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(54) **METHOD OF USING MEDICAL TUBINGS IN FLUID ADMINISTRATION SETS**

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(58) **Field of Search** 604/264, 280, 604/246, 49, 131, 151, 500, 523, 524

(56) **References Cited**

U.S. PATENT DOCUMENTS

813,918	2/1906	Schmitz .
2,551,710	5/1951	Slaughter .
3,157,724	11/1964	Salyer et al. .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

250874	8/1988	(CS) .
0 133 355	7/1984	(EP) .
0 256 644	2/1988	(EP) .
0 450 088 A1	10/1991	(EP) .
4-332624	11/1992	(JP) .
5-017639	1/1993	(JP) .
7-205275	8/1995	(JP) .
7-205276	8/1995	(JP) .
WO 80/02671	12/1980	(WO) .
WO 92/18173	10/1992	(WO) .
WO 94/26793	11/1994	(WO) .
WO 96/08520	3/1996	(WO) .
WO 96/36374	11/1996	(WO) .
97/07032	4/1997	(WO) .
97/07033 PCT/US	4/1997	(WO) .
97/07034 PCT/US	4/1997	(WO) .
97/07040	4/1997	(WO) .

OTHER PUBLICATIONS

European Plastic News, Jun. 1996; Medical Tubes Use Metallocene Resin, p. 17.

Industrial & Production Engineering (PE), Dec. 1988, Extrusion Line for Medical Tubes, p. 17.

Patrick J. Courtney and James Serenson, "Adhesive Bonding of Medical Plastics: An Overview", Jan./Feb. 1996 Medical Plastics and Biomaterials, pp. 20–25.

Functionalized Modified High Melt Flow Polyolefins, Wilpers et al., United States Statutory Invention Registration No. H1419.

The Effect of Plastic Formulation Variables on Bond Strengths Achieved With Typical Medical Device Adhesives, presented at Manufacturing Medical Plastics '95 by Pat Courtney, Senior Application Engineer, Loctite Corporation.

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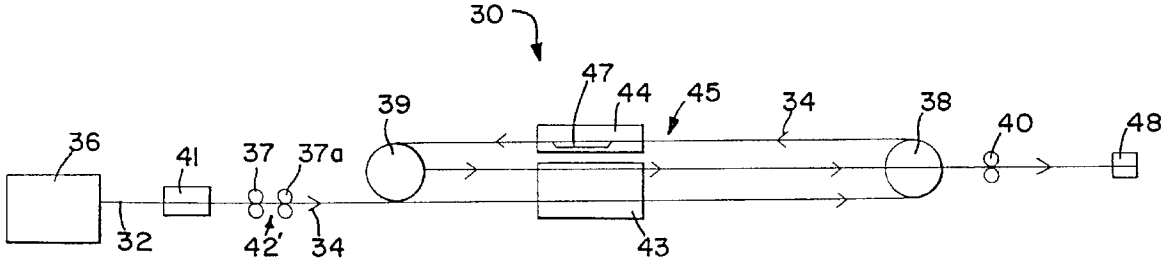
(57) **ABSTRACT**

The present invention provides a method for using medical tubing for infusing therapeutic fluids to a patient comprising the steps of: providing a medical tubing having a sidewall of a polymeric blend, the blend having a polymeric material in an amount by weight within the range of 99.999%–90.0%, and an additive in an amount by weight within the range of 0.001%–10%, the tubing having been oriented along a longitudinal axis of the tubing to define a oriented diameter that is less than a diameter of the tubing before orienting; and providing fluid under pressure through the tubing to the patient.

1 Claim, 3 Drawing Sheets



U.S. PATENT DOCUMENTS

3,218,380		11/1965	Euling et al. .	
3,260,776		7/1966	Lindstrom, Jr. et al. .	
3,581,776		6/1971	Sheahan .	
3,775,523		11/1973	Haley .	
3,856,889		12/1974	McConnell .	
3,886,227		5/1975	VanBrederode et al. .	
3,974,240		8/1976	Bock et al. .	
4,014,369		3/1977	Kobres, Jr. .	
4,157,194		6/1979	Takahashi .	
4,157,235		6/1979	Lagabe et al. .	
4,193,899		3/1980	Brenner et al. .	
4,374,882		2/1983	Harlan .	
4,422,999		12/1983	Mitchell .	
4,444,817		4/1984	Subramanian .	
4,613,533		9/1986	Loomis et al. .	
4,623,334	*	11/1986	Riddell	604/85
4,623,567		11/1986	Hert .	
4,678,834		7/1987	Boivin et al. .	
4,698,196		10/1987	Fabian .	
4,721,637		1/1988	Suzuki et al. .	
4,737,547		4/1988	White .	
4,886,634		12/1989	Strutzel et al. .	
4,906,496		3/1990	Hosono et al. .	
4,948,643		8/1990	Mueller .	
4,957,974		9/1990	Ilenda et al. .	
5,018,945		5/1991	D'Silva .	
5,032,112	*	7/1991	Fairchild et al.	604/80
5,045,620		9/1991	Itaba et al. .	
5,048,572		9/1991	Levine .	
5,151,019		9/1992	Danby et al. .	
5,169,708		12/1992	Amaral et al. .	
5,225,451		7/1993	Rogers et al. .	
5,241,031		8/1993	Mehta .	
5,246,752	*	9/1993	Raczkowski	428/35.7
5,264,488		11/1993	Takeuchi et al. .	
5,274,035		12/1993	Chundury .	
5,281,670		1/1994	Lee et al. .	
5,343,738		9/1994	Skaggs .	
5,439,454		8/1995	Lo et al. .	
5,525,388		6/1996	Wand et al. .	
5,562,127		10/1996	Fanselow et al. .	
5,565,523	*	10/1996	Chen et al.	525/176
5,573,822		11/1996	Nishikawa et al. .	
5,599,329	*	2/1997	Carter	604/282
5,620,760		4/1997	Galimberti et al. .	
5,629,059		5/1997	Desai et al. .	
5,638,660		6/1997	Kuo .	

* cited by examiner

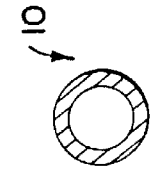


FIG. 1

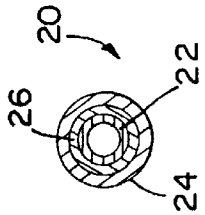


FIG. 2

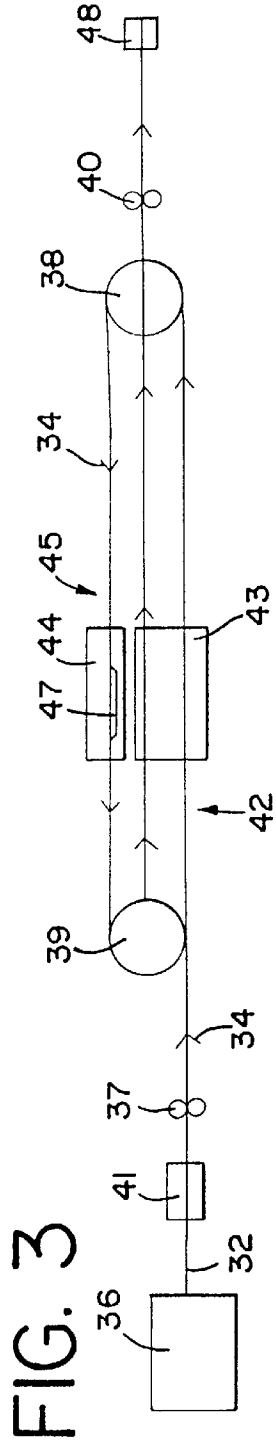


FIG. 3

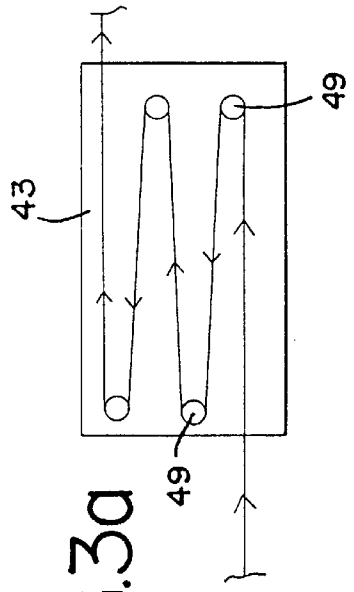


FIG. 3a

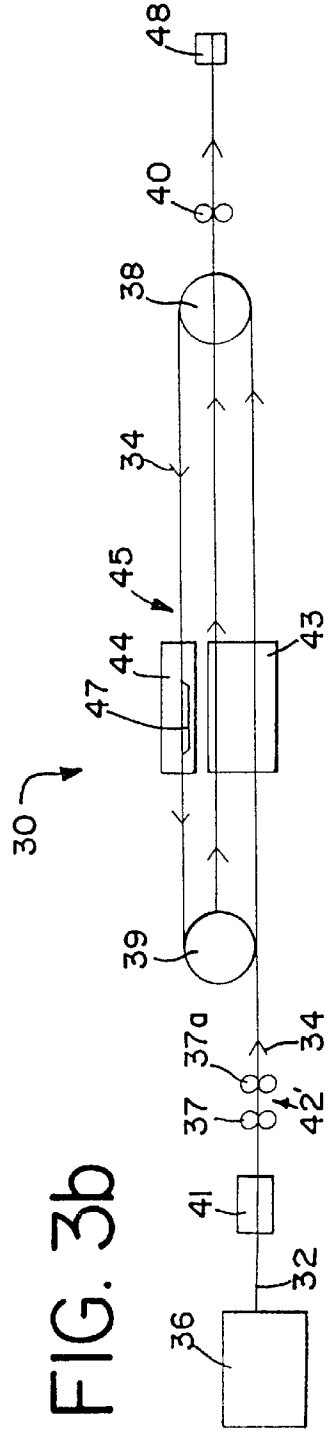


FIG. 3b

FIG. 4

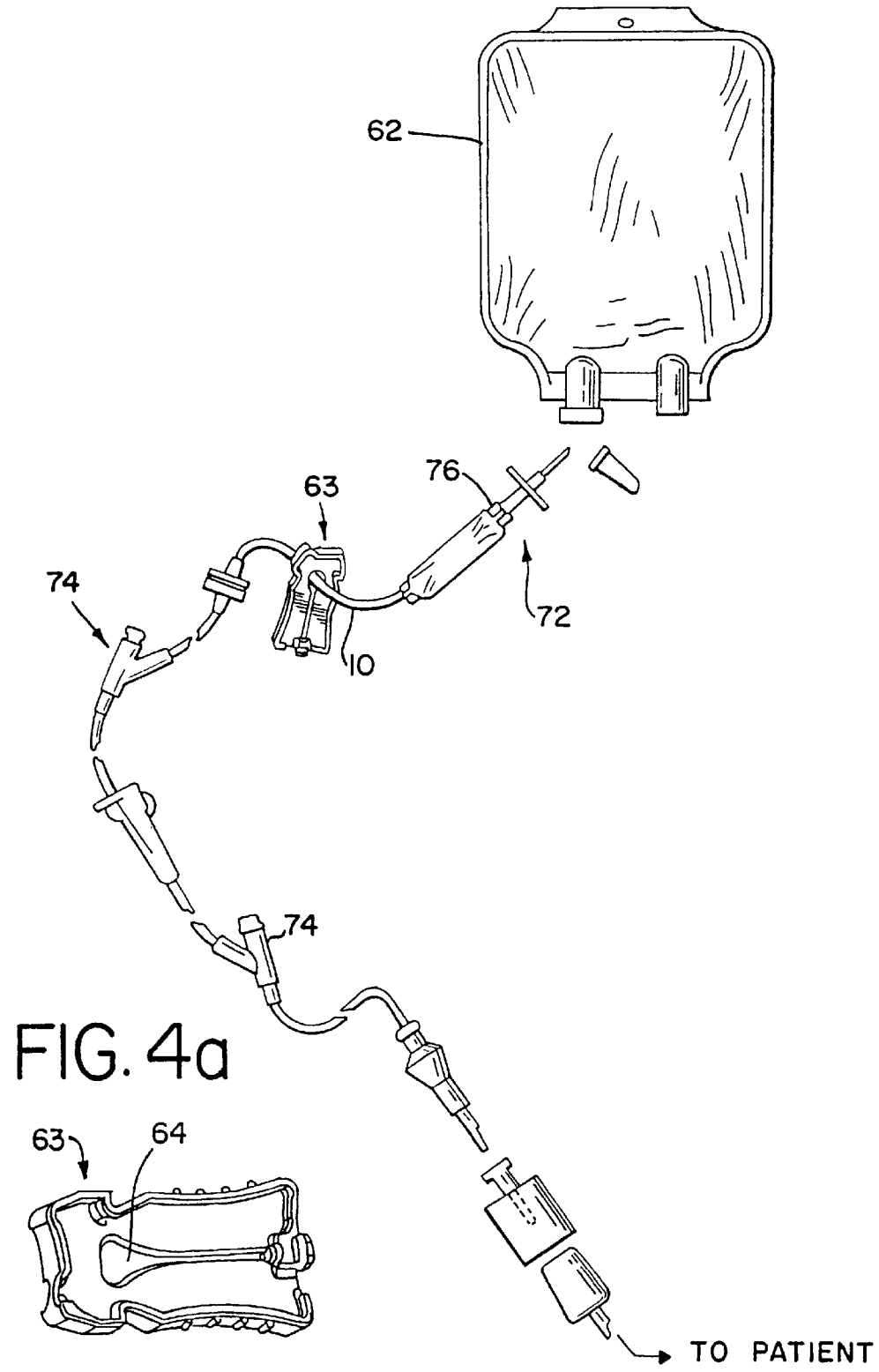


FIG. 4a

FIG. 5

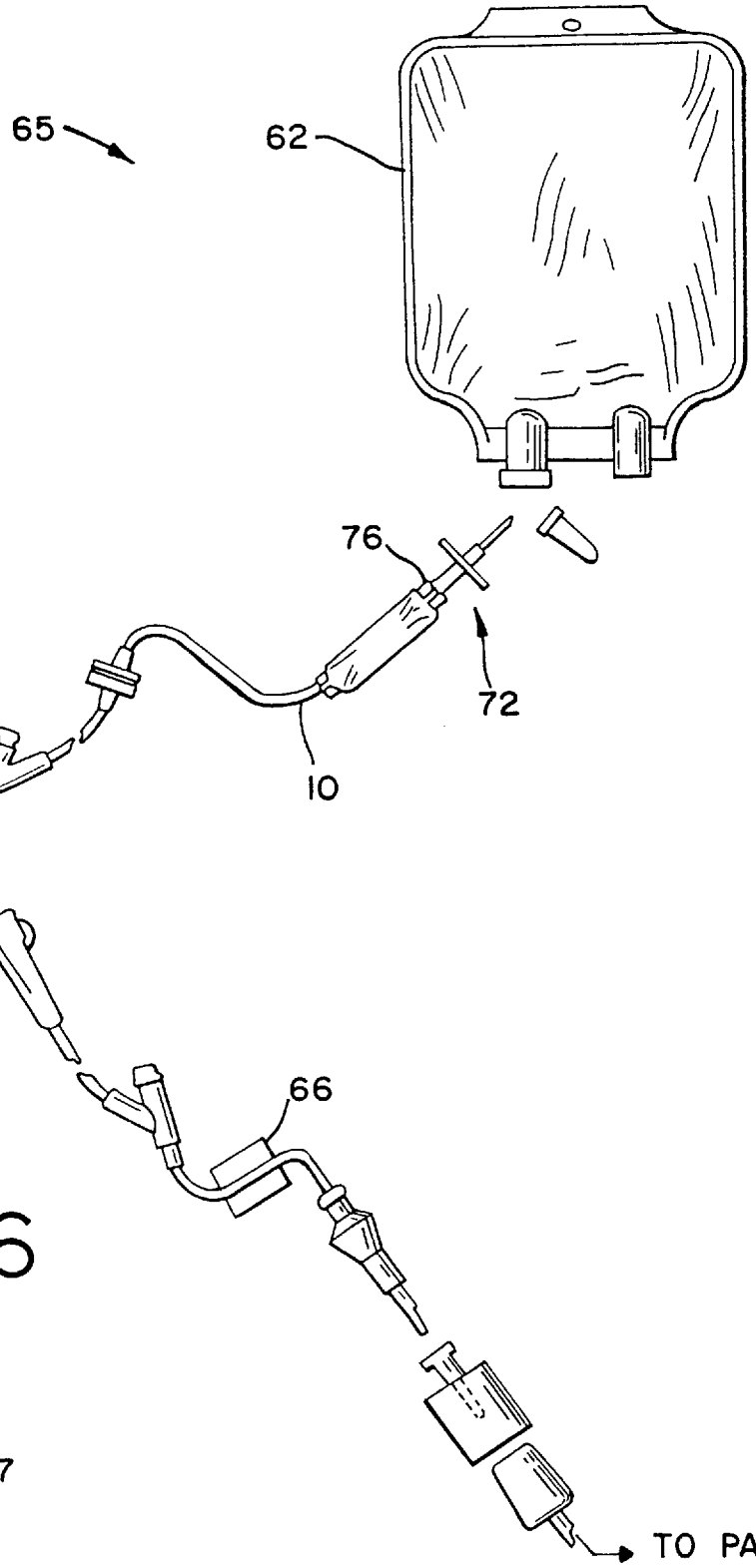
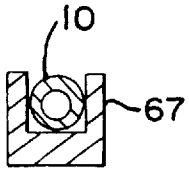


FIG. 6



METHOD OF USING MEDICAL TUBINGS IN FLUID ADMINISTRATION SETS

TECHNICAL FIELD

This invention relates to a method for using medical tubing and more particularly using tubings with fluid administration sets.

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 tubings 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 landfills and through incineration. For tubing disposed of in landfills, it is desirable to use as little material as possible to fabricate the tubing. Further benefits are realized by using a material which is thermoplastically 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 minimizes 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 minuscule losses 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 tubings 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 slide clamps which operate by crimping the sidewall of the tubing to stop or reduce the flow of fluid through the tubing. The slide clamp may be used without causing scoring 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 incinerating 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. Most polyolefins are environmentally sound as they do not generate harmful degradants upon incineration, and in most cases are capable of being thermoplastically recycled. Many polyolefins are cost effective materials that may provide an economic alternative to PVC. However, there are many **4** 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 scoring when clamping the tubing using a slide 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 consecutively impinging upon the sidewalls 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 detectors 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 strain 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 tubings' 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 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 polyolefins' 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 coiling 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 THE INVENTION

The present invention provides a method for fabricating flexible medical tubings 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 orienting process shares the steps of extending the tubing between a first puller and a second puller spaced apart by a distance and controlling the relative speeds of the first puller and the second puller so that the, rate of pulling of the second puller is greater than that of the first puller to orient the tubing therebetween. 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 oriented macro-molecule 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 rollers in the heating bath. The tubing is trained about the rollers to define a serpentine pattern so that the tubing makes several lengthwise passes through the heating bath. It may be desirable to motorize these rollers.

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, wet orienting and heat setting medical tubing;

FIG. **3***a* is a plan view of a serpentine pattern that tubing may follow through a heating or cooling bath of the process shown in FIG. **3**;

FIG. **3***b* 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. **4***a* is a plan view of a slide clamp;

FIG. **5** is a plan view of a fluid administration set with an infusion pump; and

FIG. **6** is a pump sensor housing clamping a segment of medical tubing.

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 herein 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.

I. Polymer Blends

The polymer blends of the present invention may be embodied in monolayer polymer structures or may be adhered to other substrates such as polymers to 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 attached 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 polyester copolymers such as those sold under the tradename PEBAX, and copolyesters such as those sold under the tradename HYTREL, polybutadiene, polyisoprene, polyisobutylene, styrene butadiene rubbers, and other cross-linked elastomers.

Suitable polyolefins include both homo and copolymers of polyethylene. Suitable comonomers may be selected from the group consisting of aliphatic 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 33% methyl acrylate comonomer), vinyl acetate (with less than 33% methyl acrylate comonomer). ULDPE generally has a density within the range of about 0.8 g/cm^3 to about 0.95 g/cm^3.

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 amines; amides; hydroxyls; acids; acetate, ammonium salts; organometallic compounds such as metal alcoholates, metal carboxylates, and metal complexes of numerous 1,3 dicarbonyl compounds; phenyl phosphines; pyridines; pyrrolidones; imidazoline, and oxazolines.

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 molten 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 tradename FLO-GARD®, and COLLEAGUE®, have an inner diameter within the range of 0.099–0.105 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 50,000 psi, and more preferably less than 40,000 psi.

FIG. **2** shows a multilayered tubing **20** having a first layer **22**, which is a solution contact layer, a second layer **24** and a tie layer **26** therebetween. The first layer **22** may be selected from the same group of polymers set forth above 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 tie layer **26**.

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%–50%, the second layer **24** should have a thickness within the range of 2–50%, and the tie 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 tubings **10,20** to be oriented along their longitudinal axes. 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 therein. 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 orientation ratio. The orienting step orients the molecules of the tubing along the longitudinal axis to increase the resistance to necking upon subsequent longitudinal stressings. 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 puller **37**, a second puller **38**, a third puller **39**, and a fourth puller **40**. The pullers **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 pullers **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 pullers **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 pullers **37** and **38** where the tubing **32** is oriented by operating the second puller **38** at a greater rate of speed than the first **13** puller **37** to achieve the desired orientation ratio. This section of the line will be referred to as the orienting section **42**. Preferably the second puller **38** is operated at a rate within the range of about 4–10 times faster than the first puller **37**. By controlling the relative speeds of the first and second pullers **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 40° 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 ordered lower melting crystals are melted leaving higher melting crystals which will be thermally stable over the application temperature range. Part of the highly oriented macro-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** trains about the second puller **38** and extends between the second puller **38** and the third puller **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 an amount, between the second and third pullers **38** and **39**, to prevent or control the shrinkage. Thus, the second and third pullers **38** and **39** should be operated at similar speeds or puller **39** could be operated at a slightly slower speed than puller **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 puller **39** and the fourth puller **40**. Puller **40** should be operated at a similar speed of puller **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 lengthwise passes through the cooling bath **43** or heating bath **44** as shown in FIG. **3***a* 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 puller **40** at a similar speed or slightly slower rate of speed than the third puller **39**.

After passing the fourth puller **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. **3***b* 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 pullers **37** and **37***a*. Puller **37***a* is operated at a speed greater than puller **37**. During the dry orientation step **42'**, the tubing **32** is not submerged in the aqueous bath **43** as is the case in the wet orientation step **42**. In the dry orientation process, pullers **38**, **39**, and **40** will be run at a rate similar to or slower than puller **37***a*.

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 tapers 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 system **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 control the flow rate of fluid flow through the tubing by successively impinging upon the sidewalls of the tubing **32**. Applicants incorporate herein by reference U.S. Pat. No. 5,018,945 in its entirety disclosing an Accurate Peristaltic pump.

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 mounted 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 operatively engage 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 in its entirety and in particular those portions of the text describing the general principles of operation of such a pump namely the text located at Col. 4, line 63-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. Back pressure sensors are provided to detect an increased resistance to fluid flow which result from a patient crimping the tubing or from the tubing being otherwise kinked. 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 ultrasonic waves through the tubing to detect air bubbles. Fluid back pressure may be sensed by detecting changes in the diameter of the tubing **32**.

V. EXAMPLES

A. Example 1

Exxon Exact 4011 (ULDPE) was extruded with and without additives. The Exact 4011 was obtained from Exxon

Chemical Company and the Ethomeen additives were obtained from Akzo Nobel Chemical Company. The Henkel additives were obtained from Henkel Corporation. The extrusion equipment was obtained from several suppliers as noted: 1.5" extruder from Killion, belt pullers model 212-2 and 118 from RDN, vacuum sizer model 2.0 PVS from RDN. The material blends comprised 0.23% additive and 99.77% Exact 4011 resin. 0% additive 0/15 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 bushing inner diameter 0.185"; Temperatures, Barrel Zone (BZ)#1 375° F., BZ#2 375° F., BZ#3 375° F.; Die Zone (DZ) #1 374° F., DZ#2 375° F.; head Pressure 1600 psi; Motor Amperes 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 1 lists the results for Exxon Exact 4011 with and without additives and indicates an improved computability for ULDPE with the additive.

TABLE 1

Material	Air Sensor-Minimum	Air Sensor-Normal
Exact 4011	330	339
Exact 4011 + Ethomeen 0/15	386	407
Exact 4011 + Ethomeen 0-12	501	503
Exact 4011 + Ethomeen S-12	431	405
Henkel E32054	382	378
Henkel E32052	471	457
Henkel E32053	518	520

B. Example 2

Another indication that the additive is assisting in improving the tubing compatibility with pump air sensors is the improvement gained in how the tubing seats 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 "teardrop" or "pinched" 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 2 lists additional test samples that exhibited this phenomenon as well as their air sensor values.

TABLE 2

Material	Air Sensor-Normal	Shape of tubing at sensor region
Exact 4011 without Ethomeen 0/15	339	Pinched
Exact 4011 with Ethomeen	407	Square
EVA without Ethomeen 0/15	001	Pinched
EVA with Ethomeen 0/15	330	Square

J. Example 3

Dow Affinity VP1770 ULDPE was extruded with and without oleylimidazoline. The VP1770 was obtained from Dow and the oleylimidazoline was obtained from Henkel Corporation. The extrusion equipment was obtained from several suppliers as noted: 1.5" extruder from Davis Standard, belt pullers model 212-2 and 118 from RDN vacuum sizer model 2.0 PVS from RDN. The material blends comprised 0.20% oleylimidazoline and 99.80% VP1770 resin. 0% oleylimidazoline and 100% VP1770 was also extruded as a control. Tubings were extruded by blending the resin and oleylimidazoline and then placing them into a single screw extruder for extrusion into tubing form. The extrusion conditions were as follows: Die Pin outer diameter 0.240"; Die bushing inner diameter 0.325"; Temperatures, Barrel Zone (BZ)#1 425° F., BZ#2 427° F., BZ#3 432° F., BZ#4 440° F.; Die Zone (DZ)#1 440° F., Die Zone (DZ)#1 440° F., DZ#2 440° F., DZ#3 440° F.; head Pressure 2460 psi; Motor Amperes 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 Flo-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 5/5 samples tested showed shredding. The tubing with the additive shows that 5/5 samples tested produced scoring of the tubing. Scoring is more desirable than shredding as is does not produce any lose particulate where shredding does.

C. Example 4

Exxon Exact 4011 (ULDPE) was extruded with and without additives. The Exact 4011 was obtained from Exxon Chemical Company and the Ethomeen additives were obtained from Akzo Nobel Chemical Company. The Henkel additives were obtained from Henkel Corporation. The extrusion equipment was obtained from several suppliers as noted: 1.5" extruder from Killion, belt pullers model 12-2 and 118 from RDN, vacuum sizer model 2.0 PVS from DN. The material blends comprised 0.23% additive and 9.77% Exact 4011 resin. 0% additive and 100% Exact 4011 was also extruded as a control. Tubings were extruded by blending the resin and Ethomeen 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 bushing inner diameter 0.185"; Temperatures, Barrel Zone (BZ)#1 375° F., BZ#2 375° F., BZ#3 375° F.; Die Zone (DZ) #1 374° F., DZ#2 375° F.; head Pressure 1600 psi; Motor Amperes 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 Flo-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 5/5 samples tested produced shredding of the tubing. The tubing with 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 lose particulate where shredding does. Table 3 lists the tubes with and without additives and the results from the 10 cycle slide clamp testing.

TABLE 3

Material	10 Cycle Slide Clamp Test
Exact 4011	5/5 shred
Exact 4011 + Ethomeen 0/15	5/5 score
Exact 4011 + Ethomeen 0-12	4/5 shred
	1/5 score
Exact 4011 + Ethomeen S-12	4/5 shred
	1/5 score
Henkel E32054	4/5 shred
	1/5 score
Henkel E32052	4/5 shred
	1/5 score
Henkel E32053	5/5 shred

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 method for using medical tubing for infusing therapeutic fluids to a patient comprising the steps of:

providing a medical tubing having a sidewall of a polymeric blend, the blend having a polymeric material in an amount by weight within the range of 99.999%–90.0%, and an additive in an amount by weight within the range of 0.001%–10%, the tubing having been oriented along a longitudinal axis of the tubing to define an oriented diameter that is less than a diameter of the tubing before orienting, and wherein the tubing has been heat set to maintain the oriented diameter during the use of the tubing; and

providing fluid under pressure through the tubing to the patient.

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