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Medical device

Abstract

A medical device that cuts an object in a body lumen includes: a drive shaft; a shaft portion connected to the drive shaft; a cutting portion connected to the shaft portion; and first and second bearings that rotatably support the shaft portion. The first bearing has a ring shape, the second bearing has a ring shape and is spaced from a proximal side of the first bearing. The shaft portion includes a first sliding portion slidably supported by the first bearing, a second sliding portion slidably supported by the second bearing, and an intermediate portion between the first and second sliding portions. The intermediate portion has a protruding portion protruding radially outward, the protruding portion is disposed between the first bearing (**81**) and the second bearing in an axial direction, and the shaft portion has a passage that communicates from the first sliding portion to the second sliding portion).

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Background/Summary

CROSS-REFERENCES TO RELATED APPLICATIONS (1) This application is a continuation of International Application No. PCT/JP2019/051518 filed on Dec. 27, 2019, the entire content of which is incorporated herein by reference.

TECHNOLOGICAL FIELD
(1) This disclosure relates to a medical device for cutting an object in a body lumen.
BACKGROUND DISCUSSION
(2) Examples of a treatment method for a stenosed site caused by a thrombus, a plaque, a calcified lesion, and the like in a blood vessel include dilating the blood vessel by using a balloon, and causing a mesh-shaped or coil-shaped stent to indwell the blood vessel as a support for the blood vessel. However, in these methods, it is difficult to treat a stenosed site that is hardened by calcification or a stenosed site that is formed at a bifurcated portion in the blood vessel. A method that can perform treatment in such a case includes cutting and removing the stenosed site such as a thrombus, a plaque, or a calcified lesion.
(3) For example, U.S. Pat. No. 8,394,078 describes a device in which a cutting portion that cuts a stenosed site in a blood vessel is disposed at a distal end of a drive shaft. This device has a function of aspirating a cut object.
SUMMARY
(4) The device described in U.S. Pat. No. 8,394,078 includes a ball bearing on a proximal side of the cutting portion in order to support the rotating cutting portion. The ball bearing includes a large number of balls arranged in a circumferential direction in order to smoothly rotate the cutting portion. Therefore, it is difficult to dispose a passage for aspirating the object in a portion where the ball bearing is disposed. Therefore, an inlet for aspirating the cut object from an outside into the device is disposed on the proximal side with respect to the ball bearing. Therefore, this device cannot efficiently aspirate the cut object.
(5) The medical device disclosed here is capable of efficiently aspirating an object cut by a rotating cutting portion and maintaining a stable rotation axis.
(6) The medical device includes: a drive shaft that is rotatable; a shaft portion that is connected to a distal portion of the drive shaft; a cutting portion connected to a distal portion of the shaft portion or the distal portion of the drive shaft; an outer tube shaft that rotatably accommodates the drive shaft; and a first bearing and a second bearing that are accommodated in the outer tube shaft and rotatably support the shaft portion, in which the first bearing has a ring shape, the second bearing has a ring shape and is disposed away from a proximal side of the first bearing, the shaft portion includes a first sliding portion slidably supported on an inner peripheral surface of the first bearing, a second sliding portion slidably supported on an inner peripheral surface of the second bearing, and an intermediate portion disposed between the first sliding portion and the second sliding portion, the intermediate portion has at least one protruding portion protruding outward in a radial direction, the protruding portion is disposed between a proximal surface of the first bearing and a distal surface of the second bearing in an axial direction, and the shaft portion has a passage that communicates from the first sliding portion to the second sliding portion.
(7) In the medical device configured as described above, since an aspiration force can be applied to

a distal side through the passage disposed inside the bearings, an external object can be aspirated inside on a distal side with respect to the bearings and the shaft portion. Therefore, the medical device can efficiently aspirate the object cut by the cutting portion. In addition, since the shaft portion is supported at two positions of the first bearing and the second bearing, stable rotation can be maintained. In addition, the first bearing and the second bearing can support the protruding portion by sandwiching the protruding portion therebetween in the axial direction. Therefore, when the medical device is pushed and pulled, a force in an axial direction applied from the shaft portion is received by the first bearing and/or the second bearing. Therefore, the medical device can maintain a stable rotation axis even when the shaft portion receives a force in a radial direction or the axial direction.

(8) According to another aspect, a medical device positionable inside a body lumen to cut an object in the body lumen includes: an outer tubular shaft extending in the axial direction; a rotatable drive shaft positioned in the outer tubular shaft; a shaft portion connected to the drive shaft so that rotation of the drive shaft results in rotation of the shaft portion; and a ring-shaped first bearing and a ring-shaped second bearing that both rotatably support the shaft portion. The first bearing possesses an inner peripheral surface facing the outer peripheral surface of the shaft portion and an outer peripheral surface facing the inner peripheral surface of the outer tubular shaft, and the second bearing possesses an inner peripheral surface facing the outer peripheral surface of the shaft portion and an outer peripheral surface facing the inner peripheral surface of the outer tubular shaft. A cutting portion is connected to and rotatable together with the shaft portion or the drive shaft, and the cutting portion is distal of the first and second bearings. The proximal end surface of the ring-shaped first bearing and the distal end surface of the ring-shaped second bearing face one another and are spaced apart from one another in the axial direction. The shaft portion includes an intermediate portion positioned between the proximal end surface of the ring-shaped first bearing and the distal end surface of the ring-shaped second bearing, and the intermediate portion of the shaft portion possesses a distal end surface facing the proximal end surface of the ring-shaped first bearing and a proximal end surface facing the distal end surface of the ring-shaped second bearing. A groove is provided in the outer peripheral surface of the shaft portion to aspirate the object cut by the cutting portion. The groove possesses an open distal end and an open proximal end that are spaced apart from one another in the axial direction, the inner peripheral surface of the ring-shaped first bearing faces towards and overlies an axially extending first portion of the groove, and the inner peripheral surface of the ring-shaped second bearing faces towards and overlies an axially extending second portion of the groove.

(9) Another aspect involves a method of cutting an object in a body lumen. The method comprises introducing a cutting portion of a medical device into a body lumen, wherein the medical device also includes: a rotatable drive shaft; a shaft portion connected to the rotatable drive shaft; an outer tubular shaft rotatably accommodating the drive shaft; a cutting portion connected to the distal portion of the shaft portion or the distal portion of the drive shaft; and a ring-shaped first bearing and a ring-shaped second bearing both accommodated in the outer tubular shaft and rotatably supporting the shaft portion, with the ring-shaped first bearing and the ring-shaped second bearing being spaced apart from one another in the axial direction so that a space exists between the proximal end surface of the ring-shaped first bearing and the distal end surface of the ring-shaped second bearing. The method also involves moving the cutting portion toward and into contact with the object in the body lumen, and cutting the object in the living body by rotating the cutting portion while the cutting portion is in contact with the object in the body lumen to produce cut parts of the object. The ring-shaped first bearing and a first portion of the outer peripheral surface of the shaft portion and the ring-shaped second bearing and a second portion of the outer peripheral surface of the shaft portion function as radial load bearings that receive a radial load during the cutting of the object in the living body. The ring-shaped first bearing, the ring-shaped and a portion of the shaft portion located between the proximal end surface of the ring-shaped first bearing and

the distal end surface of the ring-shaped second bearing function as axial load bearings that receive an axial load during the cutting of the object in the living body. The method further comprises aspirating at least some of the cut parts of the object through a passage that is formed in the outer peripheral surface of the outer shaft and that extends from distal of a distal end surface of the ring-shaped first bearing to proximal of a proximal end surface of the ring-shaped second bearing.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) FIG. **1** is a plan view showing a medical device according to an embodiment.
(2) FIG. **2** is a perspective view showing a distal portion of the medical device as seen through a cutting portion and an accommodation portion.
(3) FIG. **3** is a cross-sectional view showing the distal portion of the medical device.
(4) FIGS. **4**A-**4**C show the distal portion of the medical device, in which FIG. **4**A is a cross-sectional view taken along the section line A-A in FIG. **3**, FIG. **4**B is a cross-sectional view taken along the section line B-B in FIG. **3**, and FIG. **4**C is a cross-sectional view taken along the section line C-C in FIG. **3**.
(5) FIG. **5** is a schematic view showing a state in which cutting is performed by the medical device.
(6) FIG. **6** is a plan view showing a drive shaft of a modification of the medical device.
DETAILED DESCRIPTION
(7) Set forth below with reference to the accompanying drawings is a detailed description of embodiments of a medical device representing examples of the medical device disclosed here. The dimensions or scales on the drawings may be exaggerated or different from actuality/reality for convenience of description and illustration. For convenience of explanation, dimensions in the drawings may be exaggerated and may be different from actual dimensions. In addition, in the present description and the drawings, structural elements that have substantially the same function are denoted with the same reference numerals, and repeated explanation of these structural elements is omitted. In the present description, a side to be inserted into a lumen is referred to as a “distal side”, and a side to be operated is referred to as a “proximal side”.
(8) A medical device **10** according to an embodiment is inserted into a blood vessel, and is used for a procedure for cutting and removing a plaque, a calcified lesion, and the like in an acute lower limb ischemia or a deep vein thrombosis. An object to be cut by the medical device is not particularly limited, and may be, for example, an atheroma and a thrombus. Further, all the objects that may be present in the body lumen may be objects to be cut by the medical device **10**.
(9) As shown in FIGS. **1** to **3**, the medical device **10** includes a rotation structure portion **11** that is rotatable, an accommodation portion **12** that rotatably accommodates the rotation structure portion **11**, and a handle portion **90** that is operated by an operator. The rotation structure portion **11** includes a drive shaft **20** that transmits a rotational force, a shaft portion **30** that is rotatably supported by the accommodation portion **12**, a cutting portion **50** that cuts a plaque or a calcified lesion, and a protective tube **60** that is accommodated in the drive shaft **20**. The accommodation portion **12** includes an outer tubular shaft **70** that accommodates the drive shaft **20**, and a bearing **80** that rotatably supports the shaft portion **30**.
(10) The drive shaft **20** is an elongated tube body. The drive shaft **20** is flexible and has a characteristic capable of transmitting a rotational force acting from the proximal side to the distal side. The shaft portion **30** is fixed to a distal portion of the drive shaft **20**. The drive shaft **20** is a tubular body in which a plurality of wire rods are arranged around an axis X of the rotation structure portion **11** and interlocked in a spiral shape. The axis X is a structural central axis of the rotation structure portion **11** and is a central axis of the rotation structure portion **11**. A proximal portion of the drive shaft **20** is located inside the handle portion **90**. The drive shaft **20** may be

configured or constructed in a way that does not include the wire rods.

(11) A constituent material from which the drive shaft **20** is fabricated is not particularly limited, and may be for example, stainless steel, nitinol, fluoropolymers such as polytetrafluoroethylene (PTFE) and an ethylene tetrafluoroethylene copolymer (ETFE), polyether ether ketone (PEEK), polyimides, polyolefins such as polyethylene and polypropylene, polyamides, and polyesters such as polyethylene terephthalate.

(12) As shown in FIGS. **1** to **3**, the cutting portion **50** is a member that cuts and reduces the object (size of the object) such as a plaque or a calcified lesion. Therefore, the "cut" means applying a force to the object in contact to make the object smaller. A method for applying the force to perform the cutting and a shape or a form of the object after the cutting are not limited.

(13) The cutting portion **50** has a large number of minute abrasive grains on a surface thereof. Alternatively, the cutting portion **50** may include a sharp blade. The cutting portion **50** is formed with a first through-hole **51** located on a distal side and a second through-hole **52** located on a proximal side of the first through-hole **51**. The first through-hole **51** and the second through-hole **52** communicate with each other and penetrate or pass through the cutting portion **50** in a direction along the axis X. A distal portion of the shaft portion **30** is fitted into and interlocked with an inside of the second through-hole **52**.

(14) An outer peripheral surface of the cutting portion **50** has groove-shaped cutout portions **53** extending in the direction along the axis X. The cutout portions **53** function as flow paths for conveying the cut object in a proximal direction. The cutout portions **53** are arranged, for example, at an interval of 120 degrees in a circumferential direction. Therefore, the cutting portion **50** has three cutout portions **53** uniformly arranged in the circumferential direction. An edge portion of each cutout portion **53** is smoothly formed with a curvature. The number of the cutout portions **53** is not limited to three.

(15) A constituent material from which the cutting portion **50** may be fabricated preferably has sufficient strength to cut a plaque, a calcified lesion, or the like, and examples of suitable material include stainless steel, nitinol, Ta, Ti, Pt, Au, W, brass, a shape memory alloy, and a cemented carbide. When a soft material such as a thrombus is to be cut, fluoropolymers such as polytetrafluoroethylene (PTFE) or an ethylene tetrafluoroethylene copolymer (ETFE), polyether ether ketone (PEEK), polyimides, polyolefins such as polyethylene and polypropylene, polyamides, polyesters such as polyethylene terephthalate, and the like can be suitably used.

(16) The protective tube **60** is a flexible tubular body disposed inside the drive shaft **20** and the cutting portion **50**. The protective tube **60** is rotatable relative to the drive shaft **20** and the cutting portion **50**. The protective tube **60** is formed with a guide wire lumen **61** through which a guide wire passes. The protective tube **60** prevents the guide wire passing through the inside of the drive shaft **20** from coming into direct contact with the drive shaft **20** and rubbing against the drive shaft **20**. A distal portion of the protective tube **60** is interlocked with a tubular protective tube stopper **62**. A proximal portion of the protective tube stopper **62** has an outer diameter larger than that of the protective tube **60**, and covers the distal portion of the protective tube **60**. A distal portion of the protective tube stopper **62** has an outer diameter smaller than that of the proximal portion of the protective tube stopper **62**, and protrudes toward the distal side with respect to the protective tube **60**. The proximal portion of the protective tube stopper **62** is rotatably disposed in a gap between the shaft portion **30** and the cutting portion **50** in an axial direction. Therefore, the protective tube stopper **62** can rotate while being restricted from moving in the axial direction between the shaft portion **30** and the cutting portion **50**. Therefore, movement of the protective tube **60** in the axial direction can be restricted by the protective tube stopper **62**, and falling-off of the protective tube **60** can be suppressed.

(17) As shown in FIGS. **2**, **3** and **4**A-**4**C, the shaft portion **30** is a portion that rotatably supports the rotation structure portion **11** with respect to the accommodation portion **12**. The shaft portion **30** includes a proximal interlock portion **31** interlocked with the drive shaft **20** and a distal interlock

portion **32** interlocked with the cutting portion **50**. The shaft portion **30** further includes a first sliding portion **33** supported by a first bearing **81**, a second sliding portion **34** supported by a second bearing **82**, and an intermediate portion **35** disposed between the first sliding portion **33** and the second sliding portion **34**. The shaft portion **30** is formed with at least one passage **40** (three in the present embodiment) extending along the axis X.
(18) The proximal interlock portion **31** is a cylindrical portion disposed at a proximal portion of the shaft portion **30**. The proximal interlock portion **31** includes a proximal fitting portion **37** into which the distal portion of the drive shaft **20** is fitted from the proximal side, and a proximal stepped portion **36** against which a distal surface of the drive shaft **20** abuts. The proximal stepped portion **36** is a portion whose inner diameter decreases stepwise from the proximal fitting portion **37** toward the distal side. An inner diameter of the proximal fitting portion **37** is substantially equal to an outer diameter of the distal portion of the drive shaft **20**. The distal surface of the drive shaft **20** is attached to the proximal stepped portion **36**. Therefore, the shaft portion **30** is fixed at an appropriate position with respect to the drive shaft **20**. The proximal interlock portion **31** is joined to the drive shaft **20** by welding or the like at a plurality of positions in a circumferential direction. Since the proximal interlock portion **31** has a tubular shape, the proximal interlock portion **31** can be firmly fixed to the drive shaft **20** by surrounding the drive shaft **20**. The proximal interlock portion **31** may be disposed inside the drive shaft **20** instead of outside the drive shaft **20**. In addition, a proximal surface of the proximal interlock portion **31** may abut against the distal surface of the drive shaft **20**.
(19) The distal interlock portion **32** includes a distal fitting portion **38** fitted inside the second through-hole **52** of the cutting portion **50**, and a distal stepped portion **39** against which a proximal surface of the cutting portion **50** abuts. The distal stepped portion **39** is a portion whose inner diameter increases stepwise from the distal fitting portion **38** toward the proximal side. An outer diameter of the distal fitting portion **38** is substantially equal to an outer diameter of the second through-hole **52** of the cutting portion **50**. The proximal surface of the cutting portion **50** is attached to the distal stepped portion **39**. Therefore, the cutting portion **50** is fixed at an appropriate position with respect to the shaft portion **30**.
(20) The first sliding portion **33** is a portion that is disposed on a proximal side of the distal interlock portion **32** and is rotatably supported by the first bearing **81**. The three groove-shaped passages (grooves) **40** extending in an axial direction are formed on an outer peripheral surface of a circular tube of the first sliding portion **33** having a uniform outer diameter. The first sliding portion **33** includes three first rotational contact portions **41** that are in contact with an inner peripheral surface of the first bearing **81** between the three groove-shaped passages **40** equally arranged in a circumferential direction. Outer diameters of the first rotational contact portions **41** are slightly smaller than an inner diameter of the first bearing **81**. Therefore, the first rotational contact portions **41** are slidably in contact with the inner peripheral surface of the first bearing **81**.
(21) The second sliding portion **34** is a portion that is disposed on a distal side of the proximal interlock portion **31** and is rotatably supported by the second bearing **82**. The three groove-shaped passages **40** extending in the axial direction are formed on an outer peripheral surface of a circular tube of the second sliding portion **34** having a uniform outer diameter. The second sliding portion **34** includes three second rotational contact portions **42** that are in contact with an inner peripheral surface of the second bearing **82** between the three groove-shaped passages **40** equally arranged in the circumferential direction. Outer diameters of the second rotational contact portions **42** are slightly smaller than an inner diameter of the second bearing **82**. Therefore, the second rotational contact portions **42** are slidably in contact with the inner peripheral surface of the second bearing **82**.
(22) The intermediate portion **35** is disposed between the first sliding portion **33** and the second sliding portion **34**. The three groove-shaped passages **40** extending along the axis X are formed on an outer peripheral surface of a circular tube of the intermediate portion **35** having a uniform outer

diameter. The intermediate portion **35** has three protruding portions **43** that protrude outward in a radial direction from the first sliding portion **33** and the second sliding portion **34** between the three groove-shaped passages **40** equally arranged in the circumferential direction. Each of the protruding portions **43** includes a protruding distal surface **44** and a protruding proximal surface **45**. The three protruding distal surfaces **44** are disposed on the same plane orthogonal to the axis X. The three protruding proximal surfaces **45** are disposed on the same plane orthogonal to the axis X.
(23) The passages **40** have open distal and proximal ends, and form flow paths for aspirating the object cut by the cutting portion **50**. Distal portions of the passages **40** communicate with proximal portions of the cutout portions **53**. The passages **40** are formed from the distal stepped portion **39** disposed on the distal side with respect to a portion of the shaft portion **30** supported by the bearing **80** to the proximal side with respect to a portion of the shaft portion **30** supported by the bearing **80**. That is, the passages **40** are formed from the distal side to the proximal side with respect to the bearing **80**. Also, as seen in FIGS. **4**A and **4**B, the inner peripheral surface of the first bearing **81** faces towards and overlies an axially extending portion of each passage **40**, and the inner peripheral surface of the second bearing **82** faces towards and overlies a different axially extending portion of each passage **40**. The groove-shaped passages **40** may partially penetrate to an inner peripheral surface of the shaft portion **30**. In the present embodiment, proximal portions of the passages **40** do not reach a proximal end of the shaft portion **30**, but may reach the proximal end of the shaft portion **30**. The passages **40** are connected to an outer peripheral surface of the shaft portion **30** on the distal side with respect to the bearing **80**. Accordingly, spaces of the passages **40** communicate with a space outside the shaft portion **30** on the distal side with respect to the bearing **80**. Further, the passages **40** are connected to the outer peripheral surface of the shaft portion **30** on the proximal side with respect to the bearing **80**. Accordingly, the spaces of the passages **40** communicate with the space outside the shaft portion **30** on the proximal side with respect to the bearing **80**. Therefore, the passages **40** can take in the cut object from the outside of the shaft portion **30** on the distal side with respect to the bearing **80**. Then, the passages **40** can release the object taken in on the distal side with respect to the bearing **80** to the outside of the shaft portion **30** on the proximal side with respect to the bearing **80**. In addition, by providing the passages **40** on the shaft portion **30**, an aspiration opening portion **74** for performing aspiration can be positioned near the cutting portion **50**. Further, by providing the passages **40** on the shaft portion **30**, friction between the shaft portion **30** and the bearing **80** is reduced, and slidability can be improved.
(24) The passages **40** may not be formed in a groove shape on the outer peripheral surface of the shaft portion **30**, but may be formed as holes penetrating in the axial direction inside the shaft portion **30**. In this case, the first rotational contact portions **41** of the first sliding portion **33** may be formed as a single ring-shaped portion. In addition, the second rotational contact portions **42** of the second sliding portion **34** may be formed as a single ring-shaped portion. In addition, the protruding portions **43** may be formed as a single ring-shaped portion. In addition, the passages **40** may be formed in a groove shape on the first sliding portion **33** and the second sliding portion **34**, and may be formed as holes penetrating in the axial direction in the intermediate portion **35**. In this case, the plurality of first rotational contact portions **41** and the plurality of second rotational contact portions **42** are formed, and the protruding portions **43** are formed by one ring-shaped portion.
(25) As shown in FIGS. **1** to **3**, the outer tubular shaft **70** is a tubular body that accommodates the drive shaft **20** and the protective tube **60**. The outer tubular shaft **70** includes an outer tubular main body **71** and a support tube **72** fixed to a distal side of the outer tubular main body **71**. An aspiration lumen **73** for aspirating an object which is obtained by cutting and reducing a plaque, a calcified lesion, or the like is formed between the outer tubular shaft **70** and the drive shaft **20**. The outer tubular shaft **70** includes, at a distal end thereof, the aspiration opening portion **74** for aspirating the cut object or a liquid discharged from the drive shaft **20**. The distal end of the outer tubular shaft **70** is disposed with a predetermined gap G from a proximal end of the cutting portion

50 to the proximal side. The gap G has a length exceeding 0 along the axis X when the rotation structure portion **11** is disposed closest to the proximal side with respect to the accommodation portion **12**. Therefore, the distal end of the outer tubular shaft **70** is prevented from coming into contact with the cutting portion **50**. The outer tubular shaft **70** includes, at a proximal end thereof, a proximal opening portion **75** that opens inside the handle portion **90**.
(26) The outer tubular main body **71** is a tubular body having flexibility. The outer tubular main body **71** extends from the handle portion **90** to the vicinity of the cutting portion **50**. The outer tubular main body **71** may formed with, on a distal portion thereof, a curved portion **78** at which an extending direction of the outer tubular main body **71** changes. A proximal portion of the outer tubular main body **71** is fixed to the handle portion **90**. The proximal opening portion **75** is disposed at a proximal end of the outer tubular main body **71**.
(27) The support tube **72** is a circular tube made of metal and fixed to the distal portion of the outer tubular main body **71**. The support tube **72** includes a support tube main body **76** having a constant inner diameter, and a stopper **77** disposed on a distal side of the support tube main body **76** and having an inner diameter smaller than that of the support tube main body **76**. The aspiration opening portion **74** is disposed at a distal end of the support tube **72**. The stopper **77** is in contact with a ring-shaped or annular distal surface **85** of the first bearing **81** of the bearing **80**, which will be described later. Accordingly, the stopper **77** restricts the first bearing **81** from moving toward the distal side with respect to the support tube **72** and falling off from the support tube **72**. Since the stopper **77** can restrict the movement of the first bearing **81** if the stopper **77** is contactable with the ring-shaped distal surface **85** of the first bearing **81**, the stopper **77** may be slightly separated from the first bearing **81**. The inner diameter of the stopper **77** is preferably smaller than an outer diameter of the first bearing **81** and larger than the inner diameter of the first bearing **81**. The structure of the stopper **77** is not particularly limited as long as the movement of the first bearing **81** can be restricted, and may be partially disposed in a circumferential direction, for example.
(28) A constituent material for fabricating the outer tubular main body **71** preferably has a certain degree of strength, and examples of suitable materials include stainless steel, nitinol, Ta, Ti, Pt, Au, W, a shape memory alloy, an ABS resin, engineering plastics such as polycarbonate (PC), polymethyl methacrylate (PMMA), polyacetal (POM), polyphenylsulfone (PPSU), polyethylene (PE), a carbon fiber, or polyether ether ketone (PEEK), or a combination thereof.
(29) A constituent material for fabricating the support tube **72** preferably has a certain degree of strength, and examples of suitable materials include stainless steel, nitinol, Ta, Ti, Pt, Au, W, a shape memory alloy, engineering plastics such as polyether ether ketone (PEEK), or a combination thereof.
(30) As shown in FIGS. **2**, **3** and **4**A-**4**C, the bearing **80** includes the first bearing **81** and the second bearing **82** each having a ring shape. The first bearing **81** and the second bearing **82** are disposed inside the support tube **72** and are spaced apart from each other along the axis X. Each of the first bearing **81** and the second bearing **82** includes an outer peripheral surface **83** having a constant outer diameter and an inner peripheral surface **84** having a constant inner diameter. In addition, each of the first bearing **81** and the second bearing **82** includes the ring-shaped or annular distal surface **85** and a ring-shaped or annular proximal surface **86** which are disposed on a plane orthogonal to the axis X. The first bearing **81** and the second bearing **82** have the same shape, but may have different shapes. The outer peripheral surface **83** of the bearings is fixed in close contact with an inner peripheral surface of the support tube **72**. The inner peripheral surface **84** of the first bearing **81** is slidable on outer peripheral surfaces of the first rotational contact portions **41**. The ring-shaped or annular proximal surface **86** of the first bearing **81** is slidable with the protruding distal surface **44** of the intermediate portion **35**. The inner peripheral surface **84** of the second bearing **82** is slidable with respect to outer peripheral surfaces of the second rotational contact portions **42**. The ring-shaped or annular distal surface **85** of the second bearing **82** is slidable with the protruding proximal surface **45** of the intermediate portion **35**. Therefore, the first bearing **81**

and the first sliding portion **33** function as bearings that receive a radial load. In addition, the second bearing **82** and the second sliding portion **34** function as bearings that receive a radial load. Further, the first bearing **81**, the second bearing **82**, and the intermediate portion **35** function as bearings that receive an axial load.

(31) The outer peripheral surfaces **83** of the first bearing **81** and the second bearing **82** are formed rougher than the inner peripheral surface **84** and the ring-shaped proximal surface **86** of the first bearing **81** and the inner peripheral surface **84** and the ring-shaped distal surface **85** of the second bearing **82**. Since the inner peripheral surface **84** and the ring-shaped proximal surface **86** of the first bearing **81** and the inner peripheral surface **84** and the ring-shaped distal surface **85** of the second bearing **82** are surfaces that slide on other members, the surfaces are preferably smooth. Then, since the outer peripheral surfaces **83** of the first bearing **81** and the second bearing **82** are formed rougher than the inner peripheral surface **84** and the ring proximal surface **86** of the first bearing **81** and the inner peripheral surface **84** and the ring-shaped distal surface **85** of the second bearing **82**, the outer peripheral surfaces **83** of the bearings are less likely to slide with respect to the inner peripheral surface of the support tube **72**. Therefore, the outer peripheral surfaces **83** of the first bearing **81** and the second bearing **82** are firmly fixed to the inner peripheral surface of the support tube **72**. The ring-shaped distal surface **85** of the first bearing **81** and the ring-shaped proximal surface **86** of the second bearing **82** do not slide on other members. Therefore, roughness of the ring-shaped distal surface **85** of the first bearing **81** and roughness of the ring-shaped proximal surface **86** of the second bearing **82** are not particularly limited. Since the first bearing **81** and the second bearing **82** can be manufactured by fitting into a mold, and roughness of an inner surface of the mold can vary from place to place, the outer peripheral surfaces **83** of the first bearing **81** and the second bearing **82** can be made rougher than the inner peripheral surfaces **84** of the bearings, the ring-shaped distal surfaces **85**, and the ring-shaped proximal surfaces **86**. In addition, by adding a polishing process to the inner peripheral surfaces **84** of the bearings, the ring-shaped distal surfaces **85**, and the ring-shaped proximal surfaces **86** of the first bearing **81** and the second bearing **82**, the outer peripheral surfaces **83** of the first bearing **81** and the second bearing **82** can be made rougher than the inner peripheral surfaces **84**, the ring-shaped distal surfaces **85**, and the ring-shaped proximal surfaces **86**.

(32) Constituent materials for fabricating the first bearing **81** and the second bearing **82** are preferably ceramics, and examples may include zirconia toughened alumina (ZTA), corundum which is also called ruby or sapphire, and alumina. In addition, only surfaces of the first bearing **81** and the second bearing **82** may be formed of ceramics. Therefore, the first bearing **81** and the second bearing **82** may be formed by coating the surfaces made of a metal material or a resin material with the ceramics. The entire surfaces of the first bearing **81** and the second bearing **82** may be coated with the ceramics, or may be partially coated with the ceramics. It is preferable that at least surfaces of the first bearing **81** and the second bearing **82** that slide on the other members are coated with the ceramics. The surfaces of the first bearing **81** and the second bearing **82** that slide on the other members are the inner peripheral surface **84** and the ring-shaped proximal surface **86** of the first bearing **81**, and the inner peripheral surface **84** and the ring-shaped distal surface **85** of the second bearing **82**. The constituent materials for fabricating the first bearing **81** and the second bearing **82** are not necessarily limited to the ceramics, and may be, for example, stainless steel or engineering plastics such as PEEK as long as the number of rotation and torque are not so large. In addition, the coating applied to the surfaces made of the metal material or the resin material may be a DLC coating, a titanium nitride coating, a nitriding treatment, or the like.

(33) The shaft portion **30** may be formed integrally with the cutting portion **50**. As a constituent material for fabricating the shaft portion **30**, materials like those mentioned above for fabricating the first bearing **81** and second bearing **82** can be used. Therefore, for example, the first rotational contact portions **41**, the second rotational contact portions **42**, and the protruding portions **43** of the shaft portion **30** may be formed by applying a DLC coating, a titanium nitride coating, or a surface

smoothing treatment such as a nitriding treatment to stainless steel in order to improve wear resistance. In addition, the bearing **80** may be formed integrally with the outer tubular shaft **70**.
(34) As shown in FIG. **1**, the handle portion **90** includes a casing **91**, a drive unit **92**, an aspiration port **93**, and a rotation operation unit **94**.
(35) The proximal portion of the outer tubular main body **71** is fixed to a distal portion of the casing **91**. An aspiration space **95** communicating with the aspiration port **93** is formed inside the casing **91**. The proximal opening portion **75** of the outer tubular main body **71** is rotatably disposed in the aspiration space **95**.
(36) The rotation operation unit **94** is a portion operated by an operator with fingers thereof to apply a rotation torque to the outer tubular shaft **70**. The rotation operation unit **94** is rotatably interlocked with the distal portion of the casing **91**. The rotation operation unit **94** is fixed to an outer peripheral surface of the proximal portion of the outer tubular main body **71**.
(37) The drive unit **92** is, for example, a hollow motor. The drive unit **92** is rotated by a battery or electric power supplied from an outside. The drive shaft **20** is fixed to a hollow drive rotor of the hollow motor. A rotation speed of the drive unit **92** is not particularly limited, but may be, for example, 5,000 rpm to 200,000 rpm. The configuration of the drive unit **92** is not particularly limited.
(38) The aspiration port **93** can be connected to an aspiration source **100** such as an external aspiration pump. The aspiration port **93** is aspirated by the aspiration source **100**, and conveys an object, a liquid, or the like inside the aspiration space **95** toward the aspiration source **100**. A pump, a syringe, or the like may be used as the aspiration source **100** as long as an aspiration pressure can be generated.
(39) Next, a method of using the medical device **10** according to the present embodiment will be described using, as an example, a case in which a lesion area such as a plaque or a calcified lesion in a blood vessel is cut and aspirated.
(40) First, the operator inserts a guide wire W into the blood vessel and causes the guide wire W to reach the vicinity of a lesion area S. Next, the operator inserts a proximal end of the guide wire W into the guide wire lumen **61** of the medical device **10**. Thereafter, as shown in FIG. **5**, the cutting portion **50** is moved to the vicinity of the lesion area S by using the guide wire W as a guide.
(41) Next, the operator operates the aspiration source **100**. At the same time or after a certain period of time has elapsed, the drive unit **92** is operated. Accordingly, the drive shaft **20** rotates, and the cutting portion **50** and the shaft portion **30** rotate together with the drive shaft **20**. Accordingly, the operator can cut the lesion area S by the cutting portion **50**.
(42) When the shaft portion **30** rotates, as shown in FIGS. **3** and **4**, the first rotational contact portions **41** of the shaft portion **30** slide on the inner peripheral surface **84** of the first bearing **81**, and the second rotational contact portions **42** slide on the inner peripheral surface **84** of the second bearing **82**. That is, the bearing **80** receives and supports the radial load of the shaft portion **30** at two positions of the first bearing **81** and the second bearing **82**. Therefore, even if the cutting portion **50** receives a force in a radial direction at the time of cutting by the cutting portion **50**, the shaft portion **30** is well supported by the bearing **80** and can rotate stably.
(43) In addition, the operator can reciprocate the outer tubular shaft **70** along a longitudinal direction of the blood vessel by moving the entire handle portion **90** or the outer tubular shaft **70** exposed to an outside of a body. Therefore, the operator can cut the lesion area S along the longitudinal direction of the blood vessel by the cutting portion **50**. When the cutting portion **50** receives a force in the proximal direction due to pushing and pulling of the medical device **10**, the rotating shaft portion **30** is moved to the proximal side inside the bearing **80**. Accordingly, the protruding proximal surface **45** of the protruding portions **43** of the shaft portion **30** is supported by the ring-shaped distal surface **85** while sliding with respect to the ring-shaped distal surface **85** of the second bearing **82**. In addition, when the cutting portion **50** receives a force in a distal direction due to the pushing and pulling of the medical device **10**, the rotating shaft portion **30** is moved to

the distal side inside the bearing **80**. Accordingly, the protruding distal surface **44** of the protruding portions **43** of the shaft portion **30** is supported by the ring-shaped proximal surface **86** while sliding with respect to the ring-shaped proximal surface **86** of the first bearing **81**. In this way, the bearing **80** receives and supports the axial load of the shaft portion **30** at the two positions of the first bearing **81** and the second bearing **82**. Therefore, even if the cutting portion **50** receives a force in the direction along the axis X at the time of cutting by the cutting portion **50**, the shaft portion **30** is well supported by the bearing **80** and can rotate stably. Therefore, the cutting portion **50** can effectively cut the lesion area S.

(44) When the operator wants to change a position of the cutting portion **50** in the circumferential direction, the operator can rotate the rotation operation unit **94** while holding the casing **91**. Accordingly, a direction of the curved portion **78** of the outer tubular shaft **70** is changed, and the position of the cutting portion **50** can be changed.

(45) The aspiration source **100** applies a negative pressure to the aspiration space **95** via the aspiration port **93**. Therefore, the negative pressure acts on the aspiration lumen **73** from the proximal opening portion **75** of the outer tubular main body **71** located in the aspiration space **95**. Therefore, the lesion area S cut by the cutting portion **50** results in debris and this debris is aspirated into the aspiration lumen **73** from a distal opening portion. The debris can efficiently enter the passages **40** communicating with the cutout portions **53** through the cutout portions **53** of the cutting portion **50**. In addition, the debris can enter the passages **40** through the gap G between the cutting portion **50** and the support tube **72**. The passages **40** may be formed in spiral shapes around the axis X. Accordingly, when the drive shaft **20** is rotated by the rotating passages **40**, the rotating spiral passages **40** can function as Archimedean screws (screw pumps). Accordingly, the passages **40** can smoothly convey the object and the fluid inside the aspiration lumen **73** to the proximal side.

(46) The debris that entered the passages **40** on the distal side with respect to the first bearing **81** moves inside the first bearing **81** and the second bearing **82** toward the proximal side. Thereafter, the debris moves from the passages **40** to an outer peripheral surface side of the shaft portion **30** on the proximal side with respect to the second bearing **82**. Thereafter, the debris moves through the aspiration lumen **73** toward the proximal side, passes through the aspiration space **95** and the aspiration port **93**, and is discharged to the aspiration source **100**. After the cutting of the lesion area S and the aspiration of the debris are completed, the operator stops operations of the aspiration source **100** and the drive unit **92**. Accordingly, the cutting of the lesion area S and the discharge of the debris are stopped. Thereafter, the operator removes the medical device **10** from the blood vessel and completes the procedure.

(47) As described above, the medical device **10** according to the present embodiment is a medical device **10** that cuts an object in a body lumen. The medical device **10** includes: the drive shaft **20** that is rotatable; the shaft portion **30** that is connected to the distal portion of the drive shaft **20**; the cutting portion **50** that is connected to the distal portion of the shaft portion **30** or the distal portion of the drive shaft **20**; the outer tubular shaft **70** that rotatably accommodates the drive shaft **20**; the first bearing **81** and the second bearing **82** that are accommodated in the outer tubular shaft **70** and rotatably support the shaft portion **30**, in which the first bearing **81** has the ring shape, the second bearing **82** has the ring shape and is disposed away from a proximal side of the first bearing **81**, the shaft portion **30** includes the first sliding portion **33** slidably supported on the inner peripheral surface of the first bearing **81**, the second sliding portion **34** slidably supported on the inner peripheral surface of the second bearing **82**, and the intermediate portion **35** disposed between the first sliding portion **33** and the second sliding portion **34**, the intermediate portion **35** has at least one protruding portion **43** protruding outward in the radial direction, the protruding portions **43** are disposed between the ring proximal surface **86** of the first bearing **81** and the ring distal surface **85** of the second bearing **82** in the axial direction, and the shaft portion **30** has the passages **40** that communicates from the first sliding portion **33** to the second sliding portion **34**.

(48) In the medical device **10** configured as described above, the aspirate force can be applied to the distal side through the passages **40** disposed inside the bearing **80**. Therefore, an external object can be aspirated to the inside on the distal side with respect to the bearing **80**. Therefore, the medical device **10** can efficiently aspirate the object cut by the cutting portion **50**. In addition, since the shaft portion **30** is supported at the two positions of the first bearing **81** and the second bearing **82**, stable rotation can be maintained. In addition, the first bearing **81** and the second bearing **82** can support the protruding portions **43** by sandwiching the protruding portions **43** therebetween in the axial direction. Therefore, when the operator pushes and pulls the medical device **10**, a force in the axial direction applied to the shaft portion **30** is received by the first bearing **81** and/or the second bearing **82**. Therefore, the medical device **10** can maintain the stable rotation even when the shaft portion **30** receives a force in a radial direction or the axial direction.
(49) In addition, a distal end of the first bearing **81** is disposed away from the cutting portion **50** toward the proximal side. Accordingly, the external object is easily aspirated into the passages **40** from a portion between the cutting portion **50** and the distal end of the first bearing **81**. Therefore, the medical device **10** can efficiently aspirate the object cut by the cutting portion **50**. In addition, since the rotating cutting portion **50** is not in contact with the distal end of the first bearing **81**, the cutting portion **50** can smoothly rotate. In addition, it is possible to prevent the cutting portion **50** and the first bearing **81** from being damaged by contact.
(50) In addition, the outer tubular shaft **70** includes the support tube **72**, the support tube **72** includes the inner peripheral surface that holds the first bearing **81** and the second bearing **82**, the support tube **72** includes the stopper **77** on the distal side with respect to the first bearing **81**, and the stopper **77** protrudes inward in a radial direction and is contactable with a surface on a distal side of the first bearing **81**. Accordingly, the stopper **77** prevents the first bearing **81** from coming off the support tube **72** toward the distal side. Therefore, the medical device **10** can maintain the stable rotation.
(51) In addition, the first bearing **81** and/or the second bearing **82** have/has the outer peripheral surfaces **83** rougher than the inner peripheral surfaces **84**. Accordingly, the outer peripheral surfaces **83** of the first bearing **81** and the second bearing **82** are less likely to move with respect to contact targets, and can maintain stable positions.
(52) In addition, at least a surface of the first bearing **81** and/or the second bearing **82** that slides on the rotation structure portion **11** is made of the ceramic. Accordingly, it is possible to prevent wear of the first bearing **81** and the second bearing **82** that support the rotation structure portion **11** that rotates at a high speed.
(53) In addition, distal surfaces and/or proximal surfaces of the protruding portions **43** are flat surfaces. Accordingly, the distal surfaces and/or the proximal surfaces of the protruding portions **43** are in smooth contact with the first bearing **81** and/or the second bearing **82**. Therefore, it is possible to prevent wear of the sliding protruding portions **43** and the bearing **80**.
(54) In addition, the outer tubular shaft **70** includes the outer tubular main body **71** having an elongated tubular shape, and a distal end of the outer tubular main body **71** is attached to the second bearing **82**. Accordingly, the outer tubular main body **71** prevents the second bearing **82** from moving toward the proximal side. Therefore, the medical device **10** can maintain a stable rotation axis.
(55) In addition, the passages **40** are formed in a groove shape on the outer peripheral surfaces of the first sliding portion **33**, the intermediate portion **35**, and the second sliding portion **34**. Accordingly, the passages **40** can be easily formed by communicating with the first sliding portion **33**, the intermediate portion **35**, and the second sliding portion **34**. In addition, the passages **40** are easily connected to the outer peripheral surfaces on a distal side of the rotation structure portion **11** with respect the first sliding portion **33** and on a proximal side of the rotation structure portion **11** with respect to the second sliding portion **34**.
(56) In addition, the cutting portion **50** has the groove-shaped cutout portions **53** positioned along

the axis X, and the cutout portions **53** communicate with the passages **40**. Accordingly, the medical device **10** can aspirate the object cut by the cutting portion **50** from the cutout portions **53** into the passages **40** with high efficiency.

(57) This disclosure is not limited to the embodiment described above, and various modifications can be made by those skilled in the art within a scope of the technical idea of this disclosure. For example, the body lumen into which the medical device **10** is inserted is not limited to the blood vessel, and may be, for example, a vessel, a urinary duct, a bile duct, a fallopian tube, or a hepatic duct.

(58) In addition, the aspiration port **93** may be opened to an atmospheric pressure without being connected to the aspiration source **100**. Even with such a configuration, when a pressure in the body lumen is higher than the atmospheric pressure, the aspiration space **95** can aspirate the object in the body lumen.

(59) In addition, as in a modification shown in FIG. **6**, the drive shaft **20** may include a first layer **21** in which a plurality of wire rods are arranged around the axis X and interlocked in a spiral shape, and a spiral second layer **22** in which wire rods are sparsely wound around an outer peripheral surface of the first layer **21**. When the drive shaft **20** rotates, the rotating spiral second layer **22** can function as an Archimedean screw (screw pump). Accordingly, the second layer **22** can smoothly convey the object and the fluid inside the lumen **73** to the proximal side.

(60) In addition, the second bearing **82** may not be provided. In this case, when the rotation structure portion **11** moves in the proximal direction with respect to the accommodation portion **12**, the proximal end of the cutting portion **50** is in contact with the distal end of the outer tubular shaft **70**. Therefore, a distal surface of the outer tubular shaft **70** can receive the axial load.

(61) In addition, the drive shaft **20** may be directly interlocked with the cutting portion **50** without the shaft portion **30**. In this case, the shaft portion **30** can be fixed to the outer peripheral surface of the cutting portion **50** or the drive shaft **20**.

(62) In addition, central axes of the first sliding portion and the second sliding portion of the shaft portion **30** may be shifted from each other. Alternatively, a central axis of the drive shaft and a central axis of the shaft portion **30** may be shifted from each other. Alternatively, the central axis of the shaft portion **30** and a central axis of the cutting portion **50** may be shifted from each other. These methods enable the cutting portion **50** to precess, meaning the cutting portion can cut away the object by tracing a rotational path of movement larger than the outer dimension of the cutting portion. Therefore, the cutting portion **50** performing the precession can improve a cutting force.

(63) The detailed description above describes embodiments of a medical device and operational method representing examples of the medical device and operational method disclosed here. The invention is not limited, however, to the precise embodiments, modifications and variations described. Various changes, modifications and equivalents can be effected by one skilled in the art without departing from the spirit and scope of the invention as defined in the accompanying claims. It is expressly intended that all such changes, modifications and equivalents which fall within the scope of the claims are embraced by the claims.

REFERENCE SIGNS LIST

(64) **10** medical device **11** rotation structure portion **12** accommodation portion **20** drive shaft **30** shaft portion **31** proximal interlock portion **32** distal interlock portion **33** first sliding portion **34** second sliding portion **35** intermediate portion **40** passage **41** first rotational contact portion **42** second rotational contact portion **43** protruding portion **44** protruding distal surface **45** protruding proximal surface **50** cutting portion **53** cutout portion **70** outer tubular shaft **71** outer tubular main body **72** support tube **73** aspiration lumen **74** aspiration opening portion **75** proximal opening portion **76** support tube main body **77** stopper **80** bearing **81** first bearing **82** second bearing **83** outer peripheral surface **84** inner peripheral surface **85** ring-shaped distal surface **86** ring-shaped proximal surface W guide wire X axis

Claims

1. A medical device that cuts an object in a body lumen, the medical device comprising: a drive shaft that is rotatable, the drive shaft possessing a distal portion; a shaft portion that is connected to the distal portion of the drive shaft, the shaft portion possessing a distal portion; a cutting portion connected to the distal portion of the shaft portion or the distal portion of the drive shaft; an outer tubular shaft that rotatably accommodates the drive shaft; a first bearing and a second bearing that are accommodated in the outer tubular shaft and rotatably support the shaft portion, the first bearing possessing an inner peripheral surface and a proximal surface, the second bearing possessing an inner peripheral surface and a distal surface; the first bearing being ring-shaped, the second bearing being ring-shaped and being spaced proximally from the first bearing in an axial direction; the shaft portion including a first sliding portion slidably supported on the inner peripheral surface of the first bearing, a second sliding portion slidably supported on the inner peripheral surface of the second bearing, and an intermediate portion disposed between the first sliding portion and the second sliding portion; the intermediate portion including at least one protruding portion protruding outward in a radial direction, the protruding portion being disposed between the proximal surface of the first bearing and the distal surface of the second bearing in the axial direction; the shaft portion including a passage that communicates from the first sliding portion to the second sliding portion; and the outer tubular shaft including a support tube, the support tube possessing an inner peripheral surface that holds at least the first bearing, the support tube including a stopper that protrudes inward in a radial direction on a distal side with respect to the first bearing, and the stopper being contactable with a distal end surface of the first bearing.
2. The medical device according to claim 1, wherein the first bearing possesses a distal end, the distal end of the first bearing being proximally spaced from the cutting portion.
3. The medical device according to claim 1, wherein the first bearing has an outer peripheral surface rougher than the inner peripheral surface of the first bearing and/or the second bearing has an outer peripheral surface rougher than the inner peripheral surface of the second bearing.
4. The medical device according to claim 1, wherein at least a surface of the first bearing and/or the second bearing that slides on the shaft portion is made of a ceramic.
5. The medical device according to claim 1, wherein a distal surface and/or a proximal surface of the protruding portion is a flat surface.
6. The medical device according to claim 1, wherein the outer tubular shaft includes an outer tubular main body possessing an elongated tubular shape, and a distal end of the outer tubular main body is attached to the second bearing.
7. The medical device according to claim 1, wherein the passage is a groove-shaped passage on outer peripheral surfaces of the first sliding portion, the intermediate portion, and the second sliding portion.
8. The medical device according to claim 1, wherein the cutting portion has a groove-shaped cutout portion extending along the axial direction, and the cutout portion communicates with the passage.
9. A medical device positionable inside a body lumen to cut an object in the body lumen, the medical device comprising: an outer tubular shaft extending in axial direction and possessing an inner peripheral surface; a rotatable drive shaft positioned in the outer tubular shaft; a shaft portion connected to the drive shaft so that rotation of the drive shaft results in rotation of the shaft portion, the shaft portion possessing an outer peripheral surface; a ring-shaped first bearing and a ring-shaped second bearing that both rotatably support the shaft portion, the first bearing possessing an inner peripheral surface facing the outer peripheral surface of the shaft portion and an outer peripheral surface facing the inner peripheral surface of the outer tubular shaft, the second bearing possessing an inner peripheral surface facing the outer peripheral surface of the shaft portion and an outer peripheral surface facing the inner peripheral surface of the outer tubular shaft, the ring-

shaped first bearing possessing a proximal end surface and the ring-shaped second bearing possessing a distal end surface; a cutting portion connected to and rotatable together with the shaft portion or the drive shaft, the cutting portion being distal of the first and second bearings; the proximal end surface of the ring-shaped first bearing and the distal end surface of the ring-shaped second bearing facing one another and being spaced apart from one another in the axial direction; the shaft portion including an intermediate portion positioned between the proximal end surface of the ring-shaped first bearing and the distal end surface of the ring-shaped second bearing, the intermediate portion of the shaft portion possessing a distal end surface facing the proximal end surface of the ring-shaped first bearing, the intermediate portion of the shaft portion possessing a proximal end surface facing the distal end surface of the ring-shaped second bearing; a groove in the outer peripheral surface of the shaft portion to aspirate the object cut by the cutting portion, the groove possessing an open distal end and an open proximal end that are spaced apart from one another in the axial direction, the inner peripheral surface of the ring-shaped first bearing facing towards and overlying an axially extending first portion of the groove, the inner peripheral surface of the ring-shaped second bearing facing towards and overlying an axially extending second portion of the groove; and a gap between a distal end of the outer tubular shaft and a proximal end of the cutting portion, the gap being in communication with the passage to communicate the passage with an exterior of the medical device so that the object cut by the cutting portion and positioned exterior of the medical device can pass through the gap, can enter the passage and can be aspirated.
10. The medical device according to claim 9, wherein the outer tubular shaft comprises an outer tubular main body and a support tube connected to one another, the support tube possessing a distal portion at which is located a stopper that restricts the ring-shaped first bearing from moving distally with respect to the support tube, the outer tubular main body possessing a distal end, the ring-shaped second bearing being located between the distal end of the outer tubular main body and the intermediate portion of the shaft portion.
11. The medical device according to claim 9, wherein the outer tubular shaft comprises an outer tubular main body and a support tube connected to one another, the support tube possessing an inner peripheral surface in contact with the outer peripheral surface of the ring-shaped first bearing and the outer peripheral surface of the ring-shaped second bearing.
12. The medical device according to claim 9, wherein the shaft portion extends distally beyond the ring-shaped first bearing and proximally beyond the ring-shaped second bearing.
13. The medical device according to claim 9, wherein the outer tubular shaft includes a stopper that is configured to contact the ring-shaped first bearing to restrict the ring-shaped first bearing from moving distally with respect to the outer tubular shaft.
14. The medical device according to claim 9, wherein the outer peripheral surface of the first ring-shaped bearing is rougher than the inner peripheral surface of the ring-shaped first bearing and/or the outer peripheral surface of the ring-shaped second bearing is rougher than the inner peripheral surface of the ring-shaped second bearing.
15. The medical device according to claim 9, wherein the inner peripheral surface of the first ring-shaped bearing and/or the inner peripheral surface of the ring-shaped second bearing is made of a ceramic.
16. The medical device according to claim 9, wherein an outer peripheral surface of the cutting portion includes a groove-shaped cutout portion extending along the axial direction, the cutout portion being in communication with the groove in the outer peripheral surface of the shaft portion.
17. A medical device configured to be positioned in a body lumen to cut an object in the body lumen, the medical device comprising: a drive shaft that is rotatable, the drive shaft possessing a distal portion; a shaft portion that is connected to the distal portion of the drive shaft, the shaft portion possessing a distal portion; a cutting portion connected to the distal portion of the shaft portion or the distal portion of the drive shaft; an outer tubular shaft that rotatably accommodates

the drive shaft; a first bearing and a second bearing that are accommodated in the outer tubular shaft and rotatably support the shaft portion, the first bearing possessing an inner peripheral surface and a proximal surface, the second bearing possessing an inner peripheral surface and a distal surface; the first bearing being ring-shaped, the second bearing being ring-shaped and being spaced proximally from the first bearing in an axial direction; the shaft portion including a first sliding portion slidably supported on the inner peripheral surface of the first bearing, a second sliding portion slidably supported on the inner peripheral surface of the second bearing, and an intermediate portion disposed between the first sliding portion and the second sliding portion; the intermediate portion including at least one protruding portion protruding outward in a radial direction, the protruding portion being disposed between the proximal surface of the first bearing and the distal surface of the second bearing in the axial direction; the shaft portion including a passage that extends in an axial direction and has a radial dimension, the passage providing communication between the first and second sliding portions; the passage including a first passage portion and a second passage portion, the radial dimension of the first passage portion being less than the radial dimension of the second passage portion; and wherein the first passage portion axially overlaps one of the first and second bearing, and the second passage portion axially overlaps the intermediate portion at which is located the at least one protruding portion.
18. The medical device according to claim 17, wherein the first passage portion is located on a distal side of the second passage portion.
19. The medical device according to claim 17, wherein the second passage portion is located on a distal side of the first passage portion.