

AVISO DE NOTIFICACION

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CORREO CERTIFICADO

Bogotá, D.C.

Señor (a) (es)
FERRERO EMILIO
CARRERA 4 NO. 72 - 35
BOGOTA D.C.

Radicación :00065983 00000005 Fecha: 30/09/2005 8:30:33
Tramite :2 PATENTES DE INVENCION
Evento :1 REGISTRO/DEPOSITO/CONCESION/DEPOSITO
Actuación :432 COMUNICACION ACTO ADMINISTRATIVO
Solicitante :FERRERO EMILIO Folios:1

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REF: RESOLUCION No: 25038
FECHA No. 29/09/2005
EXPEDIENTE No. 0 65983
Tramite :2 PATENTES DE INVENCION
Evento :1 REGISTRO/DEPOSITO/CONCESION/DEPOSITO
Actuación :432 COMUNICACION ACTO ADMINISTRATIVO

Estimado Doctor (a) :

Comendidamente le solicito presentarse a este Despacho ubicado en la Carrera 13 No. 27 - 00 Piso Quinto (5), de la ciudad de Bogotá D.C., dentro del término de cinco (5) días hábiles contados a partir del envío de la presente citación, en horario de 8:30 a.m. a 5:00 p.m. jornada continua, con el fin de notificarle personalmente el contenido de la resolución de la referencia proferida dentro del expediente tramitado con el número de radicación citado en el asunto.

De no hacerse presente en el término indicado anteriormente, la providencia en mención se notificará por edicto, el cual se fijará por el término de diez (10) días en el Centro de Documentación e Información. Para su comodidad el texto completo de la resolución se encontrará disponible en la página web de la Entidad, desde el día hábil siguiente al que se desfije el edicto.

La consulta del listado notificación y del acto administrativo puede ser realizada desde un computador con acceso a Internet, en la página web www.sic.gov.co, con el número de resolución a través de la opción servicios en línea - caracter general - consulta actos administrativos.

Secretaría General
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

RESOLUCIÓN 25038

Por la cual se niega una patente de invención

Rad. N° 00-65983

EL SUPERINTENDENTE DE INDUSTRIA Y COMERCIO
en ejercicio de sus facultades legales, en especial de las que se confirieron en el artículo 4, numeral 5 del decreto 2153 de 1992, y

CONSIDERANDO:

PRIMERO: Que mediante escrito radicado en esta Superintendencia el 01 de septiembre del 2000, bajo el número 00065983, se presentó la solicitud de patente para la invención denominada: "METODO PARA FABRICAR TUBERIA MEDICA CON ADHERENCIA Y LUBRICIDAD MEJORADA", contenida en el expediente de la referencia.

SEGUNDO: Que efectuado el examen de forma en cuanto a los requisitos que debe llenar la solicitud y cumplidas las exigencias legales, se ordenó publicar el extracto sin que se hubieran presentado oposiciones por parte de terceros.

TERCERO: Que el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina establece que: "Si la oficina nacional competente encontrara que la invención no es patentable o que no cumple con alguno de los requisitos establecidos en esta Decisión para la concesión de la patente, lo notificará al solicitante. Este deberá responder a la notificación dentro del plazo de sesenta días contados a partir de la fecha de la notificación. Este plazo podrá ser prorrogado por una sola vez por un período de treinta días adicionales... si el solicitante no respondiera a la notificación dentro del plazo señalado, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, la oficina nacional competente denegará la patente".

CUARTO: Que realizado el examen de fondo, se requirió al solicitante en los términos del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, para que presentara respuesta a las observaciones de carácter técnico visibles a folios 176 a 184 del cuaderno administrativo, relacionadas con la patentabilidad o cumplimiento de los requisitos establecidos por esta Decisión para la concesión de la patente. Frente a dicho requerimiento no hubo pronunciamiento alguno por parte del mismo, motivo por el cual es procedente negar el privilegio de patente solicitado con fundamento en lo dispuesto en el artículo 45 de la Decisión 486.

RESUELVE:

ARTICULO PRIMERO: Negar el privilegio de patente de invención para la solicitud correspondiente a "METODO PARA FABRICAR TUBERIA MEDICA CON ADHERENCIA Y LUBRICIDAD MEJORADA".



Industria y Comercio
SUPERINTENDENCIA

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

RESOLUCION: 25038

Por la cual se niega una patente de invención

Rad. N° 00-65983

ARTICULO SEGUNDO: Notificar personalmente el contenido de la presente resolución al doctor Emilio Ferrero, o a quien haga sus veces, en su calidad de apoderado de Baxter International Inc., entregándole copia de la misma, advirtiéndole que contra ella procede el recurso de reposición interpuesto ante el Superintendente de Industria y Comercio, al momento de la notificación o dentro de los 5 días hábiles siguientes a ella.

NOTIFÍQUESE Y CUMPLASE

Dada en Bogotá, D.C., a los **29 SET. 2005**

EL SUPERINTENDENTE DE INDUSTRIA Y COMERCIO (E),


GIANCARLO MARCENARO JIMÉNEZ

Doctor
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referred to as ultra low density polyethylene (ULDPE), methyl acrylate (with less than 33% methyl acrylate comonomer), vinyl acetate (with less than 33% methyl acrylate comonomer), ULDPE generally has a density within the range of about 0.91 g/cm³ to about 0.93 g/cm³.

The additive should be a polymer or an aliphatic or aromatic hydrocarbon having greater than 5 carbon atoms in the backbone and further having electron negative groups selected from the group of sulfones, imides, hydroxyacids, esters, succinimide salts, organometallic compounds such as metal alkoxides, metal carboxylates, and metal complexes of monomers 1,3 dicarbonyl compounds; phenyl phosphines; pyridines; pyrimidines; imidazoles; and oxazolones.

The blends should have the polymeric component in an amount by weight within the range of 90%-99.999%, more preferably 95.7%-99.999%. The additive should be in an amount by weight within the range of 0.001%-10%, and more preferably 0.01%-5%.

II. Method of Blending

The components of the polymer blends should be blended through means 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 0.001-0.4 inches, and an outer diameter dimension within the range of 0.01-0.5 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 trademark FLO-GARD[®], and COLLEAGUE[®], have an inner diameter within the range of 0.009-0.165 inches, an outer diameter within the range of 0.114-0.195 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 50,000 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 therebetween. The first layer 22 may be selected from the same group of polymers as those for the polymer blends. The second layer 24 will be of the same polymer as the first layer 22, but will not have the additive. The third layer 26 will be of the same polymer as the first layer 22, but will have the additive. The tubing should be flexible having a modulus of elasticity of less than 50,000 psi, and more preferably less than 40,000 psi.

The first layer 22 of the tube 20 should have a thickness as a percentage of the total wall thickness within the range of 10%-50%, the second layer 24 should have a thickness within the range of 2-50%, and the third layer 26 should have a thickness within the range of 5-10%.

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 step increases 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 shall 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 orienting ratio. The orienting step orients 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 location along the line in a direction opposite the direction to the flow of the tubing 32. Conversely, the term "down-line" shall refer to location 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 forced 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 30%-70% greater, 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.-40° 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 collected by opening 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 tendency 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 ordered lower melting crystals are melted leaving higher melting crystals which will be thermally stable upon the application temperature range. Part of the highly oriented micro-molecule 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 cooling bath 41 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 straight and the tubing should be allowed to sag in an 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. Soluble 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 cordrail having a diameter greater than that of the tubing whereas the tubing 32 is supported by the interior surface of the cordrail.

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 longwinded passes through the cooling bath 43 or heating bath 44 as shown in FIG. 3a to provide for maximum cooling 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. 3b shows a dry orientation process 30. The dry orientation process is used in most respects in the wet orientation process with the major exception that the tubing 32 is oriented in section 42 between pulleys 37 and 39. Pulley 37 is operated at a speed greater than pulley 39. During the dry orientation step 45, the tubing 32 is not submerged in the aqueous bath 44 as is the case in the wet orientation step 45. 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 fluid is infused from a fluid container such as a 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 64 which has a stop 66 that opens along its length. By positioning the tubing at various positions within the stop 66, the walls of the stop 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 68 (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 proximate 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. 5,515,015 move fluid through tubing in a continuous fashion by deforming the tubing out of round in a non-occlusive fashion. That is to say the tube is deformed in a manner such that the opposite internal surfaces of the tubing which approach each other, do not meet contact. Applicants hereby incorporate by reference U.S. Pat. No. 5,515,015 and in particular those portions of the patent describing the general principles of operation of such a pump, namely the part located at Col. 4, line 51-Col. 5, line 25 and Col. 7, line 6-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. Such pressure sensors are provided to detect an increased resistance to fluid flow which results from a patient occluding the tubing or from the tubing being otherwise blocked. As shown in FIG. 4, the sensor usually have a sensor housing 67 in which a segment of the tubing 32 of the administration set is inserted. 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.

VI. Rigid Moulded Housing

The administration set 80 in FIGS. 4 and 5 include tubing 33 connected to and in fluid communication with various rigid plastic housings such as Y-type injection sleeve 76. The tubing 33 connects to a housing sleeve 76 on each of these housings 73 and 74.

The housings 72 and 74 and their housing sleeves 76 are preferably constructed of a rigid polymer such as polycarbonate, copolymers, ABS, acrylics, styrenes, polypropylenes, high density polyethylene, polyethylene, and polyimides. The term "rigid polymer" as those having a modulus of elasticity of greater than 30,000 psi and preferably greater than 100,000 psi. Typically, the housing 74 is constructed using injection molding techniques.

As shown in FIGS. 7 and 8, it is preferred that housing sleeve 76 have a generally elongate cylindrical body 80 having an opening 82 at its distal end. The opening 82 leads to a chamber 84 which is dimensioned to receive an end portion of the tubing 33. The housing chamber 84 is connected to an exterior fluid flow channel 86. As shown in FIG. 4, the interior channel 82 is in fluid communication with a connector 88 holding a beneficial agent to be conveyed to a patient.

Referring again to FIG. 7, the housing sleeve 76 has an inner surface 90 which defines a generally funnel-shaped chamber 84. The chamber 84 has a first area 84a proximate the opening 82 and having a first diameter, and a second area 84b where a plurality of ribs 92 are positioned. The interior flow channel 86 preferably has a second diameter which is less than the first diameter. A taper 94 connects the second area 84b to the interior flow channel 86. The degree of taper 94 preferably is within the range of 0.25-1.0 degrees as measured from a centerline 94a of the housing sleeve 76.

Preferably, the first and second chamber areas 84a and 84b first diameter portion serves or decreases diameter from the opening 82 to the flow channel 86. This taper is known as the draft angle θ as measured from the centerline 94a. Because the housing is typically fabricated using an injection molding process, the chamber 84 is formed by a tool whose shape defines the chamber 84. The tool must be removed after fabricating the housing and the draft angle θ of the interior surface 90 assists in removing the tool by reducing the frictional interference with the tubing.

It is desirable that the second diameter of the flow channel 86 be less than that of the outer diameter of the flexible tubing 33 so that a portion of the taper 94 may serve as a stop 98 to prevent further insertion of the tubing 33 into the housing sleeve 76 and to prevent the migration of adhesive into the fluid path. (See also FIG. 5). Also, it is preferable that the tubing 33 fluid passage 35 be in alignment with the housing sleeve 76 flow channel 86 to minimize the resistance to fluid flow at the junction. In effect, the taper 94 defines a recess where the tubing 33 fits to achieve this desirable alignment.

As shown in FIGS. 4, 8 and 9 the housing sleeve 76 also has a plurality of circumferentially spaced ribs 92 positioned in area 84b. As shown in FIG. 8, preferably there are at least three ribs 92 spaced apart about 120° and more preferably 5 ribs. Of course the ribs 92 could also be unevenly spaced without departing from the present invention. There may also be any number of ribs 92 greater than three. The ribs 92 extend from the inner diameter surface 90 in the second chamber area 84b and preferably terminate at some point prior to the fluid channel 86. Each of the ribs 92 may be of varying and differing lengths from one another and each may

start and stop at various locations within area 84b. Preferably, a portion of the ribs 92 outer surface 96 extends parallel to the housing centerline 94a.

The ribs 92 have a height measured from the interior surface 90 to a highest point 102 of the ribs 92 ranging from about 0.001 inches to about 0.010 inches. The height of the ribs 92 provides the desired circumferential clearance between an outer surface 104 of the tubing 33 and the outer portion 102 of the ribs 92 to define an adhesive area 106 therebetween. The adhesive area 106 should be large enough to accommodate a sufficient quantity of adhesive to create a secure adhesive bond, but not so large as to risk creating a leak between the tubing 33 and the housing sleeve 76 and a poor bond.

The height of the ribs 92, and their position inward of the opening 82 minimizes interference and scraping off of adhesive from the outer surface 104 of the tubing 33 upon insertion of the tubing 33 into the chamber 84. The ribs 92 can have any geometric profile, but are preferably rounded, or slightly rounded, again so that the ribs 92 minimally interfere with the adhesive. If a significant amount of adhesive is removed during insertion of the flexible tubing 33, channels could form between the tubing 33 and the housing sleeve 76, allowing for undesirable leakage of the fluid being transferred through the tubing 33.

The ribs 92 also serve as a guiding means that assists in centering the tubing 33 within the housing sleeve 76. Centering the tubing 33 within the housing sleeve 76 is important for providing equal circumferential distribution of the adhesive between the tubing 33 and housing sleeve 76, and providing for a more reliable adhesive bond.

FIG. 9 shows the housing and tubing assembly 78 in a connected position. Tubing 33 is positioned in the chamber 84 of the housing sleeve 76 such that a tubing end 108 abuts the stop 98. The adhesive area 106 is shown filled with an adhesive.

A further aspect of the present invention provides a method of forming a tubing and housing assembly 78 shown in FIG. 10 using the tubing 33 and the housing sleeve 76 described above.

The method comprises the steps of providing a rigid housing sleeve 76 having an opening 82, leading to a chamber 84 which in turn connects to an interior channel 86. A plurality of circumferentially spaced ribs 92 as described above are positioned in the chamber 84. The method further includes the step of applying a quantity of adhesive to the adhesive area 106, inserting the end portion of the tubing 33 into the sleeve opening 82 until the tubing end 108 contacts the stop 98. More preferably the tubing 33 is inserted into the chamber 84 and the adhesive is then added to the adhesive area 106 and allowed to cure about the circumference of the tubing 33. The ribs 92 guide the end portion 108 of the tubing 33 into a central portion of the housing sleeve 80 thereby defining the boundaries of the adhesive area 106 between the outer surface of the tube 104 and the inner surface 90 of the housing sleeve 80. The method finally includes the step of hardening the adhesive forming a bond in the adhesive area 106 to secure the tube 33 within the housing sleeve 80. The curing step may include the step of applying heat, U.V. energy, pressure or other means to harden the adhesive.

Suitable adhesives for use in the above method include cyanoacrylates, hot melt adhesives, U.V. cured adhesives, epoxies, and pressure sensitive adhesives.

VII. EXAMPLES

A. Example 1

The polymer components shown in Table 1 were blended having 0.23 weight percent of the additive and the

remainder the polymeric material. The blend had 0.33 weight percent of the additive and the remainder the Exact 4011. The blend was extruded into tubing having an outer diameter within the range of 0.135-0.145 inches and an inner diameter within the range of 0.101-0.105 inches. The tubing was cut into three inch segments for testing. A cyanoacrylate adhesive sold by Loctite under the product number 4061 was used to connect the tubing segments to an acrylic test housing.

The test housing has an opening having a diameter of 0.150 inches that leads to a chamber having diametrically inwardly tapering sidewalls to a dimension of 0.142 inches. An end of the tubing is inserted into the opening of the test housing as shown in FIG. 11. A quantity of the cyanoacrylate is added to the test housing which wicks about the outer circumference of the tubing.

The tensile strength of the tubing and housing assemblies were tested using an Instron apparatus. The tubing and housing assemblies were mounted on an Instron where a pull test study was conducted. The force required to break either the tubing or the bond is reported below in Table 1.

The tensile strength data for the polymeric material and additive blends compare favorably with the tensile strength of tubing constructed without any additive as shown below.

TABLE 1

Polymeric material	Additive	Avg. Pull Force
Exact 4011	None	6.833 lbs
Exact 4011	Exact 4011	6.14 lbs
Exact 4011	Exact 4011	6.14 lbs
Exact 4011	Exact 4011	6.14 lbs
Exact 4011	Exact 4011	6.14 lbs
Exact 4011	Exact 4011	6.14 lbs
Exact 4011	Exact 4011	6.14 lbs
Exact 4011	Exact 4011	6.14 lbs
Exact 4011	Exact 4011	6.14 lbs
Exact 4011	Exact 4011	6.14 lbs

Exact 4011 is an ultra-low density polyethylene. Ethomeren U15 is polyoctylthene/ethylene. Ethomeren S12 is bis-hydroxyethyl/propylenes. Ethomeren U12 is bis-hydroxyethyl/ethylene. Ethomeren 18/12 is polyoctylthene/ethylene. Ethomeren 18/12 is polyoctylthene/ethylene. E-33752 is an additive. Lanbecast-104 is a fatty amide additive.

B. Example 2

Tubing constructed in accordance with Example 1 having the additive Ethomeren U15 (Akzo Nobel Chemical Company) has been found to be effective in forming secure adhesive bonds with rigid housings even after 6 weeks after blending. For tubing where a primer is sprayed onto the outer surface of the Exact 4011 the so-called life is roughly 24 hours.

C. Example 3

An ultra-low density polyethylene sold under the name EXACT 4011 (Akzo Nobel Chemical Company) was fabricated into tubing, oriented to various orientations and tested. The EXACT 4011, in an amount by weight of 99.77%, was blended with an ETHOMEREN U15 (Akzo Nobel Chemical Company) in an amount by weight of 0.23%.

The tubing was fabricated by extruding in a 1.5 inch extruder (Davis Standard). The extrusion conditions were as

follows: die pin outer diameter: 0.240 inches, and die bushing inner diameter: 0.235 inches. Barrel zone Nos. 1-4 temperatures were in degrees Fahrenheit, respectively: 425, 425, 425, 425. Die Zone Nos. 1-3 temperatures were, in degrees Fahrenheit, respectively: 425, 425, 425.

The tubing extruder was heated about a series of 5 rollers as schematically set forth in FIG. 12. Rollers 1-5 were operated at the following respective speeds in feet per minute: 17 FPM, 56 FPM, 41 FPM, 33 FPM, and 33 FPM. The tubing was passed through heating and cooling baths as schematically shown in FIG. 13. The heating and cooling bath equipment is a triple pass air-heating system sold by Valmet under model No. CS6073. The temperature of the heat setting bath varied as set forth in Table 2 below. The heat setting bath was in the heating bath for 13 seconds.

Tubing made in accordance with the above conditions was subjected to shrinkage tests. The tubing length was measured and recorded for each group of tubing. Tubing samples were then placed in a conditioning oven at 150° F. and 50% relative humidity for 1 hour. Tubing samples were then removed and allowed to cool to ambient temperature. The samples were measured for length and recorded. The percentage change in length was calculated as set forth in Table 2.

Tensile strength tests were also conducted on other samples of the tubing. The inner and outer diameter of the tubing and the tubing wall thickness was measured using a Lamellville 163 Benchtop Optical Microscope. The samples were then tested with an Instron 1130 tester with a crosshead speed of 20 inches per minute. Stress at 100% elongation was used to represent the yield of the tubing in psi as reported in Table 2.

Exact 4011 was also extruded under similar conditions and tested. The tubing, without the heat set process, showed a significant decrease in tensile strength and elongation at break when tested with and without heat set and oriented change in elongation at break when tested with and without heat set. The shrinkage was measured as a percentage change from the initial length before being placed in the oven and the final length after being removed from the oven.

TABLE 2

ULTRADEN	Temp (°C)	Shrinkage	Yield
Exact 4011	150	21.00	920
Exact 4011	150	2.00	1100
Exact 4011	150	1.00	1000
Exact 4011	150	2.00	800
Exact 4011	150	2.00	800
Exact 4011	150	2.00	800
Exact 4011	150	2.00	800
Exact 4011	150	2.00	800
Exact 4011	150	2.00	800
Exact 4011	150	2.00	800

D. Example 4

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 ethylene vinyl acetate (EVA) (UE-634, 0.13% by weight) (Akzo Nobel Chemical Company). Tubing samples were also prepared from pure EVA of the same type in the blend.

The barrel zone temperature for zone Nos. 1-4 were respectively as follows in degrees Fahrenheit: 374, 375, 376, and 375. Die zone temperature for zone Nos. 1-3 were as follows in degrees Fahrenheit: 375, 375, 376. The puller speeds of puller Nos. 1-4 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 Comp.	Temp. °C. of extr. zone	Shrinkage	Yield
Base	90	1000	923
Base	90	420	140
Base	90	180	180
Base	90	147	199
Base	90	140	200
Base	90	133	490
Base	90	133	230
Base	90	133	230
Base	90	133	230
Base	90	133	230

E. 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 Low Chemical Company under the name Dura Affinity VP1770, and Ethomom 015 (0.25% by weight) (Alko Nobel Chemical Company). Another sample of tubing was formed from Dura Affinity ULDPE alone.

The barrel zone temperature for zone Nos. 1-4 were respectively as follows in degrees Fahrenheit: 424, 425, 422, 425. Die zone temperature for zone Nos. 1-3 were as follows in degrees Fahrenheit: 425, 425, 425. The puller speeds of puller Nos. 1-4 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 Comp.	Temp. °C. of extr. zone	Shrinkage	Yield
VP 1770	90	235	240
VP 1770	90	430	110
VP 1770	90	430	110
VP 1770	90	430	110
VP 1770	90	430	110
VP 1770	90	430	110
VP 1770	90	430	110
VP 1770	90	430	110
VP 1770	90	430	110
VP 1770	90	430	110

F. Example 6

Tubing samples were also produced in a similar orientation 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 compositions set forth below in Table 5, namely, Exact

4011, BVA, and VP1770. The necking 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 Chastillon gauge was attached to the opposite end of the tubing. The Chastillon 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	30.45
Exact 4011 (50% orientation)	0.75
Exact 4011 (50% orientation)	0.75
Exact 4011 (50% orientation)	0.75
Exact 4011 (50% orientation)	0.75
Exact 4011 (50% orientation)	0.75
Exact 4011 (50% orientation)	0.75
Exact 4011 (50% orientation)	0.75
Exact 4011 (50% orientation)	0.75
Exact 4011 (50% orientation)	0.75

G. Example 7

An ultra-low density polyethylene Exact 4011 was produced into tubing having an outer diameter within the range of 0.139-0.145 inches and an inner diameter within the range of 0.101-0.105 inches. One sample of the tubing was oriented to a 50% orientation ratio and a second sample of the tubing was oriented to a 35% orientation ratio. Samples of the tubing that were oriented to a 50% orientation ratio were separately extruded in a water bath at 65° C., and 70° C. for 10 seconds and 85° C. for 5 seconds with opposite ends of the tubing clamped to prevent movement or shrinkage of the tubing. After the exposure to the heat the tubing was removed 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 35% orientation was not heat treated in a water bath. This 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 setting step greatly reduces the tendency for the tubing to shrink.

TABLE 6

Temperature of Heat Set (°C.)	Time in Heat (hrs.)	% Change in Length (before over)	% Change in Length (after over)
65	10	1.40	-3.68
70	10	1.75	-1.60
85	5	1.75	-0.83
85	5	1.75	-21.9

H. Example 8

Exact Exact 4011 (ULDPE) was extruded with and without additives. The Exact 4011 was obtained from Exxon Chemical Company and the Ethomom additives were obtained from Alko Nobel Chemical Company. Heptal additives were obtained from Heskel 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 slider model 2.0 PVS from RDN. The material blends comprised 0.21% additives and 99.79% 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 extruder diameter 0.120"; Die heating inner diameter 0.185"; Temperature, Barrel Zone (BZM) 375° F., BZM 375° F., BZM 375° F., Die Zone (DZ) 413° F., DZ 413° F., DZ 413° 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 solution (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 400-650. Table 7 lists the results for Exact 4011 with and without additives and indicates an improved compatibility for ULDPPE with the additive.

TABLE 7

Material	Air Sensor - Normal	Air Sensor - Normal
Exact 4011	330	330
Exact 4011 + Ethomom 015	26	607
Exact 4011 + Ethomom 015	52	745
Exact 4011 + Ethomom 015	41	400
Exact 4011 + Ethomom 015	47	719
Exact 4011 + Ethomom 015	47	657
Exact 4011 + Ethomom 015	519	120

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 reacts in an air sensor housing. Tubings with the additive maintain their rounded cross-sectional shape when placed in a pump air sensor housing. Without the additive the tubing forms a "mushy" or "pinched" shape which indicates the tubing is not fully seated in the air sensor housing. When the tube was fully seated in the air sensor housing, the tube took a "square" shape and some 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 test results.

TABLE 8

Material	Air Sensor - Normal	Shape of tubing at sensor inlet
Exact 4011 without Phosmox 015	330	Flattened
Exact 4011 with Phosmox 015	407	Square
Exact 4011 with Phosmox 015	101	Flattened
Exact 4011 with Phosmox 015	100	Square

J. Example 10

Dura Affinity VP1770 ULDPE was extruded with and without alkyldimethylamine. The VP1770 was obtained from Dow and the alkyldimethylamine was obtained from Heskel 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 slider model 2.0 PVS from RDN. The material blends comprised 0.20% alkyldimethylamine and 99.80% VP1770 resin. 0% alkyldimethylamine and 100% VP1770 was also extruded as a control. Tubings were extruded by blending the resin and alkyldimethylamine and then placing them into a single screw extruder for extrusion into tubing form. The extrusion conditions were as follows: Die Pin extruder diameter 0.120"; Die heating inner diameter 0.185"; Temperature, Barrel Zone (BZM) 425° F., BZM 425° F., BZM 425° F., Die Zone (DZ) 440° F., DZ 440° F., DZ 440° F., head Pressure 2400 psi, Motor Amps 1.3, 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 released Fls-Gard® slide clamp (stock number 03-20-16-490) 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 samples tested showed shredding, produced scoring of the tubing. Scoring is more desirable than shredding as it does not produce any loose particulate when 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 Ethomom additives were obtained from Alko Nobel Chemical Company. The Heptal additives were obtained from Heskel 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 slider model 2.0 PVS from RDN. The material blends comprised 0.21% Ethomom additives and 99.79% 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 extruder diameter 0.120"; Die heating inner diameter 0.185"; Temperature, Barrel Zone (BZM) 375° F., BZM 375° F., BZM 375° F., Die Zone (DZ) 413° F., DZ 413° F., DZ 413° 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 released Fls-Gard® slide clamp (stock number 03-20-16-490) 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 samples tested produced scoring of the tubing. Scoring is more desirable than shredding because it does not produce any loose particulate when shredding does. Table 9 lists the tubes with and without additives and the results from the 10 cycle slide clamp testing.

TABLE 9

Material	10 Cycle Slide Clamp Test
Exact 4011	50 times
Exact 4011 + Ethomom 015	50 times
Exact 4011 + Ethomom 015	43 times
Exact 4011 + Ethomom 015	11 times
Exact 4011 + Ethomom 015	43 times
Exact 4011 + Ethomom 015	11 times

TABLE 9-continued

Material	10 Cycle Size Comp Test
Resin E2354	45 mm
Resin E2352	45 mm
Resin E2353	50 mm

While specific embodiments have been illustrated and described, numerous modifications are possible without departing from the spirit of the invention, and the scope of protection is only limited by the scope of the accompanying claims.

We claim:

1. A single-layered polymeric tubing having an initial diameter not suitable for connecting to rigid housings comprising:
 - a sidewall defining a fluid pathway and having a longitudinal axis, the sidewall being of an ultra-low density polyethylene material in an amount by weight within the range 99.999%-99.99% and an additive having functional groups selected from the group consisting of amine, amides, hydroxyl, acids, acetate, ammonium salts, organometallic compounds such as metal alkoxides, metal carboxylates, and metal complexes of numerous 1,3-dicarbonyl compounds, phenyl phosphines, pyridines, pyrrolidones, imidazoles, and oxadiazines and in an amount by weight within the range of 0.001%-10%; and
 - wherein the tubing has been oriented along its longitudinal axis to decrease its initial diameter to define an oriented diameter, the initial diameter being within the range of 30%-300% greater than the oriented diameter.
2. The tubing of claim 1 wherein the initial diameter of the tubing is within the range of 30%-120% greater than the oriented diameter.
3. A multi-layered medical tubing having an initial diameter for connecting to rigid housings comprising:
 - a wall defining a fluid pathway having a longitudinal axis, the wall having a first layer being of a ultra-low density polyethylene material and an additive, the additive being selected from the group consisting of hydrocarbons having electron-negative functional groups selected from the group consisting of amine, amides, hydroxyl, acids, acetate, ammonium salts, organometallic compounds such as metal alkoxides, metal carboxylates, and metal complexes of numerous 1,3-dicarbonyl compounds, phenyl phosphines, pyridines, pyrrolidones, imidazoles, and oxadiazines;
 - a second layer of a second polymeric material; and
 - wherein the tubing is oriented along its longitudinal axis to decrease its initial diameter to define an oriented diameter, the initial diameter being within the range of 30%-300% greater than the oriented diameter.
4. The tubing of claim 3 wherein the initial diameter of the tubing is within the range of 30%-120% greater than the oriented diameter.
5. The tubing of claim 4 wherein the second polymeric material is selected from the group consisting of polyethylene and their copolymers, ethylene-propylene rubber, ethylene vinyl acetate copolymers, ethylene methyl acrylate copolymers, styrene and hydrocarbon block copolymers, hydrogenated derivatives of styrene and hydrocarbon block copolymers, thermoplastic elastomers, polyurethanes, polyamides and polyester copolymers, copolyesters, polycarbonate, polypropylene, polybutylenes, styrene-butadiene rubbers, and cross-linked elastomers.
6. The tubing of claim 4 wherein the second polymeric material is selected from the group consisting of both homo and copolymers of polyethylene, polypropylene, polybutene-1, polyisoprene, polyoctene.
7. The tubing of claim 6 wherein the second material may be selected from the group consisting of aliphatic olefins, methyl acrylate and vinyl acetate.
8. A polymeric tubing having an initial diameter and suitable for connecting to rigid housings comprising:
 - a sidewall defining a fluid pathway and having a longitudinal axis, the sidewall being of an ultra-low density polyethylene material in an amount by weight within the range 99.999%-99.99% and an additive having greater than 5 carbon atoms and electron-negative functional groups selected from the group of amines, amides, hydroxyl, acids, acetate, ammonium salts, organometallic compounds such as metal alkoxides, metal carboxylates, and metal complexes of numerous 1,3 dicarbonyl compounds, phenyl phosphines, pyridines, pyrrolidones, imidazoles, and oxadiazines in an amount by weight within the range of 0.001%-10%;
 - wherein the tubing has been oriented along its longitudinal axis to decrease its initial diameter to define an oriented diameter that is smaller than the initial diameter; and
 - wherein the tubing has been set in the oriented diameter.
9. The tubing of claim 8 wherein the initial diameter of the tubing is within the range of 30%-300% greater than the oriented diameter.
10. The tubing of claim 8 wherein tubing is set by exposing the tubing to heat.
11. The tubing of claim 10 wherein the process of exposing the tubing to heat comprises:
 - heating the tubing after orienting the tubing; and
 - cooling the tubing after the heating step.
12. The tubing of claim 10 wherein the process of exposing the tubing to heat includes the step of raising the temperature of the tubing to a temperature above which it normally will be exposed during shipping, storage and use.
13. The tubing of claim 10 wherein the process of exposing the tubing to heat includes the step of raising the tubing to a temperature below which the tubing will be fully melted.
14. The tubing of claim 10 wherein the process of exposing the tubing to heat includes the step of exposing the tubing to a heated liquid.
15. The tubing of claim 14 wherein the heated liquid is water.
16. The tubing of claim 14 wherein the process of exposing the tubing to heat includes the step of exposing the tubing to heated air.

• • • • •

FIG. 1



FIG. 2



FIG. 3

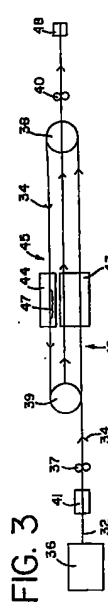


FIG. 3a

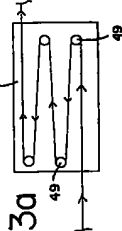


FIG. 3b

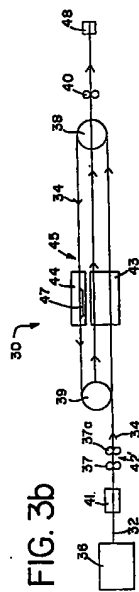


FIG. 4

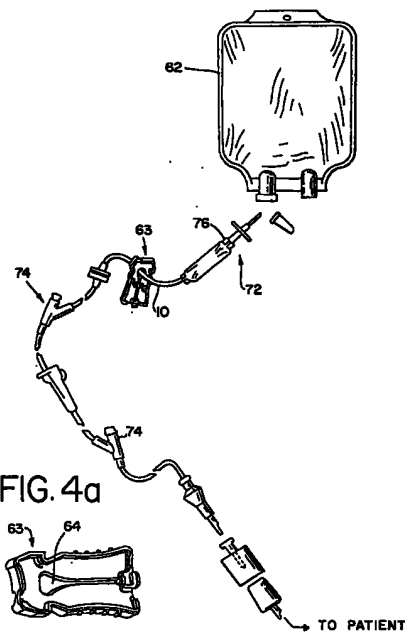
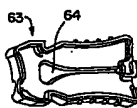


FIG. 4a



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FIG. 5

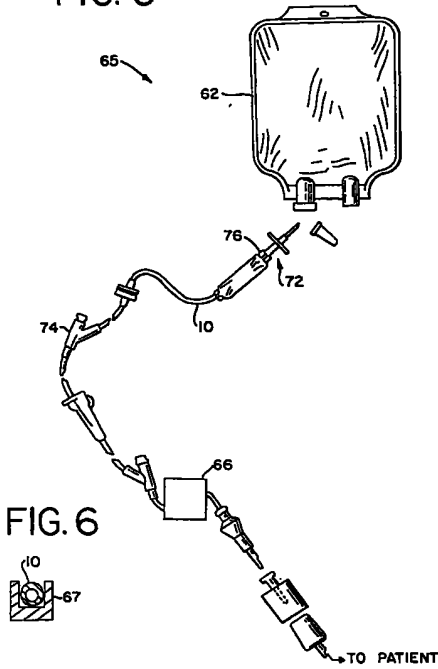


FIG. 6



FIG. 7

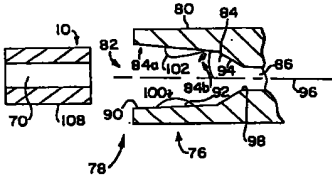


FIG. 8

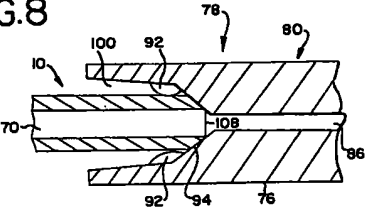
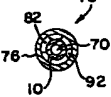


FIG. 9



FIG. 10



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Date: 23.08.04

Reference BAXR/P28002EP	Application No./Patent No. 00863288.0 - 2107 / 1207920
Applicant/Proprietor BAXTER INTERNATIONAL INC.	

Communication regarding the expiry of the time limit within which notice of appeal may be filed

You are hereby informed that on expiry of the nine-month time limit from the publication of the mention of the grant of European Patent No 1207920 no notice of opposition had reached the files.

The entry in the Register of European Patents will be automatically generated by the electronic data processing system.

Examining Dytalon



EPPU 02: 22.10.03 2107

502 From 1957 to 1966



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Delivery Date	11/09/03
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Zaskenná Pod. Míst. BAXR/P26002EP	Ažurnování Nr./Aktualizace Nr./Dovozová Nr./Převzetí Nr./Převzetí Nr./Kontrola Nr./ 00963286.0-2307 1207920
Ažurnování Pod. Míst. / Aktualizace Pod. Míst. / Dovozová Pod. Míst. / Převzetí Pod. Míst. / Kontrola Pod. Míst. BAXTER INTERNATIONAL INC.	

DECISION TO GRANT A EUROPEAN PATENT PURSUANT TO ARTICLE 97(2) EPC

Following examination of European patent application No. 00963286.0 a European patent with the title and the supporting documents indicated in the communication pursuant to Rule 51(4) EPC dated 09.12.02 is hereby granted in respect of the designated Contracting States.

The modifications subsequently requested by the applicant and received at the EPO on 09.06.03 have been taken into account.

Patent No. : 1207920
Date of filing : 31.08.00
Priority claimed : 03.09.99/US 389518
Designated Contracting States and Proprietor(s) : AT-EE-CH-CY-DE-DK-ES-FI-FR-GB-GR-IE-IT-IL-LU-MC-ML-PT-SE
BAXTER INTERNATIONAL INC.
One Baxter Parkway
Deerfield, Illinois 60015/US

This decision will take effect on the date on which the European Patent Bulletin mentions the grant (Art. 97(4) and (5) EPC).

The mention of the grant will be published in European Patent Bulletin 03/43 of 22.10.03.

Examining Division
DE WAARD W LANZ P G DUFUIS J L M



Registered letter

EPO Form 2006A 07-02

7061001 to EPO postal service: 05/09/03

ANMERKUNG ZUR ENTSCHEIDUNG ÜBER DIE erteilung
EINES EUROPÄISCHEN PATENTS (EPA Form 2006)

1. EPA Informationsbroschüre "Multilingual Recht zum EPC"
Diese Broschüre enthält wichtige Informationen zu den formalen Erfordernissen und den Handlungen, die vor den Patentbehörden der Vertragsstaaten vorzunehmen sind, um Rechte in diesen Staaten zu erlangen. Da diese Handlungen einen erheblichen Wandel unterworfen sind, sollte immer nur die neueste Ausgabe der Broschüre benutzt werden. Nachträgliche Informationen werden im Amtsblatt veröffentlicht.
2. Übersetzung der europäischen Patentschrift nach Artikel 69(1) des Europäischen Patentsicherheitsabkommens
Sie werden ersucht, darauf hinzuwirken, dass bestimmte Vertragsstaaten nach Artikel 69(1) EPC eine Übersetzung der europäischen Patentschrift verlangen. Hierfür wird in der Mitteilung gemäß Regel 51(5) verwiesen. Die Nichtbeachtung dieser Übersetzung kann zur Folge haben, dass das Patent in den betreffenden Staaten des betreffenden Staates als von Anfang an nicht eingereicht gilt. Weitere Einzelheiten entnehmen Sie bitte der oben genannten Broschüre.
3. Zahlung von Jahresgebühren für europäische Patente
Nach Artikel 141 EPC können "nationalen" Jahresgebühren für das europäische Patent für die Jahre erhoben werden, die an das Jahr angeschlossen, in dem der Hinweis auf die Erteilung des europäischen Patents im "Europäischen Patentblatt" bekanntgegeben wird. Weitere Einzelheiten entnehmen Sie bitte der oben genannten Broschüre.

NOTE RELATING TO THE DECISION TO GRANT A
EUROPEAN PATENT (EPO Form 2006)

1. EPO Information Brochure "National law relating to the EPC"
This brochure provides useful information regarding formal requirements and the steps to be taken before the patent authorities of the Contracting States in order to acquire rights in these states. Since the necessary steps are subject to change the latest edition of the brochure should always be used. Subsequent information is published in the Official Journal.
2. Translation of the European patent specification under Article 69(1) of the European Patent Convention
Your attention is again drawn to the requirements regarding translation of the European patent specification laid down by a number of Contracting States under Article 69(1) EPC, to which reference is made in the communication under Rule 51(5). Failure to supply such translation(s) may result in the patent being deemed to be void "ab initio" in the State(s) in question. For further details you are recommended to consult the above-mentioned brochure.
3. Payment of renewal fees for European patents
Under Article 141 EPC "national" renewal fees in respect of a European patent may be imposed for the years which follow that in which the mention of the grant of the European patent is published in the "European Patent Bulletin". For further details you are recommended to consult the above-mentioned brochure.

REMARQUE RELATIVE A LA DECISION DE DELIVRANCE
D'UN BREVET EUROPEEN (OEB Form 2006)

1. Brochure d'Informations de l'OEB "Droit national relatif à la CBE"
Cette brochure fournit d'utiles renseignements sur les conditions de forme requises et sur les actes à accomplir auprès des offices de brevets des Etats contractants aux fins d'obtenir des droits dans les Etats contractants. Étant donné que les actes indispensables sont susceptibles de modifications, il serait bon de toujours consulter la dernière édition de la brochure. Toute information ultérieure est publiée au Journal Officiel.
2. Traduction du fascicule du brevet européen en vertu de l'article 69(1) de la Convention sur le brevet européen
Votre attention est de nouveau attirée sur l'obligation faite par certains Etats contractants, en vertu de l'article 69(1) CBE, de fournir une traduction du fascicule du brevet européen, à laquelle il est fait référence dans la notification établie conformément à la règle 51(5). Si la(les) traduction(s) d'office(s) n'est (sont) pas fournie(s), le brevet européen peut, dès l'origine, être réputé sans effet dans ce(s) Etat(s). Pour plus de détails, nous vous renvoyons à la brochure susmentionnée.
3. Paiement des taxes annuelles pour le brevet européen
Conformément à l'article 141 CBE, les taxes annuelles "nationales" dues au titre du brevet européen peuvent être perçues pour les années suivant celle au cours de laquelle la mention de la délivrance du brevet européen est publiée au "Bulletin européen des brevets". Pour plus de détails, nous vous renvoyons à la brochure susmentionnée.

EP/POC/05 Form 2006 03.03



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Application No.
00 963 288.0-2307

Ref.
BAXRP/28002EP

Date
26.07.2002

Applicant
BAXTER INTERNATIONAL INC.

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 86(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 86(2) EPC).



DUPUIS J L M
Primary Examiner
for the Examining Division

Enclosure(s): 2 page/s reasons (Form 2806)

Registered Letter
pro Form 2806 or 2806a

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 34 and Rule 70)

REC'D 21 AUG 2001

WIPO PCT

Applicant's or agent's file reference MPVC-0011A CIP	FOR FURTHER ACTION See Notification of Transmitted of International Preliminary Examination Report (Form PCT/ISPEA/400)
International application No. PCT/US00/12345	International filing date (day/month/year) 01 AUGUST 2000
International Patent Classification (IPC) or related classification and IPC Please see Supplemental Sheet.	Priority date (day/month/year) 03 SEPTEMBER 1999
Applicant BAXTER INTERNATIONAL INC.	EPO - DG 1 08-12-2001

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 34.
2. This REPORT consists of a total of 4 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims, drawings which have been accepted and are the basis for this report under-claim, containing modifications made before this Authority. (see Rule 70.10 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 0 sheets.
3. This report contains indications relating to the following items:
- I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Issued statement under Article 34(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 02 APRIL 2001	Date of completion of this report 10 JULY 2001
Name and mailing address of the IPEA/US Supervisor of Patents and Trademarks Box PCT Washington, D.C. 20541 Facsimile No. (703) 552-9390	Authorized Officer <i>Patricia E. L. Smith</i> Patricia E. L. Smith Telephone No. (703) 552-9391

Form PCT/ISPEA/400 (cover sheet) (July 1999)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/12345

1. Basis of the report

1. With regard to the elements of the international application:

☒ the international application as originally filed

☒ the description:

pages 1-32, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the claims:

pages 33-33, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the drawings:

pages 1-4, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

☒ the sequence listing part of the description:

pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 33.1(d)).

☐ the language of publication of the international application (under Rule 49.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 53.2 and/or 53.3).

3. With regard to any nucleotide and/or amino acid sequences disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

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

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheet(s) NONE

5. ☐ This report has been drawn up as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Sheet (Rule 70.20(i)).

* Supplemental sheets which have been furnished to the receiving Office in response to an invitation under Article 34 are referred to in this report as "originally filed" and are not attached to this report since they do not contain amendments (Rule 70.10 and 70.17).

**After publication, these amendments must be referred to under Item 1 and entered in this report.

Form PCT/ISPEA/400 (Form 1) (July 1999)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US80/0000

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statements

1. statement

Novelty (N)

Claim 1-78

YES

Claim NONE

NO

Inventive Step (IS)

Claim 1-78

YES

Claim NONE

NO

Industrial Applicability (IA)

Claim 1-78

YES

Claim NONE

NO

B. citations and explanations (Rule 70.7)

Claims 1-78 meet the criteria set out in PCT Article 35(2)(a), because the prior art does not teach or fairly suggest a method of fabricating a medical tubing which has its surface modified via a bromine solution that is applied onto the tubing as it extrudes an extrusion die where the tubing is in a molten or semi-molten state.

NEW CITATIONS

US 4,069,888 A (RAYNER) 27 JANUARY 1978, see entire document.

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Form PCT/ISA/400 (Rev V) (July 1989)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US80/0000

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Roman I - VIII

Sheet 18

CLASSIFICATION:
The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC76: A61L 28/00; A61M 39/00; B29C 53/28 and US Cl.: 606/151; 606/26.8, 36.9; 264/070, 47A, 171.38, 174.11, 184, 211.13, 210.1, 288.4

Form PCT/ISA/400 (Supplemental Box) (July 1989)

INTERNATIONAL SEARCH REPORT

Number of Application No.
PCT/US 00/23899

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L29/04 A61M39/08 B29C55/22

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

B. PUBLICATIONS

IPC 7 A61L A61M B29C

Examination of the prior art documents has been carried out in the field of the invention

Examination of the prior art documents has been carried out in the field of the invention

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Character of document, with indication, where appropriate, of the relevant passages	Relevant to class No.
A	WO 97 42020 A (BAXTER INT) 13 November 1997 (1997-11-13) claim 7; examples 1-5	1-67
A	WO 97 41906 A (BAXTER INT) 13 November 1997 (1997-11-13) figures 1-38; table 9	
A, P	WO 99 61083 A (BAXTER INT) 2 December 1999 (1999-12-02) cited in the application the whole document	1-15; 18-31; 35-51; 55-56
A	US 5 932 307 A (QIN CHUAN ET AL) 3 August 1999 (1999-08-03) cited in the application the whole document	1-67

1. Further documents are listed in the continuation of item C.

2. Patent family members are listed in annex.

* Second category of cited documents:

- *1 document defining the general state of the art which is not considered to be of particular relevance
- *2 document published on or after the international filing date
- *3 document which may have priority claims or which is cited to establish the priority date of another claim or other aspect of the invention (see specification)
- *4 document relevant to an oral disclosure, use, exhibition or other means
- *5 document published prior to the international filing date but not taken into account

- *6 document published after the international filing date of priority claim and not to establish the priority date of another claim
- *7 document of particular relevance to the invention, but not taken into account in the examination of the invention
- *8 document of particular relevance to the invention, but not taken into account in the examination of the invention
- *9 document relevant to an oral disclosure, use, exhibition or other means
- *10 document published prior to the international filing date but not taken into account
- *11 document relevant to the same patent family

Date of the actual receipt of the international search report

13 December 2000

Date of receipt of the international search report

22/12/2000

Address and mailing address of the ISA
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AL - 69111 Heidelberg
Tel. (49-6221) 91-3100, Fax. (49-6221) 91-3100-3100

Authorized officer
Dupuis, J-L

Form PCT/ISA/210 (second sheet) (July 1999)

INTERNATIONAL SEARCH REPORT

Number of Application No.
PCT/US 00/23899

D. COMBINATIONS OF DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Character of document, with indication, where appropriate, of the relevant passages	Relevant to class No.
A	EP 0 142 315 A (GRACE M R & CO) 22 May 1985 (1985-05-22) page 3, line 26 - page 4, line 8	2, 3, 19, 20
A	US 5 562 127 A (JO JOHN H ET AL) 8 October 1996 (1996-10-08) claim 1; figure 1	1-67

Form PCT/ISA/210 (second sheet) (July 1999)

INTERNATIONAL SEARCH REPORT

International Patent Classification
PCT/US 00/23899

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From PCT/US/99/023899 (priority claim) dated 1999