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EDIFICIO SISKI
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BOGOTÁ 8, COLOMBIA

SUPERINDUSTRIA Y COMERCIO

Radicación : 00065983 00000002

3611
Folios: 3 4995

Fecha (AND): 2002-11-29 17:19:07

Trámite : 002 PATENTES D I REGISTRO/ 538 PETICION
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Señora Jefe de la
DIVISION DE NUEVAS CREACIONES
Superintendencia de Industria y Comercio
E. S. D.

Trámite : 002

Evento : 001

Actuación : 538

Referencia : Expediente No. 00-065.983

Asunto : Solicitud de patente para: METODO PARA
FABRICAR TUBERÍA MEDICA CON ADHERENCIA Y
LUBRICIDAD MEJORADA.

Solicitante : BAXTER INTERNATIONAL INC.

Fecha de solicitud : 01 de septiembre de 2000

Publicada en la : Gaceta No. 516 del 30 de Mayo de 2002

1. Yo, Emilio FERRERO, identificado como aparece al pie de mi firma, actuando como apoderado en el asunto de la referencia, atentamente, solicito se efectúe el examen de patentabilidad de la solicitud en referencia según lo establecido en el artículo 44 de la Decisión 486 de la Comisión de la Comunidad Andina. Para tal efecto presento junto con este escrito los recibos Nos. 02-70,622 y el 02-20,908 por valor de \$318.000.00, que corresponde a la tasa fijada según lo dispuesto en la resolución No. 44691 del 31 de diciembre de 2001.

2. Ruego atentamente a la Señora Jefe se sirva ordenar que se anexe este recibo, para que se efectúe dicho examen y se continúe con el trámite de la solicitud.

Bogotá, 29 NOV 2002
Señora Jefe,


EMILIO FERRERO
T.P.A. No. 31.929

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MRE/JFR/ID-000349/WPCL5873

NIT. 860.041.367-3

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Industria y Comercio
SUPERINTENDENCIA

SUPERINTENDENCIA Y COMERCIO
Radicacion : 00065963 00000002 Folios: 3
Fecha (RAD): 2002-11-29 17:19:07
Tramite : 000 PATENTES D 1 REGISTRO/ 538 PETICION
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 02 - 70,622
FECHA : OCTUBRE 22 DE 2002

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Vr. PAGO
CAVEL ABOGADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	7030562	22/10/2002	39,342,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	82 INVOCACION DE UNA PRIORIDAD EN NU	106,000.00
		TOTAL :	\$ 106,000.00

SON: CIENTO SEIS MIL PESOS

RESPONSABLE : 207

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

66 05893-801-024-6

Carrera 13 No. 27-00 Pisos 5, 7 y 10
Conmutador 382 0840
Fax 350 5220
E-mail: info@sic.gov.co
www.sic.gov.co
Bogotá, D.C., Colombia

172 178

Industria y Comercio
SUPERINTENDENCIA

NIT : 800174089-2

RECIBO OFICIAL DE CAJA : 02 - 20,908
FECHA : ABRIL 1 DE 2002

SUPERINDUSTRIA Y COMERCIO	
Radicacion : 00063983 00000002	Folios: 3
Fecha (AMD): 2002-11-29 17:19:07	
Tramite : 002 PATENTES D 1 REGISTRO/ 538 PETICION	
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES	

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CAVELIER ABOGADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	8087339	01/04/2002	37,092,000.00

***** CONCEPTO *****

CANT.	ANALITICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	86 EXAMEN DE PATENTABILIDAD DE MODEL	212,000.00
		TOTAL :	212,000.00

SON: DOSCIENTOS DOCE MIL PESOS

RESPONSABLE : 

RECIBO DE CAJA APLICADO AL EXPEDIENTE No.

Carrera 13 No. 27-00 Pisos 5, 7 y 10
Conmutador 382 0840
Fax 350 5220
E-mail: info sic.gov.co
www.sic.gov.co
Bogotá, D.C., Colombia

Colo 05893-801-024-6

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES**

2020

Bogotá, D. C., 17 de Junio de 2005

Doctor

EMILIO FERRERO

Representante **BAXTER INTERNATIONAL INC.**

ASUNTO

Radicación No. **00-65983.**

Trámite 002

Evento 001

Actuación 430

Oficio

Folios 009

13967

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica

1) Documentos estudiados:

- a) Para el presente estudio se tendrán en cuenta el capítulo descriptivo, comprendido en los folios 2 a 34 de la solicitud en estudio.
- b) Para el presente estudio se tendrán en cuenta los dibujos comprendidos en los folios 50 a 54A y 152 a 154 de la solicitud en estudio.
- c) Para el presente estudio se tendrá en cuenta el capítulo reivindicatorio que comprende 52 reivindicaciones en los folios 137 a 148 de la solicitud en estudio.
- d) Conforme lo establece los artículos 9, 10 y 11 de la decisión 486 de la Comisión de la Comunidad Andina, la presente solicitud en estudio fue presentada el 1 de septiembre de 2000, y en el momento de la radicación **SI** se reclamo prioridad de la primera solicitud presentada en Estados Unidos US 09/389518

2) Objeto de la invención

- a) Las reivindicaciones 1 a 52 de la solicitud en estudio se refieren a Un método para fabricar una tubería médica, que comprende los pasos siguientes: Proveer un material seleccionado de entre el grupo consistente en los homopolímeros de etileno y copolímeros de etileno, siendo los copolímeros de etileno, obtenidos copolimerizando el etileno con un comonomero seleccionado de entre el grupo consistente en olefinas de alquilo inferior, ésteres de alquilo inferior de ácido carboxílico y esteres de alqueno inferior de un ácido carboxílico, teniendo el alquilo inferior y el alqueno inferior, cada uno de ellos, de 3 a 18 átomos de carbono, o mezclas de los mismos; Proveer una extrusora con una matriz de extrusión;

Extruir el material en forma de una tubería médica; Proveer una solución modificadora de superficies; Precalentar la solución modificadora de superficies a una temperatura en el intervalo de 30 a 95°C; y Aplicar la solución, precalentada, por sobre la tubería a medida que la misma sale de la matriz de extrusión, cuando la tubería se halla en un estado fundido o semi-fundido.

- b) El anterior procedimiento busca mejorar las propiedades de tuberías empleadas en medicina.
- c) Según la Clasificación Internacional de Patentes, la codificación para esta solicitud corresponde a B 29 D 23/00

3) Claridad de la Solicitud

- a) El artículo 30 de la Decisión 486 de la Comisión de la Comunidad Andina establece que

"Las reivindicaciones definirán la materia que se desea proteger mediante la patente. Deben ser claras y concisas y estar enteramente sustentadas por la descripción. Las reivindicaciones podrán ser independientes o dependientes. Una reivindicación será independiente cuando defina la materia que se desea proteger sin referencia a otra reivindicación anterior. Una reivindicación será dependiente cuando defina la materia que se desea proteger refiriéndose a una reivindicación anterior. Una reivindicación será dependiente cuando defina la materia que se desea proteger refiriéndose a una reivindicación anterior.- Una reivindicación que se refiera a dos o más reivindicaciones anteriores se considerará reivindicación dependiente múltiple."

El capítulo reivindicatorio no es claro toda vez que no se precisa la materia sobre la cual se solicita protección. Cómo se explicará en el punto 4), la presente solicitud no posee unidad de invención, por lo que no está definida la materia sobre la cual se solicita protección.

De acuerdo a lo anterior, el capítulo reivindicatorio no cumple con el requisito de claridad de acuerdo a lo establecido en el Art. 30 de la Decisión 486.

4) Evaluación de la Unidad de Invención

El artículo 25 de la Decisión 486 de la Comisión de la Comunidad Andina establece

"La solicitud de patente sólo podrá comprender una invención o un grupo de invenciones relacionadas entre sí, de manera que conformen un único concepto inventivo"

La presente solicitud carece de unidad de invención toda vez que configura **TRES** diferentes objetos. Aunque se dirigen a **MÉTODOS DE FABRICAR TUBERÍA** la definición de la materia que caracteriza a cada una de las reivindicaciones independientes es muy diferente entre sí. Esto permite afirmar

que no se trata del mismo proceso. Todo el problema radica en configurar varias reivindicaciones independientes con materia diferente. El solicitante debe establecer una sola reivindicación independiente dirigida al proceso en la forma más simple de la solicitud de invención. Partiendo de allí establecer reivindicaciones dependientes que amplíen esa forma más simple hasta su forma más compleja.

De acuerdo a lo anterior, la presente solicitud no cumple con el requisito de unidad de invención de acuerdo al Art. 25 de la Decisión 486.

5) Determinación del Estado de la Técnica

El artículo 16 de la Decisión 486 de la Comisión establece:

"El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida."

"Sólo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente cuya fecha de presentación o de prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido este incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el artículo 40."

Consultadas las bases de datos y los archivos con que cuenta la entidad, especialmente bajo las clasificaciones B 29 D 23/00 y las más cercanas a ellas, se encontró que antes del 3 de septiembre de 1999 (fecha para determinar el estado de la técnica) habían sido publicados los documentos que se enumeran en la siguiente tabla los cuales se relacionan con tubería médica.

De acuerdo con o establecido en el artículo 16 se determinó el estado de la técnica y se encontró el siguiente antecedente:

Nº	Documento	Título	Fecha de Publicación
D1	US 5932307	Oriented medical tubing	3.08.1999

6) Evaluación de los requisitos de patentabilidad

El artículo 14 de la Decisión 486 de la Comisión de la Comunidad Andina establece:

"Los Países Miembros otorgarán patentes para las invenciones, sean de producto o procedimiento, en todos los campos de la tecnología, siempre que sean nuevas tengan nivel inventivo y sean susceptibles de aplicación industrial".

En cumplimiento con este artículo, se procedió a evaluar los requisitos de novedad, nivel inventivo y aplicación industrial con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

a) Evaluación del Nivel Inventivo

El art. 18 de la Decisión 486 de la Comisión de la Comunidad Andina establece:

"Se considerará que una invención tiene nivel inventivo, si para una persona del oficio normalmente versada en el arte en la materia técnica correspondiente, esa invención no hubiese resultado obvia ni se hubiese derivado de manera evidente del estado de la técnica".

El documento US 5932307 (D1) se basa en la misma materia de la actual solicitud. Un técnico que entienda del arte fácilmente encuentra lo que el solicitante para Colombia desea proteger, partiendo de D1. No se observa altura inventiva en la presente solicitud.

b) Resumen

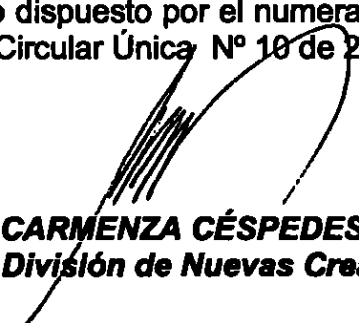
En conclusión los requisitos de patentabilidad de la presente solicitud se podrían ver afectados así:

Nº	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US 5932307	1 - 52	Nivel inventivo

7) Notificación

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que dentro del término de sesenta días contados a partir de la fecha de la notificación de la presente comunicación debe responder a la notificación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

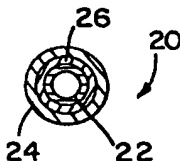
Notifíquese el presente oficio conforme a lo dispuesto por el numeral 5.2, literal e) del capítulo quinto del título primero de la Circular Única N° 10 de 2001


ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en la lista, de fecha
23 JUN. 2005

Concepto Técnico N°	EXAMINADOR TÉCNICO Código No.	EXAMINADOR JURÍDICO Código No.
891	202003	

- [54] ORIENTED MEDICAL TUBING
- [75] Inventors: Patrick T. Ryan, Crystal Lake, Ill.; Qia, Curran; Dennis L. Rostrom, Bartlett; Brenda K. La, Lake Zurich; Yanqiang B. Ding, Vernon Hills; Susan R. Manner, Round Lake; Heights; James W. Libertyville; Michael T. K. Lang, Vernon Hills; Martin F. Miller, Lake in the Hills, Ill.
- [73] Assignee: Baxter International Inc., Deerfield, Ill.
- [21] Appl. No.: 08/643,375
- [22] Filed: May 3, 1996
- [51] Int. Cl.⁶: B29D 23/00
- [52] U.S. Cl.: 428/34.9; 428/36.9; 428/36.6; 428/222; 428/239; 428/476.1; 428/483; 428/516; 428/519; 428/522; 136/137; 136/241; 604/403; 604/408; 264/512
- [56] Field of Search: 428/35.7, 34.9, 428/36.9, 36.9, 36.6, 516, 520, 519, 222, 339, 516, 476.1, 483, 404/403, 408, 264, 280, 136/137, 141; 264/512
- [56] References Cited
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- European Plastic News, Jan. 1996; Medical Tubes Use Novelty Resin, p. 17.
- Industrial & Production Engineering (IPS), Dec. 1988, Extrusion Line for Medical Tubes, p. 17.
- Primary Examiner—Rita L. Dye
Attorney, Agent, or Firm—Mark J. Roccia; Joseph A. Pacha



16 Claims, 4 Drawing Sheets

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1 ORIENTED MEDICAL TUBING TECHNICAL FIELD

This invention relates to a method for fabricating medical tubing and more particularly to a process for orienting the tubing along a longitudinal axis of the tubing.

BACKGROUND ART

In the medical field, where beneficial agents are collected, processed and stored in containers, transported and ultimately delivered through tubes by infusion to patients, there has been a recent trend toward developing materials useful for fabricating such containers and tubing without the disadvantages of currently used materials such as polyvinyl chloride. These new materials for tubing must have a unique combination of properties, so that the tubing may be used in fluid administration sets and with medical infusion pumps. Among these properties are the materials must be optically clear, environmentally compatible, have sufficient yield strength and flexibility, have a minimum quantity of low molecular weight additives, and be compatible with medical solutions.

It is desirable for medical tubing to be optically transparent to allow for visual inspection of fluids in the tubing. Ultrasonic waves must also be capable of passing through the tubing because sensors associated with an infusion pump typically use ultrasonic waves to detect abnormal conditions such as air bubbles in the tubing.

It is also a requirement that the tubing be environmentally compatible as a great deal of medical tubing is disposed of in landfill and through incineration. For tubing disposed of in landfill, it is desirable to use as little material as possible to fabricate the tubing. Further benefits are realized by using a material which is thermoplasticity recyclable so that scrap generated during manufacturing may be incorporated into virgin material and refabricated into other useful articles.

For tubing that is disposed of by incineration, it is necessary to use a material that does not generate or minimize the formation of by-products such as inorganic acids which may be environmentally harmful, irritating, and corrosive. For example, PVC may generate objectionable amounts of hydrogen chloride (or hydrochloric acid when contacted with water) upon incineration, causing corrosion of the incinerator and possible pollution to the environment.

To be compatible with medical solutions, it is desirable that the tubing material be free from or have a minimal content of low molecular weight additives such as plasticizers, stabilizers and the like. These components could be extracted by the therapeutic solutions that come into contact with the material. The additives may react with the therapeutic agents or otherwise render the solution ineffective. This is especially troublesome in bio-tech drug formulations where the concentration of the drug is measured in parts per million (ppm), rather than in weight or volume percentages. Even minute amounts of the bio-tech drug can render the formulation unusable. Because bio-tech formulations can cost several thousand dollars per dose, it is imperative that the dosage not be changed.

Polyvinyl chloride (PVC) has been widely used to fabricate medical tubing as it meets most of these requirements. PVC tubing is optically clear to allow for visual inspection of the fluid flowing through it. PVC tubing has proven to work well in pump administration sets. PVC medical tubing also has desirable stress-strain characteristics so that the material may be oriented along a longitudinal axis

of the tubing without causing a reduction in the diameter of the tubing. In other words, PVC tubing resists necking. PVC medical tubing also has favorable surface characteristics to allow for controlling the flow rate of fluid through the tubing using side clamps which operate by crimping the sidewall of the tubing to stop or reduce the flow of fluid through the tubing. The side clamps may be used without causing tearing or cutting of the tubing.

Because PVC by itself is a rigid polymer, low molecular weight components known as plasticizers must be added to render PVC flexible. As set forth above, these plasticizers may be extracted out of the tubing by the fluid. For this reason, and because of the difficulties encountered in locating PVC, there is a need to replace PVC medical tubing.

Polyolefins and polyolefin alloys have been developed which meet many of the requirements of medical containers and tubing, without the disadvantages associated with PVC. Polyolefins typically are compatible with medical applications because they have minimal extractability to fluids. Many polyolefins are environmentally sound as they do not generate harmful degradation upon incineration, and in most cases are capable of being thermoplasticity recycled. Many polyolefins are cost effective materials that may provide an economic alternative to PVC. However, there are many hurdles to overcome to replace all the favorable attributes of PVC with a polyolefin.

For example, problems have been encountered in using polyolefins, such as an ultra-low density polyethylene (ULDPE), to fabricate medical tubing. Such tubing has been found to have poor surface characteristics so that it is readily susceptible to cutting, shredding or tearing when clamping the tubing using a side clamp. ULDPE tubing also presents difficulties during use in pump pressurized administration sets where the pump controls the flow rate of fluid through the tubing by compressively impinging upon the sidewall of the tubing to deliver a precise amount of fluid over a given time period.

Pumps that are used to infuse beneficial agents to patients typically have various sensors to detect such conditions as back pressure of fluid in the tubing, and air bubbles in the fluid stream. The sensors deactivate the pump upon detecting an unacceptable back pressure or an air bubble. The sensors usually have a sensor body in which a segment of the tubing of the administration set is secured in place. It has been found that there is a tendency for the polyolefin tubing to deform when placed in the sensor body due to resistance with side walls of the sensor housing. This deformation in some cases leads the detector to indicate an abnormal condition and to inappropriately deactivate the infusion pump.

Further, polyolefin tubing has been found to have low yield strength and thus are readily susceptible to a phenomenon which is referred to as necking. Necking is a localized reduction in the diameter of the tubing that occurs upon stretching the tubing under moderate stress along the longitudinal axis of the tubing. Necking can cause a reduction or complete restriction in the flow of fluid through the tubing thereby rendering the tubing ineffective. Because there is a linear relationship between yield strength and modulus, it is possible to increase the modulus of the material to increase the yield strength. However, to get a sufficient yield strength for medical applications, the resulting tubing has too high a modulus to function in pumps.

The Applicants have found that it is possible to increase the tubing's resistance to necking by pre-orienting the tubing along the longitudinal axis of the tubing. However, the

orientation process may lead to dimensional instability. In particular, oriented polyolefin tubing experiences a phenomenon known as heat recovery, which is sometimes referred to as the "memory effect." Heat recovery is a complicated phenomenon that occurs when oriented tubing is heated above the temperature reached during the orientation process. When this occurs the tubing loses its orientation causing shrinking and dimensional changes of the tubing. Polyolefin tubings have also been shown to have poor thermal stability during storage, transportation, and end applications. The poor thermal stability is thought to be due in part to polyolefin's low melting or crystallization temperatures, low glass transition temperatures, and due to the orientation process referred to above. The poor thermal stability of polyolefin tubings can lead to changes in the desired dimensions and also lead to curling of the tubing during shipping or use. These dimensional and shape changes can in turn lead to functional problems such as accuracy, pump compatibility, and cause other cosmetic defects.

DISCLOSURE OF INVENTION

The present invention provides a method for fabricating flexible medical tubing comprising the steps of providing a polymeric tubing having a longitudinal axis and an initial diameter, orienting the tubing along the longitudinal axis of the tubing to reduce the diameter of the tubing to define an oriented diameter, and applying heat to the oriented tubing to heat set the tubing to maintain dimensional stability of the tubing. Preferably the initial diameter is 10%-300% greater than the oriented diameter. Preferably the step of orienting the tubing can be done in a wet or a dry process. Each orientation process shows the steps of clamping the tubing between a first pulley and a second pulley spaced apart by a distance and controlling the relative speeds of the first pulley and the second pulley so that the rate of pulling of the second pulley is greater than that of the first pulley to orient the tubing downstream. In the wet orientation process, the tubing is passed through an aqueous bath during the orientation step and in the dry process the tubing is not.

The present invention further provides for heat setting of the tubing to overcome the memory effect discussed above. The heat setting process includes the step of exposing the tubing to a temperature higher than that which the tubing will normally be exposed during shipping, storage, and use, but below the temperature at which the tubing is fully melted. By exposing the tubing to temperatures above the application temperature, less ordered, lower melting crystals are melted leaving higher melting crystals which will be thermally stable over the application temperature range. Part of the highly ordered micro-crystalline chains will also be relaxed at heat setting temperatures resulting in a tubing with good thermal stability.

The heat setting step includes the steps of heating the tubing after the orienting step in a heated aqueous bath. Preferably, the tubing is not oriented during the heating step but is held under sufficient tension to prevent the tubing from sagging. It is also possible to allow the tubing a little slack so the tubing may sag slightly. It is also preferable that the tubing be supported with a structure to prevent or minimize further orienting of the tubing.

Finally, it is desirable to position a plurality of spaced ridges in the heating bath. The tubing is trained about the ridges to define a suspension pattern so that the tubing makes several lengthwise passes through the heating bath. It may be desirable to maximize these ridges.

BRIEF DESCRIPTION OF DRAWINGS

- FIG. 1 is an enlarged cross-sectional view of a medical tubing fabricated from a monolayer polymer blend of the present invention.
- FIG. 2 is an enlarged cross-sectional view of a multi-layered tubing of the invention.
- FIG. 3 is a schematic representation of a method for forming, orienting and heat setting medical tubing.
- FIG. 3a is a plan view of a suspension pattern that tubing may follow through a heating or cooling bath of the process shown in FIG. 3.
- FIG. 3b is a schematic representation of a method for forming, dry orienting and heat setting medical tubing.
- FIG. 4 is a plan view of a gravity pressurized fluid administration set.
- FIG. 4a is a plan view of a side clamp.
- FIG. 5 is a plan view of a pump pressurized fluid administration set.
- FIG. 6 is a pump sensor housing clamping a segment of medical tubing.
- FIG. 7 is a side elevation view in section of a tubing and a housing prior to insertion of the tubing into the housing.
- FIG. 8 is a side elevation view in section of a tubing and housing assembly with the tubing inserted into the housing.
- FIG. 9 is an end view of a housing sleeve; and, FIG. 10 is an end view of a housing sleeve with a tubing inserted therein.

BEST MODE FOR CARRYING OUT THE INVENTION

While the invention is susceptible of embodiment in many different forms, there is shown in the drawings and will hereinafter be described in detail preferred embodiments of the invention with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the broad aspect of the invention to the embodiments illustrated.

1. Polymer Blends

The polymer blends of the present invention may be embodied in monolayer polymer structures or may be embodied in other structures such as polymers in form multi-layered structures. The polymer blends of the present invention include a polymeric material and an additive. The polymer blends are capable of being fabricated into medical tubing and stretched to rigid polymers.

The polymeric material may be selected from the group consisting of polyolefins and their copolymers, ethylene-propylene rubber, ethylene vinyl acetate copolymers, ethylene methyl acrylate copolymers, styrene and hydrocarbon block copolymers such as styrene-butadiene-styrene or styrene-isoprene-styrene copolymers and their hydrogenated derivatives, thermoplastic elastomers such as polyurethanes, polyamide and polyether copolymers such as those sold under the trademark PERAX, and copolymers such as those sold under the trademark HYTREL, polytetrafluoroethylene, polypropylene, polybutylene, styrene-butadiene rubber, and other cross-linked elastomers.

Suitable polyolefin include both homo and copolymers of polyethylene. Suitable comonomers may be selected from the group consisting of alpha-olefins, methyl acrylate and vinyl acetate.

Preferably, the polyolefin is an ethylene copolymerized with alpha-olefins including butene-1, octene-1 (collectively

referred to as ultra low density polyethylene ("ULDPE"), methyl acrylate (with less than 35% methyl acrylate comonomer), ULDPE generally has a density within the range of about 0.91 g/cm³ to about 0.94 g/cm³.

The additive should be a polymer or an oligomer or an amine hydrocarbon having greater than 5 carbon atoms in the backbone and further having electron negative groups selected from the group of amines, nitriles, hydroxy, acids, acetates, ammonium salts, organosulfonates, compounds such as metal chelates, metal carboxylates, and metal complexes of numerous 1,3 dicarboxyl compounds, phenyl phosphates, pyridines, pyridones, imidazoles, and oxazolones.

The blends should have the polymeric component in an amount by weight within the range of 90%-99.999%, more preferably 98.0%-99.99%. The additive should be in an amount by weight within the range of 0.001%-10%, and more preferably 0.01%-2%.

II. Method of Blending

The components of the polymer blends should be blended through mechanical mixing, physical blending such as tumble blending, or other means such as reactive extrusion.

III. Method of Fabricating Medical Tubing

FIG. 1 shows medical tubing 10 of the present invention fabricated from one of the blends of the present invention. The tubing 10 should have an inner diameter dimension within the range of 0.003-0.4 inches, and an outer diameter dimension within the range of 0.12-0.5 inches. More particularly, medical tubing for use in the administration of fluid using a medical infusion pump, such as Baxter infusion pump sold under the trademarks FLO-GARD[®] and COLLEAGUE[®], have an inner diameter within the range of 0.099-0.108 inches, an outer diameter within the range of 0.134-0.145 inches, and a wall thickness within the range of 0.018-0.021 inches. The tubing should be flexible having a modulus of elasticity of less than 30,000 psi, and more preferably less than 40,000 psi.

FIG. 3 shows a multilayered tubing 20 having a first layer 22, which is a solution contact layer, a second layer 24 and a third layer 26 sandwiched therebetween. The first layer 22 may be selected from the same group of polymers as first shown for the polymeric component. The first layer 22, however, will not have the additive. The second layer 24 will be of the blends specified above having a polymeric material and an additive selected from the groups and amounts specified above. In many cases the first layer 22 will be sufficiently compatible with the second layer 24 to do without the first layer 24.

The first layer 22 of the tube 20 should have a thickness as a percentage of the total wall thickness within the range of 98%-99%, the second layer 24 should have a thickness within the range of 3-50%, and the third layer 26 should have a thickness within the range of 0-10%.

IV. Method of Heat Setting and Orienting the Tubing

It is also desirable for the tubing 10, 20 to be oriented along their longitudinal axis. This orientation may increase the yield strength of the tubing in the longitudinal direction thereby reducing the tendency for the tubing to neck during use. In effect, pre-orienting of the tubing increases the resistance to further necking. Preferably, the tubing 10, 20

should be oriented so that the initial inner and outer diameters of the tubing are anywhere from 10%-300% greater than the diameter of the tubing 10, 20 after orienting and more preferably from 20%-120% and most preferably from 30%-70% higher. These ranges further include all combinations and subcombinations thereof. The ratio of the beginning diameter to the diameter after orienting should be referred to as the orientation ratio. The orientation process may be a wet orientation process or a dry one as set forth below.

FIG. 3 shows a schematic representation 30 of the method of orienting the tubing in a wet orientation process. The method of wet orienting includes the steps of providing a tubing 32 from a polymeric blend, and orienting the tubing 32 along its longitudinal axis so that the tubing 32 has a desired inner and outer diameter, as specified above in Section III, and orientation ratio. The orienting may extend the molecules of the tubing along the longitudinal axis to increase the resistance to necking upon subsequent longitudinal elongation. The tubing 32 is then heat set to reduce shrinkage of the tubing and to fix the tubing in the oriented dimension.

The tubing 32 (which may be a single layered tubing 10 or a multilayered tubing 20) is pulled in a direction indicated by arrows 34 along a continuous path that may be referred to as a line. The term "up-line" shall refer to locations along the line in a direction opposite the direction to the flow of the tubing 32. Conversely, the term "down-line" shall refer to locations in the direction of the flow of the tubing. By using the term "line" it should not be thought that the method must be carried out in a straight line, rather it should be taken to mean that the method is carried out in a sequence of consecutive steps.

As shown in FIG. 3, tubing 32 is formed with an extruder 36. The tubing 32 exiting the extruder 36 preferably has an outer diameter dimension that will be from 10%-300% greater than after orienting and more preferably from 20%-120%, and most preferably from 30%-70% greater. The diameter of the tubing exiting the extruder 36 shall be referred to as the initial diameter.

The tubing 32 is pulled from the extruder 36 with a first pulley 37, a second pulley 38, a third pulley 39, and a fourth pulley 40. The pulleys 37, 38, 39 and 40 may have a silicone or rubber coating to increase the coefficient of friction with the tubing 32. The second and third pulleys 38 and 39 may have a plurality of axially spaced and circumferentially extending grooves to accommodate more than one set of tubing 32 on a surface of the pulleys 38 and 39 at a time.

After exiting the extruder 36, the tubing 32 passes through a first cooling bath 41 where the tubing 32 is cooled with air or a liquid. Preferably, the first cooling bath 41 is a water bath at a temperature within the range of 4° C.-45° C.

After exiting the first cooling bath 41, the tubing 32 extends between the first and second pulleys 37 and 38 where the tubing 32 is oriented by operating the second pulley 38 at a greater rate of speed than the first pulley 37 to achieve the desired orientation ratio. This section of the line will be referred to as the orienting section 42. Preferably the second pulley 38 is operated at a rate within the range of about 4-10 times faster than the first pulley 37. By controlling the relative speeds of the first and second pulleys 37 and 38 one can control the final inner and outer diameters of the tubing 32 and achieve the desired orientation ratio.

In the orienting section 42 the tubing 32 is passed through a second cooling bath 43 where the tubing 32 is cooled with air or a liquid. Preferably, the second cooling bath 43, as the

first cooling bath 41, is an aqueous bath at a temperature within the range of 4° C.-45° C.

To overcome the memory effect of the oriented tubing 32, it is necessary to heat the tubing to a temperature above that which it will normally be exposed during shipping, storage and use, but below the temperature at which the tubing is fully melted. By exposing the tubing to temperatures above the application temperature, less oriented lower melting crystals are melted leaving higher melting crystals which will be thermally stable over the application temperature range. Part of the highly oriented micro-molecular chains will be relaxed to provide a tubing with enhanced thermal stability.

Toward this end, after exiting the second cooling bath 43, the tubing 32 passes about the second pulley 38 and extends between the second pulley 38 and the third pulley 39. The tubing 32 proceeds in a direction back toward the extruder 36 and through a heating bath 44 where the tubing is heat set. Preferably, the heat bath 44 is positioned above the second cooling bath 43 to save floor space. However, this positioning is optional. This portion of the process will be referred to as the heat setting section or step 45. Preferably, the heat setting step 45 is done on-line after the orienting section 42, but could be done off-line in a batch mode process. During the heat setting step 45, the tubing 32 is passed through a heating bath 44 where the tubing 32 is heated with a medium such as heated air or liquid. The heating bath 44 preferably is an aqueous solution of water at a temperature of between about 50-99° C. Additives such as salt may be added to the aqueous solution.

It is desirable that the tubing 32 not be oriented during the heat setting step 45. For this reason the tubing 32 should be kept under minimum tension to keep the tubing taught or the tubing should be allowed to sag in amount between the second and third pulleys 38 and 39, to prevent or control the shrinkage. Thus, the second and third pulleys 38 and 39 should be operated at similar speeds or pulley 39 could be operated at a slightly slower speed than pulley 38 to accommodate some shrinkage.

To further prevent orienting of the tubing 32 in the heat setting section 45, it may also be desirable to support the tubing 32 while being pulled through the heating bath 44 with a supporting structure 47. However, providing the supporting structure 47 is optional. Suitable supporting structures 47 include a conveyor that moves at the same rate of speed as the tubing 32 through the heating setting section 45. Another supporting structure 47 is a plastic or metal conduit having a diameter greater than that of the tubing wherein the tubing 32 is supported by the interior surface of the conduit.

After exiting the heating bath 44, the tubing 32 extends between the third pulley 39 and the fourth pulley 40. Pulley 40 should be operated at a similar speed of pulley 39 or slightly slower than 39 to prevent further orientation. The tubing 32 is passed again through the second cooling bath 43. Of course it is possible to provide for a separate cooling bath, but this arrangement saves floor space.

It may also be desirable to provide for the tubing 32 to make several longitudinal passes through the cooling bath 43 or heating bath 44 as shown in FIG. 3a to provide for maximum wetting or heating of the tubing in a minimal amount of space. This may be accomplished by providing a plurality of spaced rollers 49 to define a serpentine pattern through the heating bath 44 or cooling bath 43.

To prevent any further orientation of the tubing 32, it may be necessary to operate the fourth pulley 40 at a similar speed or slightly slower rate of speed than the third pulley 39.

After passing the fourth pulley 40, the tubing has an oriented diameter and passes through a cutter or spool 48 where the tubing 32 is cut to the appropriate length or wrapped about the spool for storage or shipment.

FIG. 3a shows a dry orientation process 30'. The dry orientation process is same in most respects to the wet orientation process with the major exception that the tubing 32 is oriented in section 42' between pulleys 37' and 37a. Pulley 37a is operated at a speed greater than pulley 37'. During the dry orientation step 42', the tubing 32 is not submerged in the aqueous bath 43 as in the case in the wet orientation step 42. In the dry orientation process, pulleys 38, 39, and 40 will be run at a rate similar to or slower than pulley 37a.

V. Method of Using the Tubing

The medical tubing 32 of the present invention may be used in various medical applications such as in administering fluid to a patient using an administration set 60 (FIG. 4) where fluids are infused from a fluid container such as an I.V. bag 62 to a patient's vascular system. The fluid flow rate may be controlled with fluid control devices such as a clamp 63 which has a slot 64 that opens along its length. By positioning the tubing at various positions within the slot 64, the walls of the slot can impinge upon the sidewalls of the tubing 32 and thereby alter the rate of fluid flowing through the tubing.

The tubing 32 may also be used in pump pressurized systems 65 (FIG. 5) where fluids are infused to a patient through the tubing 32 using a medical infusion pump 66. Such medical pumps 66 include a linear peristaltic pump, a rotary peristaltic pump and other pumps that effect fluid flow through the tubing by successively impinging upon the sidewalls of the tubing 32.

In a linear peristaltic pump, a plurality of pump fingers are spaced along a segment of tubing and are operated to impinge upon the tubing sidewalls in a step-wise fashion along the line of fluid flow to move fluid through the tubing.

A rotary peristaltic pump has a circular drum that is rotated for rotational movement. The tubing 32 is positioned perpendicularly to a point along the drum. The drum has a plurality of circumferentially spaced elements that successively operate to impinge the tubing sidewalls as the drum rotates to pump fluid through the tubing 32.

Other pumps such as the one described in U.S. Pat. No. 5,151,019 moves fluid through tubing in a controlled fashion by deforming the tubing out of round in a non-occlusive fashion. That is to say that in the most extreme deformation, the opposite internal surfaces of the tubing which approach each other, do not make contact. Applicants hereby incorporate by reference U.S. Pat. No. 5,151,019 and its priorities to those portions of the text describing the general principles of operation of such a pump assembly the way located at Col. 4, line 63-Col. 5, line 25; and Col. 7, line 64-Col. 8, line 9.

Each of these pumps 66 may have various built-in sensors that help control the pump. For example, medical pumps 66 typically have air bubble sensors to prevent air from being pumped into the vascular system of a patient. Back pressure sensors are provided to detect an increased resistance to fluid flow which result from a patient occluding the tubing or from the tubing being occluded. As shown in FIG. 6, the sensors usually have a sensor housing 67 in which a segment of the tubing 32 of the administration set is secured in place. Air bubbles may be sensed by passing light through the tubing to detect air bubbles. Fluid back pressure may be sensed by detecting changes in the diameter of the tubing 32.

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The barrel zone temperatures for zone Nos. 1-4 were respectively as follows in degrees Fahrenheit: 374, 375, 376, and 375. Die zone temperatures for zone Nos. 1-3 were as follows in degrees Fahrenheit: 375, 375, 376. The puller speeds of pullers Nos. 1-5 were respectively as follows in feet per minute: 17, 60, 41, 31, and 31.5.

The dimensional stability and Yield strength data are set forth below in Table 3.

TABLE 3

Tubing Temp. (°C. at last half)	Striking	Yield
170	10.20	375
170	1.20	380
170	1.20	380
170	1.20	380
170	1.20	380
170	1.20	380
170	1.20	380
170	1.20	380
170	1.20	380
170	1.20	380

B. Example 5

The procedure for fabricating tubing and testing the tubing as set forth in Example 3 was repeated with slightly different operating conditions to produce a sample of tubing from a blend of an ultra-low density polyethylene (ULDPE) sold by the Dow Chemical Company under the name Dow Affinity VP1770, and Ethacron 0/15 (0.23% by weight) (Akon Nobel Chemical Company). Another sample of tubing was formed from Dow Affinity ULDPE alone.

The barrel zone temperatures for zone Nos. 1-4 were respectively as follows in degrees Fahrenheit: 424, 425, 422, and 425. Die zone temperatures for zone Nos. 1-3 were as follows in degrees Fahrenheit: 425, 425, 425. The puller speeds of pullers Nos. 1-5 were respectively as follows in feet per minute: 17, 60, 41, 31, and 31.5.

The dimensional stability and Yield strength data are set forth below in Table 4.

TABLE 4

Tubing Temp. (°C. at last half)	Striking	Yield
VP 1770	10.20	380
VP 1770	1.20	380
VP 1770	1.20	380
VP 1770	1.20	380
VP 1770	1.20	380
VP 1770	1.20	380
VP 1770	1.20	380
VP 1770	1.20	380
VP 1770	1.20	380
VP 1770	1.20	380

F. Example 6

Tubing samples were also produced in a similar extrusion process as set forth above in Examples 1-3. One set of tubing samples was oriented to a 50% orientation ratio. A second sample was not oriented. The tubing was made from the constituents set forth below in Table 5, namely, Exact

4011, UVA, and VP1770. The extrusion resistance of the tubing was measured by initially measuring the inner and outer diameters, and length of the tubing. One end of the tubing was clamped. A Chatillon gauge was attached to the opposite end of the tubing. The Chatillon gauge exerted a 5 lb. force longitudinally on the tubing for 10 seconds. Afterward, the tubing was allowed to sit for 5 minutes. The tubing dimensions were measured again and compared with the initial dimension measurements. The percent change in the length dimension is set forth below in Table 5.

TABLE 5

Tubing Composition	Percent change in length
Exact 4011	0.40
Exact 4011 (50% orientation)	0.30
UVA	0.30
UVA (50% orientation)	0.30
VP 1770	0.40
VP 1770 (50% orientation)	0.40

G. Example 7

An ultra-low density polyethylene Exact 4011 was produced into tubing having an outer diameter within the range of 0.138-0.145 inches and an inner diameter within the range of 0.101-0.108 inches. One sample of the tubing was oriented to a 50% orientation ratio and a second sample of the tubing was oriented to a 50% orientation ratio. Samples of the tubing that were oriented to a 50% orientation ratio were separately reheated in a water bath at 65° C., and 70° C. for 10 seconds and 65° C. for 5 seconds with separate ends of the tubing clamped to prevent movement or shrinkage of the tubing. After the exposure to the heat the tubing was undrained and the length of the tubing was measured after cooling in ambient temperature water for 5 minutes. The percent difference in the change of the length of the tubing is reported in Table 6 below.

The tubing was then placed into an oven at 57° C. for 4 hours. The length after heating was measured and compared to the length before being placed in the oven. The percent difference in length was noted in Table 6 below.

The other sample of tubing of 55% orientation was not heat treated in a water bath. The non-heat treated tubing was placed in the oven and the percent difference in the length was noted. The results reported in Table 6 show that the heat treating step greatly reduces the tendency for the tubing to shrink.

TABLE 6

Temperature of Heat (°C.)	Time in Heat (hrs.)	% Change in Length (before oven)	% Change in Length (after oven)
65	10	1.40	-2.40
70	10	1.50	-2.40
65	5	0	-1.40
Non	NA	NA	-21.8

H. Example 8

Exact Exact 4011 (ULDPE) was extruded with and without additives. The Exact 4011 was obtained from Exxon Chemical Company and the Ethacron additives were obtained from Akon Nobel Chemical Company. Heatset additives were obtained from Hoesel Corporation. The

extrusion equipment was obtained from several suppliers as noted: 1.5" extruder from Killion, belt puller model 212-2 and 118 from RDN, vacuum screw model 2.0 PVS from RDN. The extruder blends comprised 0.23% additives and 99.77% Exact 4011 resin. 0% additives and 100% Exact 4011 was also extruded as a control. Tubings were extruded by blending the resin and additives and then placing them into a single screw extruder for extrusion into tubing form. The extruder conditions were as follows: Die Pin outer diameter 0.120"; Die heating inner diameter 0.185"; Temperature, Barrel Zone (BZ) 375° F., BZ2 375° F., BZ3 375° F.; Die Zone (DZ) 41 374° F., DZ2 375° F.; Head Pressure 1600 psi; Motor Amps 9.5; Line speed was 25 Feet Per Minute. The effectiveness of the additive in improving the tubing compatibility with a pump air was evaluated by filling the tubing with water (distilled water), placing the tubing in the pump and closing the door, open and close the door two more times, then reading the Air Sensor values present in the pump display. The desirable value range for each sensor is 400-450. Table 7 lists the results for Exact Exact 4011 with and without additives and indicates an improved compatibility for ULDPE with the additive.

TABLE 7

Material	Air Sensor - Moisture	Air Sensor - Noise
Exact 4011	330	330
Exact 4011 + Ethacron 0/15	360	407
Exact 4011 + Ethacron 0-15	361	403
Exact 4011 + Ethacron 0-15	431	405
Hoesel E2000	360	190
Hoesel E2000	471	407
Hoesel E2000	518	520

I. Example 9

Another indication that the additive is assisting in improving the tubing compatibility with pump air sensors is the improvement gained in how the tubing tests in an air sensor housing. Tubings with the additives maintain their rounded cross-sectional shape when placed in a pump air sensor housing. Without the additive the tubings form a "beachy" or "piled" shape which indicates the tubing is not fully seated in the air sensor housing. When the tube was fully seated in the housing the tube took a "square" shape and sensor values were greater. Samples were extruded using a similar extrusion process. Table 8 lists additional test samples that exhibited this phenomenon as well as their air sensor values.

TABLE 8

Material	Air Sensor - Moisture	Shape of tubing at sensor inlet
Exact 4011 without Ethacron 0/15	330	Planted
Exact 4011 with Ethacron	407	Square
UVA without Ethacron 0/15	401	Planted
UVA with Ethacron 0/15	330	Square

J. Example 10

Dow Affinity VP1770 ULDPE was extruded with and without ethacron. The VP1770 was obtained from Dow and the ethacron was obtained from Hoesel Corporation. The extrusion equipment was obtained from

several suppliers as noted: 1.5" extruder from Davis Standard, belt puller model 212-2 and 118 from RDN, vacuum screw model 2.0 PVS from RDN. The material blends comprised 0.23% ethacron and 99.77% VP1770 resin. 0% ethacron and 100% VP1770 was also extruded as a control. Tubings were extruded by blending the resin and ethacron and then placing them into a single screw extruder for extrusion into tubing form. The extruder conditions were as follows: Die Pin outer diameter 0.120"; Die heating inner diameter 0.185"; Temperature, Barrel Zone (BZ) 425° F., BZ2 425° F., BZ3 425° F.; Die Zone (DZ) 41 440° F., DZ2 440° F., DZ3 440° F.; Head Pressure 1600 psi; Motor Amps 13; Line speed was 26 Feet Per Minute. Testing was done on the tubing to illustrate the benefits of using the additive in the tubing with the use of a slide clamp. A production sized Pin-Guide slide clamp (stock number 05-20-16-000) was used to cycle the clamp 10 times over the same area of the tubing. The tubing was then inspected for any damage. The tubing without the additive shows that 5/5 samples tested produced scoring of the tubing. Scoring is more desirable than shredding as it does not produce any loose particulate where shredding does.

K. Example 11

Exact Exact 4011 (ULDPE) was extruded with and without additives. The Exact 4011 was obtained from Exxon Chemical Company and the Ethacron additives were obtained from Akon Nobel Chemical Company. The Heatset additives were obtained from Hoesel Corporation. The extrusion equipment was obtained from several suppliers as noted: 1.5" extruder from Killion, belt puller model 212-2 and 118 from RDN, vacuum screw model 2.0 PVS from RDN. The extruder blends comprised 0.23% Ethacron additives, and 99.77% Exact 4011 resin. 0% additives and 100% Exact 4011 was also extruded as a control. Tubings were extruded by blending the resin and additives and then placing them into a single screw extruder for extrusion into tubing form. The extrusion conditions were as follows: Die Pin outer diameter 0.120"; Die heating inner diameter 0.185"; Temperature, Barrel Zone (BZ) 375° F., BZ2 375° F., BZ3 375° F.; Die Zone (DZ) 41 374° F., DZ2 375° F.; Head Pressure 1600 psi; Motor Amps 9.5; Line speed was 25 Feet Per Minute. Testing was done on the tubing to illustrate the benefits of using the additive in the tubing with the use of a slide clamp. A production sized Pin-Guide slide clamp (stock number 05-20-16-000) was used to cycle the clamp 10 times, in the same spot on the tubing. The tubing was then inspected for damage. The tubing without the additive shows that 5/5 samples tested produced scoring of the tubing. Scoring is more desirable than shredding because it does not produce any loose particulate where shredding does. Table 9 lists the tubes with and without additive and the results from the 10 cycle slide clamp testing.

TABLE 9

Material	10 Cycle Slide Clamp Test
Exact 4011	5/5 shred
Exact 4011 + Ethacron 0/15	3/5 shred
Exact 4011 + Ethacron 0-15	4/5 shred
Exact 4011 + Ethacron 0-15	1/5 shred
Exact 4011 + Ethacron 0-15	4/5 shred
Exact 4011 + Ethacron 0-15	1/5 shred

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