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(54) **Title**: OVERMOLDED MEDICAL CONNECTOR TUBING AND METHOD

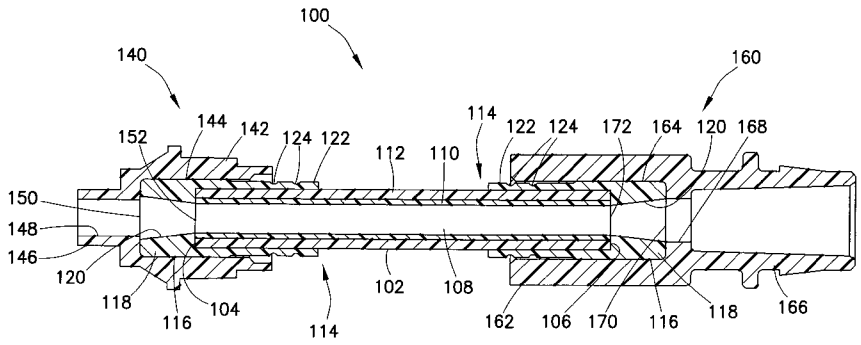

FIG.2

(57) **Abstract**: A high pressure medical connector tubing assembly includes a high pressure medical connector tubing assembly, including a tube element having opposed tube ends and a passageway, an end element overmolded to at least one of the opposed tube ends, the end element having an annular end portion having a preselected length, and a connector element having a connector hub defining a receiving cavity. The preselected length of the annular end portion may be used to pre-control the axial location of stress concentration in the connector hub. A method of forming the high pressure medical connector tubing assembly includes providing a tube element comprising opposed tube ends and a passageway therethrough, overmolding an end element onto at least one of the opposed tube ends, providing a connector element comprising a connector hub defining a receiving cavity, and securing the tube end with the overmolded end element in the receiving cavity.

OVERMOLDED MEDICAL CONNECTOR TUBING AND METHOD

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention is related to the medical field and, in particular, medical tubing used in the medical field to conduct fluids to and from a patient and/or between medical equipment which may comprise one or more end connectors for making fluid connections to conduct fluids to and from patients and medical equipment.

Description of Related Art

[0002] Numerous examples of medical tubing and connectors therefor may be found in the medical field. For example, U.S. Patent Application Publication No. 2012/0024411 to Hahn et al. is generally directed to tubing for use in connecting components of liquid chromatography and other analytical systems and discloses tubing that is comprised of three distinct portions, including an outer layer, an inner layer, and a passageway defined by the inner layer. The tubing includes a retention feature, such as a barb, machined onto the end of the outer layer. The inner layer protrudes from the barb, and the barb and the protruding portion of the inner layer are overmolded together with a tip.

[0003] U.S. Patent Application No. 2011/0306826 to Franklin et al. discloses an implantable device for use in a medical system to protect tubing from puncture. In one embodiment, a shielding device is provided that is overmolded onto a tube or is overmolded to a housing connected to the tube end as well as the tube.

[0004] U.S. Patent Application No. 2011/0127186 to Enns et al. discloses packaging tubes for elongate medical devices, such as catheters and guide wires, in which a series of plastic clips are overmolded onto a tube. Each of the clips surrounds adjacent sections of the tube such that each clip forms a closed loop, surrounding the outer surface of the tube at each section where the clip is located.

[0005] U.S. Patent Application Publication No. 2010/0130922 to Borlaug et al. discloses a medical fluid injection device comprising fluid connectors that are made of an overmolded, thermoplastic elastomer.

[0006] U.S. Patent Application Publication No. 2010/0063481 to Hoffman et al. discloses flow path assemblies for use in a fluid path for delivery of medical fluids. This publication discloses

tubing connected to a syringe outlet at one end and has a compressible sealing element connected to the opposing end. The sealing element may be formed of an elastomeric material, and is generally cylindrical in shape and dimensioned to be concentric with the tubing. The elastomeric sealing element may be overmolded onto the tubing to eliminate the need for an adhesive.

[0007] U.S. Patent Application Publication No. 2010/0022966 to Kennard discloses a fluid delivery device that includes tubing with an overmolded region, and a barbed connector end may be secured to the overmold region by way of a compression fit thereto.

[0008] U.S. Patent Application Publication No. 2008/0284167 to Lim et al. discloses fittings for connecting tubing. In one embodiment, the fitting is formed by injection molding, and then material is overmolded or co-molded over the fitting to form an extension portion, and a tube end is then inserted into the fitting to conduct fluid through the fitting.

[0009] U.S. Patent Application Publication No. 2007/0215268 to Pingleton discloses a method of applying a braid to a tube, and fusing of the braid to the tube to prevent kinking thereof, etc. The braid may be insert-molded or over-molded to the tube.

[0010] U.S. Patent Application Publication No. 2006/0170134 to Rowley et al. discloses a method of injection over-molding a connector with a tubing segment.

SUMMARY OF THE INVENTION

[0011] One embodiment described herein is directed to a high pressure medical connector tubing assembly comprising a tube element comprising opposed tube ends and a passageway therethrough, an end element overmolded to at least one of the opposed tube ends, the end element comprising an annular end portion having a preselected length, and a connector element comprising a connector hub defining a receiving cavity, the tube end with the overmolded end element fixedly secured in the receiving cavity. The preselected length of the annular end portion may be used to pre-control the axial location of stress concentration in the connector hub.

[0012] The tube end with the overmolded end element may be fixedly secured in the receiving cavity by solvent bonding. The end element may be formed with at least one external indicator to visibly identify depth of insertion of the tube end with the overmolded end element in the receiving cavity. The tube element may comprise braided tubing formed of an inner braid encapsulated by a flexible polymer layer. The connector element may comprise a connector port defining a fluid passageway. The annular end portion may define a tapered entranceway tapering from the fluid passageway to the passageway in the tube element. The entranceway may taper

inwardly at an angle of, for example, between 0° and 80°. An end element is overmolded to each of the tube ends of the tube element. The connector element may comprise a pair of connector elements, and the tube ends each having an overmolded end element fixedly secured, respectively, in the receiving cavities of the connector elements. The tube element may comprise braided tubing formed of an inner braid encapsulated by a flexible polymer layer.

[0013] Another embodiment is directed to a method of forming a high pressure medical connector tubing assembly, comprising providing a tube element comprising opposed tube ends and a passageway therethrough, overmolding an end element onto at least one of the opposed tube ends, the end element comprising an annular end portion having a preselected length, providing a connector element comprising a connector hub defining a receiving cavity, and securing the tube end with the overmolded end element in the receiving cavity. The preselected length of the annular end portion may be used to pre-control the axial location of stress concentration in the connector hub.

[0014] Securing the tube end with the overmolded end element in the receiving cavity may comprise solvent bonding. The end element may be formed with at least one external indicator to visibly identify depth of insertion of the tube end with the overmolded end element in the receiving cavity. The tube element may comprise braided tubing formed of an inner braid encapsulated by a flexible polymer layer. The connector element may comprise a connector port defining a fluid passageway. The annular end portion may define a tapered entranceway tapering from the fluid passageway to the passageway in the tube element. The entranceway may taper inwardly at an angle of, for example, between 0° and 80°. An end element may be overmolded to each of the tube ends of the tube element. The tube ends may each have an overmolded end element and are fixedly secured, respectively, in the receiving cavities of the connector elements. The tube element may comprise braided tubing formed of an inner braid encapsulated by a flexible polymer layer.

[0015] Further details and advantages of the present invention will be understood from the following detailed description read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] **FIGS. 1A-1C** are perspective end views of known medical tubing used in the medical field.

[0017] **FIG. 2** is a cross-sectional view of an overmolded medical connector tubing assembly according to one embodiment.

[0018] **FIG. 3** is an isometric view of a tube element used in the medical connector tubing assembly shown in **FIG. 2**.

[0019] **FIG. 4** is a Finite Element Analysis (FEA) plot of an exemplary connector element of the medical connector tubing assembly shown in **FIG. 2** once assembled with an overmolded tube element.

[0020] **FIG. 5** is a Finite Element Analysis (FEA) plot of the assembled connector element and tube element when under fluid pressure.

[0021] **FIG. 6** is a cross-sectional view of the medical connector tubing assembly of **FIG. 2** according to a first exemplary modification of the assembled connector element and tube element.

[0022] **FIG. 7** is a cross-sectional view of the medical connector tubing assembly of **FIG. 2** according to a second exemplary modification of the assembled connector element and tube element.

[0023] **FIG. 8** is a cross-sectional view of the medical connector tubing assembly of **FIG. 2** according to a second exemplary modification of the assembled connector element and tube element.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0024] For purposes of the description hereinafter, spatial orientation terms, as used, shall relate to the referenced embodiment as it is oriented in the accompanying drawing figures or otherwise described in the following detailed description. However, it is to be understood that the embodiments described hereinafter may assume many alternative variations and configurations. It is also to be understood that the specific components, devices, features, and operational sequences illustrated in the accompanying drawing figures and described herein are simply exemplary and should not be considered as limiting.

[0025] Referring to **FIGS. 1A-1C**, in the medical field, there are several available options for high pressure tubing with connector ends. In **FIG. 1A**, medical tubing **10** is shown in the form of high pressure PVC tubing. In this known configuration, production costs are considered to be low once dedicated, but expensive, production injection molding tooling is in place. The medical tubing **10** relies on a single wall plastic polymer that incorporates a plasticizer to make the tube

non-rigid. Such plasticizers are under scrutiny in the medical field for biocompatibility and possible migration into the fluid path. Additionally, operating pressures are usually limited to 1000 psi due to the lower tensile strength of the PVC versus engineering grade plastics. In typical applications, luer hubs may be solvent-bonded to the ends of the medical tubing **10**. Solvent bonding is known to cause luer stress crazing and cracking issues, wherein fine cracks appear in the surface of the luer hubs when the luer hubs are solvent-bonded to the ends of the medical tubing **10**. This induced cracking is due to high stresses developed with high durometer rigid tubing when end connectors are applied to the ends of the medical tubing **10** which require interference fits and solvent-bonding. These interference fits and accompanying solvent bonding attack can lead to air ingress and or pressure failures. Ultraviolet (UV) adhesive bonding is not a reliable alternative to solvent bonding because the plasticizer attacks the UV adhesive and can de-laminate the bonded joint after sterilization. Luer connector fittings may be insert-molded onto the ends of the medical tubing **10**, but production costs increase and connector geometry is limited to simple in-line fluid paths.

[0026] In **FIG. 1B**, medical tubing **20** in the form of coextruded high pressure connector tubing is shown. The medical tubing **20** has a high strength inner wall **22** formed of a suitable polymer which is coaxially surrounded by a flexible outer wall **24** formed of another polymer so that the medical tubing can achieve a 1200 psi rating, but retains a certain degree of flexibility. In this embodiment, luer hubs may be solvent-bonded to the ends of the medical tubing **20**, but direct solvent bonding to the medical tubing **20** also causes luer hub stress crazing and cracking issues in a similar manner to the foregoing medical tubing **10**. This induced cracking is due to high stresses developed with medium aggregate durometer tubing when end connectors are applied to the ends of the medical tubing **20** which require interference fits and solvent-bonding. These interference fits and accompanying solvent bonding attack can lead to air ingress and or pressure failures. Again, Ultraviolet (UV) adhesive bonding is not a reliable alternative to solvent bonding because the UV adhesive requires a clearance between the medical tubing **20** and luer hub for optimum strength and shelf life is limited due to adhesive bond breakdown over time. Luer connector fittings may be insert-molded onto the ends of the medical tubing **20** but, again, production costs increase and connector geometry is limited to simple in-line fluid paths.

[0027] In **FIG. 1C**, medical tubing **30** in the form of braided high pressure connector tubing is shown. The medical tubing **30** has a high strength inner braid **32** formed of a suitable polymer

that is encapsulated by a flexible polymer layer **34** to achieve a 1200 psi pressure rating with a high grade flexibility. The inner braid **32** keeps the medical tubing **30** from swelling and rupturing, but can inhibit visual fluid path clarity, often used to ensure air bubble visualization after air-purging operations. Additionally, when the braided medical tubing **30** is cut, it is desirable to isolate the cut ends from high pressures to keep the fluid pressure from wicking into the braid which can cause a pressure failure of the medical tubing **30**. As in the previously discussed embodiments, direct solvent bonding can cause luer hub stress crazing and cracking issues. This induced cracking is due to high stresses developed when end connectors are applied to the ends of medical tubing **30** and which require interference fits and solvent-bonding. Stress is high due to the level of interference needed to squeeze the braided medical tubing **30** into a luer hub and needed to keep pressurized liquid from wicking into the braid ends which can cause a pressure failure of the medical tubing **30**. Again, Ultraviolet (UV) adhesive bonding is not a reliable alternative to solvent bonding because the UV adhesive requires a clearance between the medical tubing **30** and luer hub for optimum strength, and shelf life is limited due to adhesive bond breakdown over time. Luer connector fittings may be insert-molded onto the ends of the medical tubing **30** but, again, production costs increase and connector geometry is limited to simple in-line fluid paths.

[0028] Referring to **FIGS. 2-3**, a high pressure medical connector tubing assembly **100** according to one embodiment (hereinafter "connector tubing **100**") is shown. The connector tubing **100** generally comprises a tube element **102** which may be a coextruded or braided tube element according to known tubing elements found in the medical field. The tube element **102** comprises opposed tube ends **104**, **106** and a defined central passageway **108** for conducting fluid therethrough. The tube element **102** comprises braided tubing in the depicted embodiment. The tube element **102** comprises a high strength inner braid **110** formed of a suitable polymer that is encapsulated by a flexible polymer layer **112** to achieve a 1200 psi pressure rating with a high grade flexibility.

[0029] With the tube element **102** present, end pieces or elements **114** may be applied to the opposing tube ends **104**, **106** of the tube element **102** to form a composite structure. The end elements **114** each comprise annular or tubular bodies **116** having annular or tube-shaped end portions **118** and are overmolded, respectively, to the opposing tube ends **104**, **106** of the tube element **102**. The tubular bodies **116** of the end elements **114** may be made of soft plastic

material, such as polyurethane or any flexible thermoplastic material that is compatible with the underlying tube element **102**, to facilitate overmolding to the tube ends **104**, **106** of the tube element **102**. Each of the tubular bodies **116** may be molded such that the end portions **118** define tapered entranceways **120** formed with a predetermined transition or taper angle, such as between 0° and 80° as examples. An exterior surface **122** of the tubular body **116** of each of the end elements **114** may be formed with one or more external indicators **124**, such as an annular grooves and the like, to indicate desired or indicated insertion points or distances for the composite tube ends **104**, **106** having overmolded end elements **114** into mating or receiving connector elements **140**, **160**, as described herein. The overmolded end elements **114** are advantageous in one respect in that, when applied, the end elements **114** seal the cut tube ends **104**, **106** of the tube element **102**. When the braided medical tubing comprising the tube element **120** is cut, it is desirable to isolate the cut ends from high pressures to keep the fluid pressure from wicking into the braid which can cause a pressure failure of the tube element **120**. The overmolded end elements **114** are advantageous in that, when applied, the end elements **114** seal the cut tube ends **104**, **106** of the braided tube element **102**.

[0030] As indicated, connector elements **140**, **160** are applied, respectively, to the opposed composite tube ends **104**, **106** of the tube element **102** having the overmolded end elements **114**. The connector elements **140**, **160** may be conventional injection molded luer connectors that are well-known in the medical field and the following discussion of specific features of the connector elements **140**, **160** is intended to be as non-limiting as to possible luer connector elements or end configurations that may be used with the tube element **102**. Moreover, any specific discussion hereinafter directed to one of the connector elements **140**, **160** is equally applicable to the opposed connector element **140, 160** and the concepts described herein may further be applicable to any suitable known luer connector elements known in the medical field. The specific configurations of the connector elements **140**, **160** shown in **FIGS. 2** and **3-8** are intended only to be exemplary.

[0031] The connector element **140** comprises a connector hub **142** defining a receiving recess or cavity **144** to receive the composite tube end **104** with overmolded end element **114**. The connector hub **142** may comprise a connector port or portion **146** adapted for connection to an upstream or downstream fluid conducting element (not shown). As shown in **FIG. 2**, the tapered entranceway **120** defined by the end portion **118** of the overmolded end element **114** is formed at

a transition or taper angle of any suitable angle, such as between and 0° and 80° as examples, to permit smooth fluid transition between a fluid passageway **148** in the connector port **146** and the tapered entranceway **120** and between the tapered entranceway **120** and the central passageway **108** in the tube element **102**. The tapered entranceway **120** desirably maintains laminar flow conditions at a first transition point or seam **150** between the fluid passageway **148** and the end portion **118** of the overmolded end element **114** defining the tapered entranceway **120**, as well as at a second transition point or seam **152** between the end portion **118** of the overmolded end element **114** defining tapered entranceway **120** and the central passageway **108** in the tube element **102**. The tapered entranceway **120** generally provides a smooth transition between the between the fluid passageway **148** in the connector port **146** to the central passageway **108** in the tube element **102** and helps minimize possible air traps or stagnation points by providing a smooth transition for fluid at the first transition point or seam **150** between the fluid passageway **148** and the tapered entranceway **120** defined by end portion **118** of the overmolded end element **114**, as well as at the second transition point or seam **152** between the tapered entranceway **120** defined by end portion **118** and the central passageway **108** in the tube element **102**. The composite tube end **104** of the tube element **102** having the overmolded end element **114** may be secured in the receiving recess or cavity **144** by solvent bonding and like joining methods, such as laser welding. The external indicators **124** on the tubular body **116** of the end element **114** disposed on the tube end **104** of the tube element **102** provide a visible indication of insertion to a desired insertion depth of the composite tube end **104** and overmolded end element **114** into the receiving cavity **144** of the connector element **140** and, further, visibly validate a solvent-bonded, interference fit between the end element **114** and the connector element **140** as well as helping to prevent under-insertion of the composite tube end **104** and overmolded end element **114** into the receiving cavity **144**. An interference-fit, solvent-bond connection is desirably present between the composite tube end **104** and overmolded end element **114** and the receiving cavity **144** of the connector element **140**.

[0032] The connector element **160** comprises a connector hub **162** defining a receiving recess or cavity **164** to receive the opposing composite tube end **106** with overmolded end element **114**. The connector hub **162** may comprise a connector port or portion **166** adapted for connection to an upstream or downstream fluid conducting element (not shown). As shown in **FIG. 2**, the tapered entranceway **120** defined by the end portion **118** of the overmolded end element **114** is

formed at a transition or taper angle of any suitable angle, 0° and 80° as examples, to permit smooth fluid transition between a fluid passageway **168** in the connector port **166** and the tapered entranceway **120** and between the tapered entranceway **120** and the central passageway **108** in the tube element **102**. The tapered entranceway **120** desirably maintains laminar flow conditions at a first transition point or seam **170** between the fluid passageway **168** and the end portion **118** of the overmolded end element **114** defining the tapered entranceway **120**, as well as at a second transition point or seam **172** between the end portion **118** of the overmolded end element **114** defining tapered entranceway **120** and the central passageway **108** in the tube element **102**. The tapered entranceway **120** generally provides a smooth transition between the between the fluid passageway **168** in the connector port **166** to the central passageway **108** in the tube element **102** and helps minimize possible air traps or stagnation points by providing a smooth transition for fluid at the first transition point or seam **170** between the fluid passageway **148** and the tapered entranceway **120** defined by end portion **118** of the overmolded end element **114**, as well as at the second transition point or seam **172** between the tapered entranceway **120** defined by end portion **118** and the central passageway **108** in the tube element **102**. The composite tube end **106** of the tube element **102** having the overmolded end element **114** may be secured in the receiving recess or cavity **164** by solvent bonding and like joining methods, such as laser welding. The external indicators **124** on the tubular body **116** of the end element **114** disposed on the tube end **106** of the tube element **102** provide a visible indication of insertion to a desired insertion depth of the composite tube end **106** and overmolded end element **114** into the receiving cavity **164** of the connector element **160** and, further, visibly validate a solvent-bonded, interference fit between the end element **114** and the connector element **160** as well as helping to prevent under-insertion of the composite tube end **106** and overmolded end element **114** into the receiving cavity **164**. An interference-fit, solvent-bond connection is desirably present between the composite tube end **104** and overmolded end element **114** and the receiving cavity **164** of the connector element **160**.

[0033] Referring further to **FIGS. 4**, a finite element analysis (FEA) plot is shown of the connector element **140** having the tube end **104** and overmolded end element **114** assembled in the receiving cavity **144** of the connector element **140** and secured therein by an interference-fit, solvent bond connection In **FIG. 4**, the FEA plot of the connector hub **142** of the connector element **140** shows a location of stress concentration **S** in the connector hub **142** once the

composite tube end **104** and overmolded end element **114** is seated and secured into the receiving cavity **144** of the connector element **140**. The position or location of stress concentration **S** may be altered in an axial direction along the connector hub **142**, according to this disclosure, to be positioned or located at preselected axial locations along an axial length L_1 in the receiving cavity **144** of the connector hub **142**. This axial position may be preselected or "pre-controlled" to locate the area of stress concentration **S** substantially at any desired position along the axial length L_1, and typically at locations away from stress risers, such as hard interfaces, corners, edges, sharp or prominent surface features, or material thin areas. In this manner, stress concentration **S** in the connector hub **142** may be set at preselected or "pre-controlled" axial locations and, thus, the stress concentrations in the connector element **140** may be "pre-controlled" in advance. Such stress concentrations **S** can induce crazing and cracking in the connector hub **142** when the tube end **104** and overmolded end element **114** are assembled in the receiving cavity **144** and the tube element **102** is repeatedly pressurized. This disclosure provides a method and physical arrangement by which the location of stress concentration **S** may be preselected or "pre-controlled" so as to be located at a preselected axial location along the connector hub **142** so as to avoid stress riser at hard interfaces, corners, edges, sharp or prominent surface features, or material thin areas, and be located at axial locations along the connector hub **142** having more "planar" surface features and generally free of the foregoing stress-inducing features.

[0034] In **FIG. 5**, an FEA plot of the overmolded end element **114** is provided showing the overmolded end element **114** seated and secured in the receiving cavity **144** of the connector element **140**. **FIG. 5** shows the stress concentration **S** in the end element **114** when the internal tube element **102** is under pressure at approximately 1200 psi. The stress concentration **S** in the end element **114** is most prominent or at a maximum generally at the location where the tube end **104** seats of fits within the end element **114**. In **FIG. 5**, when the tube element **102** is under pressure, the pressure stretches the tube element **102** and overmolded end element **114** on the tube end **104** within the connector hub **142** of the connector element **140**. The tube end **104**, while under pressure, should stay within the body of the connector hub **142** (*e.g.*, within the receiving cavity **144**) to prevent rupture, and this positioning is accomplished by preselecting or "pre-controlling" the axial positioning of the tube end **104** within the overmolded end element **114** and by preselecting the hardness of the material forming the overmolded end element **114**.

[0035] As will be generally understood from an inspection of **FIGS. 4-5** viewed together, the stress concentration **S** in the overmolded end element **114** is approximately radially coextensive with the stress concentration **S** in the connector hub **142** of the connector element **140** when assembled in the receiving cavity **144** and under pressure. Thus, preselecting or "pre-controlling" the location of stress concentration **S** in the overmolded end element **114** likewise preselects or "pre-controls" the location of stress concentration **S** in the connector hub **142** and this location is generally dependent upon the axial positioning of the tube end **104** within the overmolded end element **114**. As noted previously, it desirable to preselect or "pre-control" the location of stress concentration **S** in the connector hub **142** so that this preselected or "pre-controlled" location avoids stress risers at hard interfaces, corners, edges, sharp or prominent surface features, or material thin areas and, alternatively, is located at axial locations along the connector hub **142** having "planar" surface features and generally free of the foregoing stress-inducing features.

[0036] **FIGS. 6-8** illustrate three (3) exemplary embodiments of the connector tubing **100** in which the tube end **104** is located at different axial positions within the overmolded end element **114**, thereby changing the axial location of the stress concentration **S** in the overmolded end element **114** and, hence, the connector hub **142** located radially outward from the overmolded end element **114**. As will be understood from viewing **FIGS. 6-8** in sequence, the axial position of the tube end **104** within the overmolded end element **114** is changed by shortening or lengthening the axial length L_2 of the end portion **118** of the tubular body **116** of the end element **114**. From **FIGS. 6-8**, it will be understood that the connector elements **140**, **160** may have different configurations and the versions of the connector elements **140**, **160** in **FIGS. 2** and **6-8** are intended to be exemplary only. **FIG. 6** shows the end portion **118** with the shortest axial length L_2 so that the axial position of the tube end **104** within the end element **114** is the closest of the three (3) examples to the fluid passageway **148** in the connector port **146**. Thus, the radial stress concentration in the connector hub **142** in **FIG. 6** is closest to the connector port **146** of the three (3) examples. **FIG. 7** shows the end portion **118** with a slightly longer axial length L_2 so that the axial position of the tube end **104** within the end element **114** is spaced slightly farther away from the fluid passageway **148** in the connector port **146**. Thus, the radial stress concentration in the connector hub **142** in **FIG. 7** is now farther away from the connector port **146** of the three (3) examples. **FIG. 8** shows the end portion **118** with an even longer axial length L_2 so that the axial position of the tube end **104** within the overmolded end element **114** is spaced

even farther away from the fluid passageway **148** in the connector port **146** in the three (3) examples present. Thus, the radial stress concentration in the connector hub **142** in **FIG. 8** is now the farthest away from the connector port **146** of the three (3) examples. By altering the axial location of the tube end **104** within the overmolded end element **114**, which may be accomplished by shortening or lengthening the axial length L_2 of the end portion **118** of the tubular body **116** of the end element **114**, the stress concentration in the connector hub **142** may be shifted axially along the axial length L_1 of the receiving cavity **144** and, hence, along the axial length of the connector hub **142**. Thus, the location of stress concentration in the connector hub **142** may be preselected or "pre-controlled" to avoid stress risers at hard interfaces, corners, edges, sharp or prominent surface features, or material thin areas and, alternatively, is preselected or "pre-controlled" to be at specified axial locations along the connector hub **142** desirably having "planar" surface features and generally free of the foregoing stress-inducing features. While the foregoing discussion references connector element **140**, the foregoing discussion is equally applicable to connector element **160** or any suitable luer connector element or hub known in the medical field. The present disclosure permits the location of radial stress concentration in a medical connector element to be preselected or "pre-controlled" by adjustments to the axial length of the end portion **118** of the overmolded element **114** on the tube ends **104**, **106**.

[0037] While several embodiments of a high pressure medical connector tubing assembly and components or elements thereof are shown in the accompanying figures and described hereinabove in detail, other embodiments will be apparent to, and readily made by, those skilled in the art without departing from the scope and spirit of the invention. Accordingly, the foregoing description is intended to be illustrative rather than restrictive. The invention described hereinabove is defined by the appended claims and all changes to the invention that fall within the meaning and the range of equivalency of the claims are to be embraced within their scope.

THE INVENTION CLAIMED IS:

1. A high pressure medical connector tubing assembly, comprising:

a tube element comprising opposed tube ends and a passageway therethrough;

an end element overmolded to at least one of the opposed tube ends, the end element comprising an annular end portion having a preselected length; and

a connector element comprising a connector hub defining a receiving cavity, the tube end with overmolded end element fixedly secured in the receiving cavity; and

wherein the preselected length of the annular end portion pre-controls the axial location of stress concentration in the connector hub.

2. A high pressure medical connector tubing assembly as claimed in Claim 1, wherein the tube end with the overmolded end element is fixedly secured in the receiving cavity by solvent bonding.

3. A high pressure medical connector tubing assembly as claimed in Claim 1, wherein the end element is formed with at least one external indicator to visibly identify depth of insertion of the tube end with the overmolded end element in the receiving cavity.

4. A high pressure medical connector tubing assembly as claimed in Claim 1, wherein the tube element comprises braided tubing formed of an inner braid encapsulated by a flexible polymer layer.

5. A high pressure medical connector tubing assembly as claimed in Claim 1, wherein the connector element comprises a connector port defining a fluid passageway.

6. A high pressure medical connector tubing assembly as claimed in Claim 5, wherein the annular end portion defines a tapered entranceway tapering from the fluid passageway to the passageway in the tube element.

7. A high pressure medical connector tubing assembly as claimed in Claim 6, wherein the entranceway tapers at an angle of approximately between 0° and 80°.

8. A high pressure medical connector tubing assembly as claimed in Claim 1, wherein an end element is overmolded to each of the tube ends of the tube element.

9. A high pressure medical connector tubing assembly as claimed in Claim 8, wherein the connector element comprises a pair of connector elements, and the tube ends each having an overmolded end element fixedly secured, respectively, in the receiving cavities of the connector elements.

10. A high pressure medical connector tubing assembly as claimed in Claim 8, wherein the tube element comprises braided tubing formed of an inner braid encapsulated by a flexible polymer layer.

11. A method of forming a high pressure medical connector tubing assembly, comprising:

providing a tube element comprising opposed tube ends and a passageway therethrough;

overmolding an end element onto at least one of the opposed tube ends, the end element comprising an annular end portion having a preselected length;

providing a connector element comprising a connector hub defining a receiving cavity;

securing the tube end with the overmolded end element in the receiving cavity; and

wherein the preselected length of the annular end portion pre-controls the axial location of stress concentration in the connector hub.

12. A method as claimed in Claim 11, wherein the securing the tube end with the overmolded end element in the receiving cavity comprises solvent bonding.

13. A method as claimed in Claim 11, wherein the end element is formed with at least one external indicator to visibly identify depth of insertion of the tube end with the overmolded end element in the receiving cavity.

14. A method as claimed in Claim 11, wherein the tube element comprises braided tubing formed of an inner braid encapsulated by a flexible polymer layer.

15. A method as claimed in Claim 11, wherein the connector element comprises a connector port defining a fluid passageway.

16. A method as claimed in Claim 15, wherein the annular end portion defines a tapered entranceway tapering from the fluid passageway to the passageway in the tube element.

17. A method as claimed in Claim 16, wherein the entranceway tapers at an angle of approximately between 0° and 80°.

18. A method as claimed in Claim 11, further comprising overmolding an end element to each of the tube ends of the tube element.

19. A method as claimed in Claim 18, wherein the tube ends each having an overmolded end element are fixedly secured, respectively, in the receiving cavities of the connector elements.

20. A method as claimed in Claim 18, wherein the tube element comprises braided tubing formed of an inner braid encapsulated by a flexible polymer layer.

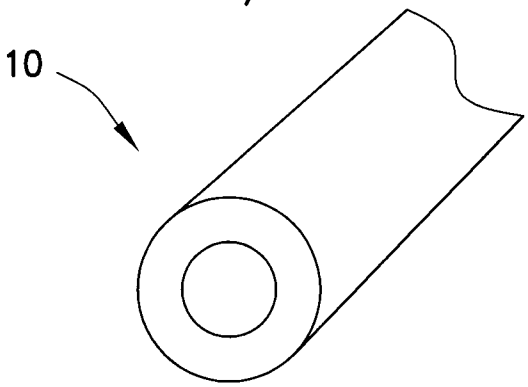

FIG. 1A
PRIOR ART

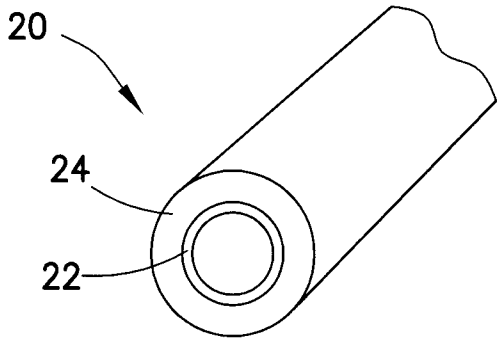

FIG. 1B
PRIOR ART

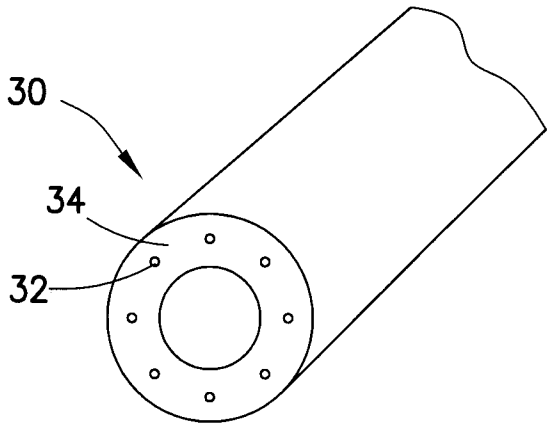

FIG. 1C
PRIOR ART

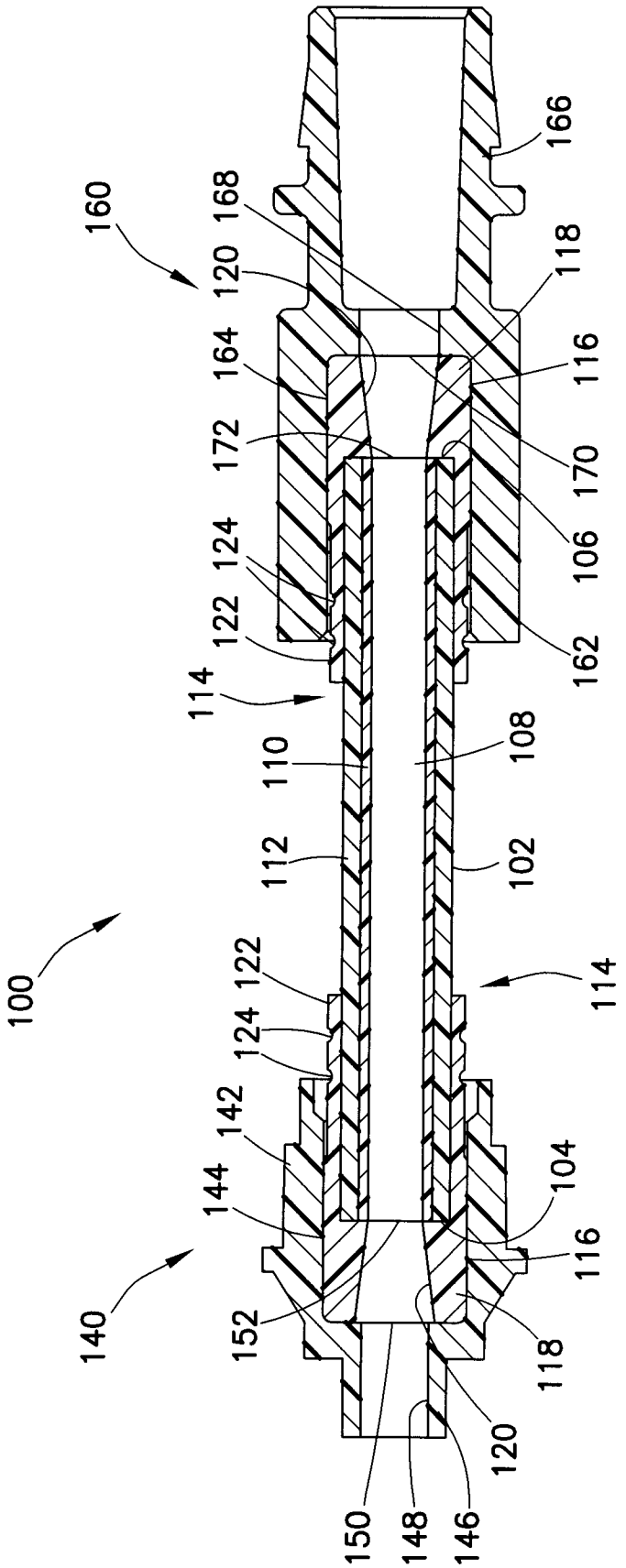
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FIG.2

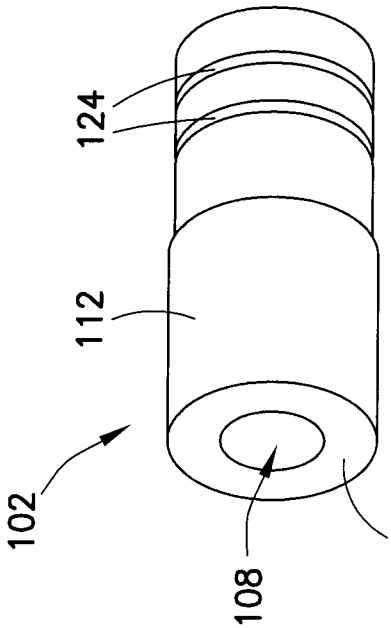
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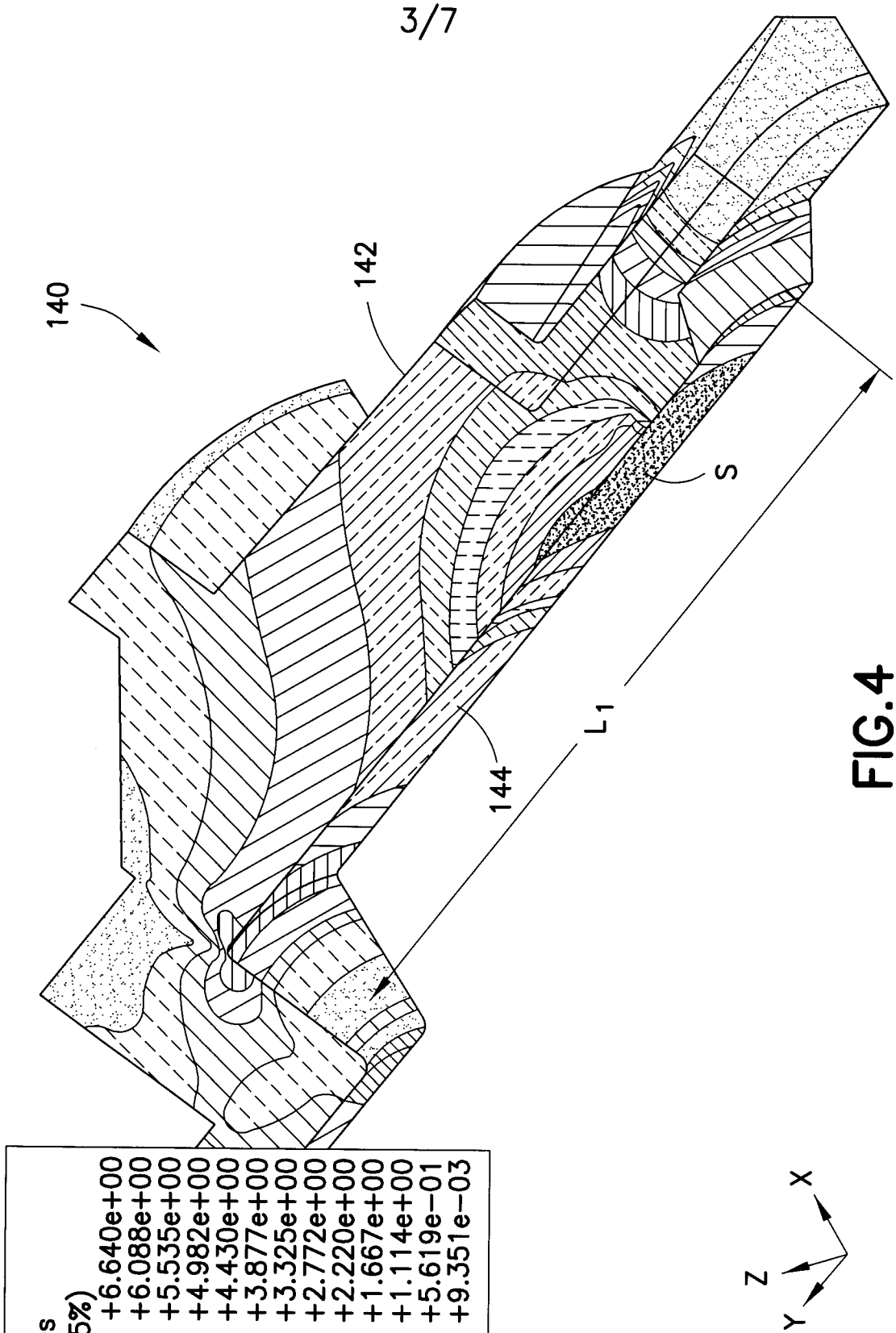
FIG.3


140
142
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S
L_1
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X
Z
Y

FIG.4

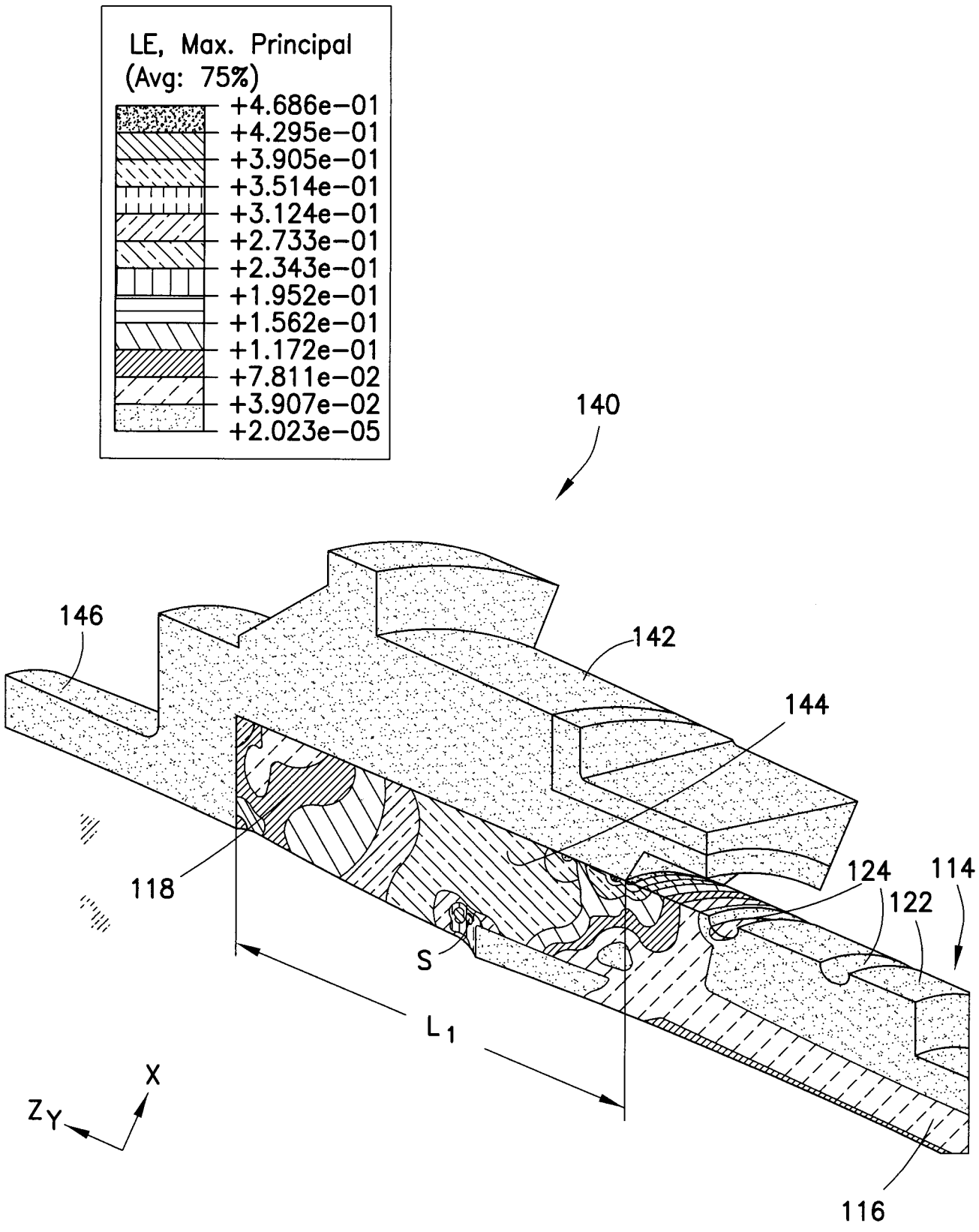
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FIG.5

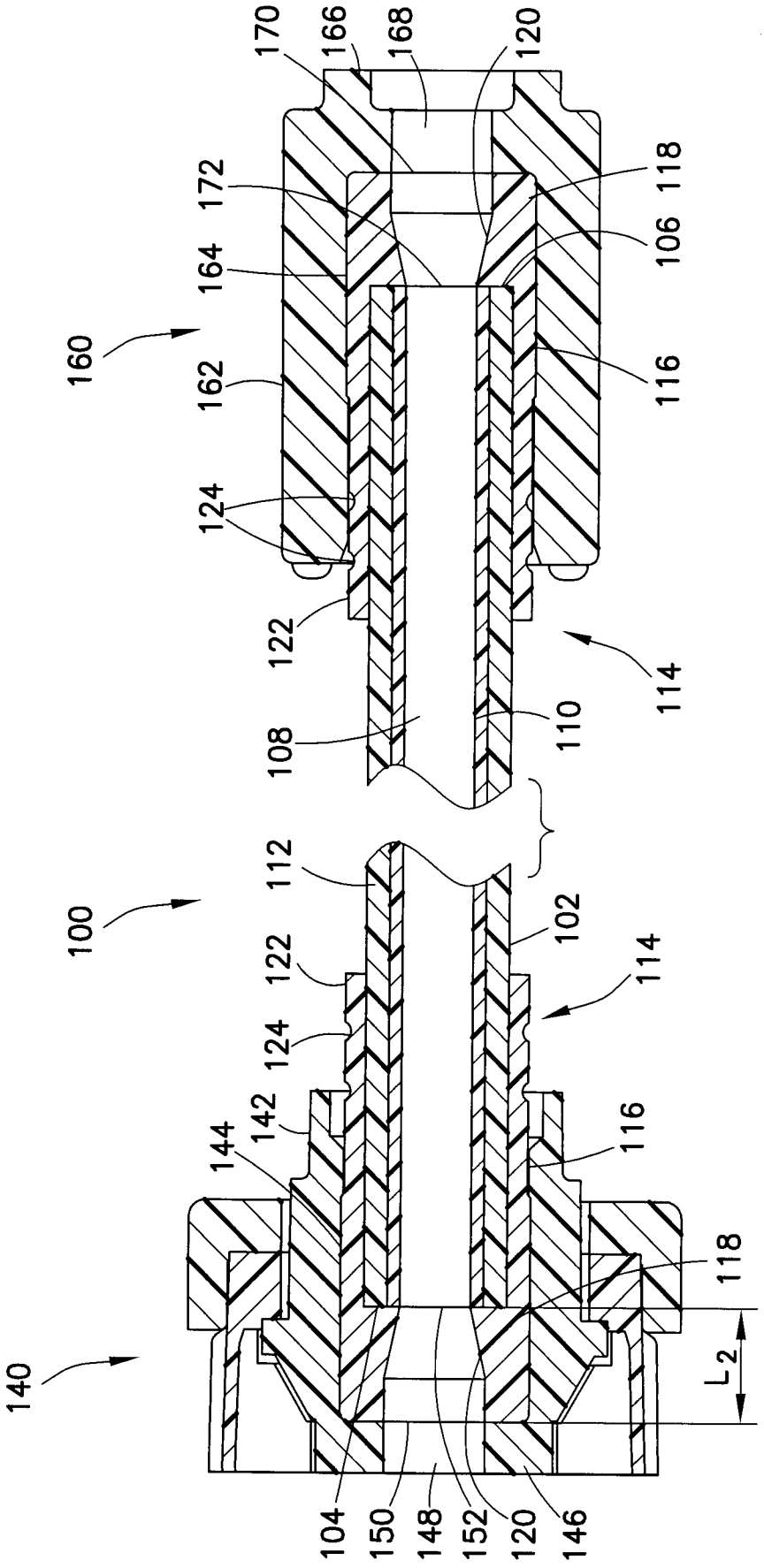
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FIG.6

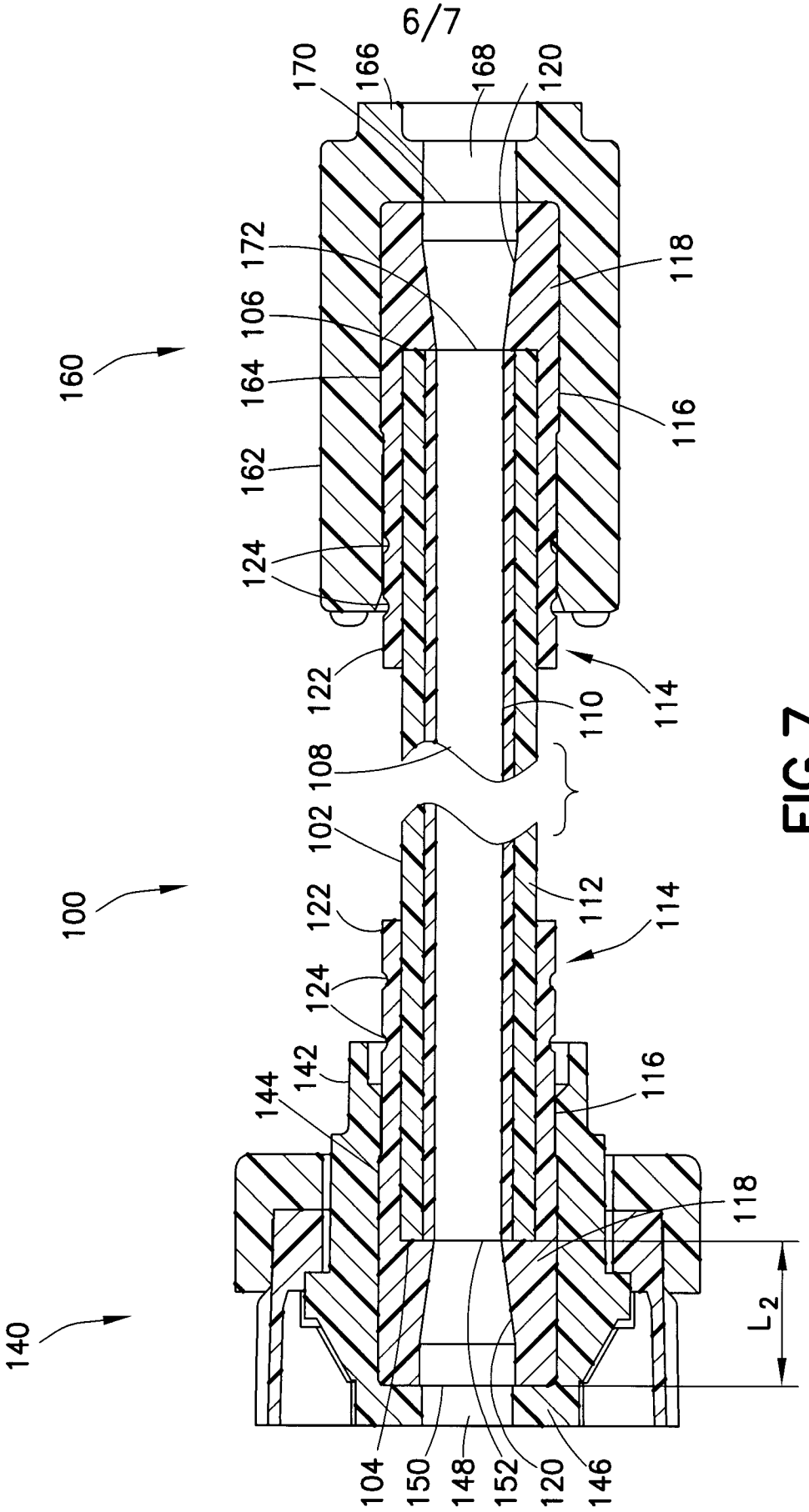
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FIG.7

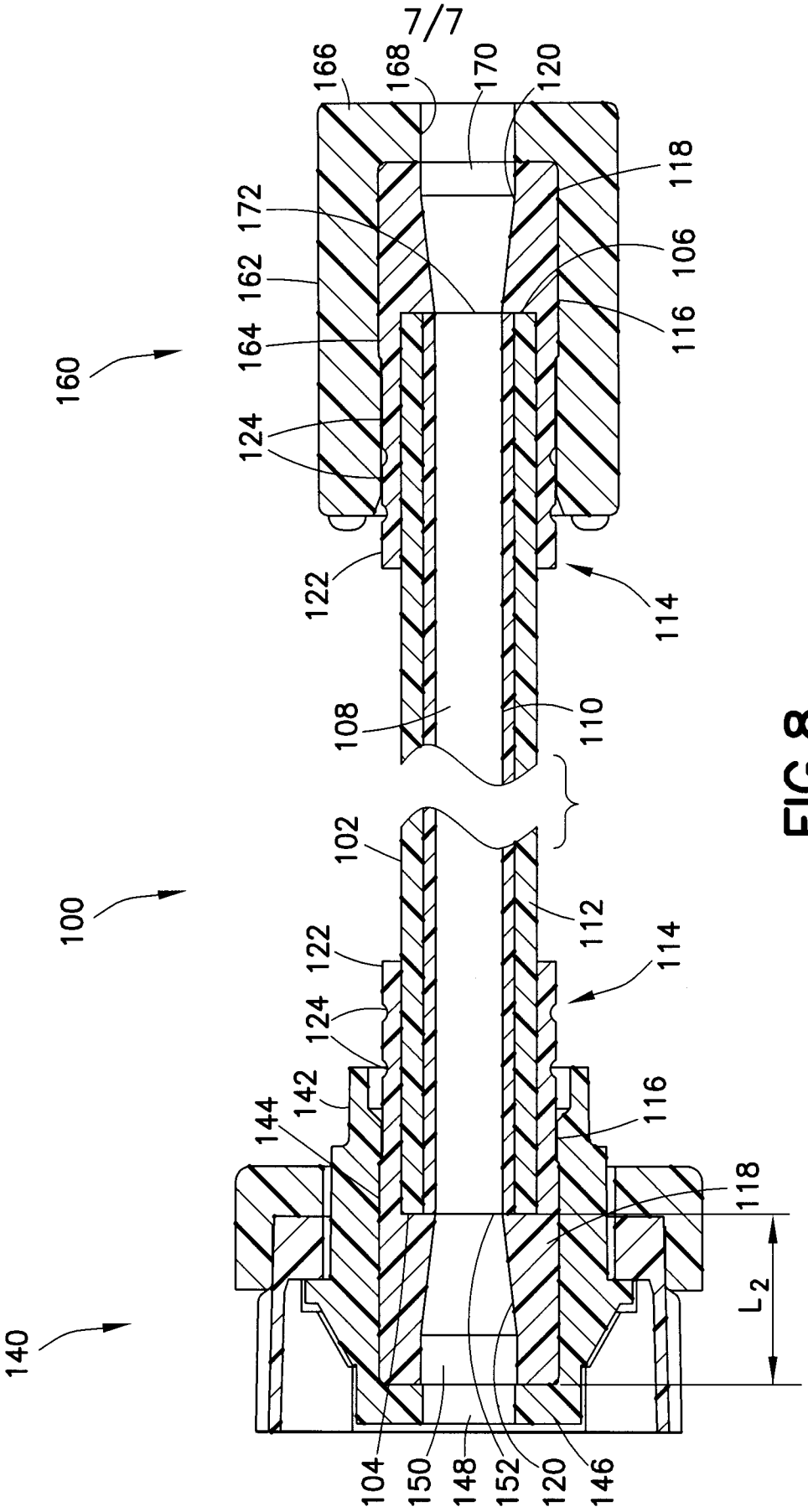
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FIG.8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/061275

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 39/12 (2014.01)
USPC - 604/535
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 39/12; B29C 63/42; F16L 9/14 (2014.01)
USPC - 138/109, 140; 156/160, 169; 264/279; 604/272, 535

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61M 39/12; B01D 15/22; G01N 30/6073 (2013.01)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0041425 A1 (TSUNEMATSU et al) 16 February 2012 (16.02.2012) entire document	1,3,5-9,11,13,15-19
Y		2, 4, 10, 12, 14, 20
Y	US 2010/0022966 A1 (KENNARD) 28 January 2010 (28.01.2010) entire document	2, 12
Y	US 2012/0024411 A1 (HAHN et al) 02 February 2012 (02.02.2012) entire document	4, 10, 14, 20
A	US 2004/0100093 A1 (LEIGH-MONSTEVENS) 27 May 2004 (27.05.2004) entire document	1-20
A	US 2006/0170134 A1 (ROWLEY et al) 03 August 2006 (03.08.2006) entire document	1-20
A, P	US 8,277,714 B1 (BLUE et al) 02 October 2012 (02.10.2012) entire document	1-20

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

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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 February 2014	20 FEB 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)