number of applications and patents involved: [1] 7. Total fee (37 CFR 3.41) \$ <u>40.00</u> ☒ Enclosed ☐ Authorized to be charged to deposit account 8. Deposit account number: 12-1830 (Attach duplicate copy of this page if paying by deposit account)	
DO NOT USE THIS SPACE		
9. Statement and signature. To the best of my knowledge and belief the foregoing is true and correct and any attached copy is a true copy of the original document.  Louis A. Mok, Reg. No. 22,585 Date: December 7, 1999		
OMB No. 0581-0011 (exp. 4/94)		
Mail documents to be recorded with required cover sheet information to: Assistant Commissioner for Patents Box Assignments Washington, D.C. 20231		

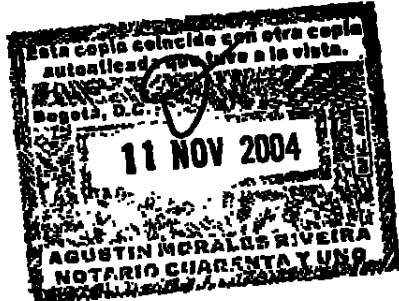
ASSIGNMENT

(1-8) Insert Name(s) of Inventor(s) (1) Andrew J. TOTI (6)
(2) Michael H. WONG (6)
(3) Jay KOTIN (7)
(4) (8)
In consideration of the sum of one dollar (\$1.00) and other good and valuable considerations paid to each of the undersigned, the undersigned agree(s) to assign, and hereby does assign, transfer and set over to
(9) Insert name of Assignee (9) Marilyn Associates, Inc.
(10) Insert state of Incorporation of Assignee (10) California
(11) Insert address of Assignee (11) of 16932 Gothard Street Unit #C, Huntington Beach, CA 92647 (hereinafter designated as the Assignee) the entire worldwide right, title and interest in the invention known as
(12) Insert identification of invention, such as Title, Case Number or Foreign Application Number (12) ENDOTRACHEAL TUBE WITH TIP DIRECTIONAL CONTROL AND POSITION PRESERVING MECHANISM, 08A405,760 for which the undersigned has (have) executed an application for patent in the United States of America and all patent applications in foreign countries corresponding thereto or based thereon.
(13) Insert Date of Signing of Application (13) on

1) The undersigned agree(s) to execute all papers necessary in connection with any original, renewal, divisional and continuing United States and foreign applications for the above-identified invention and also to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.
2) The undersigned agree(s) to execute all papers necessary in connection with any interference which may be declared concerning this application or continuation or division thereof and to cooperate with the Assignee in every way possible in obtaining evidence and going forward with such interference.
3) The undersigned agree(s) to execute all papers and documents and perform any act which may be necessary in connection with claims or provisions of the International Convention for Protection of Industrial Property or similar agreements.
4) The undersigned agree(s) to perform all affirmative acts which may be necessary to obtain a grant of a valid United States patent to the Assignee.
5) The undersigned hereby authorize(s) and request(s) the Commissioner of Patents to issue any and all Letters Patents of the United States resulting from said application or any division or divisions or continuing applications thereof to the said Assignee, as Assignee of the entire interest, and hereby covenants that he has (they have) full right to convey the entire interest herein assigned, and that he has (they have) not executed any agreement in conflict herewith.
6) The undersigned hereby appoints STUART LUBITZ, Reg. No. 20,680; LOUIS A. MOK, Reg. No. 22,585; JOHN P. SCHERLACHER, Reg. No. 23, 009; HIDEO KODA, Reg. No. 27,729; WILLIAM H. WRIGHT, Reg. No. 30,312; DAVID L. LUBITZ, Reg. No. 34,228; WEI-NING YANG, Reg. No. 38,680; KARLTON BUTTS, Reg. No. 39,128; F. JASON FAR-HADIAN, Reg. 42,523 the power to insert on this assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

Date: X 11/17/99 Signature of Inventor X
Date: X 11/19/99 Signature of Inventor X
Date: X 11/24/99 Signature of Inventor X Andrew J. Toti
Date: _____ Signature of Inventor _____

1b
20019920001
GC224318.1
RECORDED: 12/06/1999
PATENT
REEL: 010465 FRAME: 0443



TRADUCCION DE DOCUMENTO EN INGLES

ESTADOS UNIDOS DE AMERICA

A TODOS A QUIENES LOS PRESENTES LLEGAREN

DEPARTAMENTO DE COMERCIO DE ESTADOS UNIDOS

Oficina de Patentes y Marcas de Estados Unidos

Octubre 22, 2004

POR LA PRESENTE CERTIFICAMOS QUE LA ANEXA ES COPIA

AUTENTICA DE LOS ARCHIVOS DE ESTA OFICINA DE UN DOCUMENTO

REGISTRADO EL 6 de Diciembre de 1999.

Por autoridad del

COMISIONADO DE PATENTES Y MARCAS

(FDO) Ilegible

E. Borrett

Funcionario de Certificación

(Sello)

Depto. de Comercio

Oficina de Marcas y Patentes

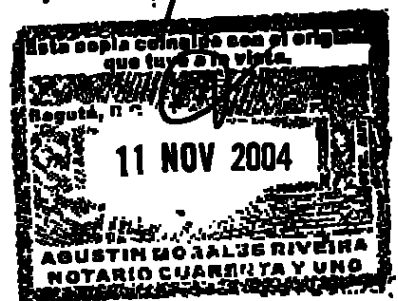
CARATULA DE FORMATO DE REGISTRO

UNICAMENTE PATENTES

Al Comisionado de Patentes y Marcas: Favor registrar los documentos
originales adjuntos o copias de los mismos.

1. Nombre de las partes cedentes:

Andrew J. Toti, Michael H. Wong y Jay Kotlin



Nombres adicionales de partes cedentes? Si () No (x)

2. Nombre y dirección de la parte receptora

Nombre: MERLYN ASSOCIATES, INC.

18932 Gothard Street Unit AC

Huntington Beach, CA 92647

Nombres y direcciones adicionales adjuntos? Si () No (x)

3. Naturaleza del Traspaso

(x) Cesión () Fusión

() Contrato Garantía () Cambio de nombre

(x) Otro DOCUMENTO DE CORRECCION de documento de cesión registrado
incorrectamente en riel/marco 010465/0442

Fecha otorgamiento: Enero 23, 2002

4. Solicitud #. O Patente #

Si este documento se está presentando junto con una solicitud nueva, la fecha
de firma de la solicitud es: _____

A. Solicitud de Patente No. 09/405.750

B. Patente No...

Números adicionales adjuntos? Si () No (x)

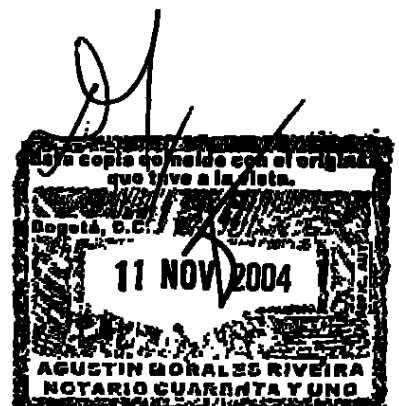
5. Nombre y dirección de la parte a quien debe dirigirse la correspondencia
relacionada con este documento:

Louis A. Mok, Esq.

LOEB & LOEB LLP

10100 Santa Monica Blvd. piso 22

Los Angeles, Estado: CA 90067-4164



6. Número total de solicitudes y patentes involucradas: 1

7. Derechos totales (37 CFR 3.41) \$40.00

(x) Adjunto

() Se autoriza cargar a la cuenta de depósito

8. Cuenta de depósito número - 12-1820

9. Declaración y firma -- De acuerdo con mi conocimiento y entendimiento, la anterior información es auténtica y correcta y cualquier copia adjunta a la misma es copia auténtica del documento original.

Louis A. Mok, Reg. 22,585 Firma: (fdo) ilegible Fecha: Diciembre 2, 1999

Envíe documentos para ser registrados con la información de la carátula a:

Comisionado Asistente de Patentes

Casilla de Cesiones

Washington, D. C., 20231

Archivo Apoderado No. 200199-2001

CESION

(Inserte nombre de inventores): (1) Andrew J. TOTI

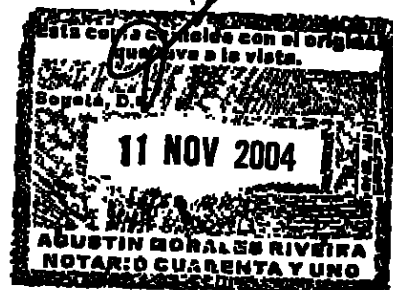
(2) Michal H. WONG

(3) Jay KOTIN

En consideración a la suma de un dólar (\$1.00) y otra compensación positiva y de valor pagada a cada uno de los suscritos, acordamos ceder y por medio del presente cedemos, traspasamos y enajenamos a:

Marlyn Associates, Inc.

California - 11 Bayleaf Lane, Irvine, CA



En adelante llamada la cesionaria, todos los derechos, títulos e intereses sobre la invención conocida como:

TUBO ENDOTRAQUEAL CON MECANISMO PRESERVATIVO DE CONTROL DE PUNTA DIRECCIONAL Y COLOCACION , 08/406,750

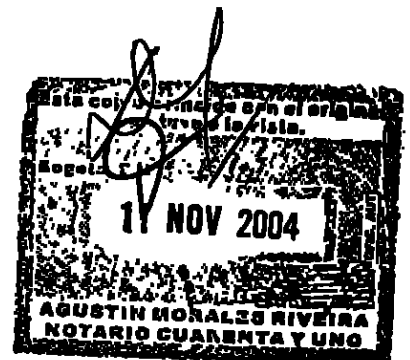
Para lo cual los suscritos hemos firmado una solicitud de patente en los Estados Unidos de América y todas las solicitudes en países extranjeros correspondientes a la misma y sobre la misma.

(1) Los suscritos nos obligamos a firmar todos los documentos necesarios relacionados con cualquier solicitud original, re-expedición, división y continuación para la invención antes mencionada y también a otorgar cesiones separadas en relación con tales solicitudes cuando el cesionario lo considere necesario o conveniente.

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(5) Los suscritos por medio del presente autorizamos y solicitamos al Comisionado de Patentes expedir toda Patente de los Estados Unidos que resulte de dicha solicitud o cualquier división o divisiones o solicitudes de continuación de la misma a dicho cesionario, como cesionario de todo interes, y por medio del presente manifestamos que tenemos pleno derecho a traspasar todo interes aquí cedido y que no hemos otorgado ningún otro contrato que esté en conflicto con el presente.

(6) Los suscritos por medio del presente nombramos a STUART LUBITZ, reg. No. 20.680, LOUIS A. MOCK Reg. 22,586; JOHN P. SCHERLACHER, reg. No. 23,009; HIDEO KODA, Reg. No. 27.729, WILLIAM H. WRIGHT, reg. No. 36.312; DAVID L. LUBITZ, Reg. No. 38.229; WEI-NING YANG Reg. No. 36.690; KARLTON BUTTS Reg. No. 39.126, F. JASON PAR-HADAN Reg. No. 42.523 el poder para insertar en esta cesión cualquier identificación posterior que pueda ser necesaria o deseable con el fin de cumplir las reglas de la Oficina de Patentes y Marcas de Estados Unidos para el registro de este documento.

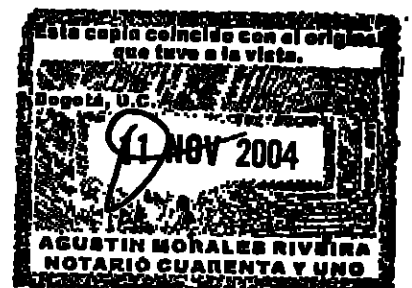
Fecha: 11/17/99 Firma del inventor (fdo) ilegible

Fecha: 11/19/99 Firma del inventor (FDO) ILEGIBLE

Fecha: 11/24/99 Firma del inventor (fdo) ilegible

ES TRADUCCION FIEL Y COMPLETA, a la cual me remito,

Bogotá, Noviembre 5, 2004.

PA 1218886



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

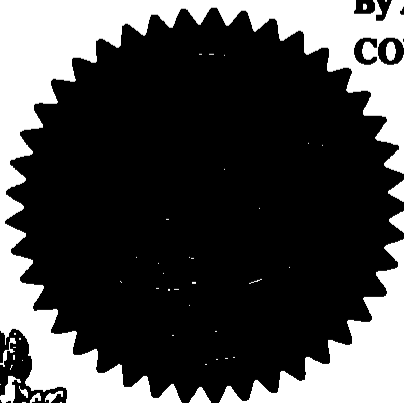
September 13, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 09/405,750

FILING DATE: September 27, 1999

**By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS**



**M. SIAS
Certifying Officer**

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U.S. PRO

FORM PTO-1082

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
Andrew J. TOTI, Michael H. WONG and Jay KOTIN
Serial No: (Not Assigned)
Filed: September 27, 1999
For: ENDOTRACHEAL TUBE WITH TIP DIRECTIONAL
CONTROL AND POSITION PRESERVING MECHANISM

3-854
09/406750
U.S. PRO

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

- Transmitted herewith for filing is the patent application identified above.
- ☒ 17 sheet(s) of drawings (☐ formal ☒ informal) is(are) enclosed.
 - ☒ 17 page(s) of specification and 1 page(s) of abstract of the invention are enclosed.
 - ☒ An unsigned assignment of the invention to Marlyn Associates, Inc. is enclosed; executed document will follow.
 - ☐ An associate power of attorney ☐ is enclosed ☐ will follow.
 - ☒ An unsigned verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed; executed document will follow.
 - ☒ An unsigned Declaration and Power of Attorney is enclosed; executed document will follow.
 - ☐ A certified copy of Patent Application No. filed from which priority is claimed under 35 U.S.C. § 119 is enclosed.
 - ☐ IDS enclosed (☐ with reference(s)).
 - ☒ Petition to Make Application Special with Declaration of Applicant In Support is enclosed.
 - ☒ Preliminary Amendment is enclosed.

CALCULATION OF FEES							
	ITEM	TOTAL NO. OF CLAIMS		NO. OF CLAIMS OVER BASE	LARGE \$ ENTITY FEE SM-02	\$ AMOUNT	\$ FEE
A	TOTAL CLAIMS FEE	27	-21	7	LG-010 SM-02	20	\$ 63
B	INDEPENDENT CLAIMS FEE*	2	-3	0	LG-076 SM-030	1	0
C	SUBTOTAL - ADDITIONAL CLAIMS FEE (ADD FINAL COLUMN IN LINES A + B)						63
D	MULTIPLE-DEPENDENT CLAIMS FEE				LARGE ENTITY FEE = \$280 SMALL ENTITY FEE = \$130		0
E	BASIC FEE				LARGE ENTITY FEE = \$780 SMALL ENTITY FEE = \$380		\$ 280
F	TOTAL FILING FEE (ADD TOTALS FOR LINES C, D, AND E)						\$ 443
G	ASSIGNMENT RECORDING FEE						\$ 40
	LIST INDEPENDENT CLAIMS 1, 20						\$ 40

- ☐ Please charge my Deposit Account No. 12-1820 the amount of \$. A copy of this letter is enclosed.
- ☐ A check in the amount of \$ to cover the filing fee is enclosed.
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 - ☐ Any filing fees under 37 C.F.R. 1.16 for presentation of extra claims

Respectfully submitted,
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Id
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I hereby declare that rights under contract of law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled ENDOTRACHEAL TUBE WITH TIP DIRECTIONAL CONTROL AND POSITION PRESERVING MECHANISM by inventor(s) Andrew J. TOTI, Michael H. WONG and Jay KOTIN described in:

- ☒ the specification filed herewith
- ☐ Application Serial No. ___, filed ___
- ☐ Patent No. ___, issued ___

If the right held by the above-identified small business concern is not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. 1.9(d) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

(d) Non-Profit Organization

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF CONCERN
ADDRESS OF CONCERN

TYPE OF ORGANIZATION

- ☐ University or Other Institution of Higher Education
- ☐ Tax Exempt Under Internal Revenue Service Code (26 U.S.C. 501(a) and 501(c)(3))
- ☐ Nonprofit Scientific or Educational Under Statute of State of the United States of America
Name of State _____
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- ☐ Would Qualify as Tax Exempt Under Internal Revenue Service Code (26 U.S.C. 501(a) and 501(c)(3)), if located in the United States of America
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Citation of Statute _____

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization, as defined in 37 C.F.R. 1.9(e), for purposes of paying reduced fees under Sections 41(a) and (b) of Title 35, United States Code, with regard to the invention entitled ___ by inventor(s) ___ described in:

- ☐ the specification filed herewith
- ☐ Application Serial No. ___, filed ___
- ☐ Patent No. ___, issued ___

If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. 1.9(d) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

II OWNERSHIP OF INVENTION BY DECLARANT

I hereby declare that rights under contract or law remain with and/or have been conveyed to the above-identified

- ☐ individual
(item (a) or (b) above)
- ☐ small business concern
(item (c) above)
- ☐ nonprofit organization
(item (d) above)

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EXCEPT, that if the rights held are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held (1) by any individual who could not be classified as an independent inventor under 37 C.F.R. 1.8(c) if that individual had made the invention, (2) any concern which would not qualify as a small business concern under 37 C.F.R. 1.8(d) or (3) a nonprofit organization under 37 C.F.R. 1.8(e).

- ☒ no such person, concern or organization
- ☐ the person, concern or organization listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)

FULL NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

III. ACKNOWLEDGMENT OF DUTY TO NOTIFY PTO OF STATUS CHANGE

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b)).

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

SIGNATURES

(complete only (e) or (f) below)

(NOTE: All inventors must sign the statement.)

Date: _____

Signature of Inventor

Date: _____

Signature of Inventor

Date: _____

Signature of Inventor

APPLICATION FOR
UNITED STATES PATENT
IN THE NAMES OF

**ANDREW J. TOTI
MICHAEL H. WONG
JAY KOTIN**

Assigned to

MERLYN ASSOCIATES INC.

for an

**ENDOTRACHEAL TUBE WITH TIP DIRECTIONAL
CONTROL AND POSITION PRESERVING MECHANISM**

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ENDOTRACHEAL TUBE WITH TIP DIRECTIONAL CONTROL AND POSITION PRESERVING MECHANISM

Background of the Invention

1. Field of the Invention

This invention generally relates to endotracheal tubes, and more particularly, to endotracheal tubes having a bendable portion designed to facilitate intubation of difficult airways (tracheal inlet opening) caused by anatomical variation, trauma and the like.

2. Description of Related Art

An endotracheal tube generally comprises a cylindrical tube used as an air passage to administer oxygen and anesthetic gases directly to the patient. The cylindrical tube terminates in an open distal end configured for insertion into the trachea and has an opposite open proximal end configured to be coupled to a gas source. The endotracheal tube typically has an inflatable cuff on the exterior of the cylindrical tube for forming a seal with the interior walls of the trachea. (See U.S. Patent No. 3,460,541 to Doherty). The cuff functions to occlude the trachea which protects the trachea and lungs against aspiration of foreign substances. In particular, food, foreign bodies or digestive system contents are prevented from entering the lungs. The endotracheal tube is used primarily in surgery, but is also frequently used in emergency rooms and emergency in-the-field situations.

In surgical procedures requiring general anesthesia, the patient is rendered unconscious by administration of anesthetic agents including drugs and/or gases. The patient is also given a muscle relaxant / paralyzing agent to minimize the patient's gagging response to the insertion of the endotracheal tube. A laryngoscope is placed in the mouth of the patient. The blade portion of the laryngoscope is used to push the tongue laterally and the intubating practitioner applies a lifting force to the laryngoscope handle in order to visualize the anatomical structures of the mouth and airway. A specific target area of the tracheal tube is the glottis, which is the opening between the vocal cords and the inlet to the trachea. The distal end of the endotracheal tube is inserted into the glottis and the inflatable cuff (balloon) is filled with air to create an airtight seal

between the cuff walls and the interior walls of the trachea. This airtight seal allows for delivery of the oxygen and anesthetic gases with positive pressure directly to the air passages below the tip and the balloon.

Patient anatomies differ greatly and fall into specific categories that are grouped according to potential difficulty of tube insertion. In a patient with an anterior glottis or target orifice (the vocal cords and opening positioned high in the patient's neck and to the front of the neck), placing the insertion end of the endotracheal tube through the opening can be extremely difficult, and can lead to serious injury and even death from lack of oxygen. Although careful evaluation by the anesthesiologist or healthcare practitioner may suggest difficulty, the condition is usually undetectable until the orifice and vocal cords are visualized with a laryngoscope and blade apparatus. When this occurs, the practitioner must remove the laryngoscope, and the insert a metal or plastic stylette (semi-rigid wire) into the lumen of the endotracheal tube, bend the tube and stylette into an appropriate configuration to aid in placing the insertion tip in its proper location and to act as a placement guide. A small bend, resembling the shape of a hockey stick, is made in the stylette and the end of the endotracheal tube, while the main body of the tube remains unchanged. Once this is accomplished, another attempt is made by the practitioner to visualize the vocal cords and inlet. The bent shape of the insertion tip improves the chances of passing the tip through the tracheal orifice. An example of early endotracheal tube including a stylette for curvature is described in U.S. Patent No. 2,458,305 to Sanders.

Although this method of using a stylette to bend the insertion end of the endotracheal is widely used, it has many shortcomings. The steps of bending the tube in the correct configuration, subsequent visualizing the path of insertion, and then removing the stylette from the lumen of the endotracheal tube wastes valuable time in completing the intubation procedure. Time is of the utmost importance in an unconscious patient who is not breathing, particularly where the patient may have a full stomach with an increased chance for aspiration of foreign substance.

Also, the use of a stylette is usually employed after an initial attempt has been made with the laryngoscope in place. Further, because of there intended use stylettes must be semi-rigid, capable of being easily bent and, once bent, and shape retaining. This inherent characteristic

places a patient at risk of an injury from the stylette to the airway with potential for bleeding in the airway as well. In the past, puncture of soft tissue and vocal cord damage has been attributed to the use of stylettes.

5 None of the prior devices have succeeded in the elimination of the use of a stylette to properly configure an endotracheal tube and successfully intubate a patient.

Many devices have been designed to assist in the placement of the tracheal tube in the target orifice. For example, laryngoscopes have been developed to aid in insertion. However, these devices do not provide any mechanism for controlling the curvature of the insertion end of the endotracheal tube itself.

10 U. S. Patent No. 4,589,410 to Miller, U. S. Patent No. 4,150,676 to Jackson and U.S. Patent No. 4,685,457 to Donenfeld each show an endotracheal tube with at least one pull cord in the wall along a portion of the length of the tube. Applying tension on the cord causes the tube at a position proximal to the balloon to curl, apparently due to the compressibility of the material of construction. However, the tip of the tube does not bend, the bending being distributed along the whole length of the pull cord. These devices do not employ a hinge or spring-type mechanism or altered tube wall, nor do they use a locking device. As a result, these prior devices do not allow selected movement at the tip of the tube. In these prior devices, the body of the tube is moved by a pulley mechanism which bends a considerable portion of the tube, thus creating problems due movement of the tube within the mouth.

20 Other devices employing tube bending mechanism include U.S. Patent No. 5,255,668 to Umeda is directed to a bendable endoscope used for bronchoscopy which includes a bendable distal portion spaced between two coils in the wall of the tube, the bendable portion is caused to bend by pulling on a wire in the wall of the tube. U.S. Patent No. 4,911,148 to Sosnowski et al. is directed to small diameter (diameter of 0.15 mm or less) endoscopes which have a series of radial notches spaced along the length of the tube and a pull wire through the notched wall. 25 Pulling on the wire causes the tube to bend along the portion containing the notches, which in turn causes the tip to deflect. U.S. Patent No. 5,304,131 to Paskar shows an arterial or venous catheter with an area of weakness along one side of the catheter. The weakness is the result of gaps cut through the wall of the catheter. Bending of the weakened portion is provided by a wire

running through the wall on the side of the gaps. To aid in returning the weakened portion to its original straight orientation that portion may be surrounded by a spring and, to seal the weakened portion, a jacket can cover the spring and the weakened portion.

U.S. Patent No. 4,353,358 to Emerson is directed to a flexible sigmoidoscope which has notches and a pull wire similar to Sosnowski et al. Other flexible tipped endoscopes and catheters with hinged portions and a pull wire are also shown in U.S. Patent No. 5,772,578 to Heimberger, et al. and U.S. Patent No. 5,448,989 to Hecke. U.S. Patent No. 5,306,245 to Heaven shows a bendable tubular device which includes a cutaway wall opposite a flexible stainless steel hinge with a pull wire in the tube wall opposite to the hinge. At least the cut-out portion is covered by an outer plastic material. This plastic cover may also cover the pull wire, as well as the full length of the tube. A balloon may be added distal to the bendable portion. These devices do not include an occlusion balloon such as is required on an endotracheal tube. While Heaven includes a balloon, it is distal to the bendable portion and used for cholangiographic purposes and is not intended to seal a trachea.

None of these devices in the preceding two paragraphs are intended to operate in the manner of an endotracheal tube. They do not incorporate features of the invention, such that a portion of the tube near the insertion tip articulates, while the main portion of the tube remains in its original preset shape.

While there have been various changes, improvements and developments in endotracheal tubes, there still remains a need for a device that can bend only at the tip and has a mechanism to temporarily lock the position in place. Such an endotracheal tube would facilitate one-handed manipulation of the tube while the other hand is free to manipulate other devices, such as a laryngoscope. Also, this should be accomplished without having to compromise the lumen of the tube.

SUMMARY OF THE INVENTION

The endotracheal tube of the present invention has a distal end configured to be inserted into a human trachea that can be manipulated, without the use of a stylette or other guiding device, while the tip of the tube is approaching the glottis. The main tube body remains in its original configuration, while allowing the distal end to be independently curved or bent and

maintained in a desired position during placement of the endotracheal tube. The lumen of the endotracheal tube remains unoccluded during the curving of the distal tip so as not to block the patient's airways. Creating the desired distal tip curvature is accomplished by the use of various designs, all contemplated as within the scope of the invention, in combination with one or more mechanisms for manipulating the distal end of the tube. In accordance with one specific, exemplary embodiment of the invention, these include:

- 1) locating a spring between distal tip and main tube body;
- 2) using ultrasound, heat, solvent treatment or like methods, to modify the molecular structure or composition of the polymer forming the portion of the tube to be bent so as to increase flexibility of that portion;
- 3) using of a polymer baffle between the distal tip and main tube body;
- 4) surrounding the portion to be bent by a polymer spring; or
- 5) providing a thin, notched or cutout area between distal tip and main body tube with or without the support spring.

All of the above mechanisms may be applied to the outside of the endotracheal tube, incorporated in the wall of the tube, or inserted within the lumen of the tube. The endotracheal tube of the present invention also contemplates a control mechanism for causing movement of the tip and temporary locking of the bend which is imposed on the distal end tube. This can be accomplished by the use of a friction lock mechanism, a single axis lock, a sliding trigger with catch, a detent system, or a similar locking device which cooperates with a pull wire. This locked position permits the practitioner to have at least one hand free to manipulate other devices. In its preferred operation, one hand holds the endotracheal tube while the laryngoscope is operated with the other hand. After the curved end of the tube is inserted in its desired position, the trigger mechanism can be easily released and the tube allowed to assume its original configuration. An endotracheal tube incorporating features of the invention preferably does not have an occluded tube lumen, allows the practitioner to have superior tip control, and allows rapid achievement of airway control.

DESCRIPTION OF THE FIGURES

Further features and benefits of the invention will become apparent from the Detailed Description below, when read in conjunction with the accompanying drawings, in which:

FIGURE 1 is a partial cutaway view of an endotracheal tube incorporating features of the invention;

FIGURE 1a is an enlarged cutaway view of the balloon shown in Figure 1;

FIGURE 2 is a partial cutaway view of the endotracheal tube of Figure 1 with the tip bending function activated;

FIGURE 3 is an enlarged, partial cutaway view of the distal portion of the endotracheal tube of Figure 2 showing the bent portion of the device;

FIGURE 4 is an enlarged, partial cutaway view of the endotracheal tube of Figure 2 showing the control portion of the device in the tip retracted position;

FIGURE 5 is an end view taken along line 5 - 5 of Figure 4 showing the proximal end of the endotracheal tube;

FIGURE 6 is an enlarged, partial cutaway view of the distal portion of a second embodiment of an endotracheal tube incorporating features of the invention showing the bendable portion of the device;

FIGURE 7 is an enlarged, partial cutaway view of the distal portion of the endotracheal tube of Figure 6 showing the bendable portion of the device in its bent configuration;

FIGURE 8 is an enlarged, partial cutaway view of the distal portion of a third embodiment of the endotracheal tube incorporating features of the invention showing the bendable portion of the device;

FIGURE 9 is an enlarged, partial cutaway view of the distal portion of the endotracheal tube of Figure 8 showing the bendable portion of the device in its bent configuration;

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FIGURE 10 is an enlarged, partial cutaway view of a fourth embodiment of the distal portion of the endotracheal tube incorporating features of the invention showing the bendable portion of the device;

FIGURE 11 is a cross sectional view taken along line 11 - 11 of Figure 10;

5 FIGURE 12 is a side view of the proximal end of an endotracheal tube in accordance with a fifth embodiment of the invention;

FIGURE 13 is a top view of the proximal end of the endotracheal tube shown in Figure 12;

FIGURE 14 is a side view of the proximal end of an endotracheal tube in accordance with a sixth embodiment of the invention;

FIGURE 15 is a top view of the proximal end of the endotracheal tube shown in Figure 14;

FIGURE 16 is a side view of an endotracheal tube in accordance with a seventh embodiment of the invention;

FIGURE 17 is a cross section view of the endotracheal tube of Figure 16 as seen along the line 17-17;

FIGURE 18 is a side of view of a portion of the endotracheal tube of Figure 16 showing certain details thereof;

FIGURES 19 and 19A comprise, respectively, a cross section view and a side view of a portion of an endotracheal tube in accordance with an eighth embodiment;

FIGURES 20 and 20A comprise, respectively, a cross section view and a side view of a portion of an endotracheal tube in accordance with a ninth embodiment;

FIGURES 21 and 22 are side views of the proximal end of an endotracheal tube in accordance with a tenth embodiment, showing the proximal end in its unbent and bent configurations, respectively;

FIGURES 23 and 24 are side views of the proximal end of an endotracheal tube in accordance with an eleventh embodiment of the invention, showing the proximal end in its unbent and bent configurations, respectively;

FIGURE 25 is a perspective view of a pair of flexible membranes used in the embodiment of Figures 23 and 24;

FIGURE 26 is a perspective view of the pair of membranes of Figure 25 shown in their nested or assembled configuration;

FIGURES 27 and 28 are enlarged side views of the proximal end of the endotracheal tube of Figures 23 and 24, respectively; and

FIGURES 29 and 30 are side views of the proximal end of an endotracheal tube in accordance with a twelfth embodiment of the invention, showing the proximal end in its unbent and bent configurations, respectively.

DETAILED DESCRIPTION OF THE INVENTION

A first embodiment of a tracheal tube 10, alternatively referred to as an endotracheal tube, incorporating features of the invention is shown in Figures 1 - 5. Tracheal tube 10, has a hollow tubular body 12 with an inflatable balloon 14, also referred to as a cuff, mounted on the external surface of tubular body 12 near the distal end 16 thereof. Connected to the space between tubular body 12 and cuff 14, or the inflatable portion of the cuff in a multi-walled balloon, is a conduit 18 which runs from the proximal end 20 of tubular body 12 to the distal end 16 of tubular body 12. Conduit 18 is used to inflate balloon 14 to a desired occluding diameter once tubular body 12 is placed in its desired location in the air passage of a patient. Conduit 18 is typically a small diameter tube 22 which runs through a passageway 24 within wall 26 of tubular body 12, or along the inner or outer surface of wall 26. Alternatively, passageway 24 in wall 26 can constitute conduit 18 with the small diameter tubular body 12 sealed into the proximal end of passageway 24. On the proximal end of the small diameter tube 22 is a valve 28, which acts to retain the inflation air in balloon 14 and, typically, a pilot balloon 30 which inflates when cuff 14 meets resistance from the trachea to further inflation. While the drawings show a cuff 14 with a diameter greater than the outer diameter of tubular body 12, the Figures all

show cuff 14 and pilot balloon 30 in a deflated configuration, the cuff and balloon being further enlarged when inflated.

On proximal end 20 of tubular body 12 is an adapter 32 for connecting tracheal tube 10 to a source of air, oxygen, or gaseous anesthetic mixture, such as a respirator or wall mounted air supply (not shown). Distal end 16 of tubular body 12 is open to allow gas fed into the tube to flow without obstruction into the patient's air ways. In Figure 1, distal end 16 shows an alternative tip design comprising two side openings and a protected tip end so that a smooth leading surface is presented to the tissue of the air passage to minimize trauma to the tissue during placement of the tracheal tube 10.

Tracheal tube 10 includes a flexible portion 34 in the wall of tubular body 12 covered by cuff 14, a cable 36 extending from proximal end 20 to distal end 16 of tubular body 12, and a control mechanism 38 attached to proximal end of the cable 36. In a first embodiment, flexible portion 34 is created by removing some or all of wall 26 in the area under cuff 14. If a portion of the wall is retained, retained portion 40 is along the side of tubular body 12 opposite where cable 36 is located as shown in the embodiment of Figures 6 - 7. Retained portion 40 bends acting as a hinge. In the first embodiment, to provide support and integrity for flexible portion 34 and to bring the bent tube back to its initial shape once the deforming force is released, a coil spring 42 is located within flexible portion 34 of tubular body 12.

Where a portion of tube wall 26 is removed, a self-contained cuff 14, such as shown in Figure 1A, is provided so that the air space within the cuff is completely isolated from the gas stream flowing through the tracheal tube 10. The self-contained cuff 14 then has an outer membrane 70 which is expanded against the trachea and an inner membrane 72 facing the open area in the tube wall. The end portions 74 are provided to seal cuff 14 to the outside surface of tubular body 12. Conduit 18 is used to inflate balloon 14.

Cable 36 is threaded through a hole 44 in wall 26 of tubular body 12 near proximal end 20 of tubular body 12, as best shown in Figure 4. Cable 36 may run through the lumen of tubular body 12 or through a second passageway 46 in the wall of tubular body 12 to the vicinity of cuff 14 where it exits through wall 26 into space 48 enclosed by cuff 14. The distal end 50 of cable 36 is then attached to wall 26 of the tubular body 12 at a point 52 more distal from the exit point,

but still within the space 48. Attachment may be by adhesives, clips, rings or other attachment devices or techniques known to those skilled in the art. Cable 36 may be formed from various materials. For example, it may be a thin wire, such as piano wire or surgical stainless wire, a plastic filament such as nylon monofilament, multifilament braided structures or sutures, or any other variety of materials typically used as sutures or tensioning cords.

Mounted on proximal end 20 of tubular body 12 is a handle or trigger 54 movable longitudinally within a slide channel 56 (Figs. 4 and 5). The proximal end of cable 36 is attached to trigger 54 so that when an operator retracts the trigger 54 in the direction indicated by the arrow in Fig. 1, the pulling force is transmitted to distal point 52 of cable attachment, causing tubular body 12 to bend in the area covered by cuff 14 and spring 42 to flex as shown in Figures 2 and 3. When the trigger is released, spring 42 causes tubular body 12 to return to the unbent configuration as shown in Figure 1. The trigger 54 and slide channel 56 may be so dimensioned that sufficient friction exists between these elements to retain the trigger 54 in its retracted position.

Figures 6 and 7 show a modification of the first embodiment where a stretchable but substantially non-expandable membrane 58 covers flexible portion 34 to separate cable 36 and lumen of tubular body 12 from spring 42 and to prevent gas flowing through tubular body 12 from creating an expanding or pulsatile force on cuff 14. In this instance, the membrane 58 acts as the inner membrane 72 of cuff 14 in Figure 1A and the cable passes through cuff 14 rather than between balloon inner membrane 72 and spring 42. Otherwise, the modification of Figures 6 and 7 functions in the same manner as the first embodiment.

Figures 8 and 9 show a further embodiment where flexible portion 34 is created by providing one or more notches 60 in wall 26 with bottom 62 of the notch 60 functioning as a hinge. While this embodiment does not show the use of the spring 42, a spring can be used within that portion of the tube for the same purposes as set forth above. A membrane 58 is shown covering the notch 60 and forming the inner membrane 72 of cuff 14.

Figure 10 shows a cutaway view and Figure 11 shows an end view of an alternative embodiment of the endotracheal tube of the present invention having a distal end with an inner membrane 58 covering the spring 42.

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Figures 12 and 13 show a fifth embodiment of the present invention including a mechanism 80 for retaining the handle or trigger 82 in its fully retracted position. The embodiment of Figures 12 and 13 includes a universal connector 84 received by the proximal end of the endotracheal tube 12. The handle or trigger is attached to a cable 86 and is movable within a longitudinally extending slide channel 88 to bend or flex the distal end 90 of the endotracheal tube 12 as already explained. Mounted on the proximal end 92 of the tube 12 is a pair of longitudinally extending, flexible retention members 94, 96 having opposed recesses 98, 100 for receiving and retaining the trigger 82 when the trigger is in its fully retracted position, as shown in Figures 12 and 13. This retention mechanism allows one-handed manipulation of the trigger as previously described.

Figures 14 and 15 show a sixth embodiment of the invention which includes an alternative retention mechanism for holding the cable trigger 82 in its fully retracted position. In this embodiment, a hook 110 rotatable about a vertical axis 112 is movable between a latched and unlatched position. In the latched position, shown in Figures 14 and 15, the trigger 82 is held by the hook 110 in its fully retracted position. The trigger is released when the hook 110 is rotated clockwise, as seen in Figure 15.

Figures 16-18 show a seventh embodiment of the invention which includes a curved, relatively rigid, sliding bar or flattened wire 120 to actuate the flexible distal tip 122. The bar or wire 120 is slidably disposed within a longitudinally extending groove or channel 124 formed in the wall of the tube 12, as best seen in Figures 17 and 18. A hook 126 on the proximal end of the bar or wire 120 is used to actuate the distal tip between its bent and unbent configurations.

Figures 19 and 19A show an eighth embodiment of the invention in which, instead of a single cable for bending the distal tip, a pair of cables 130, 132 disposed within passageways 134, 136 within the wall 138 of the endotracheal tube 12 are used to flex or bend the distal tip in either of two directions along a y-axis shown in Figure 19. An alternative to this arrangement, providing for even greater versatility, is shown in the ninth embodiment of the invention in Figures 20 and 20A. In this case, four cables 140, 142, 144 and 146, disposed within passageways 148, 150, 152 and 154 spaced at 90° intervals within the wall 156 of the endotracheal tube 12 can be used to flex the tip in either direction along an x-axis, a y-axis or

anywhere in between, thus providing the greatest degree of options so as to permit more precise control of the direction of the bending of the distal tip.

Figures 21 and 22 show a tenth embodiment of the invention in which flexibility of the distal tip of the endotracheal tube is provided by a bellows section 160 within the cuff 162. Such a flexible bellows section allows movement of the distal tip in any direction while preserving the airtight integrity of the tube without any additional covering. The embodiment of Figures 21 and 22 includes a small baffle chamber 164 disposed along the underside of the bellows section 160 of the distal tip of the endotracheal tube. Air or fluid forced into this chamber by way of a small diameter tube 166 causes expansion of the small baffle chamber 164 against a fixed projection 168 extending from the underside of the bellows section. Figure 22 shows the distal tip of this embodiment in its flexed or bent configuration upon the introduction of air or other fluid under pressure into the small baffle chamber 164.

Figure 23-28 show an eleventh embodiment of the present invention. In this embodiment, flexibility of the distal tip is provided by a V notch 170 formed in the underside of the distal end of the endotracheal tube 12. This V-shaped cutout or notch 170 is covered by a dual membrane, details of which are shown in Figures 25 and 26. A first flexible, inner membrane 172 including laterally oriented corrugations 174 is configured to nest within a similar, outer flexible membrane 176 also including laterally disposed corrugations 178. The corrugations allow expansion of the membranes. The membranes are bonded together along their edges 180, 182 so as to define an enclosed space 184 therebetween. Air or fluid under pressure is supplied to this space by means of a small diameter tube 186. Figures 27 and 28 show the distal tip of the endotracheal tube of this embodiment in its unflexed or unbent configuration and in its bent or flexed configuration when air or other fluid is forced into the space 184 between the inner and outer membranes.

Figures 29 and 39 show a twelfth embodiment of the invention comprising an endotracheal tube having a distal end including a cuff, as already described. A V-shaped cutout or notch 190 is formed in the distal end of the endotracheal tube 12 within the confines of the cuff. Inserted into the lower end of the V-shaped notch 190 is an expandable balloon 192 having a distal extremity 194 and a proximal extremity 196. The distal extremity 194 is sealed while the

proximal extremity receives the distal end of a small diameter tube 198. The distal end of the tube 198 is bonded or otherwise secured in fluid-tight fashion within the proximal end 196 of the balloon. Air or other fluid forced into the balloon causes expansion thereof and flexing or bending of the distal end of the endotracheal tube, as best seen in Figure 30.

5 Although the present invention has been described in considerable detail with reference to certain preferred versions and uses thereof, other versions and uses are contemplated by the invention. For example, it is not necessary to purposely provide a flexible portion to the wall nor is it necessary that the distal portion of the cable be placed between the cuff and the tube outer wall. The bending action can be obtained using a standard cuffed endotracheal tube with the
10 cable run through the lumen of the tube or in the wall of the tube. The cable then exits through the wall just proximal of the cuff and is attached to the wall just distal of the cuff (i.e., external to the cuff). Pulling on the cable in the manner described above causes the tube to bend in the region covered by the cuff.

15 Further, it is not necessary to limit the flexible portion 34 to the cuff area. Any portion of the tube can be caused to bend by providing a cable exiting through the tube wall before the desired bendable section and attaching the cable proximal thereto. Pulling on the cable bends the tube within that portion where the cable is external to the tube.

20 Other variations contemplated within the general scope of the device described above include other means of creating a flexible portion such as by providing the tubular body a corrugated tube wall or making the distal end portion of the tubular body of a material that is more flexible than the remainder of the tubular body.

25 It is believed that the operation and construction of the present invention will be apparent from the foregoing description and, while the invention shown and described herein has been characterized as particular embodiments, changes and modifications may be made therein without departing from the spirit and scope of the invention as defined in the following claims.

What is claimed is:

1. An apparatus for rapid intubation of the trachea, comprising:

a hollow tube having a distal end configured for insertion into the trachea and an opposite proximal end;

an inflatable cuff attached to the outer surface of the hollow tube between the distal end and the proximal end of the tube; and

a pulling mechanism for creating a temporary bend in a desired region proximate the distal end of tube, the pulling mechanism extending from the proximal end of the tube to the proximal end of the desired region,

whereby application of a pulling force to the proximal end of the pulling mechanism causes the tube to bend in the desired region.

2. The apparatus of claim 1, wherein the desired region is the portion of the tube covered by the cuff.

3. The apparatus of claim 2, wherein the cuff covers a portion of the tube having material removed therefrom, rendering that portion more flexible than the remainder of the tube.

4. The apparatus of claim 3, wherein the portion of the wall of the tube covered by the cuff is removed to create a hinged section.

5. The apparatus of claim 4, wherein the portion of the tube covered by the cuff has a coiled spring enclosed therein.

6. The apparatus of claim 3, wherein a coiled spring is located within that portion of the tube covered by the cuff and a circumferential portion of the wall of the tube surrounding the coiled spring is removed.

7. The apparatus of claim 1, wherein the desired region includes structure that renders that portion more flexible than other portions of the tube.
8. The apparatus of claim 7, wherein said structure is a corrugated tube surface.
9. The apparatus of claim 7, wherein the tube is formed from a polymeric material, the portion of the tube covered by the cuff being a polymer of different chemical properties having a greater flexibility than the remainder of the tube.
10. The apparatus of claim 7, wherein the tube is formed from a polymeric material, the portion of the tube covered by the cuff comprising a heat, ultrasound or UV radiation treated polymer of flexibility greater than the remainder of the tube.
11. The apparatus of claim 1, wherein the pulling mechanism comprises at least one cable.
12. The apparatus of claim 11, including a plurality of cables for bending the desired region in at least two directions along at least one axis.
13. The apparatus of claim 1 in which the pulling mechanism comprises a relatively stiff, longitudinally extending member.
14. The apparatus of claim 13 in which the longitudinally extending member is disposed within a longitudinally extending channel formed in the outer wall of the tube.
15. The apparatus of claim 11, wherein the pulling mechanism includes a finger actuated trigger mounted to the proximal end of the tube, said finger actuated trigger being moveable proximally to place tension on the at least one cable causing the tube to bend in the desired region of the tube.
16. The apparatus of claim 15, further including a latch for temporarily maintaining the tension on the at least one cable until purposely released by an operator.

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17. The apparatus of claim 11, wherein the at least one cable extends through an elongated space within the wall of the tube.

18. The apparatus of claim 11, wherein the at least one cable extends through the lumen of the tube.

19. The apparatus of claim 11, wherein the at least one cable is formed from a material selected from the group consisting of stainless steel wire, plastic filament and braided filament material.

20. An apparatus for rapid intubation of the trachea, comprising:

a hollow tube having a distal end configured for insertion into the trachea and an opposite proximal end;

an inflatable cuff attached to the outer surface of the hollow tube between the distal end and the proximal end of the tube; and

an expandable chamber for creating a temporary bend in a desired region proximate the distal end of tube, the expandable chamber being adapted to receive fluid under pressure;

whereby introduction of fluid under pressure into the expandable chamber causes the tube to bend in the desired region.

21. The apparatus of claim 20, wherein the desired region is the portion of the tube covered by the cuff.

22. The apparatus of claim 21, wherein the cuff covers a portion of the tube having material removed therefrom, rendering that portion more flexible than the remainder of the tube.

23. The apparatus of claim 22, wherein the portion of the wall of the tube covered by the cuff is removed to create a hinged section.

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24. The apparatus of claim 20, wherein the desired region includes structure that renders that portion more flexible than other portions of the tube.

25. The apparatus of claim 24, wherein said structure is a bellows section along the tube surface.

26. The apparatus of claim 24, wherein the tube is formed from a polymeric material, the portion of the tube covered by the cuff being a polymer of different chemical properties having a greater flexibility than the remainder of the tube.

27. The apparatus of claim 24, wherein the tube is formed from a polymeric material, the portion of the tube covered by the cuff comprising a heat, ultrasound or UV radiation treated polymer of flexibility greater than the remainder of the tube.

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ABSTRACT

An endotracheal tube which facilitates rapid intubation of the trachea, especially in situations where anatomical variation creates difficult intubating conditions, includes a portion that can be bent during placement to control the position of the distal end of the tube. The distal end of the endotracheal tube may be selectively curled or bent by a mechanism or fluid passage accessible from the proximal end of the endotracheal tube. The endotracheal tube provides for manipulation of the insertion end without occluding the lumen of the tube, to facilitate placement of the tube.

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DECLARATION
and POWER OF ATTORNEY

☒ ORIGINAL
☐ CONTINUATION
☐ DIVISIONAL

As a below named inventor, I declare that the information given herein is true, that I believe that I am the original, first and sole inventor (if only one name is listed as 1 below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
ENDOTRACHEAL TUBE WITH TIP DIRECTIONAL CONTROL AND POSITION PRESERVING MECHANISM,
the specification of which is attached hereto unless the following box is checked:

☐ was filed on _____ as United States Application Number or PCT International Application Number _____
and was amended on _____.

My residence, post office address and citizenship are as stated below next to my name.

I acknowledge my duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations § 1.56(a).
I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.
I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING Month Day Year	PRIORITY CLAIMED UNDER 35 U.S.C. 119
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I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the last paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Serial No.) (Filing Date) (Status)

☒ **POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or Agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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4	Name of Inventor	Residence: CITY	STATE or COUNTRY
	Post Office Address		CITIZENSHIP

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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DATE	DATE
SIGNATURE OF INVENTOR 3	SIGNATURE OF INVENTOR 4
DATE	DATE

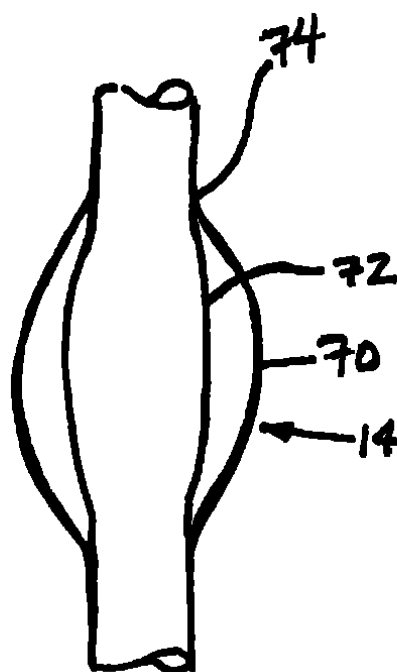
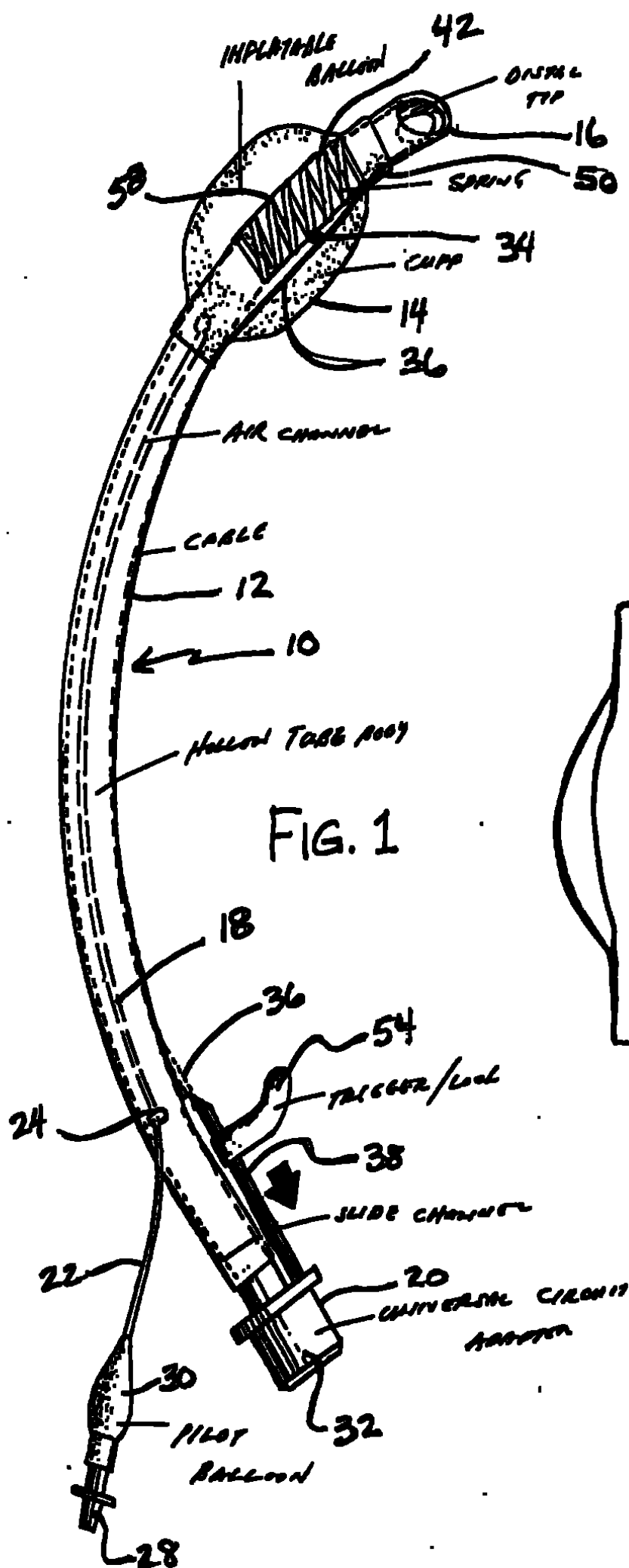
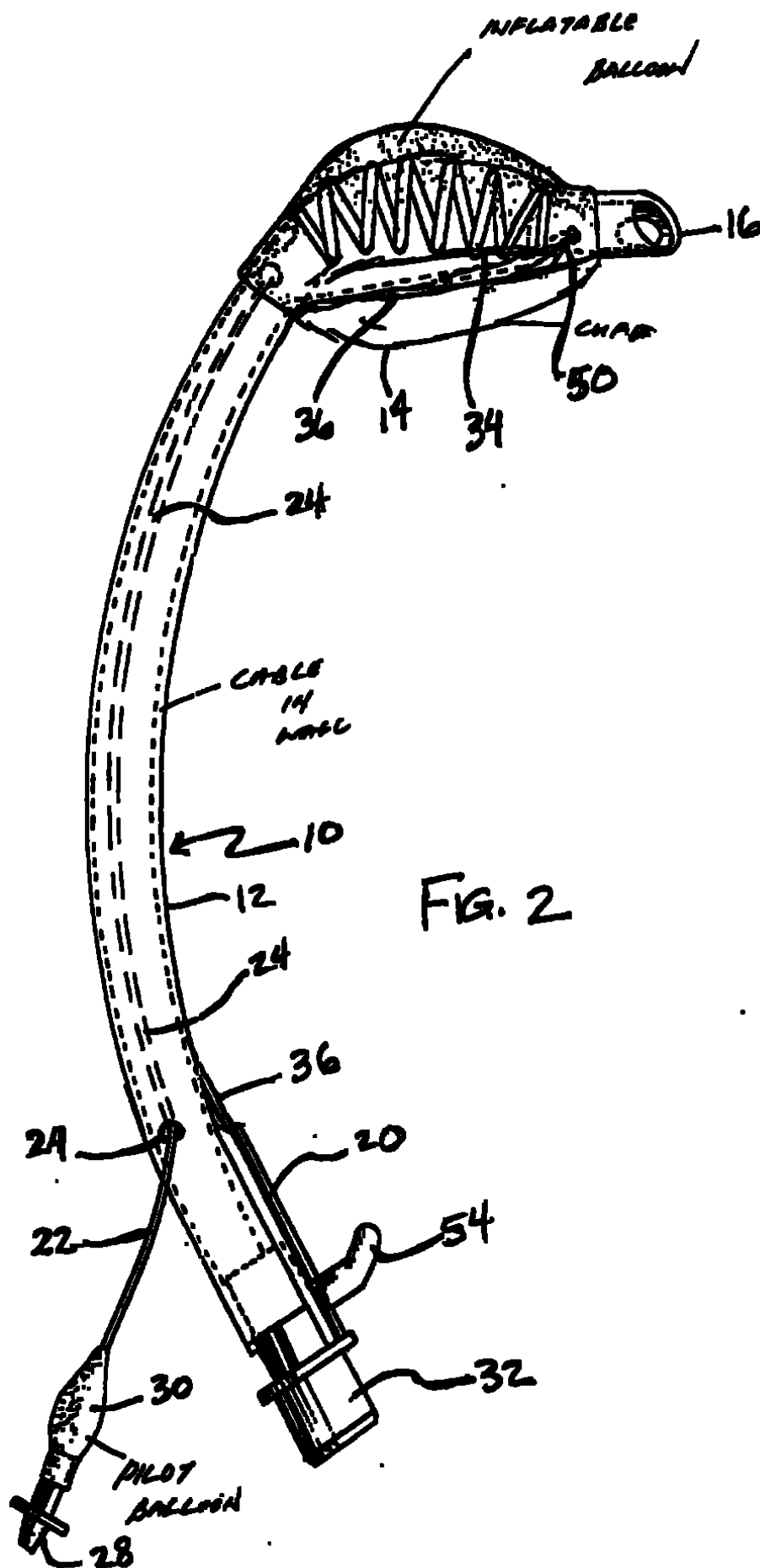


FIG. 1A



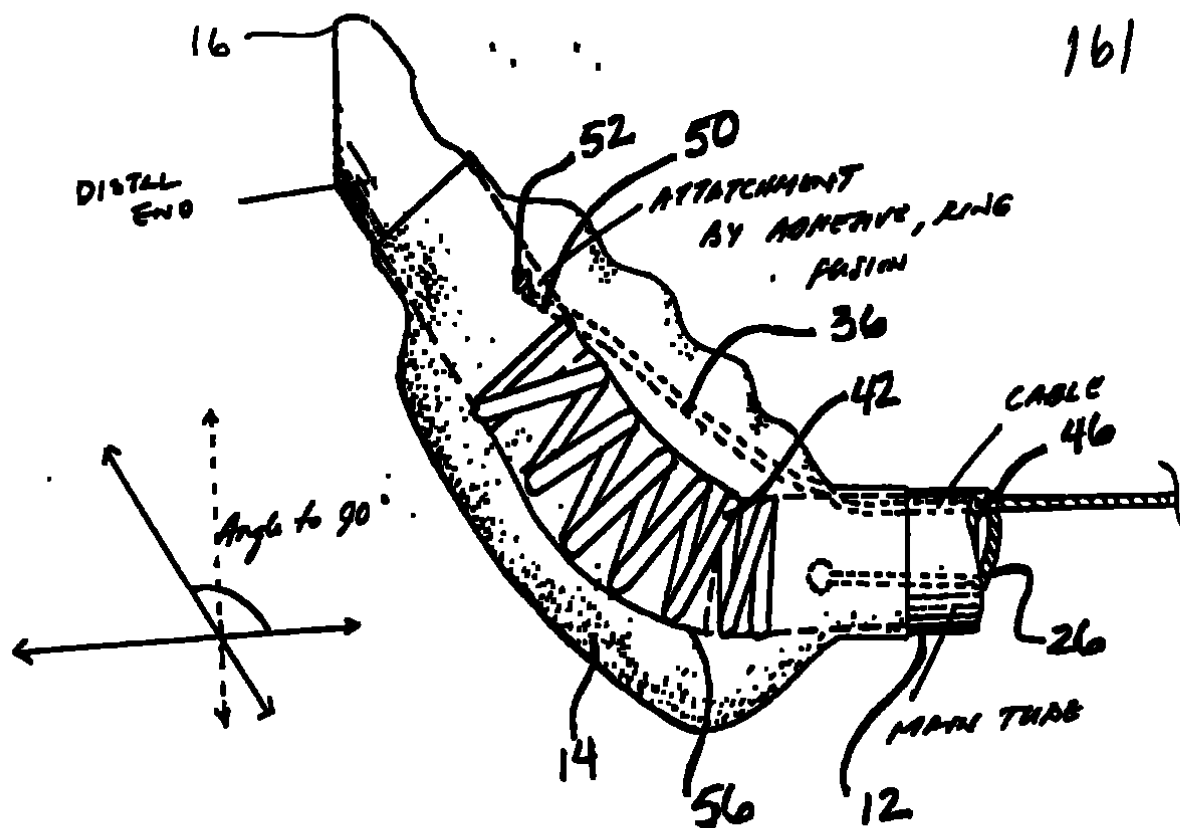


FIG. 3

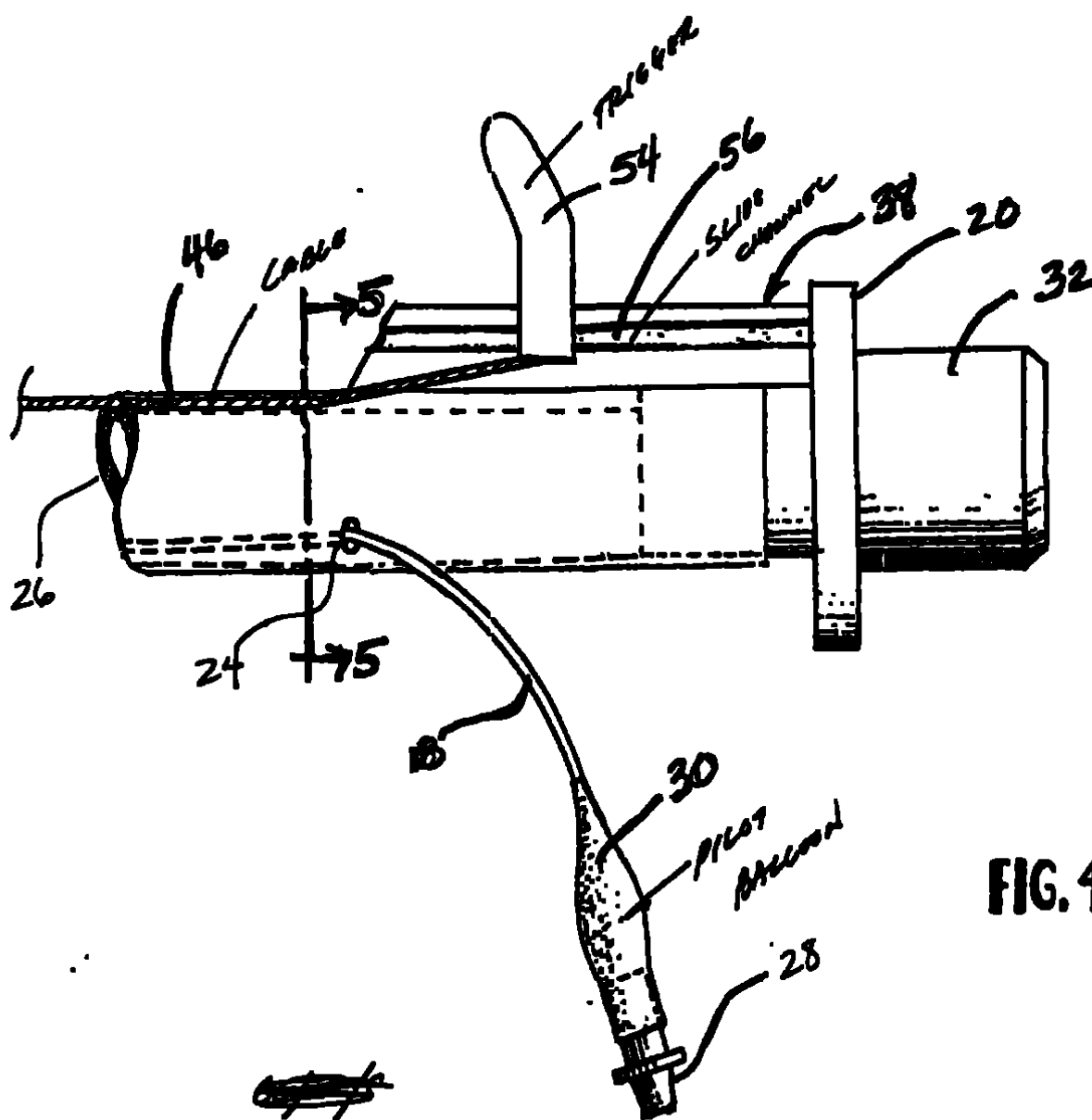
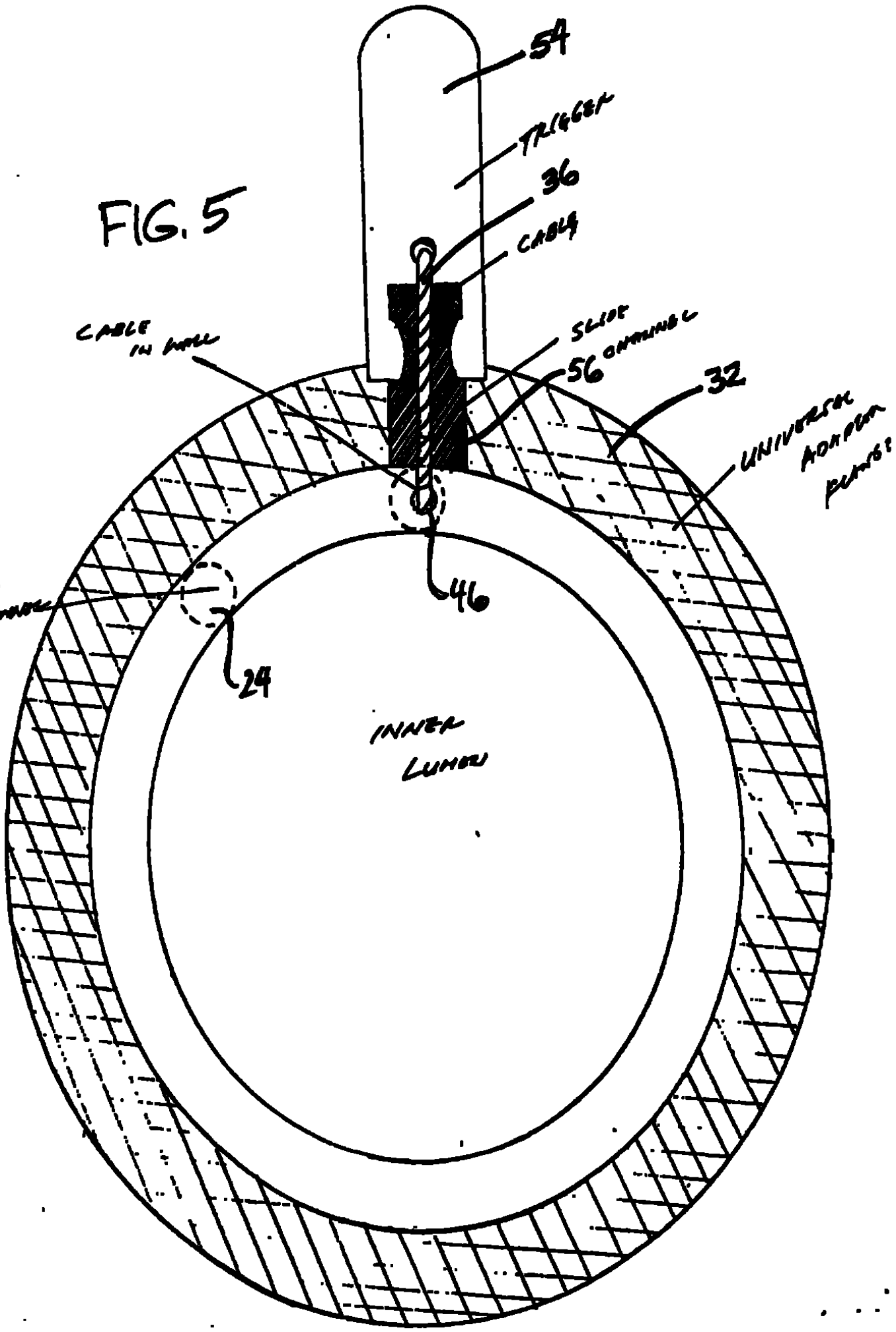


FIG. 4

— TOP —

FIG. 5



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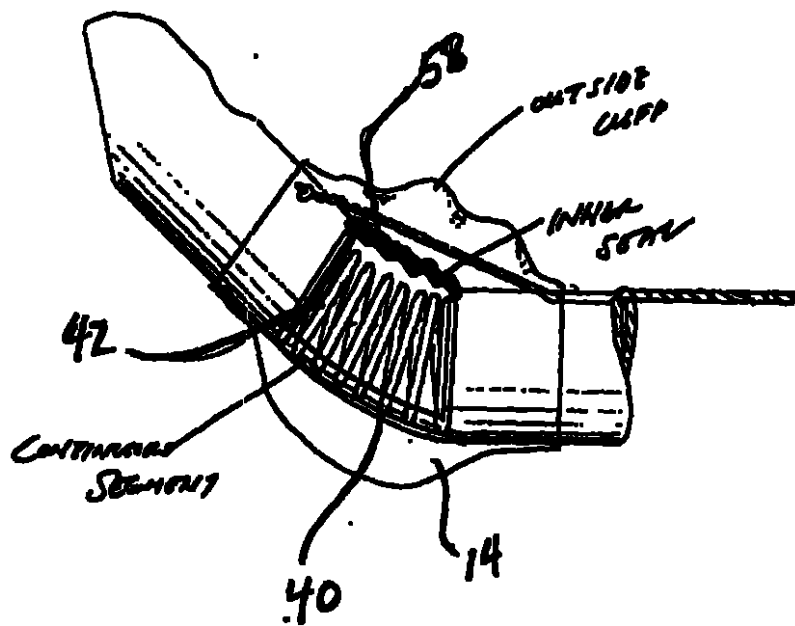
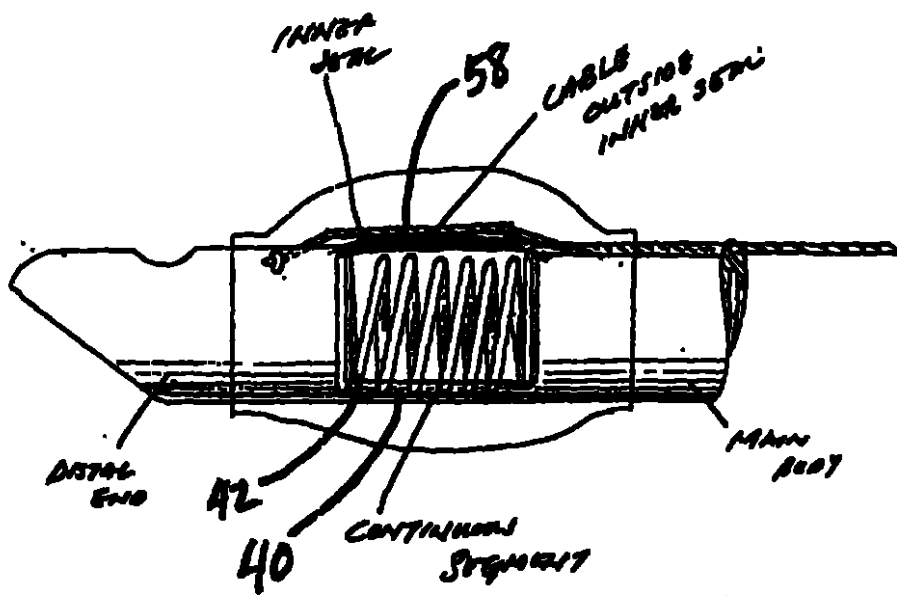


FIG. 8

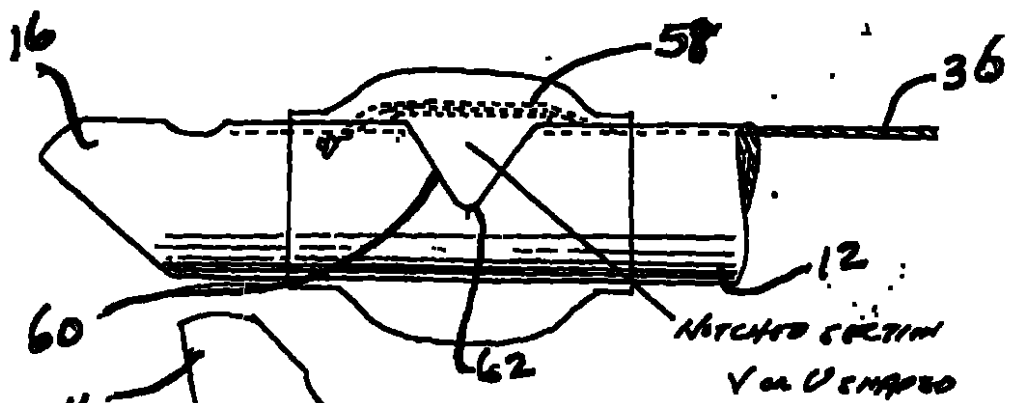
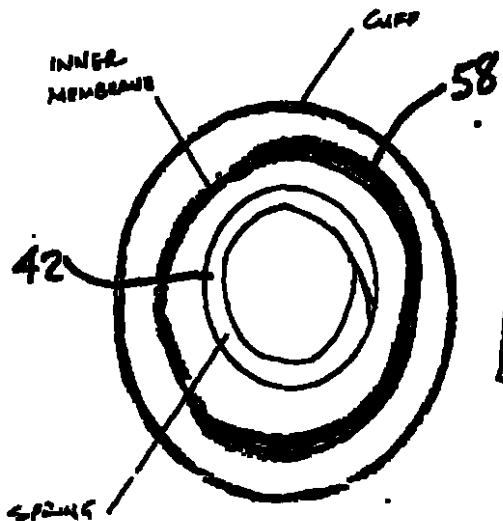
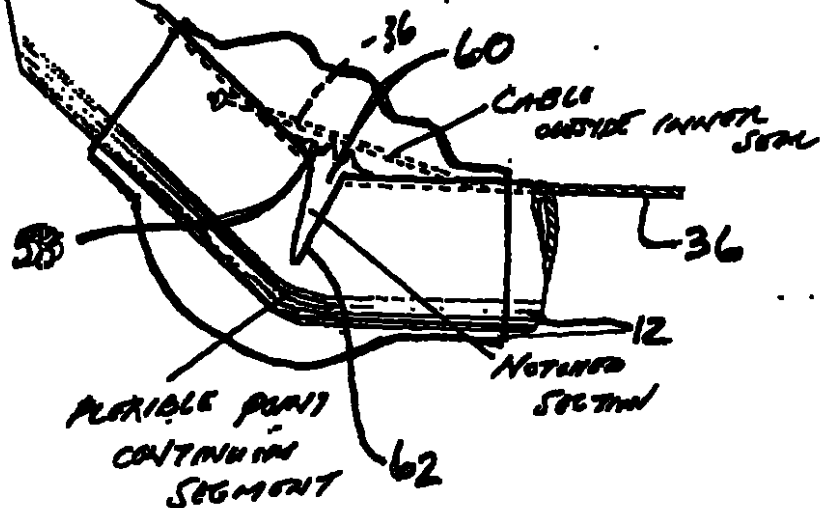
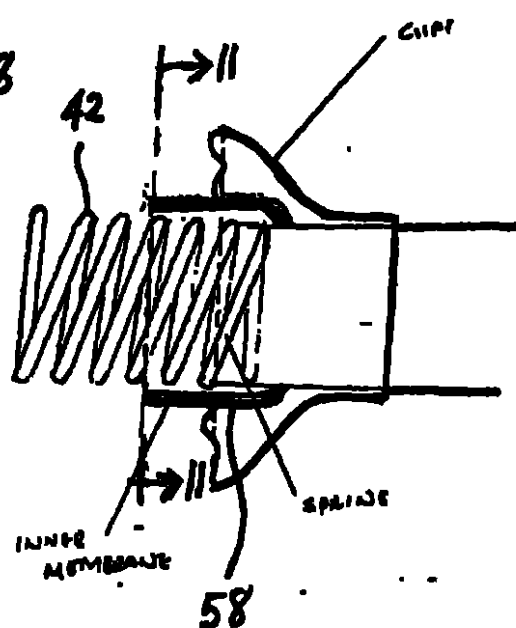


FIG. 9



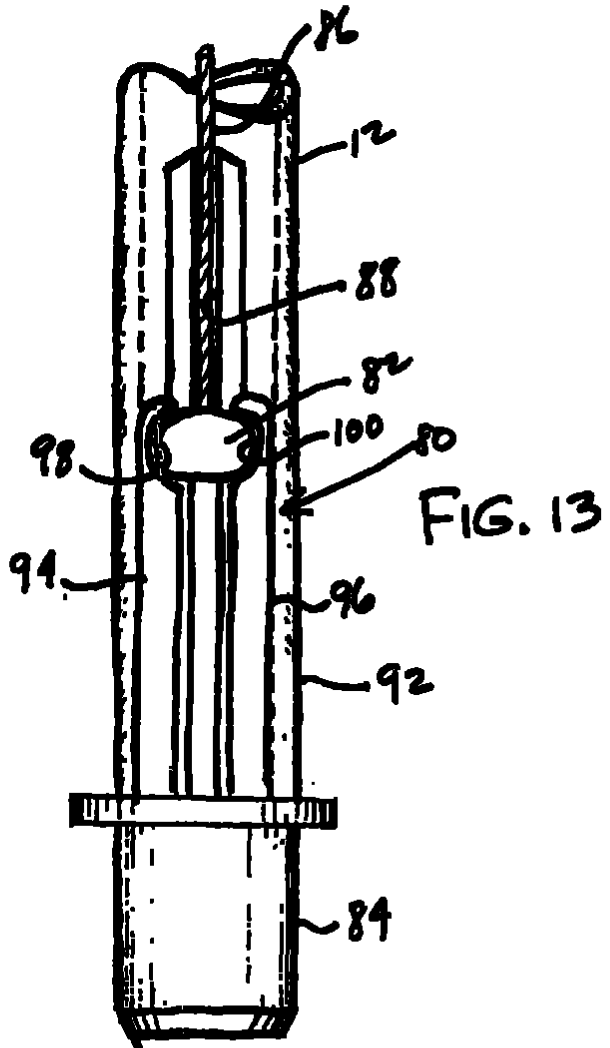
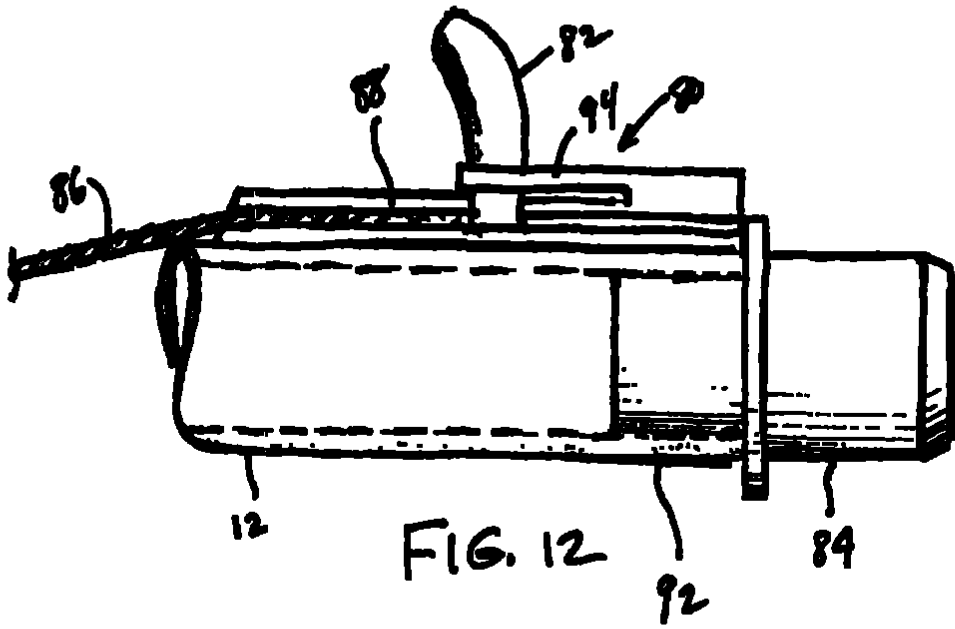
ON END VIEW

FIG. 11



SIDE VIEW

FIG. 10



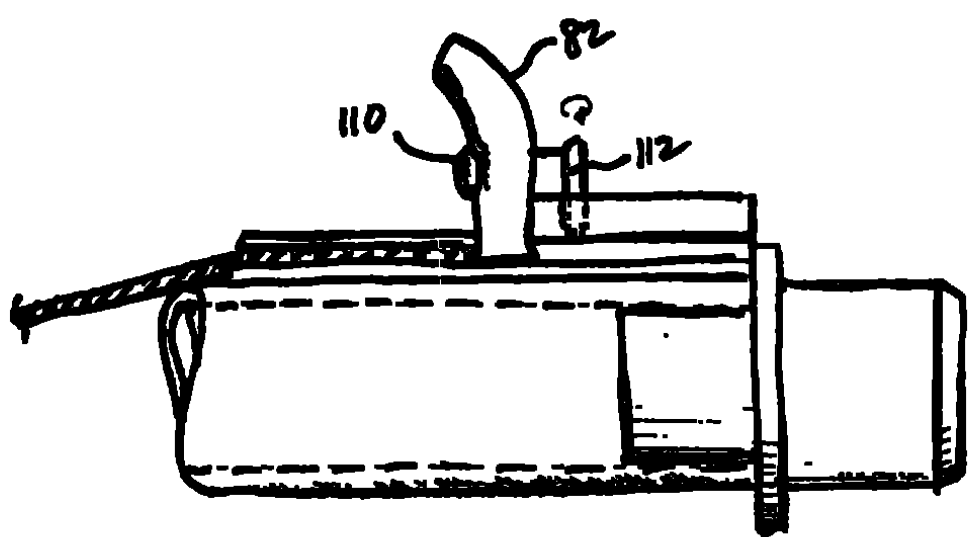


FIG. 14

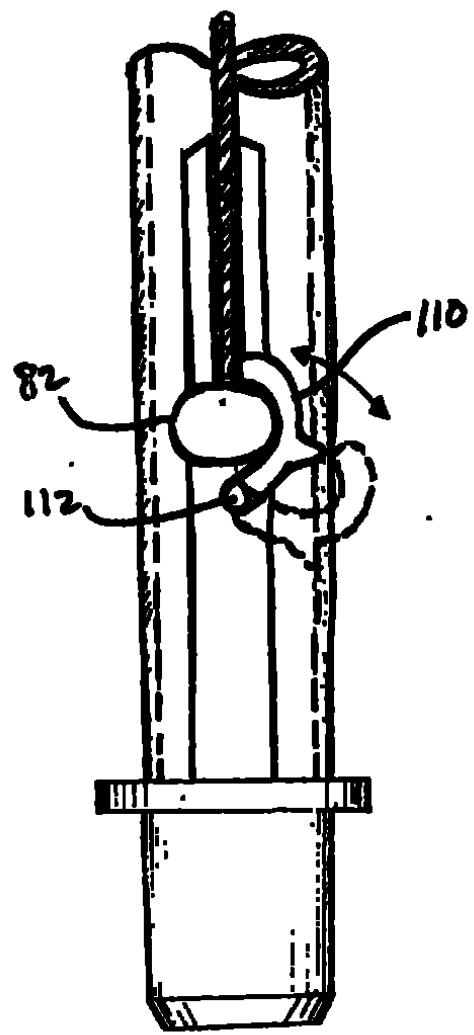


FIG. 15

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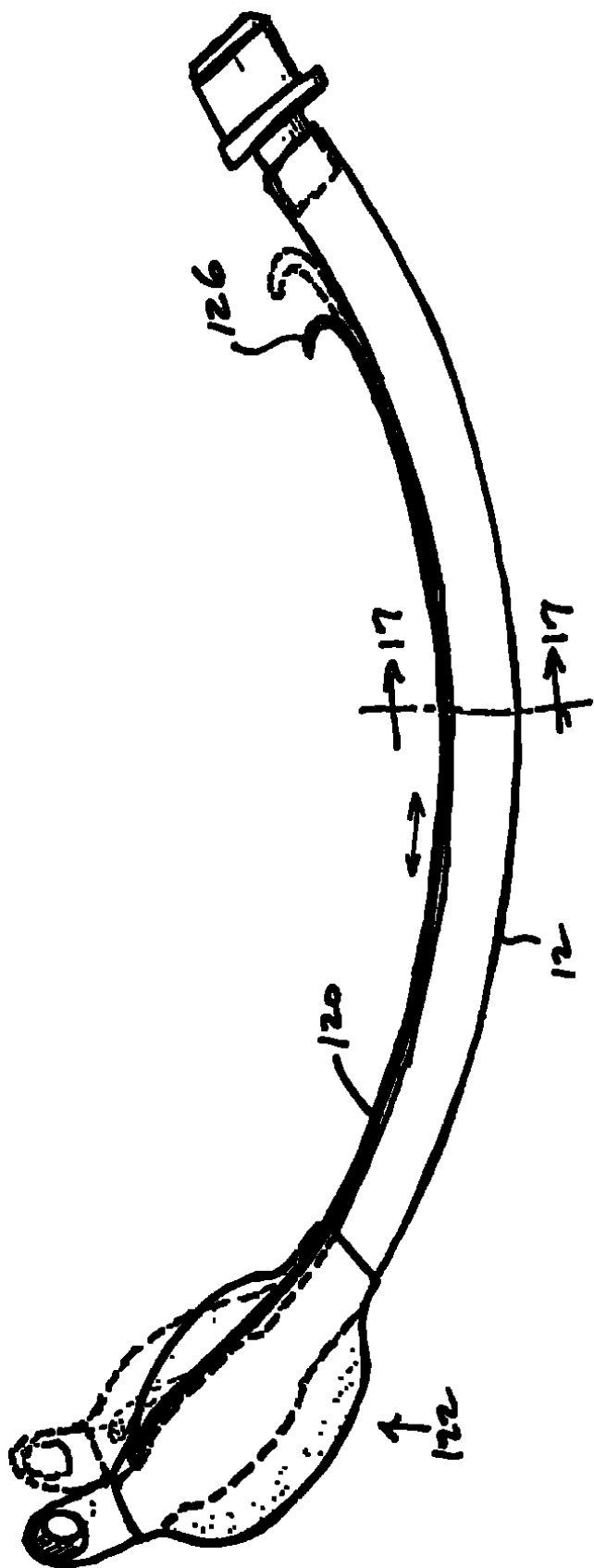


FIG. 16

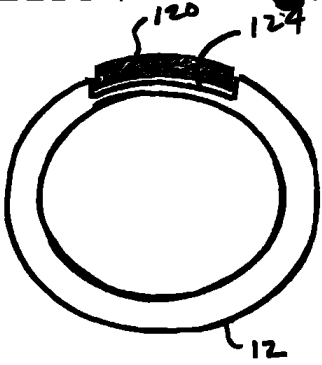


FIG. 17

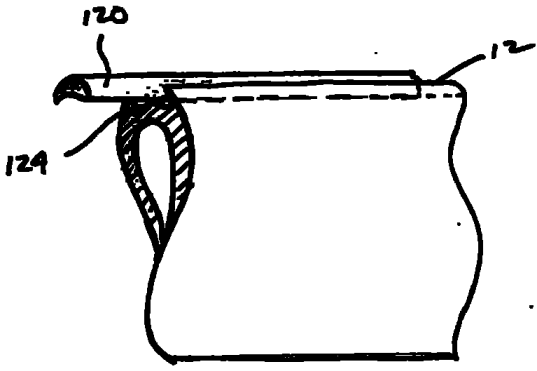
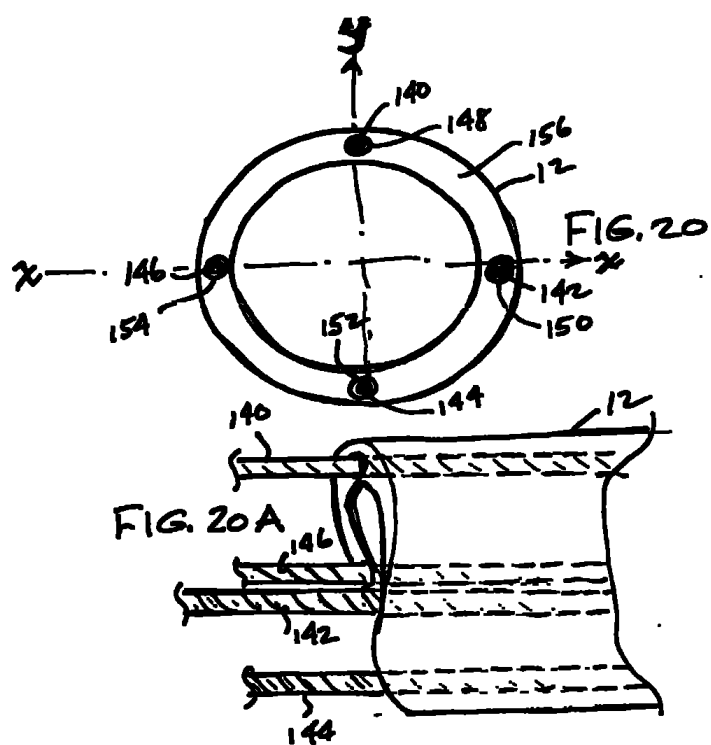
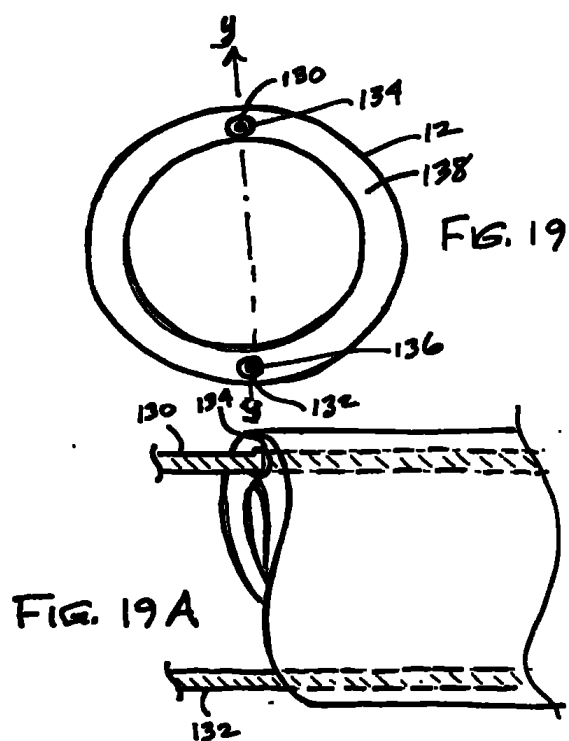
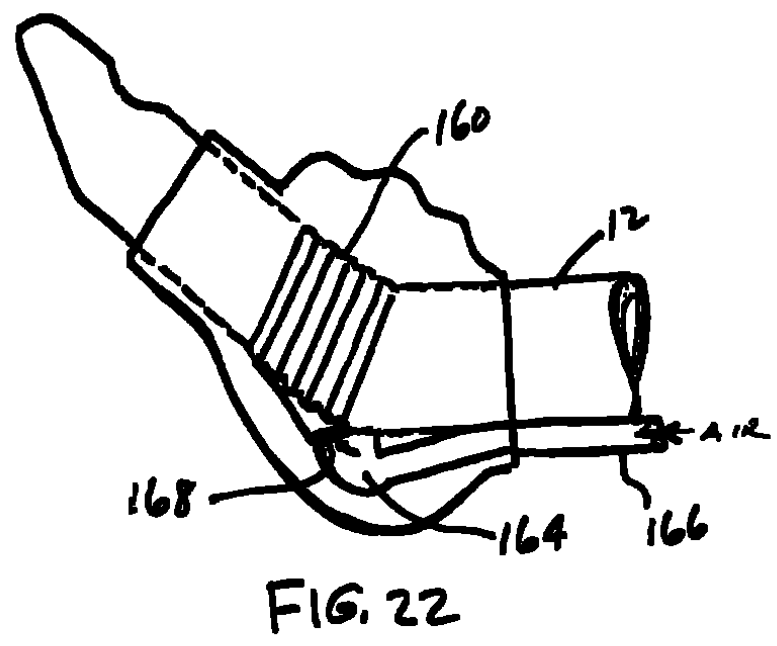
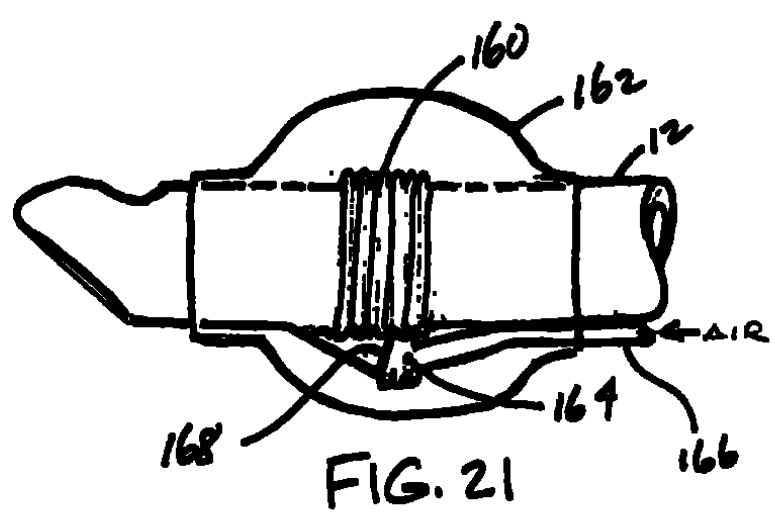


FIG. 18







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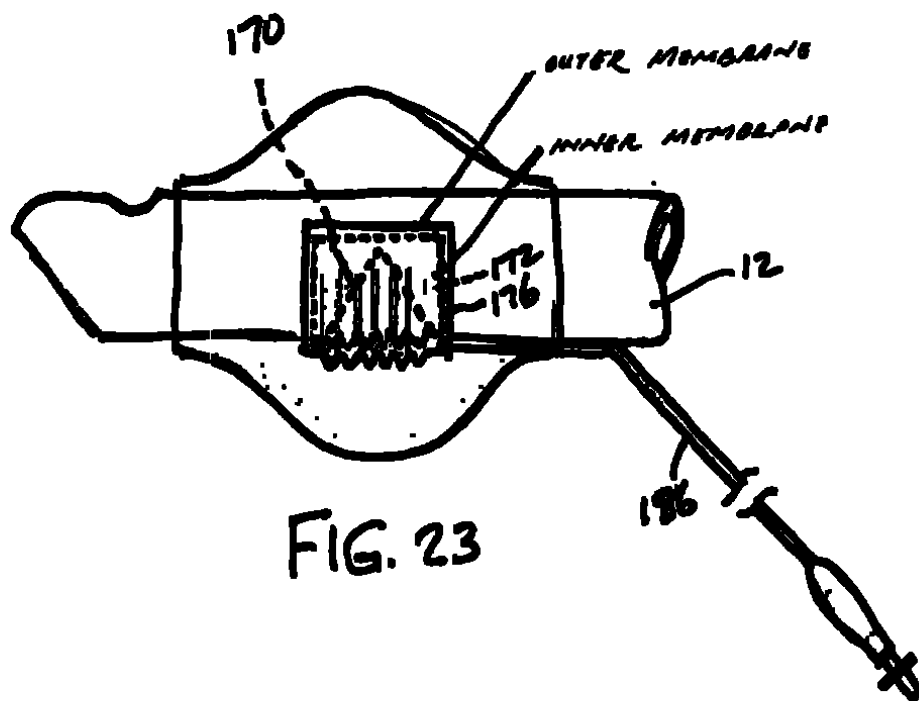


FIG. 23

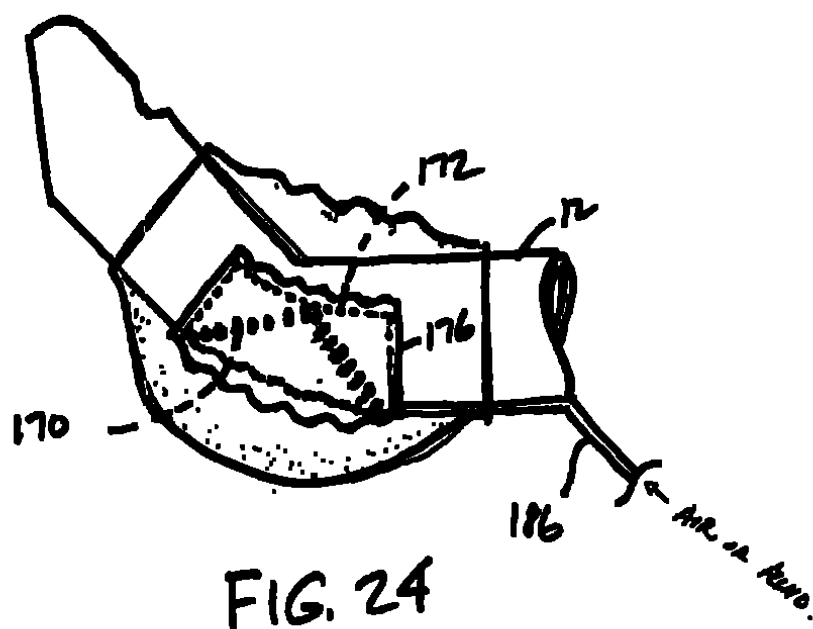
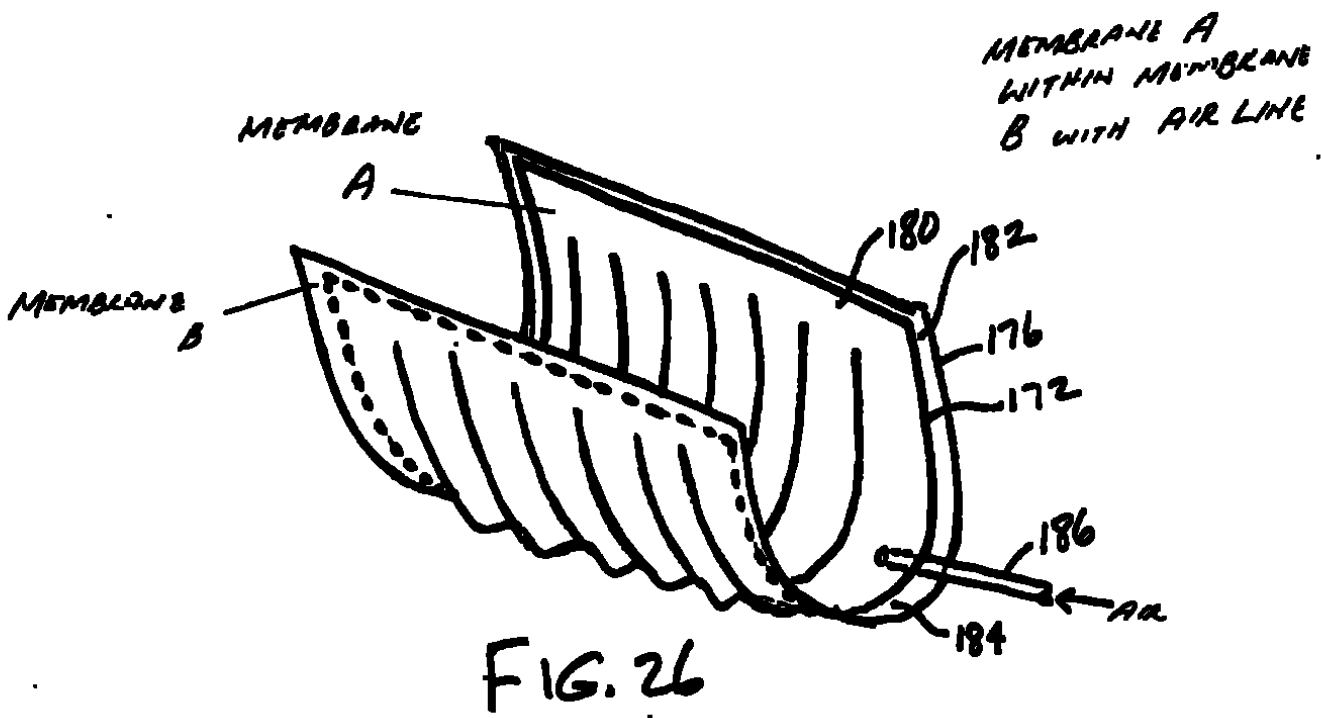
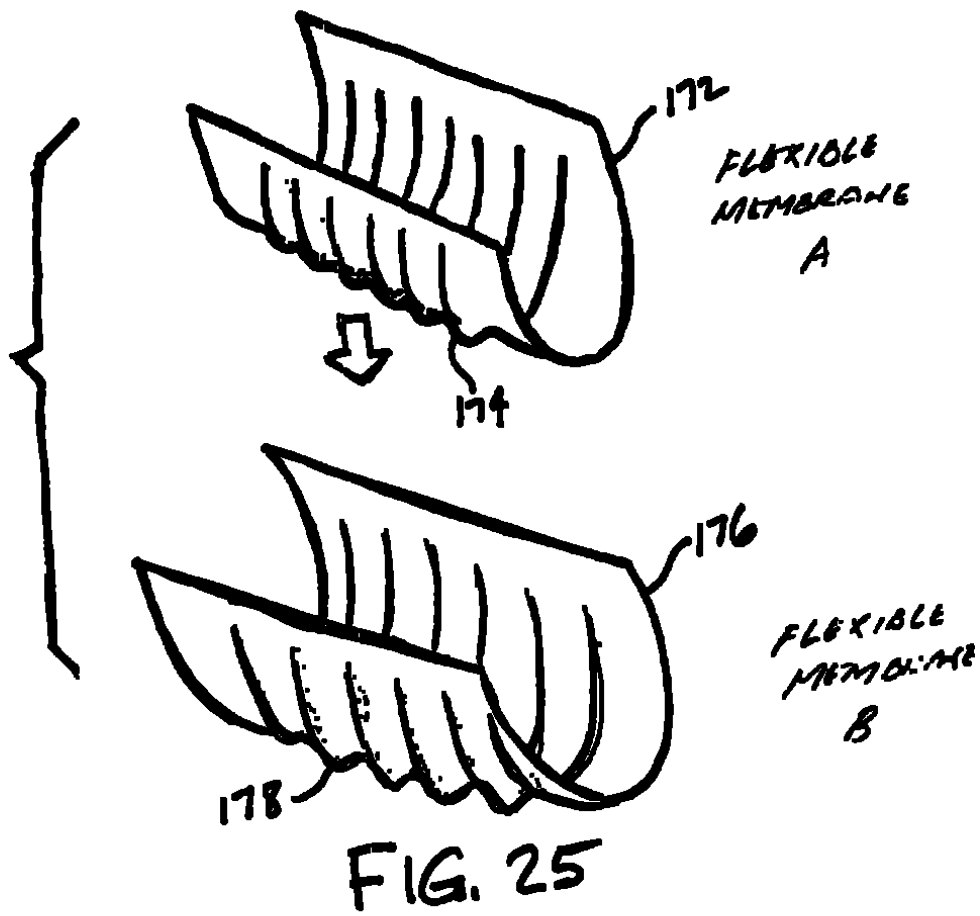


FIG. 24



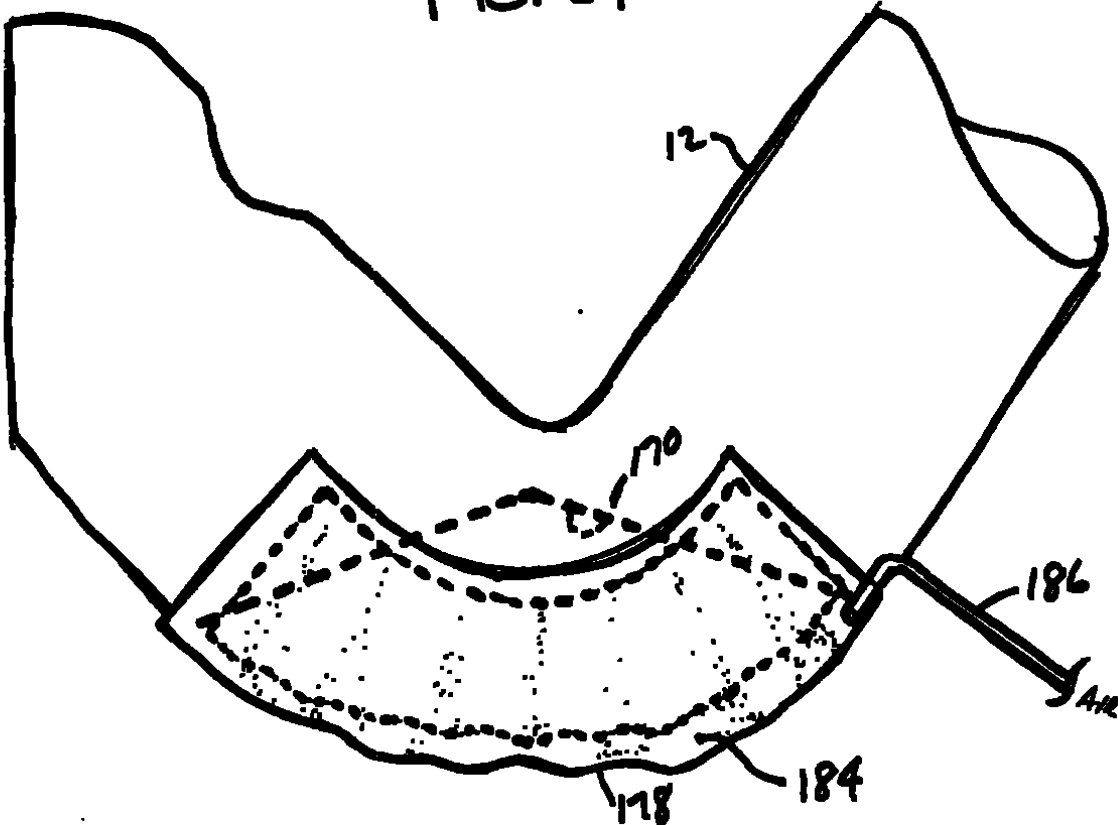
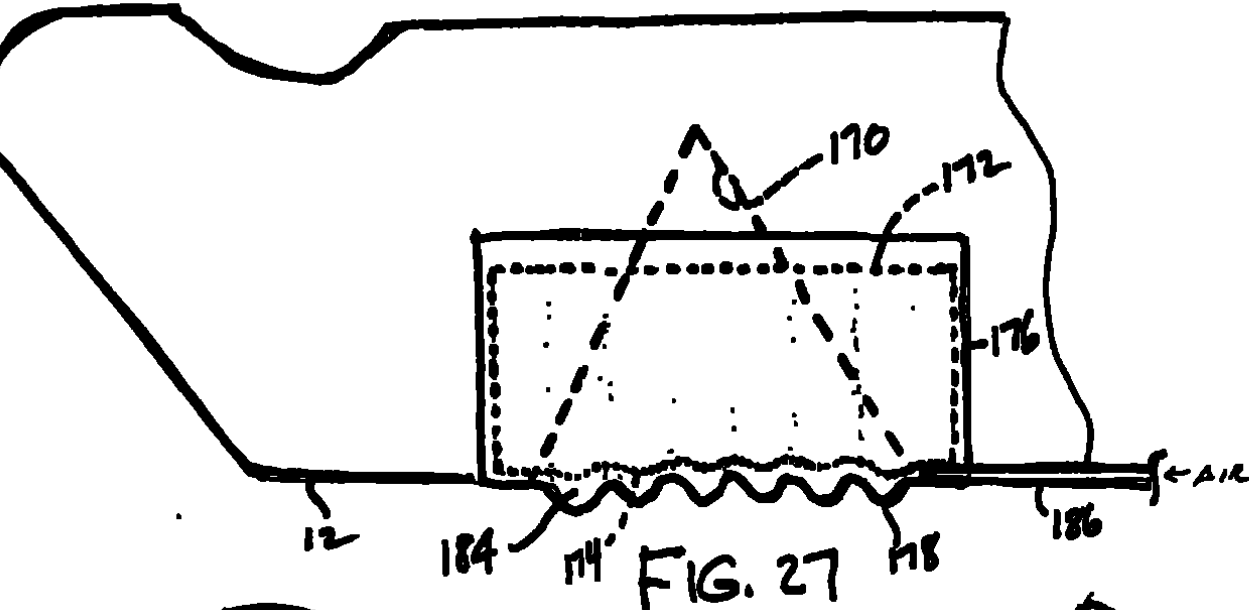


FIG. 28

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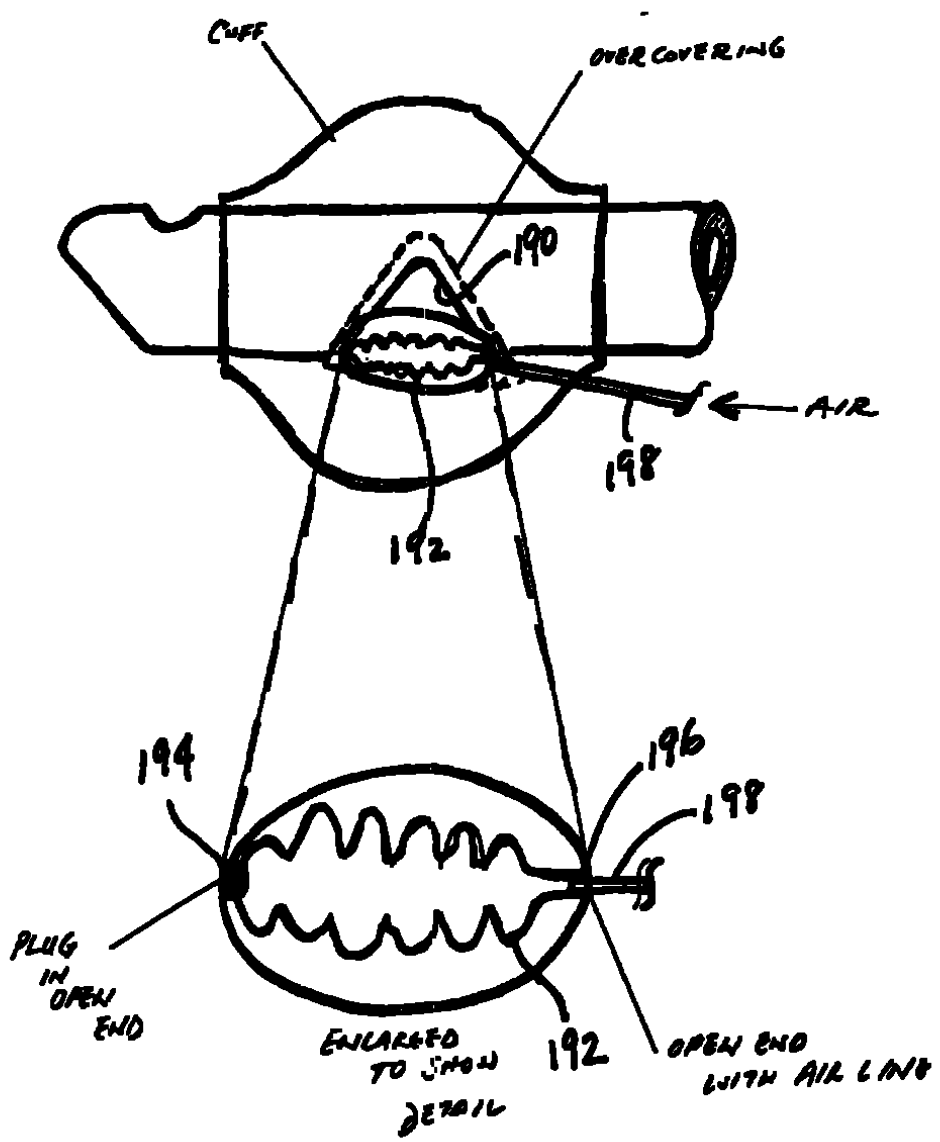


FIG. 29

COMPRESSED
BALLOON
DETAIL

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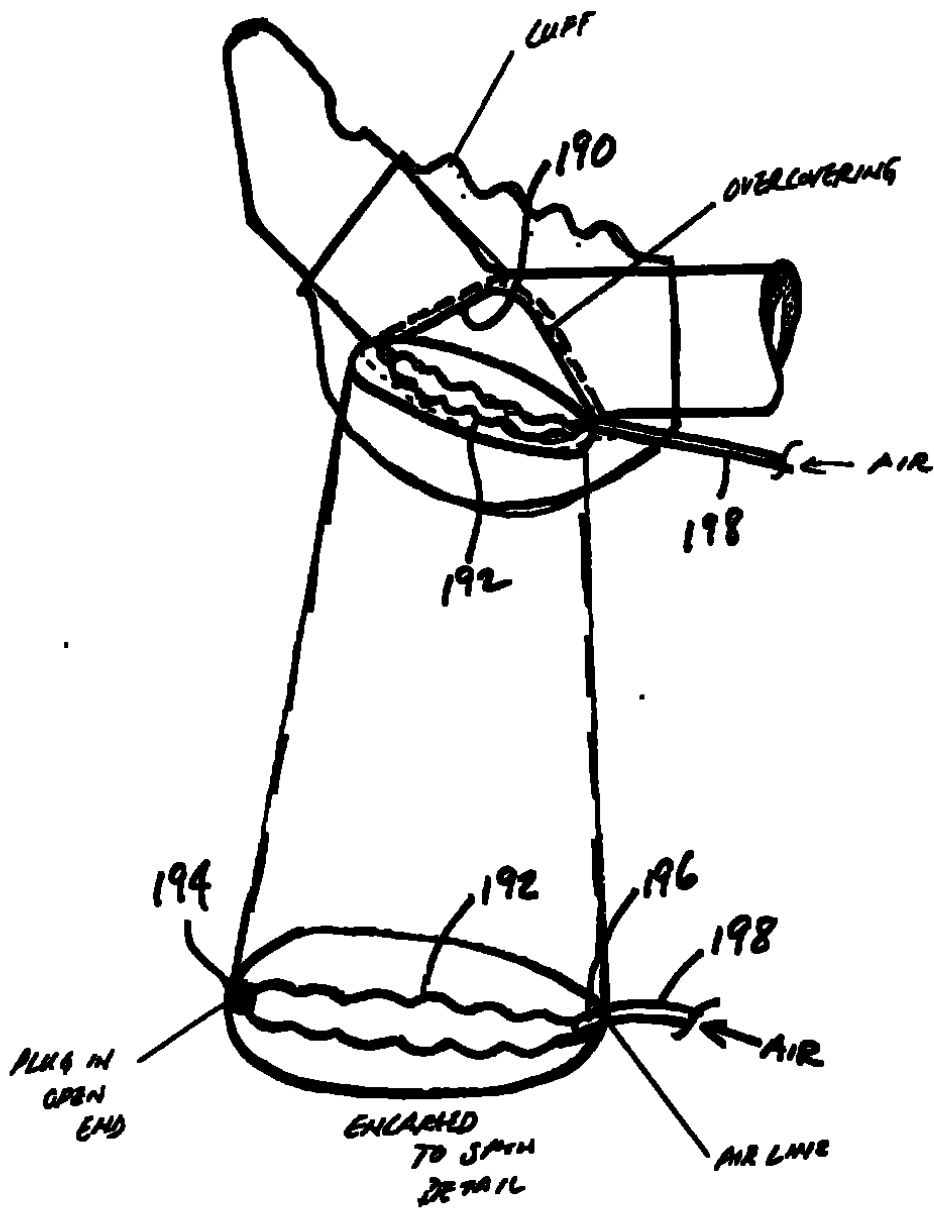


FIG 30

ELONGATED BALLOON
DETAIL

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2020
Bogotá D C

Doctor(a)
MARGARITA CASTELLANOS.
Apoderado(a)

REFERENCIA:	Radicación N°	04-58189
	Solicitud internacional	PCT/US01/44296
	Fecha limite de inicio en fase nacional	26/06/2004
	Trámite	011
	Evento	379
	Actuación	416
	Oficio N°	925
	Folios	001

Teniendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en el asunto, reúne los requisitos de forma establecidos en los artículos 26 y 27 de la Decisión 486, de la Comisión de la Comunidad Andina, el Tratado de Cooperación en Materia de Patentes (PCT), el Reglamento y la Circular Única de la Superintendencia de Industria y comercio, se envía el extracto de la solicitud a la oficina de comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial, conforme lo dispone el artículo 40 de la referida Decisión 486.

Cúmplase

Dado en Bogotá D C,


ALIX CARMENZA CESPEDES DE VERGEL
Jefe División de Nuevas Creaciones.

202028

Al contestar favor indique el número de radicación consignado en el sticker