US 20030173702A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2003/0173702 A1**

Igaki et al. (43) **Pub. Date: Sep. 18, 2003**

(54) **MELTING AND SPINNING DEVICE AND MELTING AND SPINNING METHOD**

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(21) Appl. No.: **10/311,289**

(22) PCT Filed: **Apr. 15, 2002**

(86) PCT No.: **PCT/JP02/03738**

(30) **Foreign Application Priority Data**

Apr. 18, 2001 (JP) 2001-119964

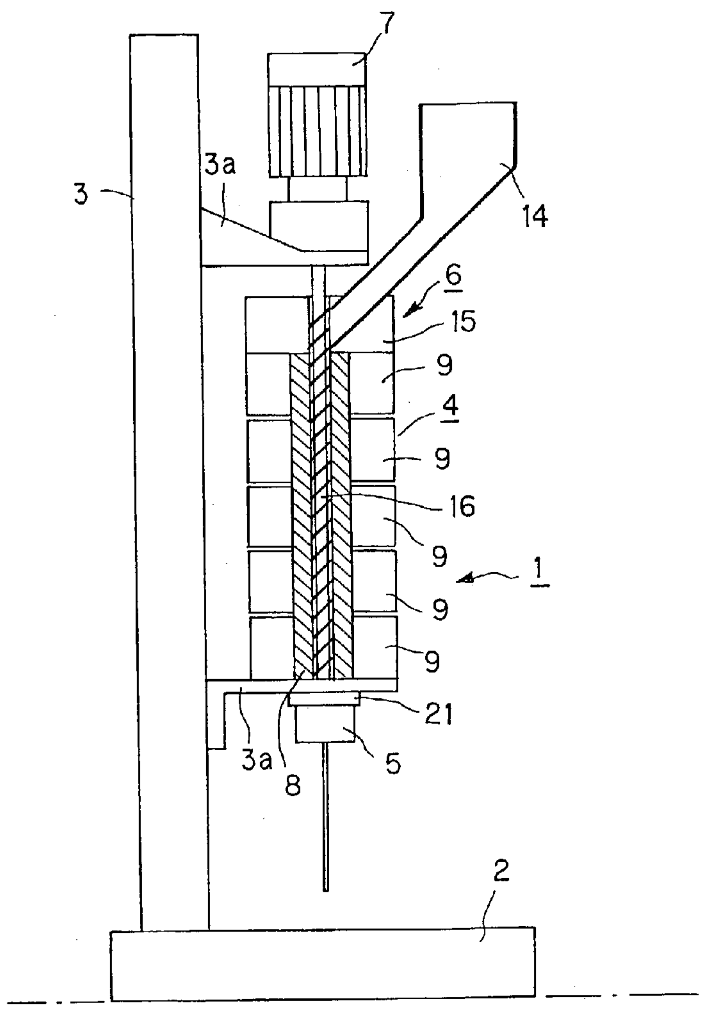
Publication Classification

(51) **Int. Cl.**[7] **D01D 1/04**; D01D 5/08

(52) **U.S. Cl.** **264/211.22**; 425/378.2

(57) **ABSTRACT**

The present invention is relative to a melt spinning apparatus for melt spinning a biodegradable polymer material. The biodegradable polymer material is melted by a melt mechanism **(4)** including a screw **(16)** which is mounted in a vertically mounted cylinder **(8)** coaxially with the cylinder **(8)** and which is rotationally driven by a rotational driving mechanism **(7)**. The screw includes at least one turn of a helical groove **(17)** on its peripheral surface. The biodegradable polymer material being melted in this way is discharged in the vertical direction from a discharge opening of a nozzle **(10)** mounted coaxially on the cylinder **(8)**.



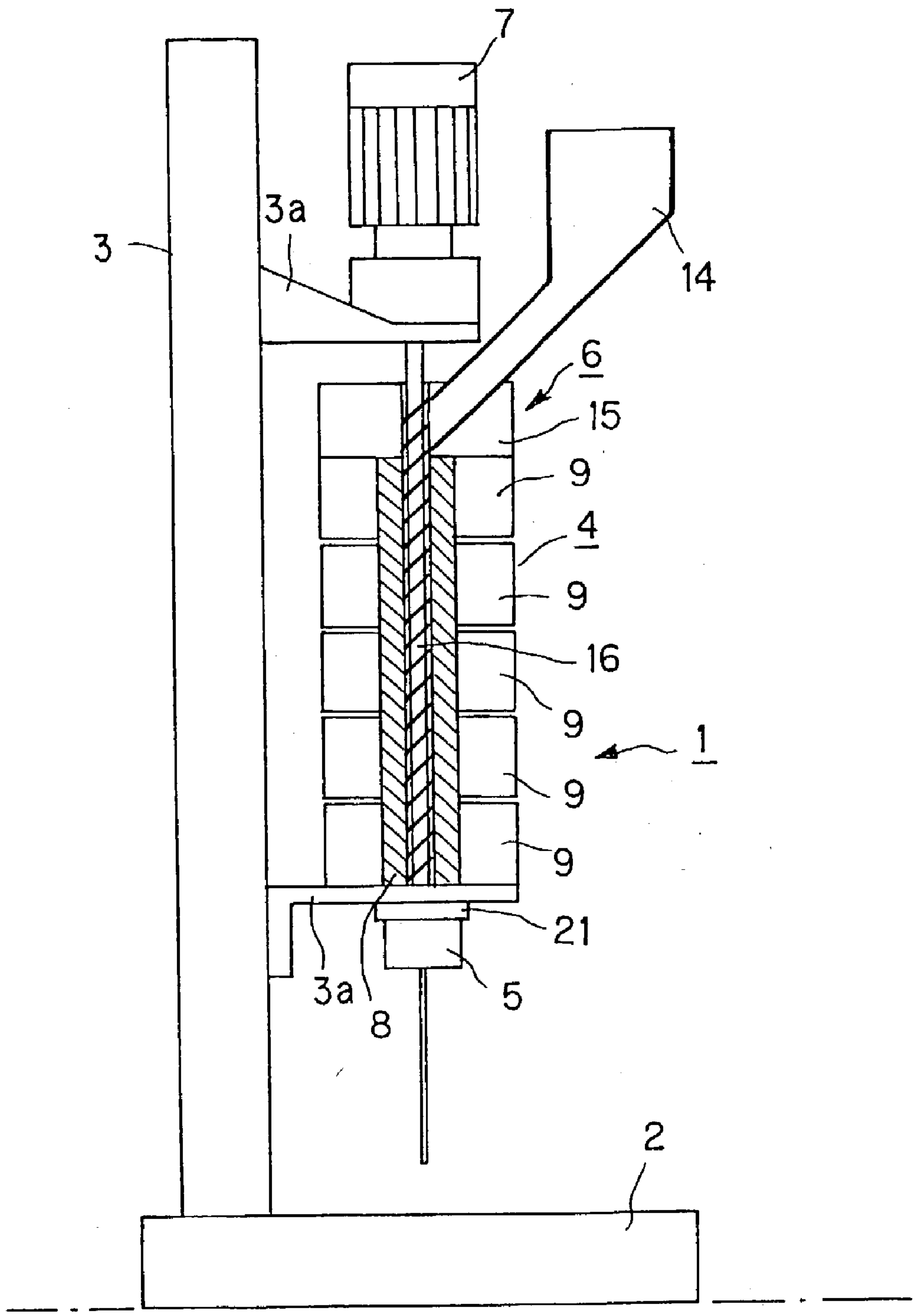


FIG. 1

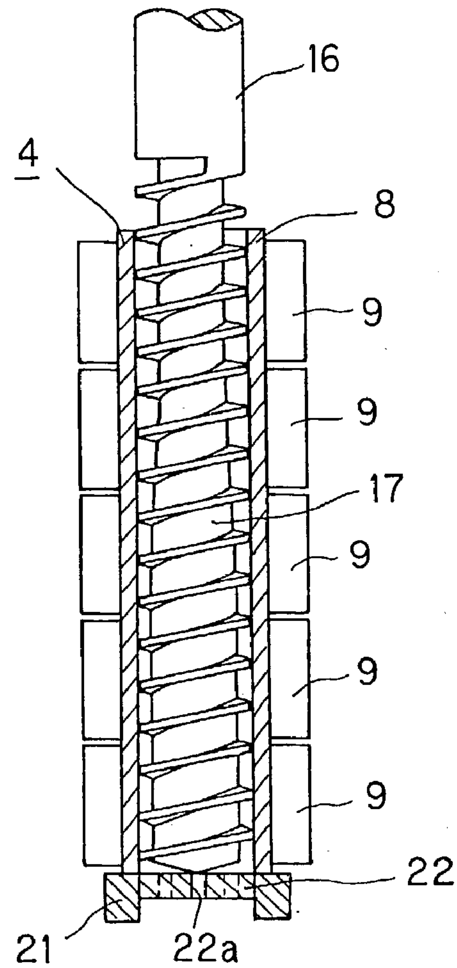


FIG. 2

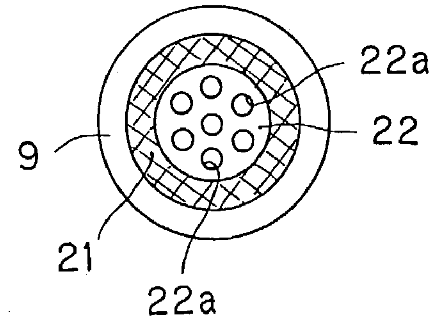


FIG. 3

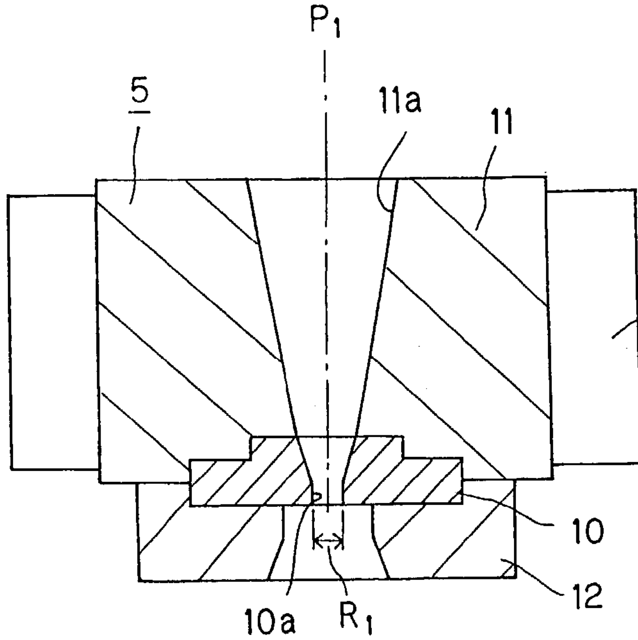


FIG. 4

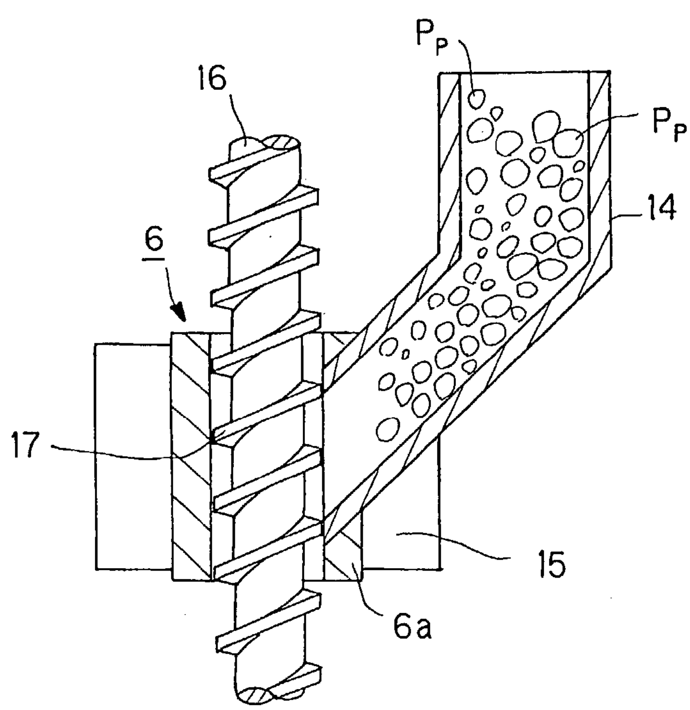


FIG. 5

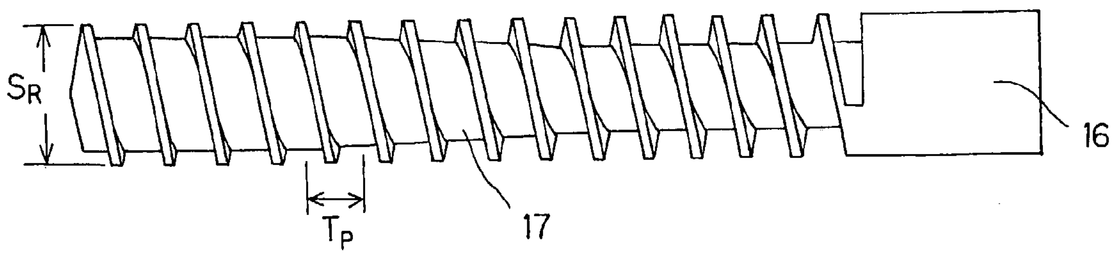


FIG. 6

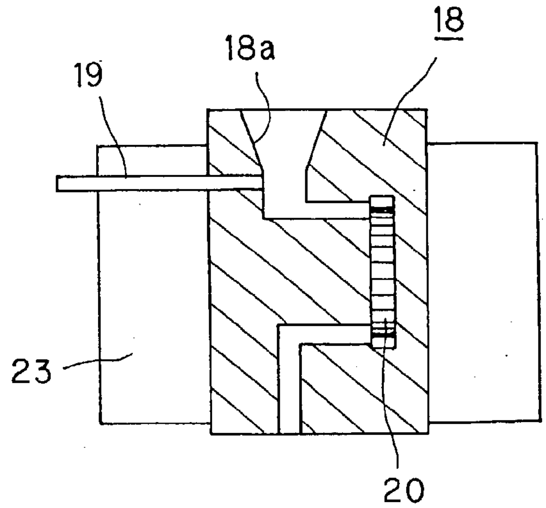


FIG. 7

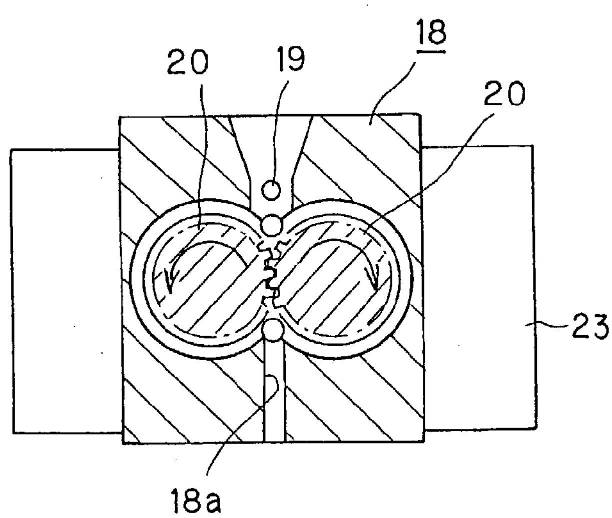


FIG. 8

MELTING AND SPINNING DEVICE AND MELTING AND SPINNING METHOD

TECHNICAL FIELD

[0001] This invention relates to a method and an apparatus for melt spinning a medical material implanted in a living body, for example, a strand of a biodegradable polymer material which forms a stent implanted in the vascular vessel of a living body.

BACKGROUND ART

[0002] When a stenosed lesion has occurred in the vascular vessel of a living body, in particular the blood vessel, such as arterial vessels, the percutaneous transluminal angioplasty (PTA) is performed by inserting a balloon mounted in the vicinity of the distal end of a catheter into the stenosed lesion and inflating this balloon to expand the stenosed lesion to keep the blood flowing.

[0003] Meanwhile, it is known that, even if PTA is applied, there is a high probability that re-stenosis is liable to occur at the once-stenosed portion.

[0004] In order to prevent this re-stenosis from occurring, the conventional practice is to implant a tubular stent on the site where the PTA has been performed. This stent is inserted in a contracted state into the blood vessel, subsequently dilated and implanted in this state in the blood vessel to support the blood vessel from its inside to prevent re-stenosis from occurring in the blood vessel. As this sort of the stent, the metallic stent formed of such as stainless steel or a Ti—Ni based alloy, is now in use.

[0005] Meanwhile, the principal objective in implanting a stent in the blood vessel in PTA is to prevent acute coronary occlusion and to decrease the frequency of re-stenosis. It has been reported that, since the acute coronary occlusion and re-stenosis are the phenomenon which occurs during a predetermined time period, so that only transient therapy is needed. Consequently, the stent is required to maintain the function of supporting the blood vessel from inside for a predetermined time period, while it is more desirable that the stent is not left in the living body as a foreign substance.

[0006] If the metallic stent is implanted in the blood vessel, it is left permanently, so that, when re-stenosis occurs on the stent site, the stent frequently proves an obstruction to the operation of re-angioplasty. Moreover, the operation of coronary-artery bypass graft is difficult to perform on the site of implanted stent. Thus, implanting the permanently persisting metallic stent offers various inconveniences to re-treatment.

[0007] In order to overcome the problem inherent in the metallic stent, such a stent formed of a biodegradable polymer material has been proposed which i s degraded after a lapse of a predetermined time, from the time it is implanted in e.g., the blood vessel of the living body to be then disappear by being absorbed in the living tissue (JP Patent No. 2842943; JP Laying-Open Patent Publication H-11-57018).

[0008] The present inventors have proposed a stent comprised of a knitting obtained on knitting a strand of the biodegradable polymer material into a tubular form (JP Patent 2842943), and a stent obtained by bending a strand of a biodegradable polymer in a zigzag shape and wrapping it in a tubular form under a non-woven non-knitted condition.

[0009] With the use of the strand formed of a biodegradable polymer, it is possible to font a stent which exhibits mechanical characteristics sufficient to support the vessel in the inflated state for certain time duration and disappears after lapse of the preset time.

[0010] Since the stent formed of the strand of the biodegradable polymer can readily be flexed and deformed, it can readily be delivered through the sinuous blood vessel so as to be implanted on the target site.

[0011] It should be noted that the biodegradable polymer material, as a high molecular material, differs in its degradation and absorption characteristics, and hence in its mechanical properties, depending on the molecular weight. For example, the molecular weight of the biodegradable polymer material, such as polylactic acid (PLA), is lowered by being melted and thermally decomposed. The degree that the molecular weight is lowered changes depending on the degree of thermal decomposition. Thus, if the melt spinning heating time of the same biodegradable polymer material is non-uniform, then the average molecular weight of the spun strand becomes non-uniform. If the strand is non-uniform in its average molecular weight, its degradation and absorption characteristics or mechanical properties undergo localized variations.

[0012] If, with non-uniform average molecular weight, a stent is formed and implanted in the vascular vessel, such as a blood vessel, the stent in its entirety cannot be degraded or absorbed evenly. Moreover, there is a fear that the stent formed using this sort of the strand cannot support the inner wall of the vascular vessel, such as blood vessels, with a uniform force, because the strand itself exhibits strength variations.

DISCLOSURE OF THE INVENTION

[0013] It is therefore an object of the present invention to provide a method and an apparatus for spinning the strand, whereby it is possible to spin the strand having uniform mechanical properties and uniform degradation and absorption characteristics free from strength variations, that is, it is possible to spin the strand having a uniform average molecular weight and making it a suitable construction material for a biodegradable stent.

[0014] The present invention provides a melt spinning apparatus for melt spinning a strand of a biodegradable polymer material, forming a stent implanted in a living body. This comprises a vertically mounted cylinder, supplied with the biodegradable polymer material, a screw mounted in the cylinder coaxially, rotationally driven by a rotational driving unit and having at least one turn of a helical groove on its peripheral surface, and a nozzle mounted to the distal end of the cylinder and having a discharge opening coaxially with the cylinder. The biodegradable polymer material supplied into the cylinder and melted by rotation of the screw is emitted vertically from a discharge opening in the nozzle for spinning the strand.

[0015] With the present melt spinning apparatus, the molten biodegradable polymer material is fed by a screw in the vertical direction and emitted from a nozzle for spinning a strand, so that the strand has a uniform molecular weight distribution is spun as stagnation or non-uniform eddying currents of the biodegradable polymer material melted in the cylinder or the nozzle may be prevented from being produced.

[0016] Moreover, with the present melt spinning apparatus, there is provided a plural number of heating units placed in juxtaposition along the axial direction of the cylinder, on the outer sides of the cylinder forming the melt mechanism for melting the biodegradable polymer material, for controlling the molten state of the biodegradable polymer material injected into the cylinder. The heating units are able to perform temperature control independently of one another.

[0017] The nozzle for discharging the molten biodegradable polymer material is kept at a constant temperature by the heating units. By controlling the nozzle temperature, the temperature of the molten biodegradable polymer material discharged from the nozzle can be made constant.

[0018] According to the present invention, the biodegradable polymer material is melted by a melt mechanism including a screw which is provided in a vertically mounted cylinder coaxially and on the peripheral surface of which at least one turn of the helical groove is formed. The screw is rotated by a rotational driving mechanism. The molten biodegradable polymer material is emitted in the vertical direction through a discharge opening in a nozzle provided coaxially with the cylinder for spinning the strand.

[0019] With the melt spinning method of the present invention, a spun filament having a uniform molecular weight distribution may be produced.

[0020] Other objects, features and advantages of the present invention will become more apparent from reading the embodiments of the present invention as shown in the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] **FIG. 1** is a side view showing a melt spinning apparatus according to the present invention.

[0022] **FIG. 2** is a cross-sectional view showing the cylinder and the screw of a melting mechanism.

[0023] **FIG. 3** is a plan view showing a flow resistance plate mounted to the distal end of the cylinder.

[0024] **FIG. 4** is a cross-sectional view showing a discharging unit at the distal end of the melt mechanism.

[0025] **FIG. 5** is a cross-sectional view showing a supply unit for supplying a polymer material to the melting mechanism.

[0026] **FIG. 6** is a side view showing the screw that is placed in the cylinder forming the melting mechanism.

[0027] **FIG. 7** is a side view showing a supply controlling mechanism which is placed between the melting mechanism and the discharging unit.

[0028] **FIG. 8** is a cross-sectional view showing a set of gears forming the melt mechanism.

BEST MODE FOR CARRYING OUT THE INVENTION

[0029] A melt spinning apparatus and method for melt spinning the biodegradable polymer material using the melt spinning apparatus are now explained in detail.

[0030] The melt spinning apparatus according to the present invention is of a vertical type in which a melt spinning unit is mounted vertically, as shown in **FIG. 1**.

[0031] The melt spinning apparatus, shown in **FIG. 1**, includes a base plate **2**, mounted horizontally on a mounting surface, and the melt spinning unit **1** is supported by member **3***a* by a support pillar **3** mounted upright on the base plate **2**. The melt spinning unit **1** includes: a melt mechanism **4** which is supported by and parallel to the upstanding support pillar **3**, a discharging unit **5** for discharging the polymer material melted by the melt mechanism **4**, a supplying unit **6** for supplying the polymer material to the melt mechanism **4**, and a rotational driving mechanism **7** for rotationally driving a screw **16** forming the melt mechanism **4**.

[0032] The melt mechanism **4** which is in the melt spinning unit **1**, includes a cylinder **8**, as shown in **FIG. 2**. The screw **16** is provided within and coaxially of the cylinder **8**. The screw **16** pressurizes the polymer material, injected into the cylinder **8** and extrudes the pressurized material towards the distal end of the cylinder **8** while melting it.

[0033] On the outer periphery of the cylinder **8**, there is a plural number of heating units **9** in juxtaposition along the axial direction of the cylinder **8**. These heating units **9** are controlled independently of one another to enable the multistage control of the temperature axially of the cylinder **8**.

[0034] On the distal end of the cylinder **8**, there is mounted a connecting member **21** for connecting the discharging unit **5** to the cylinder. The discharging unit **5** is adapted for discharging the melted polymer material. The connecting member **21** is ring-shaped and has at its center portion a flow resistance plate **22** including a plural number of through-holes **22***a* matching the axial direction of the screw **16**, as shown in **FIG. 3**. The molten polymer material, supplied from the distal end of the cylinder **8**, by rotating the screw **16**, is pressurized by the flow resistance when traversing the flow resistance plate **22**. The pressurized polymer material is discharged towards the discharging unit **5** from the distal end of the cylinder **8**.

[0035] The diameter or the number of the through-holes **22***a* provided on the flow resistance plate **22** is changed depending on the amount or supply rate of the molten polymer material supplied from the distal end of cylinder **8**, on rotation of screw **16**, or on the viscous resistance of the polymer material.

[0036] The flow resistance plate **22** may be of any shape provided that it affords the flow resistance to the polymer material supplied melted from the distal end of the cylinder **8** on rotation of the screw **16** to pressurize the polymer material.

[0037] The discharging unit **5**, mounted by the connecting member **21** at the distal end of the cylinder **8**, includes a sprue bush **11**, connected to the distal end of cylinder **8**, and a nozzle **10** mounted to the distal end of the sprue bush **11**, as shown in **FIG. 4**. The nozzle **10** is secured to the distal end of the sprue bush **11** by a mounting member **12**. Meanwhile, the nozzle **10** and the mounting member **12** can be the same.

[0038] The sprue bush **11**, which is part of the discharging unit **5**, supplies the molten polymer material from cylinder **8**, to the nozzle **10** in a stable state at a constant rate of amount per unit time. A flow passage **11**a is in the center co-axially of the cylinder **8**, as shown in **FIG. 4**. That is, the flow passage **11**a and the cylinder **8** are placed vertically with a common axis P1. The flow passage **11**a is tapered moderately from the vertically placed cylinder **8** towards the nozzle **10** so that the polymer material supplied melted from the cylinder **8** may be supplied in succession by predetermined amounts per unit time to the nozzle **10** without producing stagnation or eddying currents.

[**0039**] The nozzle **10** includes a discharge opening **10**a for discharging the polymer material supplied melted from the sprue bush **11**, as shown in **FIG. 4**. The discharge opening **10**a operates for controlling the diameter of the spun strand and is formed by an optimum diameter depending on the thickness of the spun strand. The discharge opening **10**a is also formed to be coaxial with the flow passage **11**a. That is, the discharge opening **10**a and the flow passage **11**a are set upright coaxially as the cylinder **8**.

[**0040**] Meanwhile, plural different nozzles with different diameters R_1 at the discharge opening **10**a may be provided and exchanged from time to time to spin the strand with different thicknesses.

[**0041**] On the outer periphery of the discharging unit **5**, there is a heating unit **13** for controlling the temperature of the discharging unit **5**. This heating unit **13** controls the temperature of the discharging unit **5** to control the temperature of the polymer material discharged from the nozzle **10**.

[**0042**] The supplying unit **6** for supplying the molten polymer material to the melt mechanism **4** includes a hopper **14** for loading the polymer material into the cylinder **8** and a mounting unit **6**a for mounting the unit **6** to the cylinder **8**, as shown in **FIG. 5**. On the outer periphery of the mounting unit **6**a, there is provided a temperature controller **15** for controlling the temperature of the supplying unit **6**. This temperature controller **15** keeps the polymer material, loaded into the hopper **14**, at a constant temperature, and is comprised of a heating/cooling means.

[**0043**] The melt mechanism **4** is explained more specifically. Referring to **FIG. 6**, the melt mechanism **4** includes the screw **16**, having a helically extending groove **17** on its peripheral surface, is mounted coaxially within the cylinder **8**. The screw **16** is rotationally driven by the rotational driving mechanism **7** at the proximal end where the screw is connected. When the screw **16** is driven rotationally, the polymer material, loaded into the cylinder **8** and melted by the heating units **9**, is fed to the distal end of the cylinder **8**.

[**0044**] Meanwhile, the helical groove of the screw used in the routine melt spinning apparatus, is formed to a pitch subsequently equivalent to the screw diameter. The helical groove **17** of the screw **16** used in the melt spinning apparatus according to the present invention has a pitch Tp equal to one-half the diameter Sr of the screw **16**. By forming the helical groove **17** in this manner, the dwelling time of the injected polymer material in the cylinder **8** can be protracted, such that melting can be achieved reliably by sufficient heating in the heating unit **9** even though the screw **16** is of a reduced length. By employing the screw **16**, the screw length may be reduced, as a result of which the melt mechanism **4** including the cylinder **8** can be reduced in size.

[**0045**] It should be noted that the melt spinning apparatus of the present invention may be provided with a supply controlling mechanism **18**, between the melt mechanism **4** and the discharging unit **5**, for controlling the supply quantity of the polymer material in molten state, which is supplied to the discharging unit **5**. This supply controlling mechanism **18** may be configured as shown for example in **FIG. 7**. The supply controlling mechanism **18**, shown in **FIG. 7**, includes a pressure detection means **19** for measuring the pressure of the polymer material extruded from the melt mechanism **4** and circulated in the molten state through a flow passage **18**a, and a set of gears **20** for feeding the melted polymer material to the discharging unit **5**. This supply controlling mechanism **18** detects the pressure of the polymer material flowing through the flow passage **18**a by the pressure detection means **19**. The rotation of the set of gears **20** is controlled by this detection output to keep the pressure of the polymer material flowing through the flow passage **18**a constant. By controlling the pressure of the polymer material flowing through the flow passage **18**a at a constant magnitude, a preset constant quantity of the polymer material can be supplied to the discharging unit **5**.

[**0046**] A heating unit **23** is on the outer periphery of the portion of the supply controlling mechanism **18**, which controls the temperature of the polymer material flowing through the flow passage **18**a at a preset temperature.

[**0047**] The melt spinning method employed by the melt spinning apparatus of the present invention is now explained.

[**0048**] The present invention melt-spins the strand, formed of a biodegradable polymer material used for forming a stent implanted in the living body. The melt spun polymer material, used herein, is the biodegradable polymer material. The biodegradable polymer material may be enumerated by polylactic acid (PLA), polyglycolic acid (PGA), polyglactin (polyglycolic acid-polylactic acid copolymer), polydioxanone, polyglyconate (trimethylene carbonate-glycoid copolymer) and a polylactic acid-ε-caprolactone copolymer.

[**0049**] For spinning the polymer material, a pellet-like polymer material Pp is charged into a hopper **14** of the supplying unit **6**. The polymer material, loaded into the hopper **14**, is supplied to the cylinder **8** of the melt mechanism **4**.

[**0050**] In order for the polymer material, loaded into the hopper **14**, to be quickly supplied into the helical groove **17** formed in the screw **16** rotating in the cylinder **8**, the polymer material needs to be in solid state. That is, the polymer material, supplied into the cylinder **8**, needs to be controlled to a temperature not higher than its melting point (Tm) or softening point. For shortening the melt time in the melt mechanism **4**, the polymer material, supplied to the cylinder **8**, needs to be melted immediately. Thus, the temperature controller **15**, provided in the supplying unit **6**, sets the temperature of the polymer material, charged into the hopper **14**, to a temperature at which the polymer material can be melted immediately as it maintains its solid state.

[**0051**] The polymer material, supplied into the cylinder **8** through the hopper **14**, is introduced into the helical groove **17** of the screw **16**, rotated by the rotational driving mechanism **7**, so as to be extruded towards the distal end of the cylinder **8**, as it is heated by the heating units **9** provided on the outer periphery of the cylinder **8**. As the polymer material is extruded, the temperature of the polymer material is controlled to be lower than its thermal decomposition temperature so as not to cause transmutation of the polymer material. The polymer material, thus controlled to a temperature not higher than its thermal decomposition temperature, is positively extruded from the distal end of the cylinder **8** as it is kept in molten state without undergoing transmutation.

[**0052**] The polymer material, extruded at the distal end of the cylinder **8** while in its molten state, is afforded with flow resistance by the flow resistance plate **22**, in such a manner that it is evenly pressurized by the through-holes **22***a*. The polymer materia, thus pressurized, is supplied to the discharging unit **5**.

[**0053**] Since the through-holes **22***a* formed in the flow resistance plate **22** are oriented vertically in order not to produce stagnation or eddying currents in the polymer material, the polymer material can be supplied to the discharging unit **5** as the molecular weight distribution is maintained to be constant.

[**0054**] If the melt spinning apparatus has the supply controlling mechanism **18** between the melt mechanism **4** and the discharging unit **5**, the molten polymer material, extruded from the cylinder **8** of the melt mechanism **4**, is maintained at a constant pressure by the supply controlling mechanism **18**, so that it is controlled in flow rate at the discharging unit **5** and is reliably supplied to the discharging unit **5** at a constant flow rate.

[**0055**] The polymer material supplied to the supply controlling mechanism **18** is heated by the heating unit **23** provided on the outer periphery of the supply controlling mechanism **18** and hence is delivered to the discharging unit **5**, reliably in its molten state. The heating unit **23** maintains the heating temperature at less than the thermal decomposition temperature so as not to cause transmutation of the polymer material.

[**0056**] The molten polymer material, delivered from the melt mechanism **4** or the supply controlling mechanism **18** to the discharging unit **5**, is heated in the sprue bush **11** by the heating unit **23** to a temperature less than the thermal decomposition temperature. Since the flow path of the discharging unit **5** from the sprue bush **11** to the nozzle **10** is oriented vertically, the polymer material flowing therein is not subjected to stagnation or eddying currents. Since the polymer material, maintained in its molten state, may thus be supplied to the nozzle **10** through the vertical flow path, it can be discharged at the nozzle **10** as it maintained in the state of uniform molecular weight distribution, and hence the strand of the polymer material can be spun with uniform molecular weight distribution.

[**0057**] It should be noted that a monofilament strand may be spun because the sole discharge opening **10***a* is formed through the nozzle **10** for extending in the vertical direction.

[**0058**] Industrial Applicability

[**0059**] With the melt spinning method and apparatus of the present invention, it is possible to prevent stagnation or nonuniform eddying currents of the biodegradable polymer material in order to spin the strand into a uniform average molecular weight. That is, the strand of the biodegradable polymer material may be spun which is uniform mechanical properties and degradation and absorption characteristics. This spun strand can be used to the utmost advantage for forming a stent inserted into the vascular vessel of the living body.

1. A melt spinning apparatus for melt spinning a strand of a biodegradable polymer material, forming a stent implanted in a living body, comprising:

a vertically mounted cylinder, supplied with said biodegradable polymer material;

a screw mounted in said cylinder coaxially therewith, said screw being rotationally driven by a rotational driving unit and having at least one turn of a helical groove on its peripheral surface; and

a nozzle mounted to the distal end of said cylinder and having a discharge opening coaxially with said cylinder;

said biodegradable polymer material supplied into said cylinder and melted by rotation of said screw being emitted vertically from a discharge opening in said nozzle for spinning the strand.

2. The melt spinning apparatus according to claim 1 wherein a sole discharge opening is provided in said nozzle for extending in the vertical direction for spinning a filament.

3. The melt spinning apparatus according to claim 1 further comprising a plurality of heating units in juxtaposition along the axial direction of said cylinder, with the heating temperature of said heating units being controlled independently of one another.

4. The melt spinning apparatus according to claim 2 further comprising heating units on the outer periphery of said nozzle for controlling the nozzle temperature.

5. The melt spinning apparatus according to claim 1 wherein the helical groove formed on the peripheral surface of said screw is formed to a pitch smaller than one-half the screw diameter.

6. The melt spinning apparatus according to claim 1 further comprising a supplying unit for loading a biodegradable polymer material into said cylinder and temperature controlling mechanism for controlling the temperature of the biodegradable polymer material charged into said supplying unit.

7. A method for melt spinning a strand of a biodegradable polymer material, forming a stent implanted in a living body, comprising:

melting the biodegradable polymer material by a melt mechanism including a screw which is provided in a vertically mounted cylinder coaxially therewith and on the peripheral surface of which at least one turn of the spiral groove is formed, said screw being rotated by a rotational driving mechanism;

the molten biodegradable polymer material being emitted in the vertical direction through a discharge opening in a nozzle provided coaxially with said cylinder for spinning the strand.

8. The melt spinning method according to claim 7 wherein the molten biodegradable polymer material is emitted in the vertical direction from a sole discharge opening provided in said nozzle for spinning into a filament.

9. The melt spinning method according to claim 7 wherein the biodegradable polymer material is heated in a supplying unit to a temperature lower than the melting temperature and is loaded into said melt mechanism for melting.

10. The melt spinning method according to claim 7 wherein said biodegradable polymer material is one of polylactic acid (PLA), polyglycolic acid (PGA), polyglactin (a polyglycolic acid-polylactic acid copolymer), polydioxanone, polyglyconate (a trimethylene carbonate-glycoid copolymer) and a polylactic acid-ϵ-caprolactone copolymer.

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