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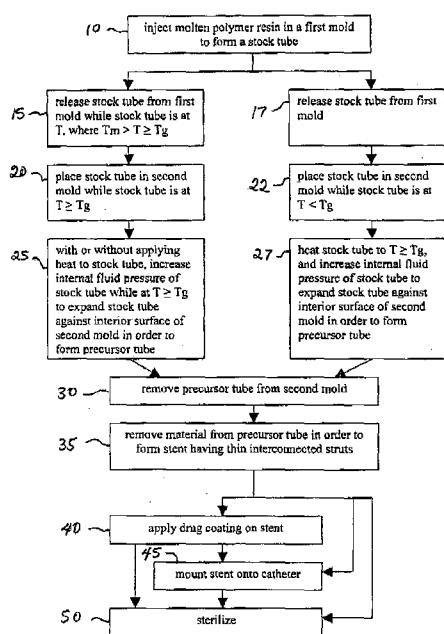
(54) Title: METHOD AND SYSTEM FOR MANUFACTURING A POLYMER ENDOPROSTHESIS BY INJECTION MOLDING
AND BLOW MOLDING

FIG. 1

(57) Abstract: A polymer endoprosthesis is fabricated by a combination of injection molding and blow molding which form a tubular substrate of polymer material, followed by laser cutting, crimping and sterilization. After the injection and blow molding processes, a subtractive process is performed on the tubular substrate to transform it into a stent having a network of stent struts. The tubular substrate can be made in an injection mold and blow mold which are attached to each other. The transition from injection molding and blow molding can be performed while the injection molded substrate remains at a temperature at or above Tg of the polymer material.



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**METHOD AND SYSTEM
FOR MANUFACTURING A POLYMER ENDOPROSTHESIS
BY INJECTION MOLDING AND BLOW MOLDING**

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FIELD OF THE INVENTION

This invention relates generally to fabrication of implantable endoprostheses, more particularly, to fabrication of polymer stents from injection molded and blow
10 molded tubes.

BACKGROUND OF THE INVENTION

An endoprosthesis is an artificial device that is placed inside a human or animal body. An anatomical lumen is a cavity of a tubular organ such as a blood vessel. Stents are generally cylindrically shaped devices, which function to hold open and sometimes
15 expand a segment of a blood vessel or other anatomical lumen such as urinary tracts and bile ducts. Stents are often used in the treatment of atherosclerotic stenosis in blood vessels. In such treatments, stents reinforce blood vessels and prevent restenosis following angioplasty in the vascular system.

Stents are relatively small, as they are often required to be passed through tight
20 confines of anatomical lumens. A stent must often have great longitudinal flexibility to allow it to pass through tortuous curves of anatomical lumens. Stents typically comprise a fine network of struts which form a tubular scaffold. The tubular scaffold must often be capable of being crimped onto a delivery device, such as a balloon, to reduce its size to allow passage through anatomical lumens, and then forcibly expanded by the balloon
25 to an enlarged, deployed state at the desired location within the body. For some stents, the tubular scaffold must be capable of self-expanding from its crimped state at the desired location within the body. After implantation and deployment, the tubular

scaffold must have sufficient strength to support surrounding anatomical structures.

Thus it will be appreciated that stents present unique design challenges.

Stents have in the past been made of metals, such as nickel-titanium alloys having shape memory and superelastic properties. The advent of polymer stents have
5 presented further design challenges. The design of a polymer stent must take into account that, as compared to metal stents of the same dimensions, polymer stents typically have less radial strength and rigidity and less fracture toughness. Thus, there is a continuing need for a method and system for manufacturing polymer stents that (a) increase uniformity from stent to stent, (b) allow for tight control of design parameters,
10 such as the thickness and dimension of individual stent struts, and/or (c) increase manufacturing efficiency.

SUMMARY OF THE INVENTION

Briefly and in general terms, the present invention is directed to a method and system for forming a polymer endoprosthesis.

15 In aspects of the present invention, a method comprises injecting a polymer material into a cavity of a first mold in order to form a stock tube, placing the stock tube in a cavity of a second mold, wherein the stock tube enters the second mold as it exits the first mold, and expanding the stock tube to form a precursor tube within the second mold.

20 In aspects of the present invention, a method comprises forming a stock tube of polymer material in an injection mold, transferring the stock tube from the injection mold to a blow mold, the transferring step performed while the stock tube is at a temperature at or above T_g of the polymer material, and expanding the stock tube in the blow mold in order to form a precursor tube.

In aspects of the present invention, a system comprises an injection mold having an injection mold cavity, a blow mold having a blow mold cavity, and a door movable from an first position to a second position, the injection mold cavity and the blow mold cavity being separated from each other by the door when at the first position, the
5 injection mold cavity and the blow mold cavity being exposed to each other with when the door is at the second position.

The features and advantages of the invention will be more readily understood from the following detailed description which should be read in conjunction with the accompanying drawings.

10 BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is flow diagram showing a method according to some embodiments of the present invention.

FIG. 2A is a cross-section view of a system according to some embodiments of the present invention, showing the system prior to injection of a polymer resin.

15 FIG. 2B is a cross-section view of the system of FIG. 2A, showing the system after polymer resin is injected into an injection mold cavity.

FIG. 2C is a cross-section view of the system of FIG. 2A, showing the system after the polymer resin, referred to as a stock tube, is ejected in a non-molten state directly into a blow mold cavity.

20 FIG. 2D is a cross-section view of the system of FIG. 2A, showing the system after the stock tube is radially expanded against an interior surface of the blow mold cavity.

FIG. 2E is a cross-section view of the expanded polymer resin, referred to as a precursor tube, after having been removed from the blow mold.

FIG. 2F is a cross-section view of the precursor tube carried on a mandrel, showing a cutter removing material from the precursor tube in order form stent struts.

FIGS. 3A-3F are perspective views of a system according to some embodiments of the present invention, showing a stock tube formed from polymer resin injected into an injection mold, and showing a precursor tube formed from the stock tube having been expanded in a blow mold, and showing a stent being formed by removal of material from the precursor tube.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

All publications and patents mentioned in the present specification are incorporated herein by reference to the same extent as if each individual publication or patent was specifically and individually indicated to be incorporated by reference. To the extent there are any inconsistent usages of words and/or phrases between an incorporated publication or patent and the present specification, these words and/or phrases will have a meaning that is consistent with the manner in which they are used in the present specification.

As used herein, any term of approximation such as, without limitation, near, about, approximately, substantially, essentially and the like mean that the word or phrase modified by the term of approximation need not be exactly that which is written but may vary from that written description to some extent. The extent to which the description may vary will depend on how great a change can be instituted and have one of ordinary skill in the art recognize the modified version as still having the properties, characteristics and capabilities of the modified word or phrase. For example without limitation, a material that is described as “substantially at ambient room temperature” refers to a material that is perfectly stabilized at room temperature and a material that one skilled in the art would readily recognize as being at room temperature even though

some areas of the material are not perfectly at room temperature. In general, but with the preceding discussion in mind, a numerical value herein that is modified by a word of approximation may vary from the stated value by $\pm 15\%$, unless expressly stated otherwise.

5 Referring now in more detail to the exemplary drawings for purposes of illustrating embodiments of the invention, wherein like reference numerals designate corresponding or like elements among the several views, there is shown in FIG. 1 a flow diagram of a method for manufacturing a polymer endoprosthesis which involves a combination of injection molding, blow molding, and formation of stent struts. Injection molding is performed first and is followed by deformation of the injection molded item, then forming the network or pattern of stent struts from the deformed injection molded item.

Methods of injection molding a polymer stent have been described in, for example, U.S. Pub. No. 2008/0001330 of Application No. 11/477,333 filed June 28, 15 2006. In prior methods, the network of stent struts was formed during the injection molding process. A potential difficulty in having stent struts formed directly through injection molding is that the mold cavity will have grooves that correspond to the intricate shapes and pattern of the desired stent struts. The polymer resin would have to flow through the network of grooves that can be 0.1 mm wide and 0.1 mm deep, or even 20 smaller. Depending on the actual width and depth of the grooves, the viscosity of the molten resin, and manufacturing throughput requirements, it may be impractical to have stent struts formed directly from injection molding.

In some embodiments of present invention, none of the stent struts in the finished stent are formed through injection molding. In alternative embodiments, some stent 25 struts are formed through injection molding (an additive process) and other stent struts

on the same stent are formed at a later time by removal of material (a subtractive process) as described below.

Prior to formation of the stent struts by a subtractive process, changes are made to the mechanical characteristics of the injection molded item from which the stent struts will later be formed. The structure from which stent struts are formed, such as the injection molded item of the present invention, is referred to herein as the "substrate." In general, a substrate can be a flat sheet or a cylindrical tube. After injection molding, the mechanical characteristics of the substrate can be changed by inducing deformation, such as by stretching, in one or more directions. Such deformation causes polymer molecule chains to become oriented in a particular direction and/or causes polymer crystallization and growth in a particular direction. These morphological changes involving microstructure orientation give the substrate the desired mechanical characteristics which will allow a network of stent struts, subsequently formed from the substrate, to have the necessary balance between flexibility, strength, and fracture toughness.

Methods of deforming the injection molded substrate can involve blow molding. For a description of blow molding, see, for example, U.S. Pub. No. 2009/0001633 of Application No. 11/771,967 filed June 29, 2007 and U.S. Pub. No. 2011/0066222 of Application No. 12/558,105 filed June 28, 2006.

Referring again to FIG. 1, in block 10 polymer material is heated until it is molten, then injected under pressure into the cavity of a first mold. The cavity of the first mold is annular in shape. The first mold is configured to form a tube of the polymer, which is a substrate from which stent struts will be formed at a later time. At this stage (prior to making morphological changes to the substrate), the substrate is referred to as a "stock tube." The shape and dimensions of the stock tube corresponds to those of the annular mold cavity. The stock tube is cylindrical and has a circumferential

wall having a predetermined wall thickness. The wall thickness is carefully selected to provide optimal results in the finished stent. The wall thickness can be, without limitation, about 1 mm. The thickness can be selected based in part on the polymer material being used and the amount of expansion the substrate will be subjected to at a later time. Optionally, the circumferential wall has no radial perforations though there can be axial openings at the opposite ends of the circumferential wall.

In some embodiments, the method proceeds to block 15 in which the stock tube is released from the first mold while still at a temperature greater than the glass temperature (T_g) of the polymer material but lower than the melt temperature (T_m) of the polymer material. T_g is the temperature at which the amorphous domains of a polymer change from a brittle vitreous state to a solid deformable or ductile state at atmospheric pressure. T_g corresponds to the temperature where the onset of segmental motion in the chains of the polymer occurs. Between T_g and T_m rotational barriers exist, however, the barriers are not great enough to substantially prevent segmental mobility.

The polymer material is at a temperature substantially below T_m when released from the first mold. It is to be understood that the stock tube is in a substantially non-molten state when it comes out of the first mold, even though it is at a temperature at or above T_g . Having the stock tube substantially non-molten helps to ensure that the circumferential wall thickness is not inadvertently altered in the time period between release from the first mold (block 15) and expansion in the second mold (block 25 discussed below). This non-molten state of the stock tube upon release from the first mold is distinct from extrusion processes in which an extruded polymer is substantially molten when it exits an extruder die.

The stock tube is released from the first mold after the flow of polymer material in the mold cavity has substantially stopped. This condition is distinct from extrusion

processes in which the polymer material continues to flow through the extruder cavity while exiting the extruder die.

Next in block 20, before the stock tube has cooled to a temperature substantially below T_g , the stock tube is placed in the cavity of a second mold, which can be a glass-lined blow mold. The cavity has an inner diameter that is greater than the outer diameter of the stock tube.

In some embodiments of the present invention, at least some portions of the first mold are contained within the cavity of the second mold. Upon completion of polymer material injection, those portions of the first mold can open and thereby eject or release the stock tube directly from the first mold cavity and into the cavity of the second mold. This direct transfer of the stock tube from the first mold to the second mold, without exposure to external atmospheric conditions and handling, eliminates or minimizes cooling of the stock tube and eliminates or minimizes the chance of inadvertent alteration of the circumferential wall thickness prior to expansion in the second mold (block 25 discussed below).

Next in block 25, the internal fluid pressure of the stock tube is increased, such as by pumping a gas into the stock tube. The internal fluid pressure is increased to a level which causes the circumferential wall of the stock tube (i.e., substrate) to stretch and expand radially outward against the surfaces of the second mold cavity, thereby changing the mechanical characteristics of the substrate. The surfaces of the second mold cavity limit the outward radial expansion of the circumferential wall.

Upon completion of block 25, after changes to the mechanical characteristics of the substrate have been made, the substrate is referred to as a "precursor tube."

In some embodiments, substantially the entire longitudinal length of the stock tube is radially expanded simultaneously. In alternative embodiments, expansion of the

stock tube occurs in a progressive manner, as described in Pub. No. 2011/0066222, in which a limited longitudinal segment of the stock tube is radially expanded at any one time, and the deformation propagates longitudinally over a period of time from one end of the stock tube to the other end.

5 By keeping the substrate at a temperature above T_g during transfer from the first mold to the second mold, manufacturing time is decreased by eliminating or reducing the need to reheat the substrate to a temperature necessary for expansion. In some embodiments, the substrate has not cooled to a temperature below a predetermined process temperature (T_p) prior to expansion of the substrate, thereby allowing expansion
10 to be performed substantially without applying heat to the substrate. The process temperature is carefully predetermined to provide optimal results in the finished stent. Typically, T_p is between T_g and T_m . T_p can depend in part on the composition of the polymer material and the desired amount of radial expansion. For example, T_p can be from about 160 degrees F to about 220 degrees F when the polymer material being used
15 is poly(L-lactide). Without limitation, the composition of the polymer material, levels for T_p , internal fluid pressure, radial expansion ratio, axial extension ratio, and other blow molding parameters can be as described in U.S. Pub. No. 2011/0066222 of Application No. 12/558,105 filed June 28, 2006.

 In some embodiments, the substrate is heated during or before expansion of the
20 circumferential wall, even though the substrate has not cooled to a temperature below T_g subsequent to removal from the first mold. The application of heat in block 20 and/or block 25 can help ensure uniformity in temperature and uniformity in the resultant mechanical characteristics. The application of heat may be needed to bring the stock tube to a temperature at or about T_p .

Next in block 30, the precursor tube is removed from the second mold. In some embodiments, the precursor tube which is removed from the second mold is used as an endoprosthesis.

Continuing from block 30 to block 40, material is removed from the precursor tube, in what is referred to as a subtractive process, in order to form a stent having a network of stent struts. Material is removed from the precursor tube so that what remains of the precursor tube is the network of stent struts. Material can be removed with a cutter, which can be sharp blade and/or a laser cutting tool. For a description of laser removal from a polymer substrate, see, for example, U.S. Pat. No. 7,622,070 issued November 24, 2009.

Next in block 50, the stent is sterilized, making it ready for implantation within a patient. Sterilization can be performed in any number of ways, such as by ethylene oxide gas or electron beam (E-beam) radiation.

Alternatively, as shown in block 45, the stent can be mounted onto a catheter prior to sterilization. Mounting can involve crimping the stent onto an inflatable balloon of the catheter.

Alternatively, as shown in block 40, a coating can be applied to the stent prior to sterilization or prior to mounting the stent onto a catheter. The composition of the coating and any drugs carried therein can be as described in any of the publications which are cited and incorporated herein by reference.

In alternative embodiments of the present invention, the method can proceed from block 10 to block 17 in which the stock tube is released from the first mold at any temperature. For example, the stock tube can be removed from the first mold after the polymer material in the injection mold cavity has cooled to a temperature T , where $T < T_g$ or where $T_g < T < T_m$.

Continuing from block 17 to block 22, the stock tube is placed in the cavity of a second mold. The cavity has an inner diameter that is greater than the outer diameter of the stock tube. This step can be performed after the stock tube is at a temperature about the same as ambient room temperature, such as in situations where the stock tube has
5 been stored for a long period of time prior to placement in the second mold. Alternatively, this step (placing the stock tube in the second mold) can be performed while the stock tube is still at a temperature substantially above room ambient temperature due to heat from injection molding. Alternatively, this step (placing the stock tube in the second mold) can be performed while the stock tube is at a temperature
10 substantially below ambient room temperature, such as in situations where the stock tube has been actively cooled or quenched within the first mold or upon removal from the first mold.

Next in block 27, the internal fluid pressure of the stock tube (i.e., substrate) is increased, such as by pumping a gas into the stock tube, in order to cause expansion and
15 produce the precursor tube. Expansion is the result of a pressure differential in which fluid pressure outside of the stock tube is lower than pressure inside the stock tube. While the substrate is in the second mold, the substrate is heated to a process temperature (T_p) above T_g and below T_m . Parameters such as internal fluid pressure, T_p , and others can be as previously described in connection with block 25.

20 The method proceeds from block 27 to blocks 30-50 previously described with optional application of a drug coating and optional mounting onto a catheter.

As indicated above, the method can include a series of steps with blocks 15, 20 and 25, or alternatively, a series of steps with blocks 17, 22 and 27. The method with blocks 15, 20 and 25 is optionally performed as described below in connection with
25 FIGS. 2A-2F. The method with blocks 17, 22 and 27 is optionally performed as

described below in connection with FIGS. 3A-3F. It is to be understood that the method described above in connection with blocks 10-50 can be performed using systems other than those shown in FIGS. 2A-3F.

FIGS. 2A-2F show a system for manufacturing a polymer endoprosthesis, with
5 each figure illustrating a sequential step.

An injection molding process is shown in FIGS. 2A and 2B. Injection mold 100 includes cavity 102 into which molten polymer resin is injected through gate 104. The cavity is configured to produce a stock tube. The cavity is cylindrical in shape and is bounded by inner circumferential surface 106 and outer circumferential surface 108 of
10 mold 100. The distance between circumferential surfaces 106 and 108 defines the thickness of the circumferential wall of the resultant stock tube. Outer circumferential surface 108 defines a maximum diameter 109 of injection mold cavity 102. The size and shape of the exterior surface of the resultant stock tube will correspond to the outer circumferential surface 108. Inner circumferential surface 106 is provided by mold core
15 110 in the shape of a cylindrical rod. The size and shape of the interior lumen of the resultant stock tube will be that of mold core 110.

FIG. 2B shows polymer resin 112 having been injected through injection gate 104 and into injection mold cavity 102. It is to be understood that there can be one or more injection gates and that the injection gates can be arranged and oriented in any
20 suitable manner, such as to prevent voids and other structural defects in the resultant stock tube. When the flow of polymer resin 112 into injection mold cavity 102 has stopped and after polymer resin 112 has cooled to a temperature below T_m , door 114 slides from a closed position shown in FIG. 2B to an open position shown in FIG. 2C. Door 114 can be pneumatically or electrically controlled.

As shown in FIG. 2C, movement of door 114 allows the non-molten polymer resin, referred to now as stock tube 116, to be released from injection mold 100 and placed into blow mold 120. Injection mold 100 and blow mold 120 are connected to each other such that movement of door 114 exposes stock tube 116 to cavity 122 of blow mold 120. With door 114 at its open position, injection mold cavity 102 and blow mold cavity 122 form a common, enlarged cavity that is substantially sealed from the external, ambient environment by the interconnected housings 101 and 121 of injection mold 100 and blow mold 112. With door 114 open, injection mold cavity 102 and blow mold cavity 122 are exposed to each other. After door 114 has opened, ejector 119 pushes stock tube 116 out of injection mold cavity 102 and directly into blow mold cavity 122. Ejector 119 can be pneumatically or electrically controlled. Stock tube 116 is transferred from injection mold cavity 102 into blow mold cavity 122 while shielded from the external, ambient environment.

Blow mold cavity 122 is bounded by circumferential surface 124 which defines a maximum diameter 125 of the blow mold cavity 122. Diameter 125 is greater than maximum diameter 109 of injection mold cavity 102, which thus allows space for stock tube 116 to expand radially outward.

There are axial openings at opposite end segments 117 and 118 of stock tube 116. First end segment 117 remains partially contained within injection mold 100 so that the axial opening at first end segment 117 is sealed against fluid flow. Second end segment 118 is engaged against conical member 128 of blow mold 120. Conical member 128 is wedged into second end 118 to prevent fluid flow through the interface between second end 118 and conical member 128. Gas passageway 130 extends through the center of conical member 118 and is in communication with the interior of stock tube 116.

FIG. 2D shows the result after gas is pumped through gas passageway 130 and into the interior of stock tube 116. The gas has increased the fluid pressure within the interior of stock tube 116 to a level which caused the circumferential wall of stock tube 116 to expand radially outward and press against circumferential surface 124 of blow mold cavity 122. Blow mold 120 can include vent 131 in its housing 121 to allow gas between the circumferential wall of stock tube 116 and circumferential surface 124 of blow mold cavity 122 to escape during expansion of the circumferential wall. After expansion is completed, blow mold 120 can be opened to allow for removal of the expanded stock tube, now referred to as precursor tube 134. For example, conical member 128 can be retracted out of blow mold 120 to provide an opening through which precursor tube 134 can be pushed by ejector 119 of injection mold 100.

FIG. 2E shows precursor tube 134 after having been removed from blow mold 120.

As shown in FIG. 2F, precursor tube 134 can be carried on cylindrical mandrel 136 and placed adjacent cutter 138 for removing portions of precursor tube 134 to form a network of stent struts. Perforation 139 has been made by cutter 138 through precursor tube 134. With removal of material, precursor tube 134 is transformed to a stent having a network of stent struts. Mandrel 136 is inserted within precursor tube 134 and can be connected to rotation and slide motor and gear assembly 40 under computer numerical control (CNC). Relative movement between mandrel 136 and cutter 138 can be programmed into a CNC software application operating within electronic controller 142 to provide the desired pattern of stent struts.

FIGS. 3A-3F show a system for manufacturing a polymer endoprosthesis, with each figure illustrating a sequential step.

An injection molding process is shown in FIGS. 3A and 3B. Injection mold 200 includes cavity 202 into which molten polymer resin is injected. Mold cavity 202 is configured to produce stock tube 116 having a circumferential wall with a predetermined wall thickness.

5 FIG. 3B shows two halves of injection mold 200 separated to expose mold cavity 202 and allow stock tube 116 to be ejected out from mold cavity 202. Prior to ejection, a mold core can be retracted out from the interior of stock tube 116. There are axial openings at opposite end segments 117, 118 of stock tube 116. In some embodiments, stock tube 116 has only one axial opening in which end segment 117 is closed and end segment 118
10 is open to allow for introduction of gas during blow molding.

Stock tube 116 is in a substantially non-molten state when it is ejected from injection mold 220. In some embodiments, stock tube 116 is at a temperature between T_g and T_m when ejected from injection mold 220. In alternative embodiments, stock tube 116 is at a temperature below T_g when ejected from injection mold 220.

15 The injection molded item, namely stock tube 216, has no pattern of stent struts and no radial perforations distributed across the longitudinal length of the stent.

Next, as shown in FIG. 3C, stock tube 116 is placed within blow mold 220. The step of transferring stock tube 116 from injection mold 200 to blow mold 220 can be done before stock tube 116 is able to cool to a temperature that is either: (a) below a
20 desired process temperature (T_p) predetermined to produce optimal results in the finished stent, where $T_g < T_p < T_m$; or (b) below T_g of the polymer resin. For example, stock tube 116 can be actively cooled or quenched within injection mold 200 or upon removal from injection mold 200.

Blow mold 220 has an interior diameter 226 which is greater than the maximum
25 outer diameter 209 of the circumferential wall of stock tube 116 to allow for radial

expansion of the circumferential wall. Interior surface 224 of blow mold 220 limits radial expansion of the circumferential wall. Optionally, blow molding including the application of heat is performed as described in U.S. Pub. Nos. 2009/0001633 and/or 2011/0066222.

5 FIG. 3D shows the result after gas is pumped into the interior of stock tube 216. At this stage, the expanded stock tube is referred to as precursor tube 234.

FIG. 3E shows precursor tube 234 after having been removed from blow mold 220.

As shown in FIG. 3F, precursor tube 234 can be carried on cylindrical mandrel
10 236 and placed adjacent cutter 238 for removing portions of precursor tube 234 to form a network of stent struts. Perforation 239 has been made by cutter 238 through precursor tube 234. With removal of material, precursor tube 234 is transformed to a stent having a network of stent struts. Mandrel 236 is inserted within precursor tube 234 and can be connected to rotation motor and gear assembly 240a and slide motor and gear assembly
15 240b under computer numerical control (CNC). Relative movement between mandrel 236 and cutter 238 can be programmed into a CNC software application operating within electronic controller 242 to provide the desired pattern of stent struts.

In the above-described system and method, the polymer material or resin can be any synthetic or naturally occurring polymer suitable for implantation. Without
20 limitation, the material can be selected from the group consisting of poly(L-lactide) ("PLLA"), poly(L-lactide-co-glycolide) ("PLGA"), poly(L-lactide-co-D-lactide) ("PLLA-co-PDLA") with less than 10% D-lactide, and PLLD/PDLA stereocomplex, and PLLA-based polyester block copolymer containing a rigid segment and a soft segment, the rigid segment being PLLA or PLGA, the soft segment being PCL or PTMC.

In the above-described system and method, material is removed from the precursor tube to transform the precursor tube to a stent having stent struts arranged in any pattern. The stent struts can have the patterns described in U.S. Pub. No. 2008/0275537 of Application No. 12/114,608 filed May 2, 2008 and U.S. Pat. No. 7,476,245 issued January 13, 2009. For example, the pattern can include stent struts arranged in a repeating pattern of W-shaped cells as described in Pub. No. 2008/0275537 or in a repeating pattern of hour-glass shaped cells as described in Pat. No. 7,476,245. The shape of the cells can correspond to perforations 139 and 239 in FIGS. 2F and 3F. The pattern can include a series of longitudinally arranged rings, each ring having an undulating series of stent struts oriented at oblique angles to each other, and each one of the rings is connected to an adjacent ring by other stent struts oriented substantially parallel to the longitudinal axis of the stent. The present invention is not limited to any particular pattern.

In the above-described system and method, the first mold or the injection mold can have an annular mold cavity having inner diameter ID and outer diameter OD and the second mold or the blow mold can have a cylindrical mold cavity having a diameter D. The amount of radial expansion which the stock tube undergoes depends upon the dimensional relationship between the two mold cavities. Without limitation, the following approximate dimensions for ID, OD, and D can be used.

EXAMPLE 1:

ID = about 0.17 mm; OD = about 0.41 mm; D = about 3.5 mm

EXAMPLE 2:

ID = about 0.13 mm; OD = about 0.40 mm; D = about 3 mm

EXAMPLE 3:

ID = about 0.11 mm; OD = about 0.34 mm; D = about 2.5 mm

The dimensions of the two mold cavities can be such that the circumferential wall of the substrate undergoes a radial expansion (RE) ratio in the range of about 300% to about 400%. RE ratio is defined as (Inside Diameter of Precursor Tube) / (Inside Diameter of Stock Tube). RE ratio as a percentage is defined as (RE ratio -1) x 100%.

5 While several particular forms of the invention have been illustrated and described, it will also be apparent that various modifications can be made without departing from the scope of the invention. It is also contemplated that various combinations or subcombinations of the specific features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form
10 varying modes of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A method of forming a polymer endoprosthesis, the method comprising:
injecting a polymer material into a cavity of a first mold in order to form a stock tube;
placing the stock tube in a cavity of a second mold, wherein the stock tube enters the second mold as it exits the first mold; and
expanding the stock tube to form a precursor tube within the second mold.
2. The method of claim 1, wherein the stock tube exits the first mold and enters the second mold while at a temperature at or above T_g of the polymer material.
3. The method of claim 1, further comprising, after the injecting step and before the placing step, moving a door, which separates the cavity of the first mold from the cavity of the second mold, to an open position to expose the stock tube to the cavity of the second mold.
4. The method of claim 1, wherein the expanding step includes radially expanding the stock tube by introducing gas into the stock tube.
5. The method of claim 4, wherein the expanding step includes axially extending the stock tube.
6. The method of claim 1, further comprising transforming the precursor tube into a stent having a network to stent struts.
7. The method of claim 6, wherein the transforming step includes making a plurality of perforations through a circumferential wall of the precursor tube.
8. A method of forming a polymer endoprosthesis, the method comprising:

forming a stock tube of polymer material in an injection mold;
transferring the stock tube from the injection mold to a blow mold, the transferring step performed while the stock tube is at a temperature at or above T_g of the polymer material; and

expanding the stock tube in the blow mold in order to form a precursor tube.

9. The method of claim 8, wherein the transferring step is performed while the stock tube is at a temperature above T_g of the polymer material.

10. The method of claim 8, wherein the transferring step includes exposing the stock tube, while located within the injection mold, to a cavity within the blow mold.

11. The method of claim 8, wherein the expanding step includes radially expanding the stock tube.

12. The method of claim 11, wherein the expanding step includes axially extending the stock tube.

13. The method of claim 8, further comprising transforming the precursor tube into a stent having a network of stent struts.

14. The method of claim 13, wherein the transforming step includes making a plurality of perforations through a circumferential wall of the precursor tube.

15. A system for forming a polymer endoprosthesis, the system comprising:
an injection mold having an injection mold cavity;
a blow mold having a blow mold cavity; and
a door movable from a first position to a second position, the injection mold cavity and the blow mold cavity being separated from each other by the door when at

the first position, the injection mold cavity and the blow mold cavity being exposed to each other with when the door is at the second position.

16. The system of claim 15, further comprising a cutter configured to make perforations through the precursor tube.

17. The system of claim 15, wherein the injection mold cavity is annular in shape and is configured to form a cylindrical tube when polymer material is injected into the injection mold.

18. The system of claim 15, wherein the blow mold cavity has a diameter greater than that of the injection mold cavity.

19. The system of claim 15, wherein the injection mold includes an ejector configured to push contents of the injection mold cavity into the blow mold cavity.

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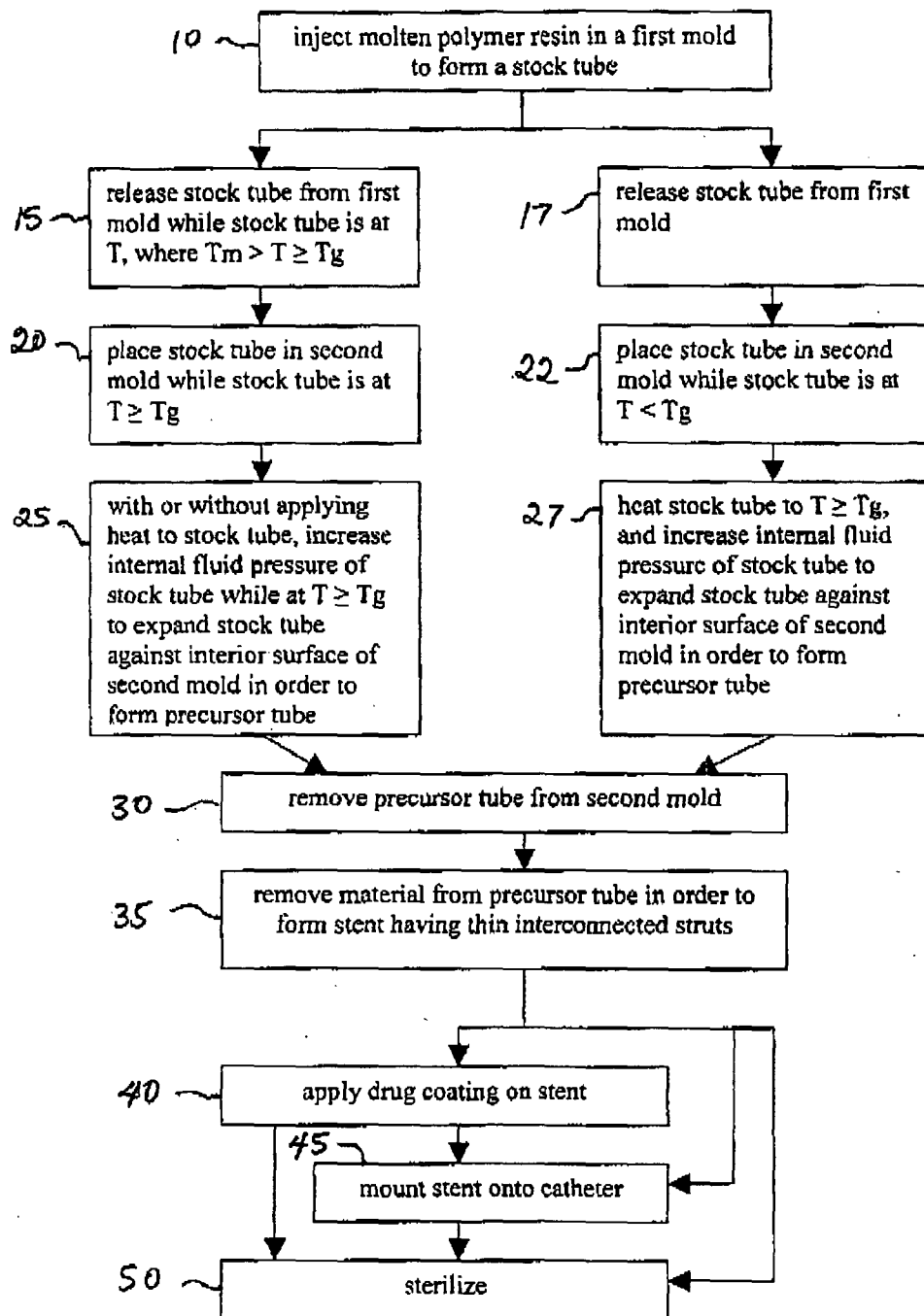


FIG. 1

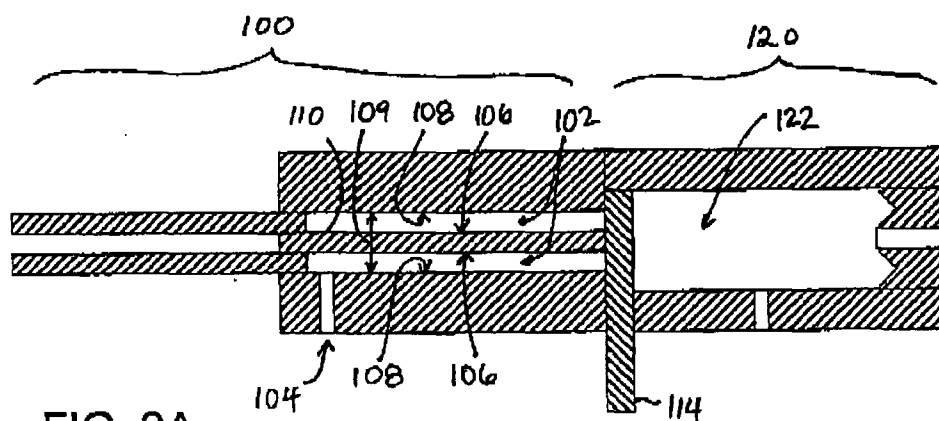


FIG. 2A

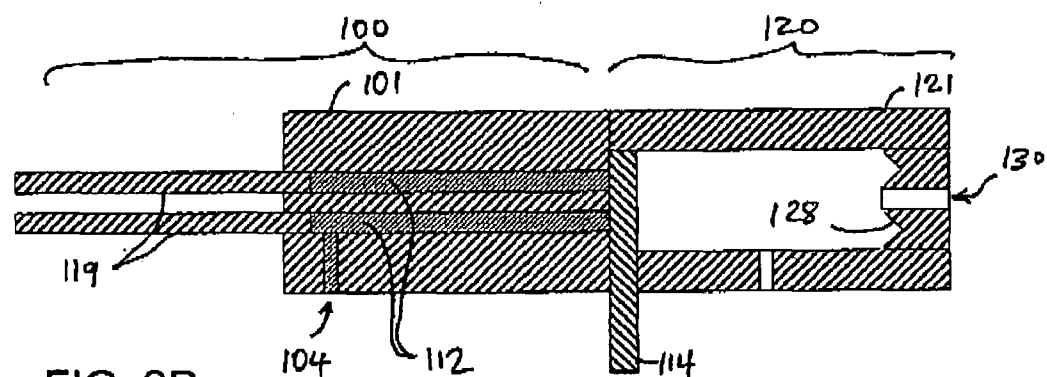


FIG. 2B

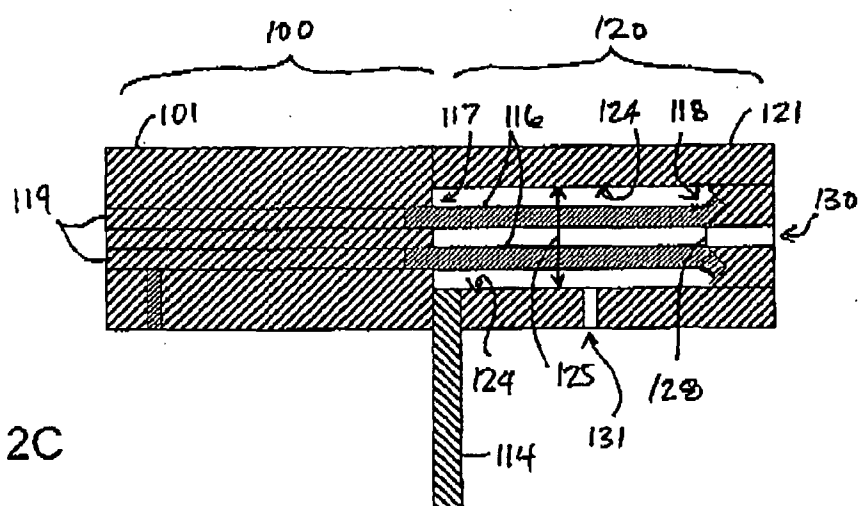


FIG. 2C

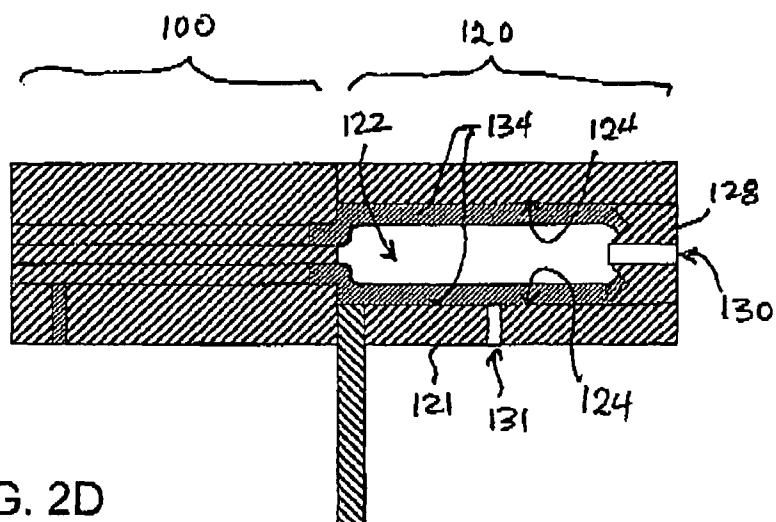


FIG. 2D

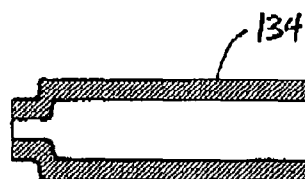


FIG. 2E

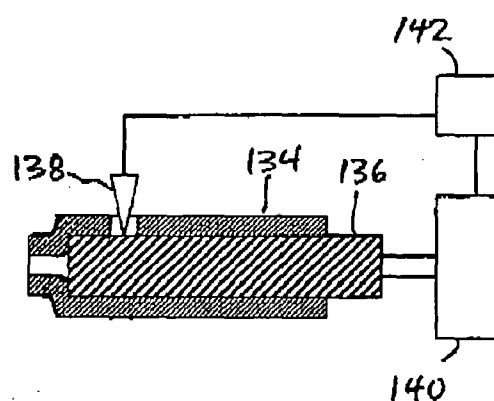


FIG. 2F

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FIG. 3A

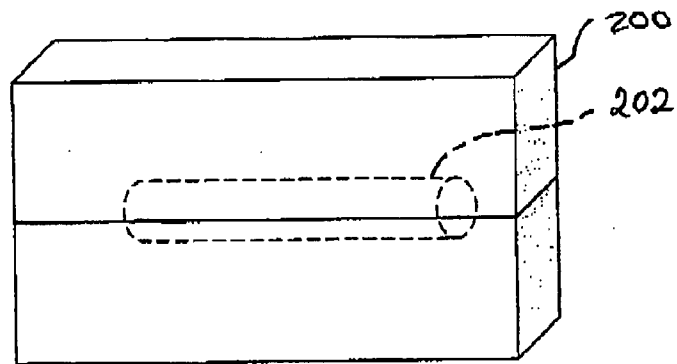


FIG. 3B

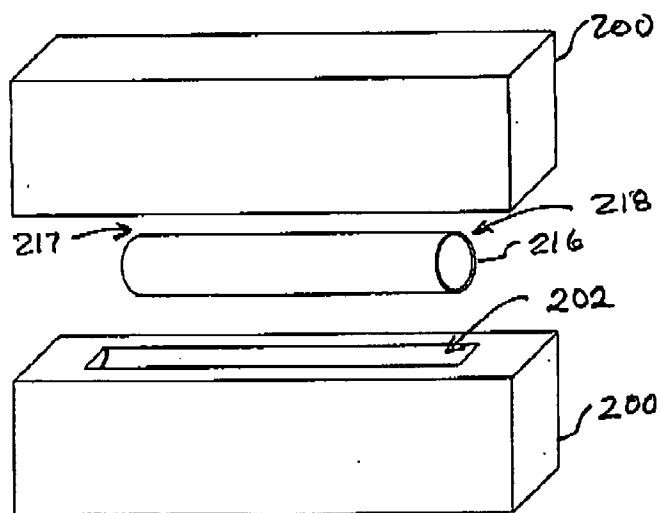
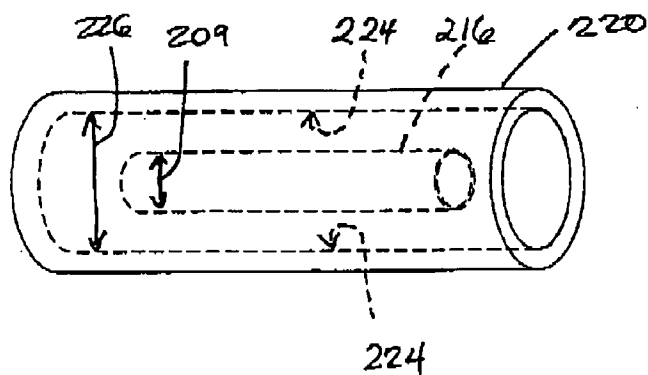


FIG. 3C



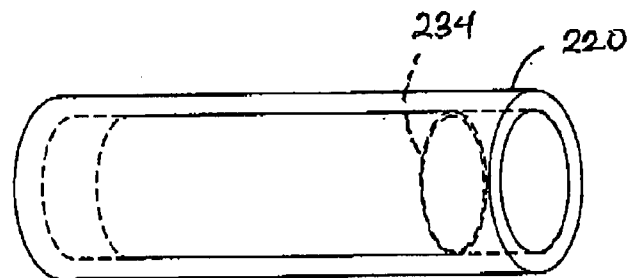


FIG. 3D

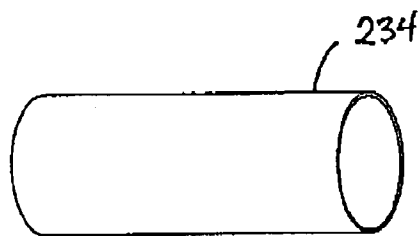


FIG. 3E

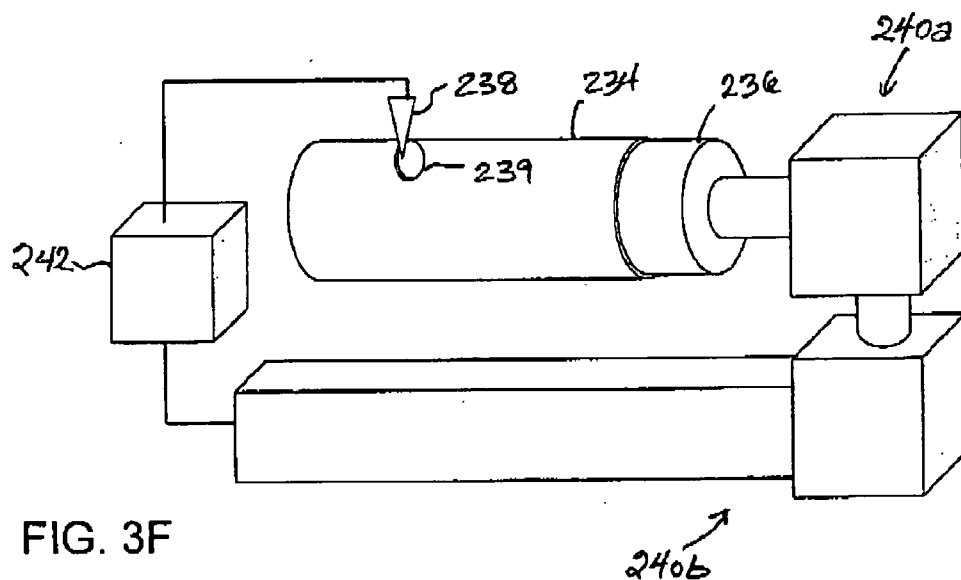


FIG. 3F

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/039164

A. CLASSIFICATION OF SUBJECT MATTER
INV. B29C49/06
ADD. A61F2/90

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)
B29C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2011/066222 A1 (WANG YUNBING [US] ET AL) 17 March 2011 (2011-03-17) cited in the application paragraph [0001] sentence 7, paragraph 39 sentence 9, paragraph 40 paragraph [0047] - paragraph [0048] claim 1	1-19
Y	----- GB 692 590 A (BASF AG) 10 June 1953 (1953-06-10) figures 1,2 page 2, line 38 - line 51 ----- -/-	1-19



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"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

26 September 2012

Date of mailing of the international search report

09/10/2012

Name and mailing address of the ISA/

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Authorized officer

Alink, Maarten

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/039164

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 3-7, 15-19

Injection-blow molding of a polymer endoprosthesis by using an attached injection molding and blow molding apparatus

2. claims: 2, 8-14

Transferring a stock tube from an injection molding apparatus to a blow molding apparatus for making a polymer endoprosthesis while the stock tube is kept above the polymer Tg

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/039164

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2008/090324 A2 (LEAFGREEN LTD [GB]; LAIDLER KEITH [GB]; MARTIN JAMES [GB]) 31 July 2008 (2008-07-31) page 29, line 25 - page 30, line 6 figures 1,2 -----	1-19
Y	US 3 002 225 A (HERBERT GOLLER) 3 October 1961 (1961-10-03) figures 7-10 column 1, lines 11-25, 47-54 -----	1,8
Y	FR 76 005 E (M. ETIENNE DURAND) 8 September 1961 (1961-09-08) figures 3-6 -----	1,8
T	"Polylactic acid", Wikipedia 22 September 2012 (2012-09-22), pages 1-5, XP002684078, Retrieved from the Internet: URL: http://en.wikipedia.org/wiki/Polylactic_acid [retrieved on 2012-09-24] page 3, line 3 - line 4 -----	2,8
A	DE 21 43 262 A1 (DYNAMIT NOBEL AG) 1 March 1973 (1973-03-01) figures 1-4 -----	1
A	WO 2008/002636 A2 (ABBOTT CARDIOVASCULAR SYSTEMS [US]; HUANG BIN [US]; CASTRO DANIEL [US]) 3 January 2008 (2008-01-03) cited in the application abstract -----	1
A	US 2008/275537 A1 (LIMON TIMOTHY A [US]) 6 November 2008 (2008-11-06) cited in the application abstract -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/039164

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GB 692590	A	10-06-1953	DE 844214 C 17-07-1952 GB 692590 A 10-06-1953
WO 2008090324	A2	31-07-2008	NONE
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FR 76005	E	08-09-1961	NONE
DE 2143262	A1	01-03-1973	NONE
WO 2008002636	A2	03-01-2008	US 2008001330 A1 03-01-2008 US 2011169197 A1 14-07-2011 WO 2008002636 A2 03-01-2008
US 2008275537	A1	06-11-2008	EP 2152207 A1 17-02-2010 JP 2010525903 A 29-07-2010 US 2008275537 A1 06-11-2008 US 2011277305 A1 17-11-2011 WO 2008137821 A1 13-11-2008