FLEXIBLE MEDICAL TUBING HAVING KINK RESISTANT PROPERTIES AND METHODS AND APPARATUS TO PRODUCE THE SAME

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ABSTRACT
A flexible, kink-resistant medical tube and a method and apparatus for making the same are provided. The tube includes a body having a first end, a second end, an outer surface and an inner surface. The tube includes a lumen defined by the inner surface of the body and extending between the first end and the second end. The tube also includes a helical structure within in the body.
START

1502
FLOW FIRST FLUID TOWARD EXTRUSION ASSEMBLY

1504
FLOW SECOND FLUID TOWARD EXTRUSION ASSEMBLY?

YES

FLOW SECOND FLUID TOWARD EXTRUSION ASSEMBLY

FLOW FLUID THROUGH EXTRUSION ASSEMBLY

INDUCE HELICAL FLOW IN FLUID FLOWING THROUGH EXTRUSION ASSEMBLY

EXTRUDE TUBING FROM EXTRUSION ASSEMBLY

1514
PERFORM POST EXTRUSION PROCESS?

YES

PERFORM POST EXTRUSION PROCESS

1518
END?

NO

END

FIG. 15
FLEXIBLE MEDICAL TUBING HAVING KINK RESISTANT PROPERTIES AND METHODS AND APPARATUS TO PRODUCE THE SAME

CROSS-REFERENCE TO RELATED PATENT APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 61/383,629, titled “Tubing Having Kink Resistant Properties and Methods and Apparatus to Produce The Same,” filed Sep. 16, 2010, which is incorporated herein by reference in its entirety.

BACKGROUND

[0002] This application relates to flexible medical tubing and, more specifically, to medical flexible tubing having kink resistant properties and methods and apparatuses to produce the same.

[0003] Tubing, for example plastic or polymer tubing, may be used in many medical applications. For example, medical tubing may be used to carry therapeutic fluids (e.g., medicines, saline, nutrient fluids, etc.) or to carry biological fluids (e.g., blood, urine, etc.). Medical tubing may become occluded through the formation of kinks limiting the ability of the tube to effectively carry fluid.

SUMMARY OF INVENTION

[0004] One embodiment of the invention relates to a method for making a flexible, kink-resistant medical tube having a body and a lumen. The method includes the step of providing a die body, such as an extrusion die body, defining an internal cavity having an inlet side and an outlet side and includes the step of providing a die pin, such as an extrusion die pin, received within the internal cavity of the die body. A die flow channel is defined between an outer surface of the die pin and an inner surface of the die body. The method includes the step of extruding the flexible tube by flowing liquid polymer through the flow channel from the inlet side toward the outlet side of the die body and includes the step of inducing a helical (e.g., a spiral) rotational flow of the liquid polymer material as the liquid polymer material flows through the flow channel. The helical rotational flow creates a helical structure within the body of the tube, and the helical structure resists formation of kinks along the body of the tube.

[0005] Another embodiment of the invention relates to a flexible, kink-resistant medical tube. The tube includes a body having a first end, a second end, an outer surface, and an inner surface. The tube includes a lumen defined by the inner surface of the body and extending between the first end and the second end. The tube also includes a helical structure within the body.

[0006] Another embodiment of the invention relates to an extrusion die system for making a flexible, kink-resistant medical tube. The extrusion die system includes an extrusion die body defining an internal cavity having an inlet and an outlet. The extrusion die system also includes an extrusion die pin received within the internal cavity of the die body such that an extrusion die flow channel is defined between an outer surface of the die pin and an inner surface of the die body that extends between the inlet and the outlet of the die body. The die pin includes a helical groove formed on the outer surface of the die pin. The extrusion die system includes a first inlet structure configured to deliver a first plastic material to the inlet of the die body and a second inlet structure configured to deliver a second plastic material to the inlet of the die body. The helical groove induces helical rotation of liquid plastic material as it flows through the die flow channel.

[0007] Another embodiment of the invention relates to a medical tube including a helical structure within the body of the tube. Another embodiment of the invention relates to medical tubing including helical non-homogeneity characteristics.

[0008] Another embodiment of the invention relates to an apparatus to produce tubing having a helical structure or helical non-homogeneity characteristic within the tubing.

[0009] Another embodiment of the invention relates to an apparatus to produce tubing, wherein the apparatus induces a spiral or helical flow pattern in at least one of the fluids or a finished tube flowing therethrough to produce tubing comprising helical non-homogeneity characteristics.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 depicts an example extrusion assembly used to produce tubing having non-homogeneity characteristics.

[0011] FIG. 2 depicts an example tube that can be produced using the examples described herein.

[0012] FIG. 3 depicts another example extrusion assembly used to produce tubing having non-homogeneity characteristics.

[0013] FIG. 4 depicts an example tube that can be produced using the examples described herein.

[0014] FIG. 5 depicts another example extrusion assembly used to produce tubing having non-homogeneity characteristics.

[0015] FIG. 6 depicts an example tube that can be produced using the examples described herein.

[0016] FIG. 7 depicts another example extrusion assembly used to produce tubing having non-homogeneity characteristics.

[0017] FIG. 8 depicts a side view of an example of fluid flowing through the extrusion assembly of FIG. 7.

[0018] FIG. 9 depicts a perspective view of the fluid flow of FIG. 8.

[0019] FIG. 10 depicts an enlarged view of a portion of the fluid flow shown in FIG. 9.

[0020] FIG. 11 depicts an example cross-linking apparatus used to induce a generally helical geometry in tubing after extrusion.

[0021] FIG. 12 depicts another example extrusion assembly used to produce tubing having non-homogeneity characteristics.

[0022] FIG. 13 depicts an example tube having non-homogeneity characteristics.

[0023] FIG. 14 depicts an example apparatus used to induce a generally helical geometry in tubing after extrusion.

[0024] FIG. 15 depicts an example method of producing the examples described herein.

[0025] FIG. 16 depicts an example extrusion pin apparatus.

[0026] FIG. 17 depicts an enlarged view of a portion of the extrusion pin apparatus shown in FIG. 16.

[0027] FIG. 18 depicts an example apparatus used to induce a generally helical geometry in tubing.

[0028] FIG. 19 depicts an apparatus used to produce tubing having non-homogeneity characteristics.

[0029] FIG. 20 is a detailed perspective view of the split plate assembly shown in FIG. 19.
FIG. 21 is an exploded perspective view of an example extrusion assembly used to produce a flexible tube. FIG. 22 is a side view of the extrusion pin assembly shown in FIG. 21. FIG. 23 is a perspective view of an exemplary flexible tube.

DETAILED DESCRIPTION

The examples described herein relate to example apparatus to produce tubing having kink resistant properties. Additionally, the examples described herein relate to tubing having kink resistant properties. In some examples, tubing having kink resistant properties may be produced using a non-rotating die design. In some examples, tubing having kink resistant properties may be produced using a rotating and/or partially rotating die design. In some examples, tubing having kink resistant properties may be produced using one or more rotating features external to the die.

In some examples, the apparatus includes an extrusion assembly that induces generally helical and/or generally spiral fluid flow enabling tubing to be produced having generally helical and/or generally spiral non-homogeneity characteristics. In some examples, the apparatus includes a fixture that emits light that cross-links and/or chemically modifies tubing after extrusion to enable tubing to be produced having helical and/or spiral non-homogeneity characteristics. In some examples, the apparatus includes a plurality of helical rollers that rotate tubing and/or relative to tubing after it exits the extrusion die to produce tubing having helical and/or spiral non-homogeneity characteristics.

FIG. 1 depicts an example extrusion assembly 100 that induces a helical flow in fluid (e.g., polymers) flowing therethrough by inducing a helical high shear field. Inducing helical fluid flow enables tubes to be extruded having helical non-homogeneity characteristics. This helical non-homogeneity enables the tubing produced to have kink resistant properties. The example extrusion assembly 100 includes an example extrusion bushing 102 and an example extrusion pin 104. The bushing 102 and the pin 104 are at least partially separated by a flow channel 106 defined by an interior surface 107 of the bushing 102 and an exterior surface 108 of the pin 104. In some examples, the interior surface 107 and/or the exterior surface 108 may be at least partially corrugated. In some examples, the exterior surface 108 may be configured to produce tubing having an aperture having a particular cross-section such as, for example, a star shaped cross-section, a triangular cross-section, a circular cross-section, etc. The corrugation and/or the cross-section of the exterior surface 108 may enable tubing produced to have kink resistant properties.

The bushing 102 defines a channel 109 having a first channel portion 110, a tapered channel portion 112 and a second channel portion 114. The pin 104 includes a first pin portion 116 positioned at least partially within the first channel portion 110, a tapered pin portion 118 positioned at least partially within the tapered channel portion 112 and a second pin portion 120 positioned at least partially within the second channel portion 114.

In this example, to induce a spiral high shear field and, thus, a helical flow pattern in the fluid (e.g., polymers) flowing through the flow channel 106, the tapered pin portion 118 and/or the second pin portion 120 define and/or include a plurality of helical grooves, protrusions and/or flanges 122. The grooves 122 may be positioned at an angle (e.g., a non-parallel angle, a thirty degree angle, a thirty five degree angle, etc.) relative to a longitudinal axis 124 of the extrusion assembly 100.

In practice, as the fluid flows past the grooves 122, a helical flow pattern is induced in the fluid flow by the grooves 122. The helical flow pattern enables tubes (e.g., medical tubes) to be produced having non-homogeneity (e.g., helical non-homogeneity) therein. While the tapered pin portion 118 and/or the second pin portion 120 are depicted as defining the grooves 122, any other surface structure, texture, etc. may be included and/or defined to induce a desired flow pattern within the flow channel 106 and/or to enable tube(s) to be produced having helical non-homogeneity therein.

In an exemplary embodiment, the second channel portion 114 of bushing 102 may include and/or define grooves, protrusions and/or flanges to induce a helical flow pattern in the fluid flowing through the flow channel 106 in addition to or in place of groove 122 of pin 104.

FIG. 2 depicts an example tube 200 having a generally helical structure, shown as helical pattern 202, wherein that enables the tube 200 to be relatively kink resistant. In some examples, the helical pattern 202 may include portions (e.g., coils) that are evenly spaced from one another. In some examples, the helical pattern 202 may include portions (e.g., coils) that are unevenly spaced from one another. In some examples, the helical pattern 202 may have the same or a similar pitch along the length of tube 200. In some examples, an optimum pitch may have a spacing lower limit (e.g., spacing between coils) and a spacing upper limit (e.g., spacing between coils) to enable tubing produced to have particular kink resistant properties. For example, the spacing lower limit may be relatively small and/or less than the diameter of the tubing and/or a stripe or rod of material positioned therein and the spacing upper limit may be relatively large and/or greater than the diameter of the tubing and/or a stripe or rod of material positioned therein.

The helical pattern 202 may be produced by the orientation of polymer chains in the tube 200, for example. In other examples, helical pattern 202 may represent a helically positioned section of a material that is different (e.g., different material type, composition or polymer, that has a different flexibility, rigidity, hardness or durometer, etc.) than the material that forms the body of tube 200. In one such example, tube 200 may include three or more helical patterns 202 formed of material having a greater durometer than the material that forms the body of tube 200. The example tube 200 may be produced using any of the examples described herein such as, for example, the example extrusion assembly 100.

FIG. 3 depicts an example extrusion assembly 300 that induces a helical flow in fluid (e.g., polymers) flowing therethrough to enable tubes to be extruded having helical non-homogeneity characteristics. This helical non-homogeneity enables the tubing produced to have kink resistant properties. In contrast to the extrusion assembly 100 described above, an extrusion pin 302 of the extrusion assembly 300 may not be provided with the grooves 122, but instead, the extrusion assembly 300 includes an extrusion flow control member or arm 304 (e.g., an angled wall, a baffle, a vane, a spider leg, a fin, etc.). The flow control member 304 is coupled between an interior surface 306 of an example extrusion bushing 308 and an exterior surface 310 of the pin 302.
In some examples, the flow control member 304 is positioned at an angle (e.g., a non-parallel angle, a thirty degree angle, a thirty-five degree angle, a forty degree angle, etc.) relative to a longitudinal axis 311 of the extrusion assembly 300.

While the extrusion assembly 300 is depicted as having one flow control member 304, the extrusion assembly 300 may have any other number of flow control members (e.g., 2, 3, 4, etc.). If the extrusion assembly 300 includes more than one flow control member 304, the flow control members 304 may be similar or different from one another, for example. If the extrusion assembly 300 includes more than one flow control member 304, the flow control member 304 may be positioned around a circumference of the exterior surface 310 of the pin, for example. Additionally or alternatively, if the extrusion assembly 300 includes more than one flow control member 304, the flow control members 304 may be positioned (e.g., circumferentially positioned and/or axially positioned) along the longitudinal axis 311 of the extrusion assembly 300 between the interior surface 306 and the exterior surface 310, for example.

The flow control member 304 may include a first side 312, a middle portion 314 and a second side 316. In some examples, the first side 312, the middle portion 314 and the second side 316 have a similar thickness. In some examples, the first side 312 has a thickness different than a thickness of the middle portion 314 and/or the second side 316. In some examples, the middle portion 314 has a thickness different than a thickness of the first side 312 and/or the second side 316. In some examples, the second side 316 has a thickness different than a thickness of the first side 312 and/or the middle portion 314. Additionally or alternatively, any of the first side 312, the middle portion 314 and/or the second side 316 may have a substantially consistent thickness or a varying thickness, for example. For example, a portion of the flow control member 304 coupled to the exterior surface 310 may have a different thickness than a portion of the flow control member 304 coupled to the interior surface 306.

In some examples, materials such as fibers and/or fibrous inclusions may be introduced into, for example, polymer pellets used to produce tubing prior to extruding and/or processing. Such fibers and/or fibrous inclusions enable tubing to be produced having fibers therein. The fibers may be nylon, polyester or any other material that does not melt during processing (e.g., PVC processing). In some examples, the fibers and/or fibrous inclusions may form in the polymer after extrusion of the tubing. In some examples, the fibers may have an index of refraction that is similar to the bulk material (e.g., the first polymer) of the tubing wall.

In practice, as the fluid flows through the flow channel 318 past the flow control member 304, a helical flow pattern is induced in the fluid flow by the flow control member 304. The helical flow pattern enables tubing (e.g., medical tubes) to be produced having non-homogeneity (e.g., helical non-homogeneity) characteristics.

FIG. 4 depicts an example tube 400 having a helical structure, shown as helically oriented or aligned fibers and/or fibrous inclusions 402. The helical pattern and/or the fibers 402 enable the tube 400 to be relatively kink resistant. In some examples, the fibers may be added to the polymer pellets prior to extrusion and/ or processing and/ or may form in the tubing after extrusion. The example tube 400 may be produced using any of the examples described herein such as, for example, the example extrusion assembly 300.

FIG. 5 depicts an example extrusion assembly 500 that induces a helical flow in fluid (e.g., polymers) flowing therethrough to co-extrude tubes having helical non-homogeneity characteristics. This helical non-homogeneity enables the tubing produced to have kink resistant properties. The example extrusion assembly 500 includes an example extrusion bushing 502, an example extrusion pin 504, an example flow control member 506 and a side port 508. The example flow control member 506 may be similar to the example flow control member 304 of FIG. 3. The side port 508 may be differently positioned (e.g., different angles and/or positions relative to the bushing 502) to produce different tubes. For example, an opening 509 of the side port 508 may be positioned adjacent an exterior surface of the pin 504. The opening 509 of the side port 508 may be positioned adjacent an interior surface of the bushing 502, for example. The opening 509 of the side port 508 may be positioned between the interior surface of the bushing 502 and the exterior surface of the pin 504, for example. The side port 508 may be positioned at any distance relative to an end of the extrusion assembly 500 to induce spiral flow and/or to ensure a relatively consistent fluid flow from the extrusion assembly 500, for example.

In practice, in some examples, a first polymer or material (e.g., bulk material, bulk extrudate, plasticized PVC, Shore A 77, a first durometer) may flow in a direction generally represented by arrow 510 into a flow channel 512 between the bushing 502 and the pin 504. In some examples, a second polymer (e.g., plasticized PVC, Shore A 85, a second durometer) may flow in a direction generally represented by arrow 514 into the flow channel 512. The first polymer may be similar or different than the second polymer and may be compatible with the second polymer. For example, the first polymer may have a first modulus and the second polymer may have a second modulus different from the first modulus. In some examples, the second polymer has a higher modulus than the first polymer. The first polymer may flow into the flow channel 512 at a first flow rate and the second polymer may flow into the flow channel 512 at a second flow rate. The first flow rate may be similar or different than the second flow rate. For example, the volume of flow of the second polymer may be approximately ten percent of the volume of flow of the first polymer.

As the first polymer flows through the flow channel 512 past the flow control member 506, a helical flow pattern is induced in the fluid flow by the flow control member 506. As the second polymer enters the flow channel 512, the second polymer may create a helical ribbon on and/or in the tube being produced. In examples in which the opening 509 is positioned adjacent the interior surface of the bushing, the addition of the second polymer enables tubing to be produced having a helical ribbon on an exterior surface of the tube. In examples in which the opening 509 is positioned between the interior surface of the bushing 502 and the exterior surface of the pin 504, the tubing produced may have a helical ribbon or rib imbedded in the tubing wall. In examples in which the side port 508 is positioned at an angle (e.g., a non-perpendicular angle, a perpendicular angle) relative to a longitudinal axis 516 of the extrusion assembly 500, the second polymers entering the flow channel 512 may further induce a helical flow pattern in the fluid flowing in the flow channel 512. As with the other examples described herein, the tubing produced using the example extrusion assembly 500 include non-homogeneity (e.g., helical non-homogeneity) therein.
FIG. 6 depicts an example tube 600 that can be produced using the examples described herein such as using the example extrusion assembly 500. The tube 600 includes a helical structure, shown as helical co-extruded section, portion or rod 602, positioned therein. The rod 602 may be a different modulus (e.g., a higher modulus) than the remainder (e.g., bulk) of the tube 600. The rod 602 enables the tube 600 to be relatively kink resistant. In some examples, the rod 602 may include portions (e.g., coils) that are evenly spaced from one another and/or the rod 602 may include portions that are evenly spaced from a longitudinal axis of the tube 600. In some examples, the rod 602 may have a minimum volume and a maximum volume. For example, the minimum volume may be approximately one percent of a tube 100 wall volume and the maximum volume may be approximately fifty percent of the tube 100 wall volume; however, different percentages (e.g., 2, 3, 4, etc.) may be used for the minimum volume and different percentages (e.g., 48, 49, 50, 51, etc.) may be used for the maximum volume. In one example, tube 600 may include more than one rod 602, and in one specific example, tube 600 includes three or more rods 602.

FIG. 7 depicts an example extrusion assembly 700 that produces helical flow in fluid flowing therethrough to co-extrude tubes having helical non-homogeneity characteristics. This helical non-homogeneity enables the tubing produced to have kink resistant properties. The example extrusion assembly 700 includes an example extrusion bushing 702, an example extrusion pin 704 and an example angled side port 706. The side port 706 may be positioned at any suitable angle (e.g., a sixty degree angle, a seventy degree angle, an eighty degree angle, a ninety degree angle, etc.) relative to a longitudinal axis 708 of the example extrusion assembly 700. The angle of the side port 706 relative to a flow channel 710 between the bushing 702 and the pin 704 enables fluid flowing though the side port 706 to induce a helical flow in fluid flowing through the flow channel 710. The side port 706 may be differently positioned to produce different tubes. For example, an opening 712 of the side port 706 may be positioned adjacent an exterior surface of the pin 704. The opening 712 of the side port 706 may be positioned adjacent an interior surface of the bushing 502. The opening 712 of the side port 706 may be positioned between the interior surface of the bushing 702 and the exterior surface of the pin 704.

In practice, first polymers (e.g., bulk material, bulk extrudate) entering the flow channel 710 flow in a direction generally represented by arrow 714 and second polymers (e.g., stiffer PVC) entering the flow channel 710 flow in the direction generally represented by arrow 716. The angle at which the side port 706 is positioned relative to the flow channel 710 induces a helical flow pattern in the fluid flow when the second polymers enter the flow channel 710. Additionally, as the second polymers enter the flow channel 710, the second polymers may create a helical ribbon on and/or in the tube being produced. In examples in which the opening 712 is positioned adjacent the interior surface of the bushing 702, the addition of the second polymers enables a tube to be produced having a helical ribbon on the exterior surface of the tube. As with the other examples described herein, the tubes produced using the example extrusion assembly 700 include non-homogeneity (e.g., helical non-homogeneity) therein.

FIGS. 8-10 depict the flow path 800 of the fluid flowing through the example extrusion assembly 700. Reference number 802 represents the flow of first polymers, reference number 804 represents the flow of second polymers and reference number 806 represents the flow of first and second polymers.

FIG. 11 depicts an example apparatus 1100 that enables helical orientation cross-linking and/or chemical modification to be obtained in tubing (e.g., medical tubes) being produced using, for example, the example extrusion assemblies described herein. The example apparatus 1100 includes a cross-linking beam or fixture 1102 that may rotate around a tube 1104 being extruded in a direction (e.g., a longitudinal direction) generally represented by arrow 1106. In some examples, the fixture 1102 may define an aperture (not shown) through which the tube 1104 passes. The fixture 1102 may emit ionizing radiation, ultraviolet radiation, etc., as the fixture 1102 is rotated about the tube 1104 as the tube 1104 is being extruded, for example. Rotating the fixture 1102 about the tube 1104 as the tube 1104 is being extruded cross-links polymers in the tube 1104 in a generally helical orientation. The example apparatus 1100 may be utilized in connection with any of the extrusion assemblies described herein to further induce helical non-homogeneity or may be used on its own to produce tubes having helical non-homogeneity, for example.

FIG. 12 depicts an example extrusion assembly 1200 that induces a spiral high shear field and, thus, a helical flow in fluid flowing therethrough to enable tubes to be extruded having helical non-homogeneity characteristics. The example extrusion assembly 1200 includes an example extrusion bushing or rotating extrusion bushing 1202 and an example extrusion pin or rotating extrusion pin 1204. In contrast to the examples described above, the extrusion pin 1204 may be coupled to a bearing mount 1206 to enable the extrusion pin 1204 to rotate (e.g., rotate freely) as fluid flows through a flow channel 1208 between the bushing 1202 and the pin 1204. In practice, a helical flow pattern is induced in fluid flowing through the flow channel 1208 by a flow control member or fin 1210. The helical fluid flow may in turn provide the rotational driving force to rotate the extrusion pin 1204, for example. The flow control member 1210 may include different geometries to provide an angled surface to induce helical fluid flow. The flow control member 1210 may be positioned at an angle (e.g., a non-parallel angle) relative to a longitudinal axis 1212 of the extrusion assembly 1200.

FIG. 13 depicts an example tube 1300 having a helical structure, shown as helical co-extruded profile (e.g., a co-extruded gear profile). In some examples, the tube 1300 includes a helical and/or rotation of a gear profile 1302 positioned within the tube 1300. The helical gear profile 1302 enables the tube 1300 to be relatively kink resistant. In some examples, an extrusion assembly used to produce the example tube 1300 may be similar to the extrusion assemblies 100, 300 and/or 700 configured for co-extrusion. In other examples, the extrusion assembly used to produce the example tube 1300 may induce helical flow in the fluid flowing therethrough.

FIG. 14 depicts an example apparatus 1400 that enables helical orientation to be obtained in tubing (e.g., medical tubes) being produced using, for example, the example extrusion assemblies described herein. The example
apparatus 1400 includes a plurality of helical rollers 1402 external to the extrusion die and positioned about tubing 1404 being extruded. In other examples, the example apparatus 1400 may include a plurality of conical or spiral rollers. In some examples, the apparatus 1400 may be positioned in a tubing water quench tank.

The plurality of rollers 1402 defines and/or includes a plurality of grooves and/or surface structures 1406 that may induce helical non-homogeneity in tubing and/or induce rotation of the tubing 1404 as the tubing is being pulled through the rollers 1402 by, for example, downstream take-up. In some examples, the plurality of rollers 1402 may be free-spinning on bearings.

In practice, as the tubing 1404 exits an extrusion die prior to quenching, helical orientation is induced in the molten portion of the tubing 1404 by the rollers 1402 rotating the tubing 1404. While the example apparatus 1400 includes three rollers 1402, any other number of rollers (e.g., 1, 2, 3, etc.) may be used instead to induce helical non-homogeneity and/or induce rotation. The example apparatus 1400 may be utilized in connection with any of the extrusion assemblies described herein to further induce helical non-homogeneity or may be used on its own to produce tubes having helical non-homogeneity, for example.

FIG. 15 represents an example method 1500 of producing the examples described herein. At 1502, the method 1500 flows first fluid toward an extrusion assembly. The first fluid may be any suitable polymer, bulk material, bulk extrudate, etc. At 1504, the method 1500 determines whether or not to flow a second fluid toward the extrusion assembly. The second fluid may be any suitable polymer and may have a higher modulus than the first fluid. Enabling the second fluid to flow toward the extrusion assembly enables a co-extruded tube to be produced, for example. If the method 1500 determines to flow the second fluid toward the extrusion assembly, control moves to block 1506.

At 1508, the method 1500 flows fluid through the extrusion assembly. In examples in which the extrusion includes one of the fluids (e.g., the first fluid), the fluid flowing through the extrusion assembly may be the first fluid. In examples in which the extrusion includes two or more fluids (e.g., the first fluid, the second fluid), the fluid flowing through the extrusion assembly may include the first fluid and the second fluid.

In some examples, the first fluid may enter the extrusion assembly at a first location and the second fluid may enter the extrusion assembly at a second location. The first location may be similar or different than the second location. For example, the first location may be at an end of the extrusion assembly and the second location may be at a side of the extrusion assembly.

In some examples, the first fluid may enter the extrusion assembly at a first angle and the second fluid may enter the extrusion assembly at a second angle. The first angle may be similar or different than the second angle. For example, the first fluid may enter the extrusion assembly substantially parallel to and/or along a longitudinal axis of the extrusion assembly and the second fluid may enter the extrusion assembly substantially perpendicular to the longitudinal axis of the extrusion assembly.

At 1510, the method 1500 induces a helical flow in the fluid flowing through the extrusion assembly. The helical flow enables tubing to be produced having helical non-homogeneity characteristics. In some examples, the helical flow may be induced by obstacles (e.g., flow control member) and/or surface structures (e.g., grooves, protrusions, flanges, etc.) of the extrusion assembly. In some examples, the helical flow may be induced by the flow of the second fluid flowing into the extrusion assembly. In some examples, the helical flow may be induced by movement of a portion of the extrusion assembly. For example, the extrusion bushing of the extrusion assembly may rotate and/or the extrusion pin of the extrusion assembly may rotate and/or may be induced to rotate by the fluid flow.

At 1512, the tubing is extruded from the extrusion assembly. At 1514, the method 1500 determines whether or not to perform a post extrusion process(es) on the tubing. If the method 1400 determines to perform a post extrusion process on the tubing, control advances to block 1516. In some examples, the post extrusion process includes cross-linking and/or chemical modification of the tubing to further induce helical non-homogeneity in the tubing. For example, the tubing may be exposed to ionizing radiation, ultraviolet radiation, etc. that moves relative to the tubing being extruded and induces helical geometry in the tubing. In some examples, the post extrusion process includes passing the tubing through a plurality of helical rollers that rotate and/or induce helical non-homogeneity in the tubing being produced.

At 1518, the method determines whether or not to move to block 1402. Otherwise, the example method 1500 is ended.

FIGS. 16 and 17 depict an example extrusion pin or rotating extrusion pin assembly or apparatus 1600 that may be used in connection with an example bushing and/or extrusion assembly to induce a spiral high shear field and, thus, a helical flow in fluid flowing adjacent thereto. The helical fluid flow enables tubes to be extruded having helical non-homogeneity characteristics and being relatively kink resistant, for example.

The example pin 1600 may include a first portion 1602, a second portion or inset 1604 and a third portion or body 1606. The first, second and/or third portions 1602-1606 may define an air passage 1607 therethrough. The first portion 1602 may include threads 1608 to threadably engage a spider 1610, for example. In some examples, the threads 1608 may be in an opposite or different direction than the helical fluid flow to substantially ensure that the fluid flow does not unthread the first portion 1602 from the spider 1610.

The second and third portions 1604 and 1606 may be rotatably coupled to the first portion 1602. In some examples, the third portion 1606 may include a plurality of fins 1612 configured to enable fluid flowing adjacent thereto to rotate the second and third portions 1604 and 1606 and, thus, to induce a helical flow pattern in the fluid. For example, the interaction between the plurality of fins 1612 and the fluid flowing adjacent thereto may provide a driving force to rotate the second and third portions 1604 and 1606 relative to the first portion 1602. The plurality of fins 1612 may be positioned at any suitable angle (e.g., a non-parallel angle, a parallel angle) relative to a longitudinal axis 1614 of the pin 1600. While the example pin 1600 includes 6 fins, any other number of fins (e.g., 1, 2, 3, 4, etc.) may be used that may be spaced (e.g., circumferentially spaced, longitudinally spaced, etc.) on the pin 1600, for example. The plurality of fins 1612 may be sized to enable the third portion 1606 to rotate relative to a bushing surrounding the pin 1600, for example.
[0071] Turning to FIG. 17, a detailed view of the first, second and third portions 1602-1606 is depicted. In some examples, the first portion 1602 includes a collar 1702 having a slot or aperture 1704 to receive a tool (e.g., a rod) to facilitate rotating the first portion 1602 relative to the spider 1610. The slot 1704 may enable the first portion 1602 to be relatively easily threaded into the spider 1610, for example. In some examples, once the first portion 1602 is threadably engaged to the spider 1610, a plug (not shown) may be inserted into and/or thread into the slot 1704 to substantially prevent the slot 1704 from affecting the fluid flow.

[0072] In some examples, a first spacer or washer 1706 may be positioned adjacent to the collar 1702. The second portion 1604 may be positioned about the first portion 1602 such that a step 1708 of the second portion 1604 engages the first washer 1706 and is positioned adjacent to the collar 1702. The interaction between the collar 1702, the first washer 1706 and/or the step 1708 enables the second portion 1604 to rotate relative to the first portion 1602, for example. The first and second portions 1602 and 1604 may be coupled to the third portion 1606 by a plurality of fasteners or screws 1710 that threadably engage the third portion 1606, for example.

[0073] In some examples, a second washer or spacer 1712 may be positioned about the first portion 1602 and adjacent to the second portion 1604. The first, second and third portions 1602-1606 may be coupled to the spider 1610. In some examples, the second portion 1604 may define an aperture (not shown) that may be aligned with the slot 1704 to enable a rod to be inserted into the slot to facilitate threading the first portion 1602 into the spider 1610 after the first, second and/or third portions 1602-1606 are coupled together. In some examples, the aperture and/or the slot 1704 may define threads orientated in a direction opposite to or different than the fluid to flow adjacent thereto. The orientation of the threads may enable a plug that threadably engages the respective aperture and/or slot 1704 to not become unthreaded by the helical fluid flow, for example. The first and/or second washers 1706 and/or 1712 may be a Teflon washer, a lubricous high temperature washer, etc.

[0074] FIG. 18 depicts an example apparatus 1800 that enables helical orientation to be induced or created in the tubing after exiting the extrusion die using, for example, the extrusion assemblies described herein. The example apparatus 1800 includes a structure and/or an annular ring 1802 and a plurality of rollers 1804 coupled to the annular ring 1802 by fixtures and/or brackets 1806. The plurality of rollers 1804 may be rotatablely coupled to the brackets 1806. In some examples, the plurality of rollers 1804 may freely rotate relative to the brackets 1806. In other examples, the plurality of rollers 1804 may be rotated by, for example, a motor (not shown) relative to the brackets 1806.

[0075] The plurality of rollers 1804 may have a relatively smooth exterior surface and/or may include a plurality of grooves and/or surface structures, for example. In some examples, some or all of the plurality of rollers 1804 may be positioned to enable the rollers 1804 to rotate in a similar direction (e.g., parallel to) as tubing 1808 being extruded. In some examples, some or all of the plurality of rollers 1804 may be positioned to enable the rollers 1804 to rotate in a different direction (e.g., nonparallel to) as the tubing 1818 being extruded to further induce a helical orientation in the tubing 1808 being produced.

[0076] In practice, the ring 1802 may be rotated (e.g., clockwise, counter clockwise) by a drive roller 1810 as the tubing 1808 is being extruded. As the ring 1802 is rotated about the solidified tubing 1808, the plurality of rollers 1804 interact with the molten portion of the tubing 1808 exiting the die, thereby inducing a helical orientation in the tubing 1808, for example. This helical orientation may enable the tubing 1818 produced to be relatively kink resistant. While the example apparatus 1800 includes three rollers 1804, any other number of rollers (e.g., 1, 2, 3, etc.) may be used to induce helical non-homogeneity and/or induce the tubing 1818 to rotate after extrusion, for example. The example apparatus 1800 may be utilized in connection with any of the extrusion assemblies described herein to further induce helical non-homogeneity or may be used on its own to produce tubes having helical non-homogeneity, for example.

[0077] Referring to FIG. 19, an extrusion die assembly 1900 for making a flexible tube is shown according to another example. Die assembly 1900 includes a first inlet structure 1902 and a second inlet structure 1904. Die assembly 1900 includes a die plate assembly 1906 and an extrusion assembly 1908. Die plate assembly 1906 includes a split plate assembly 1910 and a spider plate 1912. In the embodiment shown, split plate assembly 1910 includes a first split plate 1914 and a second split plate 1916. In the example shown in FIG. 19, inlet structure 1902 is coupled to the rear or inlet surface of split plate assembly 1910, and inlet structure 1904 is coupled to the lateral surface of split plate assembly 1910. Spider plate 1912 is coupled to the front surface of split plate assembly 1910. The rear or inlet side of extrusion assembly 1908 is coupled to the front surface of spider plate 1912. A collar 1918 is coupled to the front surface of spider plate 1914 and surrounds the rear or inlet portion of extrusion assembly 1908.

[0078] Inlet 1902 and inlet 1904 each include a channel that is in fluid communication with a supply of a polymer material and in fluid communication with polymer flow channels located within die plate assembly 1906 that deliver polymer to extrusion assembly 1908. In one embodiment, inlet 1902 is in communication with a first material that forms the bulk or body of a flexible tube, and inlet 1904 is in communication with a second material that forms helical structure within the flexible tube as shown and discussed below. Thus, as shown, inlet 1902 and 1904 allow for two different materials (e.g., two different polymer materials) to enter the polymer flow path prior to the flow path entering into extrusion assembly 1908.

[0079] In one embodiment, the flow path from inlet 1904 within die plate assembly 1906 is split into a plurality of different paths prior to joining with the flow path from inlet 1902. In this embodiment, the flexible tube that is made using die assembly 1900 may have a plurality of helical sections formed of the material from inlet 1904 embedded within a tube body made from the material from inlet 1902.

[0080] In one such embodiment shown in FIG. 20, split plate assembly 1910 includes a rear or inlet channel 1920 that receives polymer fluid flow from inlet 1902 and a side channel 1922 that receives fluid flow from inlet 1904. Side channel 1922 includes three outlet openings 1924 formed through the inner surface of split plate assembly 1910. Outlet openings 1924 are positioned to deposit the second material from inlet 1904 into the flow path of the first material from inlet 1902 at three distinct positions. The arrangement of outlet openings 1924 provides for the formation of a flexible tube having three
sections or strips of the material from inlet 1904 embedded in the body of the flexible tube. An example of one such tube is shown below in Fig. 23.

[0081] In the embodiment shown in FIG. 20, openings 1924 are evenly spaced (e.g., spaced approximately every 120 degrees) around the internal circumference of split plate assembly 1910 resulting in the even spacing of the strips of the second material within the flexible tube. In other embodiments, split plate assembly may include more than three (e.g., 4, 5, 6, 7, 8, etc.) openings 1924 in order to produce a flexible tube having more than three strips of the second material. Openings 1924 may also be spaced non-symmetrically or spaced in other patterns to vary the kink resistant properties of the extruded tube.

[0082] Referring to FIG. 19 and FIG. 21, extrusion die assembly 1900 includes an extrusion assembly 1908 coupled to the front face of spider plate 1912. Extrusion assembly 1908 includes a die body, shown as bushing 1930, and an die insert or pin, shown as an extrusion pin 1932. Generally, the die body has an inner surface that defines an internal cavity that receives the die insert, and an extrusion die cavity is defined between the outer surface of the die insert and the inner surface of the die body. With pin 1932 received within the internal cavity, central passage, channel or bore formed through bushing 1930, an extrusion flow channel is defined between the outer surface of pin 1932 and the inner surface of bushing 1930. The extrusion flow channel extends from the rear or inlet side of extrusion assembly 1908 and terminates in an outlet, shown as ring shaped aperture 1934. Ring-shaped aperture 1934 forms a generally tube-shaped article as the flowing polymer exits extrusion assembly 1908 through aperture 1934.

[0083] Extrusion assembly 1908 is configured to make or create one or more helically disposed non-homogeneity within the tube by inducing helical rotation (e.g., spiral rotation or non-spiral helical rotation) of the polymer material as it flows through extrusion assembly 1908. Specifically, in the embodiment shown, pin 1932 has a helical groove, shown as spiral groove 1936, formed on the outer surface of pin 1932. Referring to FIG. 21, as polymer flows axially, shown by arrow A, past groove 1936 within the flow channel of extrusion assembly 1908, groove 1936 induces the polymer to rotate in the counterclockwise direction, shown by arrow R. Such grooves may be oriented in the opposite direction to induce clockwise flow.

[0084] Because the external surface of pin 1932 forms the inner surface of the flow channel through extrusion assembly, groove 1936 tends to induce greater rotational flow at the inner surface of the tube (i.e., the surface of the tube that defines the passage or channel through the tube) than at the outer surface of the tube. In one embodiment, the rate of twist of the helical structure (i.e., the number of rotations of the helical structure per unit length of tube) may be greatest at the inner surface of the tube and lowest at the outer surface of the tube. In one such embodiment, the rate of twist of the helical structure is inversely related to its radial position or depth with the wall of the tube and decreases as the radial distance from the lumen of the tube increases.

[0085] A portion of bushing 1930 or the entire bushing 1930 may rotate about the extrusion flow path to induce helical rotation in the flowing polymer. Referring to FIG. 21, in one such embodiment, bushing 1930 includes a bushing insert 1938 that is rotatably mounted to the front face of bushing 1930. The inner surface of bushing insert 1938 forms the outer surface of the polymer flow channel through extrusion assembly 1908 and is located adjacent to exit aperture 1934. The front face and front portion of bushing insert 1938 extends through a central hole located in bushing collar 1939, and a sprocket gear 1940 is coupled to bushing insert 1938. Gear 1940 is coupled to an external power supply (e.g., a motor) that engages and rotates gear 1940 which in turn causes bushing insert 1938 to rotate. The rotation of bushing insert 1938 induces rotation in the polymer material as it flows through bushing insert 1938, which forms one or more helically oriented structures within the tube. As shown, gear 1940 is coaxial with bushing insert 1938 and includes a central aperture that allows the extruded tube to pass through gear 1940. In this embodiment, bushing 1930 is rotationally fixed and bushing insert 1938 rotates relative to bushing 1930. In one embodiment, a bearing may be coupled between bushing insert 1938 and bushing 1930 to facilitate rotation of bushing insert 1938. In another embodiment, bushing 1930 may not include a bushing insert and the whole bushing 1930 may rotate such that the entire outer surface of the extrusion flow channel rotates.

[0086] As shown in FIG. 21, bushing insert 1938 is configured to rotate in the counterclockwise direction, as shown by arrow R2. Thus, in the embodiment shown, both groove 1936 and rotating bushing insert 1938 are configured to induce rotation of the polymer in the same direction (e.g., counterclockwise in the embodiment of FIG. 21). In other embodiments, both grooves 1936 and rotating bushing insert 1938 are configured to induce rotation of the polymer in the clockwise direction. In another embodiment, groove 1936 and rotating bushing insert 1938 are configured to induce rotation of the polymer in opposite directions.

[0087] Because the internal surface of bushing insert 1938 forms the outer surface of the flow channel adjacent the exit of extrusion assembly 1908, rotation of bushing insert 1938 tends to induce greater rotational flow at the outer surface of the tube than at the inner surface of the tube (i.e., the surface of the tube that defines the passage or channel through the tube). In one embodiment, the rate of twist of the helical structure may be greatest at the outer surface of the tube and lowest at the inner surface of the tube. In one such embodiment, the rate of twist of the helical structure is directly related to the radial position within the wall of the tube and increases as the radial distance from the lumen of the tube increases.

[0088] In the embodiment shown in FIG. 21, extrusion assembly 1908 is configured to create rotation of the polymer using both groove 1936 of pin 1932 and via rotation of bushing insert 1938. In this embodiment, rotation of bushing insert 1938 supplements the rotation provided by groove 1936. In one embodiment, the rotational speed of bushing insert 1938 may be set such that the rate of twist of the helical structures at the outer surface and inner surface of the tube are substantially the same. In other embodiments, the rotational speed of bushing insert 1938 may be set such that the rate of twist of the helical structures at the outer surface of the tube is greater than the rate of twist of the helical structures at the inner surface of the tube. In other embodiments, the rotational speed of bushing insert 1938 may be set such that the rate of twist of the helical structures at the outer surface of the tube is greater than the rate of twist of the helical structures at the inner surface of the tube. In other embodiments, the rotational speed of bushing insert 1938 may be set such that the rate of twist of the helical structures at the outer surface of the tube is
less than the rate of twist of the helical structures at the inner surface of the tube. In other embodiments, groove 1936 and rotating bushing insert 1938 are configured to induce rotation of the polymer in opposite directions such that the direction of orientation of the helical structures along the inner surface of the tube is opposite from the direction of orientation of the helical structures along the outer surface of the tube.

In some embodiments, a flexible tube is made from a single material using extrusion assembly 1908, and in these embodiments, the rotational flow may induce a helical alignment of polymer chains within the body of the formed tube. In these embodiments, the helical structure embedded in the wall of the tube is the helically aligned polymer chains. In embodiments in which two or more materials are used, the rotation induced by extrusion assembly 1908 creates one or more helically oriented strips or sections of material embedded within the body of the tube instead of or in addition to the helical alignment of polymer molecules.

Referring to FIG. 22, a detailed side view of extrusion pin 1932 is shown. Extrusion pin 1932 includes a rear end 1942 and a front end 1944. Extrusion pin 1932 includes a body 1946 and a cylindrical tip portion 1948. Groove 1936 is formed in body 1946 and act to induce rotation of polymer through extrusion assembly 1908 as discussed above. The outer surface of cylindrical tip portion 1948 does not include grooves, and the diameter of tip portion 1948 defines the inner diameter of the tube formed using pin 1932.

As shown in FIG. 22, body 1946 includes a portion 1950 that is angled or tapered such that the diameter of the body decreases as the distance from rear end 1942 increases. Body 1946 also includes a non-tapered, substantially cylindrical portion 1951 located between rear end 1942 and tapered portion 1950. Thus, in this embodiment, the portion of groove 1936 located on tapered portion 1950 is a spiral helical groove, and the portion of groove 1936 located on cylindrical portion 1951 is a non-spiral helical portion. Angle A is the angle between the longitudinal axis 1952 and the lowest or deepest portions of groove 1936 and provides a measurement of the degree of taper along tapered section 1950. In one embodiment, angle B is between about 2 degrees and 30 degrees, specifically between about 5 degrees and 20 degrees, and more specifically between about 10 degrees and 15 degrees. In the embodiment shown in FIG. 22, angle B is about 12 degrees.

As shown in FIG. 22, groove 1936 has a width W which is the dimension of the groove parallel to longitudinal axis 1952. In one embodiment, width W of groove 1936 decreases as the distance from rear end 1942 increases. In other words, the width W of groove 1936 is inversely related (e.g., inversely proportional) to the axial position along pin 1932. Further, width W of groove 1936 decreases as the diameter of pin 1932 decreases. In other words, the width W of groove 1936 at a position along longitudinal axis 1952 is directly related (e.g., directly proportional) to the diameter of pin 1932 at that location. In one embodiment, extrusion pin 1932 having the characteristics discussed above produces a hollow tube having kink resistant properties.

FIG. 23 depicts a kink resistant tube, shown as tube 1960, according to an exemplary embodiment. Tube 1960 is an exemplary medical tube that may be produced using the above described apparatuses and methods. Tube 1960 includes a body 1962 having an outer surface 1964 and inner surface 1966 inner surface 1966 defines a central passage, channel or lumen 1968. In one embodiment, tube 1960 may be a medical tube and lumen 1968 is configured to carry a biological fluid (e.g., blood, urine, etc.), and, in another embodiment, tube 1960 is a medical tube and lumen 1968 is configured to carry a therapeutic fluid (e.g., medicine, drugs, saline, nutrient fluid, etc.). In various embodiments, tube 1960 may be used in conjunction with a medical device or system (e.g., IV bags, pumps, catheters, subcutaneous ports, implanted/implantable medical devices, implanted/implantable drug delivery devices, blood and blood component collection bags, blood collection equipment, blood separation equipment, blood filtration equipment, etc.) to deliver such fluids to a patient or to carry fluids away from a patient.

Tube 1960 includes three or more helical structures, shown as helical segments 1970, 1972 and 1974. Helical segments 1970, 1972 and 1974 are helically disposed along the length of tube 1960 such that the circumferential position of the segment varies with the longitudinal position along tube 1960. In the embodiment of FIG. 23, segments 1970, 1972 and 1974 are evenly spaced around the circumference of tube 1960 such that there is about 120 degrees of separation between adjacent segments.

In the embodiment of FIG. 23, segments 1970, 1972 and 1974 are embedded in body 1962 adjacent outer surface 1964 such that a portion of outer surface 1964 is formed by the outer surfaces of segments 1970, 1972 and 1974. In the embodiment shown, the cross-section of segments 1970, 1972 and 1974 are roughly semi-circular in shape. In other embodiments, as shown in FIG. 6, for example, segments 1970, 1972 and 1974 may be completely embedded within body 1962 such that no portion of segments 1970, 1972 and 1974 is exposed to outer surface 1964.

As shown in FIG. 23, body 1962 of tube 1960 is formed from a first material, shown as material A, and segments 1970, 1972 and 1974 are formed from a second material, shown as material B. In one embodiment, material B is different from the material A. For example, material A may be a first type of polymer (e.g., polyvinylchloride), and material B may be a second type of polymer. In another embodiment, material A may be a material that has a different property (e.g., elasticity, hardness, etc.) than material B. In one such embodiment, material A and material B may be the same general type of polymer but may be species having different material properties. In various embodiments, material A and/or material B may be a nonreactive, biocompatible polymer material.

In one embodiment, both material A and material B may be a PVC material, but material B may be a stiffer, stronger or harder PVC than material A. Specifically, material B may have a durometer greater than the durometer of material A on the Shore A durometer scale. In various embodiments, material A may be PVC material having a Shore A durometer between 60 and 80, and more specifically having a Shore A durometer between 68 and 78. In such embodiments, material B may be a PVC material having a Shore A durometer between 70 and 100 and more specifically between 80 and 90. In one embodiment, material B may be a PVC material having a Shore A durometer of 85.

It should be understood that the present application is not limited to the details or methodology set forth in the description or illustrated in the figures. It should also be understood that the terminology is for the purpose of description only and should not be regarded as limiting.

Further modifications and alternative embodiments of various aspects of the invention will be apparent to those
skilled in the art in view of this description. Accordingly, this
description is to be construed as illustrative only. The con-
struction and arrangements, shown in the various exemplary
embodiments, are illustrative only. Although only a few
embodiments have been described in detail in this disclosure,
many modifications are possible (e.g., variations in sizes,
dimensions, structures, shapes and proportions of the various
elements, values of parameters, mounting arrangements, use
of materials, colors, orientations, etc.) without materially
departing from the novel teachings and advantages of the
subject matter described herein. Some elements shown as
integratedly formed may be constructed of multiple parts or
elements, the position of elements may be reversed or other-
wise varied, and the nature or number of discrete elements or
positions may be altered or varied. The order or sequence of
any process, logical algorithm, or method steps may be varied
or re-sequenced according to alternative embodiments. Other
substitutions, modifications, changes and omissions may also
be made in the design, operating conditions and arrangement
of the various exemplary embodiments without departing
from the scope of the present invention.

3. The method of claim 2 wherein said providing a second
liquid polymer material comprises supplying the second li-
quid polymer material to the flow channel from at least three
distinct locations and further wherein the helical structure
comprises at least three helically oriented segments extend-
ing longitudinally along the body of the tube, wherein the
helically oriented segments are formed of the second liquid
polymer material.

4. The method of claim 3 wherein the at least three helically
oriented segments are evenly spaced around the circumfer-
ence of the tube and are embedded in the body of the tube
adjacent to the outer surface of the tube, and further wherein
the first liquid polymer material is a PVC material having
a first hardness and the second liquid polymer material is a PVC
material having a second hardness, wherein the second hard-
ness is greater than the first hardness.

5. The method of claim 1 wherein the helical flow is
induced by a helical groove formed in one of the surfaces
that defines the flow channel.

6. The method of claim 5 wherein the helical groove is a
spiral groove formed in a tapered portion of the an inner
surface of the flow channel.

7. The method of claim 1 wherein helical flow is induced by
rotating at least a portion of an outer surface of the flow
channel.

8. The method of claim 7 wherein the outer surface of the
flow channel is a coextrusion bushing and the rotating portion
of the outer surface is a bushing insert rotatably coupled to the
bushing, wherein the bushing insert rotates relative to the
coextrusion bushing to induce helical flow as the liquid pol-
imer flows through the flow channel.

9. The method of claim 8 wherein a helical groove is
formed in an inner surface of the flow channel, wherein heli-
cal flow is induced by both the rotation of the bushing insert
and by the helical groove.

10. The method of claim 7 wherein the entire outer surface
of the flow channel rotates relative to an inner surface of the
flow channel to induce the helical flow.

11. The method of claim 1 wherein the helical structure
comprises helically aligned polymer chains within the body
of the tube.

12. (canceled)

13. A flexible, kink-resistant medical tube comprising:
a polymeric body having a first end, a second end, an outer
surface and an inner surface;
a lumen defined by the inner surface of the body and
extending between the first end and the second end; and
a polymeric helical structure within the body.

14. The medical tube of claim 13 wherein the body is made
from a first polymer material and the helical structure is made
from a second polymer material, wherein the helical structure
comprises at least one helically oriented segment made from
the second polymer material embedded in the body.

15. The medical tube of claim 14 wherein the helical struc-
ture comprises at least three helically oriented segments made
from the second material embedded in the body, wherein the
first polymer material has a first hardness and the second
polymer material has a second hardness, wherein the first
hardness is less than the second hardness.

16. The medical tube of claim 15 wherein the tube is
formed by extrusion, wherein the first polymer material is a
first PVC material and the second polymer material is a sec-
ond PVC material, and further wherein the at least three
helically oriented segments are evenly spaced around the
17. The medical tube of claim 16 wherein the first polymer material has a Shore A durometer between 60 and 80 and the second polymer material has a Shore A durometer between 80 and 90.

18. The medical tube of claim 13 coupled to a medical device.

19. An extrusion die system for making a flexible, kink-resistant medical tube comprising:
   - an extrusion die body defining an internal cavity having an inlet and an outlet;
   - an extrusion die pin received within the internal cavity of the die body such that a die flow channel is defined between an outer surface of the die pin and an inner surface of the die body, the die flow channel extending between the inlet and the outlet of the die body, the die pin comprising a helical groove formed on the outer surface of the die pin;
   - a first inlet structure configured to deliver a first plastic material to the inlet of the die body;
   - a second inlet structure configured to deliver a second plastic material to the inlet of the die body;
   - wherein the helical groove induces helical rotation of liquid plastic material as it flows through the die flow channel.

20. The extrusion die system of claim 19 wherein the extrusion die pin has a longitudinal axis, wherein the diameter of the extrusion die pin decreases from an inlet side of the extrusion die pin to an outlet side of the extrusion die pin, wherein the dimension of the helical groove parallel to the longitudinal axis decreases as the diameter of the extrusion die pin decreases.

21. The extrusion die system of claim 19 further comprising:
   - an insert rotatably coupled to the extrusion die body such that the insert surrounds the outlet;
   - a gear coupled to the insert; and
   - an actuator coupled to the gear, wherein the actuator is configured to rotate the gear and the insert;
   - wherein rotation of the insert induces helical rotation of liquid plastic material as it flows through the insert.