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Medical device and procedure method

Abstract

A medical device insertable into a blood vessel for effectively removing an object flowing in a biological lumen while reducing the burden on the living body includes an elongated shaft portion, and an expansion portion which is an elastically deformable cylindrical body having a plurality of gaps and in which a proximal portion or a distal portion of the cylindrical body is interlocked with the shaft portion. The expansion portion has a ring-shaped or annular bent portion which protrudes toward a proximal side position radially outside the expansion portion in a bent state of being bent along an axial direction, and an axial length of a second portion from the bent portion to a proximal end of the expansion portion is shorter than an axial length of a first portion from the bent portion to the distal end of the expansion portion.

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Background/Summary

CROSS-REFERENCES TO RELATED APPLICATIONS (1) This application is a continuation of U.S. patent application Ser. No. 17/382,438, filed Jul. 22, 2021, which is a continuation of U.S. patent application Ser. No. 16/282,436, filed Feb. 22, 2019, issued as U.S. Pat. No. 11,096,705 on Aug. 24, 2021, which is a continuation of International Application No. PCT/JP2017/030309 filed on Aug. 24, 2017, which claims priority to Japanese Application No. 2016-166617 filed on Aug. 29, 2016, the entire content of all four of which is incorporated herein by reference.

TECHNICAL FIELD
(1) The present invention generally relates to a medical device to be inserted into a biological lumen and a procedure or method using a medical device.
BACKGROUND ART
(2) A thrombus partially clogging a vein may, for example, cause pain and swelling. For the treatment, there is a method of percutaneously inserting a device and physically breaking and removing the thrombus. In such a treatment, if the thrombus completely or partially separated from the blood vessel wall travels in the blood stream and reaches the lungs, there is a risk of pulmonary embolism. Accordingly, when performing such a treatment, a thrombolytic agent may be used before and after the treatment and/or during the treatment, or the separated thrombus may be aspirated and removed as much as possible during the treatment. However, even though such a procedure is taken, there is a possibility that the separated thrombus having a chronically problematic size may reach the lungs and the like.
(3) In order to avoid such pulmonary embolism, there is a method of indwelling a filter for collecting the thrombus flowing in the blood vessel in the blood vessel. For example, U.S. Reissue Pat. No. 42,983 discloses a device in which a filter in which linear bodies are knitted into a tubular

shape is provided at a distal portion of a long extending wire. The filter pushes a proximal portion into an inner side of a distal portion and turns it back in an axial direction, so that the doubly contacted linear bodies can be formed into a cup shape as a whole.

SUMMARY

(4) When a filter is disposed in the blood vessel, the thrombus is pushed and sticks to the filter by the fast blood stream. When the thrombus sticks to the filter, the flow of the blood is restricted, which is undesirable.

(5) The medical device and procedure or method disclosed here is able to effectively collect an object flowing in the biological lumen.

(6) The disclosed medical device to be inserted into a biological lumen for collecting an object in the biological lumen includes an elongated shaft possessing a distal end portion, and an expansion portion that includes an elastically deformable body, the elastically deformable body possessing a proximal portion and a distal portion, with the elastically deformable body including a plurality of through gaps that pass through the elastically deformable body. The proximal portion of the elastically deformable body is interlocked with a proximal side interlock portion, and the proximal side interlock portion includes a lumen extending throughout the proximal side interlock portion. The proximal side interlock portion is fixed to the distal end portion of the elongated shaft so that the elongated shaft and the proximal side interlock portion move together as a unit whereby movement of the elongated shaft results in movement of the proximal side interlock portion, and the elongated shaft extending away from the elastically deformable body in a proximal direction. The expansion portion includes, when the expansion portion is in a bent state, a radially outwardly located annular-shaped portion that is bent toward the proximal direction, and the expansion portion is changeable between the bent state and an extended state. The expansion portion in the bent state includes a first portion and a second portion, with the second portion being located inside the first portion when the expansion portion is in the bent state. The second portion moves in the proximal direction with respect to the first portion and is pulled out from the inside of the first portion when the expansion portion changes from the bent state to the extended state.

(7) A procedure for collecting an object generated in a lesion area in a biological lumen includes: inserting a sheath in which the expansion portion is accommodated in a contracted state into the biological lumen; pushing out the expansion portion from the sheath on a downstream side from the lesion area of the biological lumen, expanding the expansion portion by an elastic force of the expansion portion, and indwelling the expansion portion in a biological lumen; shifting the expansion portion from the contracted state to a bent state; and collecting the object in the biological lumen by the expansion portion.

(8) In the medical device and the procedure as described above, when the expansion portion is in the bent state, the first portion and the second portion hardly contact each other so that a space is formed between the first portion and the second portion. Accordingly, the gap of the expansion portion can be appropriately maintained, and the object can be effectively collected by the expansion portion by suppressing the clogging.

(9) According to another aspect, a medical device to be inserted into a biological lumen for collecting an object in the biological lumen comprises an elongated shaft possessing a distal end portion and an expansion portion that includes an elastically deformable body, with the elastically deformable body possessing a proximal portion and a distal portion, and the elastically deformable body including a plurality of through gaps that pass through the elastically deformable body. The proximal portion of the elastically deformable body is interlocked with a proximal side interlock portion, and the distal end portion of the elongated shaft is fixed in place relative to the elastically deformable body by way of the proximal side interlock portion so that the elongated shaft and the proximal side interlock portion move together as a unit whereby movement of the elongated shaft results in movement of the proximal side interlock portion. The elongated shaft extends away from the elastically deformable body in a proximal direction. The expansion portion includes, when the

expansion portion is in a bent state, a radially outwardly located annular-shaped portion that is bent toward the proximal direction. The expansion portion is changeable between the bent state and an extended state, with the expansion portion in the bent state including a first portion and a second portion, and the second portion being located inside the first portion when the expansion portion is in the bent state. The second portion moves in the proximal direction with respect to the first portion and is pulled out from the inside of the first portion when the expansion portion changes from the bent state to the extended state. The elongated shaft is the only elongated shaft that is fixed in place relative to the elastically deformable body and that also extends away from the elastically deformable body in the proximal direction.

(10) In accordance with a further aspect, a medical device to be inserted into a biological lumen for collecting an object in the biological lumen comprises: an elongated shaft possessing a distal end portion; and an expansion portion that includes an elastically deformable body having a plurality of through gaps that pass through the elastically deformable body, with the expansion portion possessing a proximal portion and a distal portion. The distal end portion of the elongated shaft is fixed to the proximal portion of the expansion portion and extends away from the expansion portion in a proximal direction. The expansion portion is changeable from an extended state to a bent state by a restoring force of the expansion portion and without application of any forces external to the expansion portion so that as the expansion portion changes form the extended state to the bent state, the expansion portion expands radially outwardly and an axial distance between the distal end portion of the expansion portion and the proximal end portion of the expansion portion is reduced. The expansion portion includes, when the expansion portion is in the bent state, a radially outwardly located annular-shaped portion that is bent toward the proximal direction, and the expansion portion in the bent state includes a first portion and a second portion, with the second portion being located inside the first portion when the expansion portion is in the bent state. The expansion portion is changeable from the bent state to an extended state, and the second portion moves in the proximal direction with respect to the first portion and is pulled out from the inside of the first portion when the expansion portion changes from the bent state to the extended state.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) FIG. **1** is a plane view showing a medical device according to an embodiment.

(2) FIG. **2** is a plane view showing a state in which an expansion tool, a pressing shaft, and a sheath of the medical device according to the embodiment are combined.

(3) FIGS. **3**(A) and **3**(B) are plane views showing an expansion portion of the expansion tool, with FIG. **3**(A) showing an expanded state of the expansion portion, and FIG. **3**(B) showing a contracted state of the expansion portion.

(4) FIG. **4** is a cross-sectional view showing the expansion portion in a bent state.

(5) FIG. **5** is a cross-sectional view showing the expansion portion in a boundary state.

(6) FIG. **6** is a plane view of linear bodies in the boundary state seen from an axial direction.

(7) FIG. **7** is a cross-sectional view showing the expansion portion in an extended state.

(8) FIG. **8** is a plane view showing an aspiration device.

(9) FIGS. **9**(A) and **9**(B) are cross-sectional views showing a state in a blood vessel, with FIG. **9**(A) showing a state when the medical device is inserted into the blood vessel, and FIG. **9**(B) showing a state when the expansion portion and an auxiliary expansion portion are expanded in the blood vessel.

(10) FIGS. **10**(A) and **10**(B) are cross-sectional views showing a state in the blood vessel, with FIG. **10**(A) showing a state in which the expansion portion is indwelled in the blood vessel in the bent state, and FIG. **10**(B) showing a state in which the aspiration device is inserted into the blood

vessel.
(11) FIG. **11** is a cross-sectional view showing a state in which the expansion portion is indwelled in the blood vessel in the bent state.
(12) FIG. **12** is a schematic view showing the expansion tool in the blood vessel.
(13) FIGS. **13**(A) and **13**(B) are cross-sectional views showing a state in the blood vessel, with FIG. **13**(A) showing an expanded state of a breaking member of the aspiration device, and FIG. **13**(B) showing a state when a thrombus is broken by the expanded breaking member.
(14) FIG. **14** is a cross-sectional view showing a state in which the broken thrombus is collected by the expansion portion.
(15) FIG. **15** is a cross-sectional view showing a state in which the expansion portion collecting the broken thrombus is deformed.
(16) FIGS. **16**(A) and **16**(B) are cross-sectional views showing a state in the blood vessel, with FIG. **16**(A) showing a state in which the breaking member is accommodated in the sheath, and FIG. **16**(B) showing a state in which the expansion portion and the auxiliary expansion portion are accommodated in the sheath.
(17) FIG. **17** is a flowchart for describing a procedure using the medical device.
(18) FIG. **18** is a cross-sectional view showing a modification example of the medical device according to the embodiment.
(19) FIG. **19** is a cross-sectional view showing another modification example of the medical device according to the embodiment.
(20) FIG. **20** is a cross-sectional view showing another using method of the medical device according to the embodiment.

DETAILED DESCRIPTION

(21) Set forth below with reference to the accompanying drawings is a detailed description of embodiments of a medical device and procedure/method representing examples of the inventive medical device and procedure/method disclosed here. The dimensions or scales on the drawings may be exaggerated or different from actuality/reality for convenience of description and illustration.
(22) A medical device **1** according to one embodiment is used for partially suppressing the flow in the blood vessel in order to aspirate and remove an object such as a thrombus, plaque, a calcified lesion, and the like in the blood vessel. In the description below, a side of the device inserted into the blood vessel is referred to as a “distal side” or “distal end”, and a hand-side to be operated is referred to as a “proximal side” or “proximal end”. Moreover, the object to be removed is not necessarily limited to a thrombus, plaque, or a calcified lesion, and may correspond to any object that can exist in the biological lumen. Moreover, in the present specification, a source side of the blood flow in the blood vessel is referred to as an “upstream side”, and a side where the blood flow is heading is referred to as “downstream side”.
(23) As shown in FIGS. **1** and **2**, the medical device **1** according to one embodiment representing an example of the disclosed medical device includes an expansion tool **10** for restricting the blood flow in the blood vessel, a sheath **30** configured to accommodate the expansion tool **10**, and a pressing shaft **40** used for pushing out the expansion tool **10** from the sheath **30**.
(24) As shown in FIGS. **3** and **4**, the expansion tool **10** includes an expansion portion **20** which is a mesh-like cylindrical body having a plurality of gaps **21**A that pass through the expansion portion **20**, an elongated shaft portion **24** which is interlocked with the expansion portion **20** so that the two move together as a unit, and an auxiliary expansion portion **80** which is provided on the distal side from the expansion portion **20**.
(25) As shown in FIGS. **1**, **3**(A) and **3**(B), the shaft portion **24** is an elongated shaft or elongated wire extending from a proximal end (operated or held by the user's hand) to the expansion portion **20**. A distal end portion of the shaft portion **24** is connected to a proximal side interlock portion **60** of the expansion portion **20**.

(26) The constituent material of which the shaft portion **24** is fabricated is not particularly limited, but, for example, stainless steel, shape memory alloy, and the like can be suitably used.
(27) As shown in FIGS. **3**(A) and **3**(B), the expansion portion **20** includes a plurality of flexibly and elastically deformable linear bodies **21** braided into a mesh shape so as to form a cylindrical body, a distal side interlock portion **50**, and the proximal side interlock portion **60** interlocked with the shaft portion **24**. The expansion portion **20** may be formed by braiding so that the gaps **21**A exist between the plurality of linear bodies **21**.
(28) As shown in FIG. **4**, the distal side interlock portion **50** includes an inner tube **51** located on the inner side of the linear bodies **21** and an outer tube **52** located on the outer side of the linear bodies **21**. The distal end portion of the linear bodies **21** and a proximal end portion of an interlock shaft **87** are interposed and fixed between the inner tube **51** and the outer tube **52**. The inner surface side of the inner tube **51** is a guide wire lumen **54** into which a guide wire can be inserted. The interlock shaft **87** is a shaft which interlocks the expansion portion **20** with the auxiliary expansion portion **80**.
(29) The proximal side interlock portion **60** includes an inner tube **61** located on the inner side of the linear bodies **21** and an outer tube **62** located on the outer side of the inner tube **61**. The proximal end portion of the linear bodies **21** and the distal end portion of the shaft portion **24** are interposed and fixed between the inner tube **61** and the outer tube **62**. Therefore, the proximal side interlock portion **60** is movable in the axial direction with the shaft portion **24**. The inner surface side of the inner tube **61** is a guide wire lumen **64** into which the guide wire can be inserted.
(30) In a natural state in which an external force is not applied, the expansion portion **20** is in a bent state (see FIG. **3**(A)) of being bent in the axial direction while being expanded in outer diameter by the elastic force (restoring force) of the linear bodies **21**. When the expansion portion **20** is in the bent state, the proximal side interlock portion **60** and the distal side interlock portion **50** approach each other. Moreover, the expansion portion **20** is accommodated in the sheath **30** (see FIGS. **1** and **2**) while the expansion portion **20** is in a contracted state (see FIG. **3**(B)) in which the expansion portion **20** is elastically deformed and the outer diameter of the expansion portion **20** is reduced. When the expansion portion **20** is in the contracted state, the proximal side interlock portion **60** and the distal side interlock portion **50** are separated from each other. The outer diameter of the braided expansion portion **20** can be changed by changing the distance between the proximal side interlock portion **60** and the distal side interlock portion **50**.
(31) The expansion portion **20** is indwelled in the blood vessel in a shape close to the natural state. In particular, the expansion portion **20** is indwelled in the blood vessel wall in a state of being contracted to a certain degree in the radial direction from the natural state so as to generate pressing force against the blood vessel wall by the expansion force of the expansion portion (see FIG. **11**).
(32) The expansion portion **20** includes a first portion **22** interlocked with the distal side interlock portion **50** and a second portion **26** interlocked with the proximal side interlock portion **60**. In the bent state, the second portion **26** enters the inside of the first portion **22** (i.e., the first portion **22** overlies the second portion **26**). That is, the expansion portion **20** is shaped in advance so as to have such a shape. The shaping can be carried out, for example, by holding it in a predetermined shape, accommodating it in a mold, and heating it. The inside of the expansion portion **20** is a region surrounded by the inner surface of the expansion portion **20**. The inner surface of the expansion portion **20** means the inner surface of the cylindrical body formed by braiding the linear bodies **21**. At this time, as shown in FIGS. **4** and **5**, the linear bodies **21** located on the distal side of the expansion portion **20** form the concave-shaped first portion **22** which opens to the proximal side. The linear bodies **21** located on the proximal side of the expansion portion **20** form the concave-shaped second portion **26**, and the concave shape opens to the proximal side on the inner surface side of the first portion **22**. The first portion **22** and the second portion **26** are interlocked with each other by a bent portion **25** constituting an end portion on the proximal side of the expansion portion **20**. Thereby, the second portion **26** on the proximal side of the expansion portion **20** is located on

the inside of the first portion **22** on the distal side, and the expansion portion **20** is in the bent state of being bent in the axial direction. The second portion **26** has a concave shape which opens to the proximal side, and forms an inner space **29** on the inner side of the concave shape. The inner space **29** is a ring-shaped or annular space located on the distal side from the bent portion **25**. In the bent state, the first portion **22** and the second portion **26** are separated from each other without coming into contact with each other. Accordingly, a space is formed between the first portion **22** and the second portion **26**.

(33) In the bent state, the first portion **22** and the second portion **26** have different shapes. Accordingly, the first portion **22** and the second portion **26** are able to be separated from each other without coming into contact with each other. Accordingly, a space is formed between the first portion **22** and the second portion **26**. That is, as shown in FIG. **4**, in the bent portion of the expansion portion, one part of the linear bodies **21** constituting the first portion **22** of the expansion portion axially overlaps another part of the linear bodies **21** constituting the second portion **26** of the expansion portion, and the two axially overlapping parts of the linear bodies are radially spaced from one another. Moreover, in the bent state, the axial length of the second portion **26** is shorter than the axial length of the first portion **22**. Accordingly, a space is easily formed between the first portion **22** and the second portion **26**. FIG. **3**(A) and FIG. **4** show that the expansion portion **20** in the bent state includes a radially outwardly located annular portion defined by spaced apart parts of the first portion **22** and the second portion **26** that face one another, and this radially outwardly located annular portion is bent in the axial direction toward the proximal direction. The expansion portion **20** is thus configured to be positioned in the bent state in which a portion of the expansion portion **20** is the bent portion that is bent back upon itself as a result of parts or opposite ends of the expansion portion **20** that are spaced apart from one another in the axial direction being relatively moved towards one another in the axial direction.

(34) It is preferable that the first portion **22** and the second portion **26** already have different shapes in a state before the shaping processing. Accordingly, by the shaping processing, the first portion **22** and the second portion **26** can have different shapes with high accuracy.

(35) In the bent state, the proximal side interlock portion **60** is located on the proximal side from the bent portion **25**. That is, the proximal side interlock portion **60** is not located in the inner space **29**. Accordingly, the expansion portion **20** extends to the proximal side from the bent portion **25**. Accordingly, an area of the expansion portion **20** functioning as a filter can be increased. The proximal side interlock portion **60** may be located on the distal side from the bent portion **25**.

(36) In a cross section of the expansion portion **20** along the axial direction, a curvature radius r**1** of a portion convex toward the distal side of the first portion **22** is larger than a curvature radius r**2** of a portion convex toward the distal side of the second portion **26**. Accordingly, the second portion **26** tends to be shorter than the first portion **22** in the axial direction. Accordingly, the first portion **22** and the second portion **26** are separated from each other without coming into contact with each other, and a space between the first portion **22** and the second portion **26** is secured. The curvature radius r**1** is appropriately set, but is, for example, 1 to 100 cm, preferably 4 to 30 cm, and more preferably 5 to 20 cm. The curvature radius r**2** is appropriately set, but is, for example, 0.01 to 10 cm, preferably 0.05 to 8 cm, and more preferably 0.1 to 4 cm. The curvature radius r**1** may be equal to or less than the curvature radius r**2**.

(37) In the bent state, the bent portion **25** is located on the proximal side of the first portion **22** and the second portion **26**. The bent portion **25** interlocks the first portion **22** with the second portion **26**. In the bent state, the bent portion **25** is a ring-shaped portion which protrudes toward the proximal side and is the radially outermost part of the expansion portion **20**. The gaps **21**A of the bent portion **25** are narrower or smaller than the gaps in the first portion **22** and the second portion **26**. Accordingly, the linear bodies **21** of the bent portion **25** are dense, and the repulsive force of the linear bodies **21** is high in the bent portion **25**, so that it is strongly fixed to or pressed against the blood vessel. Accordingly, the position of the expansion portion **20** is stabilized, and the expansion

portion **20** can be easily bent.
(38) In the bent state, a curvature radius r**3** of a portion convex toward the proximal side of the bent portion **25** is appropriately set, but is, for example, 0.001 to 5 cm, preferably 0.001 to 3 cm, and more preferably 0.001 to 1 cm.
(39) When the blood flowing in the blood vessel reaches the expansion portion **20** in a state in which the expansion portion **20** is indwelled in the blood vessel and the blood is flowing from the proximal side, the blood enters the inside of the expansion portion **20** from a first flow path S**1** passing through the gaps **21**A of the second portion **26** or a second flow path S**2** passing through the gaps **21**A of the bent portion **25**. In the bent state, the inside of the expansion portion **20** is interposed between the first portion **22** and the second portion **26**. When the bent portion **25** is bent, the linear bodies **21** are dense. Accordingly, the gaps **21**A of the bent portion **25** are narrower than the gaps **21**A of the second portion **26** and the first portion **22**. The blood entering the inside of the expansion portion **20** from the first flow path S**1** or the second flow path S**2** flows a third flow path S**3** between the first portion **22** and the second portion **26** in a distal direction. Thereafter, the blood passes through the expansion portion **20** to the distal side by a fourth flow path S**4** passing through the gaps **21**A of the first portion **22**.
(40) In the bent state, the distance between the proximal side interlock portion **60** and the distal side interlock portion **50** can be appropriately set. The distance between the proximal side interlock portion **60** and the distal side interlock portion **50** may vary depending on the applied inner diameter of the blood vessel. Moreover, in the middle of the procedure, the distance between the proximal side interlock portion **60** and the distal side interlock portion **50** may be changed.
(41) When the proximal side interlock portion **60** and the distal side interlock portion **50** are gradually separated from each other from the bent state, as shown in FIG. **5**, at some time, the second portion **26** is no longer located on the inside of the first portion **22**. The state of the expansion portion **20** at this time is a boundary state. When the proximal side interlock portion **60** and the distal side interlock portion **50** are further separated from each other from the boundary state, as shown in FIG. **7**, the entire second portion **26** is in an extended state of being located on the proximal side of the first portion **22**. When the proximal side interlock portion **60** and the distal side interlock portion **50** are further separated from each other from the extended state, as shown in FIG. **3**(B), the expansion portion **20** is in a contracted state. The contracted state is a state in which the expansion portion **20** can be accommodated in the sheath **30**. In the bent state, boundary state, extended state, and contracted state, the axial length of the second portion **26** is shorter than the axial length of the first portion **22**. The axial length of the second portion **26** may be equal to or longer than the axial length of the first portion **22** in any of the states.
(42) In the boundary state, as shown in FIGS. **5** and **6**, the linear bodies **21** have inflection points P in the second portion **26** as seen from the axial direction of the expansion portion **20**. That is, the bending direction of the linear bodies **21** is reversed at the inflection points P as a boundary. The linear bodies **21** are shaped to have the inflection points P. The inflection points of the linear bodies **21** are not provided in the first portion **22**.
(43) In the boundary state, when the linear bodies **21** have the inflection points P in the second portion **26**, it is easier to turn back the expansion portion **20** using the inflection points P. Accordingly, it is easy to bring the expansion portion **20** in the extended state or the boundary state into the bent state.
(44) When the expansion portion **20** is in the extended state, if the shaft portion **24** is moved to the distal side, as shown in FIG. **4**, the proximal side interlock portion **60** is pushed into the distal side or toward the distal direction by the shaft portion **24**. Thereby, the proximal side interlock portion **60** approaches the distal side interlock portion **50**, so that the expansion portion **20** can be in the bent state of being bent in the axial direction. At this time, the fixing force of the auxiliary expansion portion **80** against the blood vessel is larger than the pushing force at the shaft portion **24**. Thereby, when the proximal side interlock portion **60** is moved to the distal side, the proximal

side interlock portion **60** can approach the distal side interlock portion **50** without the distal side interlock portion **50** being moved.

(45) In the extended state, as shown in FIG. **7**, the shapes of the second portion **26** and the first portion **22** are non-planar symmetric with respect to an axially orthogonal cross section (i.e., with respect to a cross-section taken along a plane that contains the central axis of the expansion portion and that is perpendicular to the plane of the paper). The second portion **26** and the first portion **22** are non-planar symmetric in that the cross-section of the first portion **22** is larger than the cross-section of the second portion **26**. Note that, symmetry herein is related to a shape of the cylindrical body of the expansion portion **20** and also the size, but is not related to the disposition place of the plurality of linear bodies **21** constituting the expansion portion **20**. If the shapes of the second portion **26** and the first portion **22** are planar symmetric (or substantially planar symmetric) with respect to the axially orthogonal cross section, the second portion **26** and the first portion **22** are likely to contact each other in the bent state. On the other hand, if the shapes of the second portion **26** and the first portion **22** are non-planar symmetric, the second portion **26** and the first portion **22** hardly contact each other. Thereby, when it obtains the bent state, an interval or space between the first portion **22** and the second portion **26** can be secured widely and reliably.

(46) Moreover, in the extended state, a length from a portion **27** having a maximum outer diameter of the expansion portion **20** to the distal end of the expansion portion **20** is longer than a length from the portion **27** having the maximum outer diameter of the expansion portion **20** to the proximal end of the expansion portion **20**. Accordingly, the axial length of the second portion **26** is shorter than the axial length of the first portion **22**. Therefore, by obtaining the bent state, a space is easily formed between the first portion **22** and the second portion **26**. Thereby, the interval between the first portion **22** and the second portion **26** can be secured widely and reliably.

(47) Moreover, in the extended state, a maximum outer diameter of the second portion **26** is larger than a maximum outer diameter of the first portion **22**. That is, the portion **27** having the largest outer diameter of the expansion portion **20** in the extended state is in the second portion **26**. Accordingly, when the expansion portion **20** is in the bent state, the interval between the first portion **22** and the second portion **26** can be secured widely and reliably.

(48) Moreover, in the extended state, a maximum inclination angle of the second portion **26** of the expansion portion **20** with respect to the axial direction is larger than the maximum inclination angle of the first portion **22** with respect to the axial direction. Accordingly, the second portion **26** tends to be bent in the axial direction and to be located in the inside of the first portion **22**. Furthermore, since the first portion **22** and the second portion **26** have different shapes by obtaining the bent state, a space is easily formed between the first portion **22** and the second portion **26**. Accordingly, the interval between the first portion **22** and the second portion **26** can be secured widely and reliably.

(49) When the expansion portion **20** is in the bent state, when an interval between the first portion **22** and the second portion **26** can be secured widely and reliably, the first portion **22** and the second portion **26** do not contact each other. Thereby, the gaps **21**A appropriate for the expansion portion **20** are secured. When the first portion **22** and the second portion **26** contact each other, the gaps **21**A of the first portion **22** and the gaps **21**A of the second portion **26** can directly communicate each other, so that the range where the appropriate gaps **21**A are provided will be reduced. This will reduce the range where the expansion portion **20** appropriately functions as a filter, so that clogging can easily occur. On the other hand, as the range where the appropriate gaps **21**A are provided is increased, the range where the expansion portion **20** appropriately functions as a filter is increased, so that clogging will be less likely to occur.

(50) The shape of the second portion **26** in the extended state is different from the shape of the second portion **26** in the bent state, and is non-planar symmetric with respect to a cross section (axially orthogonal cross section) orthogonal to the central axis of the expansion portion **20** (i.e., with respect to a cross-section taken along a plane that contains the central axis of the expansion

portion and that is perpendicular to the plane of the paper). The second portion **26** and the first portion **22** are non-planar symmetric in that, for example, the cross-section of the first portion **22** is larger than the cross-section of the second portion **26**. That is, the second portion **26** does not have a planar symmetric shape before and after being pulled out when being pulled out from the first portion **22** in the bent state and the front and the rear is reversed. Accordingly, by turning back the second portion **26**, it is easy to obtain the bent state so that the first portion **22** and the second portion **26** do not contact each other. The non-planar symmetric arrangement helps make it easier for the expansion portion to turn back as illustrated in FIG. **4**.

(51) The portion **27** having the maximum outer diameter of the expansion portion **20** in the extended state is different from a portion having a maximum outer diameter in the bent state. Comparing FIG. **7** showing the extended state of the expansion portion **20** and FIG. **4** depicting the bent state of the expansion portion **20**, the portion of the expansion portion **20** having the maximum outer diameter in the extended state is radially inward of the portion of the expansion portion **20** having the maximum outer diameter in the bent state.

(52) The number of linear bodies **21** is, for example, but not limited to, **4** to **72**. Moreover, the condition of the braiding of the linear bodies **21** is not particularly limited. An outer diameter of the linear bodies **21** can be appropriately selected depending on the material of the linear bodies **21** and the use of the expansion portion **20**, which is, for example, 20 to 300 μm.

(53) The constituent material from which the linear bodies **21** are fabricated is preferably a material having flexibility. For example, a shape memory alloy to which a shape memory effect and super elasticity is imparted by heating treatment, stainless, tantalum (Ta), titanium (Ti), silver (Pt), gold (Au), tungsten (W), polyolefin such as polyethylene and polypropylene, polyester such as polyamide and polyethylene terephthalate, fluorine-based polymer such as tetrafluoroethylene-ethylene copolymer (ETFE), polyether ether ketone (PEEK), polyimide, and the like can be suitably used. As a shape memory alloy, Ni—Ti-based alloys, Cu—Al—Ni-based alloys, Cu—Zn—Al-based alloys, or a combination of these alloys is preferably used. A structure in which a plurality of materials are combined includes, for example, a structure for imparting a radiopacity that a core wire made of Pt is covered with Ni—Ti alloy, or the core wire made of Ni—Ti alloy is subjected to gold plating.

(54) The outer diameter of the outer tubes **52** and **62** is not particularly limited. For example, the outer diameter may be 0.3 to 3.0 mm. The inner diameter of the inner tubes **51** and **61** is not particularly limited. For example, the inner diameter may be 0.1 to 2.5 mm.

(55) The constituent material from which the inner tubes **51** and **61** and the outer tubes **52** and **62** are fabricated is not particularly limited. For example, stainless steel and the like can be suitably used.

(56) The maximum outer diameter of the expansion portion **20** in the bent state can be appropriately selected according to the inner diameter of the blood vessel to be treated. For example, the maximum outer diameter may be 1 to 40 mm. The outer diameter of the expansion portion **20** in the contracted state can be appropriately selected according to the inner diameter of the blood vessel to be treated. For example, the outer diameter may be 0.3 to 4.0 mm. The length of the expansion portion **20** in the bent state in the axial direction can be appropriately selected according to the blood vessel to be treated. For example, the length may be 20 to 150 mm.

(57) As shown in FIGS. **3**(A) and **3**(B), the auxiliary expansion portion **80** has a plurality of wire portions **81** and a fixing portion **82** for fixing the plurality of wire portions **81** (proximal end portions of the wires **81**) to the interlock shaft **87**. The auxiliary expansion portion **80** can exhibit the strong fixing force in the blood vessel, and collect the object in the blood vessel. In a natural state in which the external force is not applied, the auxiliary expansion portion **80** is in the bent state in which the diameter of the auxiliary expansion portion **80** is expanded by the elastic force (restoring force) of the wire portions **81**. In the bent state, the wire portions **81** expand to the outside in the radial direction from the center of the expansion toward the distal side. Moreover, the

auxiliary expansion portion **80** is accommodated in the sheath **30** (see FIGS. **1** and **2**), so that the auxiliary expansion portion **80** is in the contracted state in which the auxiliary expansion portion **80** is elastically deformed and the outer diameter of the auxiliary expansion portion **80** is reduced. The auxiliary expansion portion **80** and the distal side interlock portion **50** are interlocked with each other by the interlock shaft **87**. Since the interlock shaft **87** is flexible, the expansion portion **20** and the auxiliary expansion portion **80** become easy to move independently. Accordingly, the expansion portion **20** and the auxiliary expansion portion **80** easily follow the shape of the blood vessel.

(58) As shown in FIGS. **1** and **2**, the sheath **30** includes a tubular body **31** (tube), a hub **32**, and an anti-kink protector **33**. The tubular body **31** includes a lumen **34** capable of accommodating the expansion tool **10**. The distal end portion of the tubular e body **31** is curved. The tubular body **31** has a tubular body opening portion **36** at an end portion on the distal side. The tubular body opening portion **36** is inclined with respect to the central axis of the tubular body **31**. Accordingly, the tubular body opening portion **36** has an opening area wider than the cross-sectional area of the lumen of the tubular body **31**. That is, the opening area of the tubular body opening portion **36** is greater than the cross-sectional area of the lumen of the tubular body **31** at a cross-section perpendicular to the axis of the tubular body **31**. Accordingly, the tubular body opening portion **36** can aspirate a wide range. The tubular body opening portion **36** faces toward the distal side since the tubular body **31** is curved. The hub **32** is fixed to the end portion on the proximal side of the tubular body **31**. The hub **32** includes a hub opening portion **35** communicating with the lumen **34**. The hub opening portion **35** can be interlocked with a Y connector **190** including a side tube **191**. By interlocking with the Y connector **190**, it is possible to communicate with a syringe **180** which generates negative pressure in a state where an elongated device (for example, shaft portion **24**) is inserted into the hub opening portion **35**. Moreover, by connecting the syringe **180** to the side tube **191** of the Y connector **190**, it is possible to inject the thrombolytic agent into the lumen of the tubular body **31** from the syringe **180**. The anti-kink protector **33** is a flexible member covering the interlocking portion of the tubular body **31** and the hub **32**. The anti-kink protector **33** suppresses kinking of the tubular body **31**.

(59) The constituent material from which the tubular body **31** is fabricated is not particularly limited, but, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer, and ethylene-vinyl acetate copolymer, polyvinyl chloride, polystyrene, polyamide, and polyimide, and a combination thereof may be suitably used. The tubular body **31** may be formed of a plurality of materials, or a reinforcing member such as a wire may be embedded.

(60) The pressing shaft **40** is a tubular body which can be accommodated in the lumen **34** of the sheath **30**. The pressing shaft **40** has a t lumen **41** into which the shaft portion **24** of the expansion tool **10** can be inserted. The inner diameter of the lumen **41** is smaller than the outer diameter of the proximal side interlock portion **60** of the expansion tool **10**. Accordingly, the proximal side interlock portion **60** cannot enter the lumen **41**. Therefore, the proximal side interlock portion **60** can press against the distal side or distal end of the pressing shaft **40**. Even without the pressing shaft **40**, by pushing the shaft portion **24** itself or pulling the sheath **30** to the proximal side, the expansion portion **20** and the auxiliary expansion portion **80** can be pushed out from the sheath **30**.

(61) Next, an aspiration device **100** to be inserted into the blood vessel for removing a thrombus will be described.

(62) As shown in FIG. **8**, the aspiration device **100** includes an elongated rotationally driven drive shaft **110**, a slide portion **111** slidable with respect to the drive shaft **110**, and a breaking member **140** rotated by the drive shaft **110**. The aspiration device **100** further includes a rotationally driven portion **150** provided with a driving source (for example, motor) for rotating the drive shaft **110**, a guide wire tubular body **170** into which the guide wire can be inserted, and a hub **160** provided at the proximal end portion of the guide wire tubular body **170**. The aspiration device **100** further includes the sheath **30** capable of accommodating the drive shaft **110**, the Y connector **190** configured to be interlocked with the hub opening portion **35** of the sheath **30**, and the syringe **180**

configured to be interlocked with the side tube **191** of the Y connector **190**.
(63) The proximal end portion of the drive shaft **110** is located at the rotationally driven portion **150**. The drive shaft **110** can reciprocate along the circumferential direction by the rotationally driven portion **150**. However, the drive shaft **110** is not limited to reciprocating, and it may rotate in one direction.
(64) The guide wire tubular body **170** is provided in the hollow inside of the drive shaft **110** from the distal end portion to the hub **160**. The guide wire tubular body **170** has a guide wire lumen into which a guide wire can be inserted.
(65) The sheath **30** is a sheath used for the expansion tool **10**. The sheath **30** is coaxially disposed on the outer side of the drive shaft **110**. The lumen of the sheath **30** not only accommodates the breaking member **140** but functions as an aspiration lumen generating aspiration force under a negative pressure state. The sheath **30** can rotatably accommodate the drive shaft **110** via the Y connector **190**. Moreover, by interlocking the side tube **191** of the Y connector **190** with the syringe **180**, the lumen of the sheath **30** can be aspirated by the syringe **180** and can be brought into the negative pressure state. Moreover, by connecting the syringe **180** to the side tube **191**, the thrombolytic agent can be injected into the lumen of the sheath **30** from the syringe **180**. The thrombolytic agent entering the lumen of the sheath **30** is released from the opening portion on the distal side of the sheath **30**.
(66) The breaking member **140** is provided at the distal portion of the drive shaft **110**. The breaking member **140** includes a plurality of (six in the present embodiment disclosed by way of example) wires **141**. Each of the wires **141** is three-dimensionally curved, respectively. The number of wires **141** is not particularly limited. Each of the wires **141** is twisted in the same circumferential direction along the axial direction of the drive shaft **110**. The proximal end portion of each of the wires **141** is fixed to the slide portion **111** which is slidable with respect to the drive shaft **110**. The distal end portion of each of the wires **141** is fixed to a fixing portion **112** fixed to the drive shaft **110**. The fixing position of each of the wires **141** with respect to the fixing portion **112** and the slide portion **111** is aligned in the circumferential direction. Moreover, a substantially center portion of each of the wires **141** curved in the axial direction is located radially outwardly of the drive shaft **110** and is aligned in the circumferential direction. Thereby, the breaking member **140** as a whole has a uniform bulging in the circumferential direction. When the drive shaft **110** rotates, the breaking member **140** also rotates accordingly, so that the thrombus in the blood vessel can be destroyed or the destroyed thrombus can be stirred. The breaking member may not only be a wire but also a laser cut pipe such as a stent.
(67) The wires **141** constituting the breaking member **140** are constituted by metallic thin wires having flexibility. Until the drive shaft **110** is inserted into the target portion, the breaking member **140** is in a state accommodated in the inside of the sheath **30**. After inserting the drive shaft **110** into the target portion, if the sheath **30** is slid to the proximal side with respect to the drive shaft **110**, the breaking member **140** is exposed to the outside of the sheath **30** and expands. Accordingly, the wires **141** is desirably formed of a material having a shape memory property.
(68) Next, an example of a procedure and a method for using the medical device **1** and the aspiration device **100** according to the present embodiment will be described taking a case of aspirating and removing the thrombus (object) in the blood vessel (biological lumen) as an example with reference to the flowchart in FIG. **17**.
(69) First, on the upstream side (proximal side) of the blood vessel from a thrombus **300**, an introducer sheath is percutaneously inserted into the blood vessel, and a guide wire **90** is inserted into the blood vessel via this introducer sheath. Next, the guide wire **90** is pushed forward until it reaches the distal side of the thrombus **300**.
(70) Next, as shown in FIG. **2**, the medical device **1** in which breaking member expansion tool **10** and the pressing shaft **40** are accommodated in the sheath **30** is prepared. The Y connector **190** is connected to the hub **32** of the sheath **30**. The expansion portion **20** and the auxiliary expansion

portion **80** are disposed at a position near the distal end portion of the tubular body **31**, with both the expansion portion **20** and the auxiliary expansion portion **80** being in the contracted state. The shaft portion **24** protrudes to the proximal side through the Y connector **190** from the hub opening portion **35** of the hub **32**.

(71) Next, the proximal end portion of the guide wire **90** (shown in FIGS. **9**(A) and **9**(B)) located outside the body is inserted into the guide wire lumens **54** and **64** (see FIG. **4**) of the medical device **1**. Then, as shown in FIG. **9**(A), the medical device **1** is made to reach the distal side of the thrombus **300** by moving the medical device **1** along the guide wire **90** (step S**10**). Note that, in order to make the guide wire **90** reach the distal side of the thrombus **300**, a support catheter prepared separately may be used.

(72) Next, the sheath **30** is moved to the proximal side or in the proximal direction while suppressing movement of the pressing shaft **40** with a hand. At this time, the distal end portion of the pressing shaft **40** comes into contact with the proximal side interlock portion **60**. Thereby, since the movement of the expansion portion **20** and the auxiliary expansion portion **80** is suppressed, the positions of the expansion portion **20** and the auxiliary expansion portion **80** in the blood vessel can be optionally adjusted. Then, by moving the sheath **30** to the proximal side with respect to the pressing shaft **40**, the auxiliary expansion portion **80** and the auxiliary expansion portion **80** are sequentially released from the tubular body **31**. Thereby, as shown in FIG. **9**(B), first, the auxiliary expansion portion **80** is expanded by the restoring force of the auxiliary expansion portion, the plurality of wire portions **81** are widened our spread outwardly and come into contact with the intravascular wall surface (step S**11**). The wire portions **81** widen the blood vessel and bite into the blood vessel, so that the wire portions **81** are strongly fixed in position relative to the blood vessel.

(73) When the expansion portion **20** is released from the tubular body **31**, the proximal side interlock portion **60** moves in the distal direction so as to approach the distal side interlock portion **50**. Then, the expansion portion **20** is expanded by the restoring force of the expansion portion, and comes into contact with the intravascular wall surface. At this time, the expansion portion **20** is in the extended state. The expansion portion **20** may be set in the boundary state or the bent state upon being released from the tubular body **31**.

(74) Next, the pressing shaft **40** is moved to the distal side or in the distal direction, and the proximal side interlock portion **60** is pushed toward the distal side or in the distal direction by the distal end portion of the pressing shaft **40**. Thereby, as shown in FIGS. **10**(A) and **11**, the expansion portion **20** is set in the bent state of being bent at the bent portion **25** (step S**12**). Since the expansion portion **20** is formed into a mesh shape, it bites into the intravascular wall surface and is strongly fixed. The expandable maximum diameter of the expansion portion **20** is larger than the inner diameter of the blood vessel into which the expansion portion **20** is inserted. Accordingly, the expansion portion **20** is brought into a state not completely expanded in the blood vessel, so that the expansion force is generated and the expansion portion **20** is effectively fixed to, and fixed in position relative to, the blood vessel wall.

(75) When the expansion portion **20** is bent, the expansion portion **20** receives force in the distal direction. However, since the auxiliary expansion portion **80** is provided on the distal side of the expansion portion **20**, the expansion portion **20** is supported by the auxiliary expansion portion **80** and can maintain the appropriate position. Even if the auxiliary expansion portion **80** receives force from the expansion portion **20** in the distal direction, the auxiliary expansion portion **80** hardly moves to the distal side or in the distal direction. Accordingly, when the expansion portion **20** is bent, the position of the expansion portion **20** can be appropriately maintained and the expansion portion **20** can be easily bent. Moreover, even when a strong force is applied from the blood stream, the auxiliary expansion portion **80** is strongly fixed relative to the blood vessel as described above, so that the auxiliary expansion portion **80** and the expansion portion **20** can be maintained at the appropriate positions.

(76) Next, the pressing shaft **40** is removed from the living body leaving the sheath **30** in the living

body. Since the expansion portion **20** is shaped into the bent state in advance, the bent state can be stably maintained.

(77) Moreover, the expansion portion **20** and the auxiliary expansion portion **80** are interlocked with each other by the flexible interlock shaft **87**, so that each position of the expansion portion **20** and the auxiliary expansion portion **80** can be appropriately maintained. Therefore, for example, even if the expansion portion **20** and the auxiliary expansion portion **80** are disposed at a portion curved in the blood vessel, an appropriate position can be maintained according to the shape of the blood vessel.

(78) As shown in FIG. **12**, it is preferable to locate the expansion portion **20** and the auxiliary expansion portion **80** in the bent state on the proximal side (lower leg side) from the merging portion of a renal vein **201** of a large vein **200**. The thrombus **300** is located at, for example, an iliac vein **202**. Thereby, it is possible to suppress a thrombus **301** fallen out from the thrombus **300** from flowing into the renal vein **201**, and the safety is improved by suppressing the rise in renal pressure.

(79) Next, the proximal end portion of the shaft portion **24** is inserted into the guide wire lumen of the aspiration device **100**. Next, the distal portion of the drive shaft **110** including the breaking member **140** is inserted into the Y connector **190** connected with the sheath **30** with the shaft portion **24** as a guide. Then, as shown in FIG. **10**(B), the drive shaft **110** is pushed forward and the aspiration device **100** is inserted into the proximal side of the thrombus **300**. Thereafter, as shown in FIGS. **12** and **13**(A), when the sheath **30** is moved to the proximal side, the breaking member **140** spreads in the blood vessel.

(80) Next, in the state where the breaking member **140** is advanced to the vicinity of the thrombus **300**, the drive shaft **110** is rotated by a rotationally driving portion **150**. Thereby, as shown in FIG. **13**(B), the breaking member **140** rotates and breaks the thrombus **300** while in a state of being stuck in the blood vessel (step S**13**).

(81) When the breaking member **140** is rotated and moved to the axial direction in order to break the thrombus, as shown in FIG. **8**, it is possible to connect the syringe **180**, in which the thrombolytic agent is accommodated, with the side tube **191** on the hand-side of the sheath **30**. Then, it is possible to push the plunger of the syringe **180** and eject the thrombolytic agent from the distal end portion of the sheath **30** simultaneously destroying the thrombus **300** by the breaking member **140**. The ejection of the thrombolytic agent may be continuous or intermittent, and the ejection speed, and ejection amount may be optionally changed. In the case of intermittently ejecting the thrombolytic agent, it is possible to aspirate while the ejection is stopped. In addition, the thrombolytic agent may not be used. Moreover, when rotationally moving the breaking member **140** in the axial direction, the syringe **180** for aspiration can be connected to the side tube **191** on the hand-side of the sheath **30**. Then, simultaneously destroying the thrombus **300** by the breaking member **140**, it is possible to pull the plunger of the syringe **180** and aspirate the broken thrombus **301** by the sheath **30**. During breaking, the thrombus **301** may not be aspirated.

(82) As shown in FIG. **14**, the thrombus **301** broken by the breaking member **140** reaches the expansion portion **20** located on the downstream side. The blood can pass through the expansion portion **20** through the gaps **21**A. The first portion **22** and the second portion **26** are in a state in which the inner surfaces thereof are separated from each other without coming into contact with each other. The expansion portion **20** does not contact the bent portion **25**. Accordingly, a space is formed between the first portion **22** and the second portion **26**. Accordingly, the gaps **21**A functioning as the filter of the expansion portion **20** can be satisfactorily maintained. Therefore, it is possible to appropriately maintain the blood flowing through the gaps **21**A of the expansion portion **20**, and reduce the burden on the living body. Moreover, the first portion **22** and the second portion **26** do not contact each other so that the range where the expansion portion **20** functions as a filter can be kept wide. That is, when the inner surfaces of the first portion **22** and the second portion **26** contact each other, the expansion portion **20** is brought into a collapsed state, so that the range where the blood can flow through from the outer surface to the inner surface of the expansion

portion **20** can be reduced. On the other hand, when the range where the expansion portion **20** functions as a filter can be kept wide, the gaps **21**A can be prevented from being clogged by the object.

(83) In a case where the first portion **22** and the second portion **26** contact and come into contact with each other in the bent portion **25**, apparently the gaps **21**A of the mesh becomes small so that a thrombus **301** having a size equal to or smaller than the set size is captured. Thereby, the mesh tends to be clogged by the thrombus. On the other hand, since the expansion portion **20** is bent in a state in which the inner peripheral surfaces are separated from each other in the bent portion **25**, the gaps **21**A of the mesh is maintained, and the size for capturing the thrombus can be easily maintained. Accordingly, by being bent, the thrombus **301** can be satisfactorily collected (step S**14**).

(84) The thrombus **301** that flowed through the fourth flow path S**4** of the first portion **22** and passed through the expansion portion **20** doubled by being bent is further collected by the wire portions **81** functioning as a filter.

(85) After the breaking of the thrombus **300** is completed, the reciprocation and the rotation of the drive shaft **110** are stopped. Thereafter, as shown in FIG. **16**(A), the breaking member **140** is accommodated in the sheath **30**, and the breaking member **140** is pulled out from the sheath **30**. The state in which the Y connector **190** is connected to the hub **32** of the sheath **30** is maintained.

(86) Next, the sheath **30** is moved to the distal side or in the distal direction along the shaft portion **24**. Thereby, the pipe body opening portion **36** on the distal side of the sheath **30** is attached to the proximal side interlock portion **60** of the expansion portion **20**. At this time, the tubular body **31** is curved, and the pipe body opening portion **36** is inclined with respect to the central axis of the tubular body **31**. Accordingly, the pipe body opening portion **36** can be attached to the proximal side interlock portion **60** so as not to block the aspiration port as the proximal side interlock portion **60** enters the pipe body opening portion **36**. Next, the syringe **180** for aspiration is connected to the Y connector **190** and the plunger of the syringe **180** is pulled to bring the inside of the sheath **30** into the negative pressure state. Thereby, the destroyed thrombus **301** can be aspirated from the pipe body opening portion **36** on the distal side of the sheath **30** and discharged to the syringe **180** (step S**15**). At this time, the proximal side interlock portion **60** is located on the proximal side from the bent portion **25**. Accordingly, it is possible to effectively aspirate the thrombus **301** collected by the expansion portion **20** from the pipe body opening portion **36** attached to the proximal side interlock portion **60**.

(87) Moreover, since the filtering function of the expansion portion **20** can be satisfactorily maintained, the blood stream is secured. Accordingly, as shown in FIG. **12**, even if a side branch **203** exists in the vicinity of the disposition positions of the expansion portion **20** and the auxiliary expansion portion **80**, the thrombus **301** can hardly flow into the side branch **203** and the safety is improved.

(88) As shown in FIG. **15**, when the sheath **30** is moved to the distal side or in the distal direction along the shaft portion **24** in the state in which the sheath **30** is attached to the proximal side interlock portion **60**, the proximal side interlock portion **60** approaches the distal side interlock portion **50**. Thereby, a space between the first portion **22** and the second portion **26** is reduced. Then, the gaps **21**A functioning as a filter are pulled out in the center direction (center direction of blood vessel) of the expansion portion **20** from the portion of the expansion portion **20** in contact with the blood vessel wall. Accordingly, it is possible to improve the filtering function, for example, in a case where the gaps **21**A of the expansion portion **20** are clogged and the filtering function is reduced and the like. Moreover, when the gaps **21**A of the expansion portion **20** are clogged, the force in the distal direction that the second portion **26** receives from the blood is increased. Accordingly, the proximal side interlock portion **60** can be automatically moved so as to approach the distal side interlock portion **50** using the force received from the blood.

(89) Then, when the thrombus **300** is broken and collected, aspirated, and removed by the

expansion portion **20** and the auxiliary expansion portion **80**, the positions of the expansion portion **20** and the auxiliary expansion portion **80** can be appropriately maintained by the auxiliary expansion portion **80**. Accordingly, it is possible to appropriately perform the procedure of collecting, aspirating, and removing the thrombus **301**.

(90) After the aspiration of the thrombus **301** by the sheath **30** is completed, the sheath **30** is pushed into the distal side or in the distal direction as shown in FIG. **16**(B). At this time, the shaft portion **24** can be pulled to the proximal side. Thereby, the proximal side interlock portion **60** enters the inside of the sheath **30** as being separated from the distal side interlock portion **50**. Then, the expansion portion **20** is brought into the contracted state from the bent state, and accommodated in the inside of the sheath **30** (step S**16**). Furthermore, the auxiliary expansion portion **80** is also reduced in the diameter and accommodated in the sheath **30**. When the expansion portion **20** and the auxiliary expansion portion **80** are accommodated in the inside of the sheath **30**, since the thrombus **301** attached to these can be also accommodated in the sheath **30**, the safety is increased.

(91) After accommodating the expansion portion **20** and the auxiliary expansion portion **80** in the inside of the sheath **30**, the expansion tool **10** is removed from the blood vessel with the sheath **30** to complete the procedure (step S**17**).

(92) As described above, the medical device **1** according to the present embodiment is a device to be inserted into the blood vessel (biological lumen) for collecting the thrombus **301** (object) in the blood vessel, and includes the elongated shaft portion **24** and the expansion portion **20** which is an elastically deformable cylindrical body having the plurality of gaps **21**A and in which at least one of the proximal portion and the distal portion of the cylindrical body is interlocked with the shaft portion **24**, in which the expansion portion **20** has the ring-shaped bent portion **25** which protrudes toward a proximal side position radially outside the expansion portion **20** in a bent state of being bent along an axial direction, and the axial length of the second portion **26** from the bent portion **25** to the proximal end of the expansion portion **25** is shorter than the axial length of the first portion **22** from the bent portion **25** to the distal end of the expansion portion **20**. When the expansion portion **20** is in any of the natural state, bent state, boundary state, extended state, and contracted state, the axial length of the second portion **26** is shorter than the axial length of the first portion **22**. When the medical device **1** configured as described above is in the bent state, the first portion **22** and the second portion **26** hardly contact each other and a space is formed between the first portion **22** and the second portion **26**. Accordingly, it is possible to appropriately maintain the gaps **21**A of the expansion portion **20** and to effectively collect the thrombus **301** by the expansion portion **20** by suppressing the clogging.

(93) Moreover, in the extended state in which the second portion **26** is moved to the proximal side with respect to the first portion **22** and pulled out from the inside of the first portion **22**, the shapes of the first portion **22** and the second portion **26** are non-planar symmetric with respect to the axially orthogonal cross section (i.e., with respect to a cross-section taken along a plane that contains the central axis of the expansion portion and that is perpendicular to the plane of the paper). The second portion **26** and the first portion **22** are non-planar symmetric in that the cross-section of the first portion **22** is larger than the cross-section of the second portion **26**. Thereby, when brought into the bent state, the first portion **22** and the second portion **26** hardly contact each other, so that a space is easily formed between the first portion **22** and the second portion **26**.

(94) Moreover, since the expansion portion **20** is shaped in advance, it is in the bent state in the natural state. That is, the expansion portion **20** is in the bent state when no external or outside force is applied to the expansion portion. Accordingly, it is easy to set so as to have an optimum shape in the bent state. Therefore, the shape of the expansion portion **20** is stabilized in the bent state, and the thrombus **301** can be effectively collected.

(95) Moreover, in the extended state, the second portion **26** has an outer diameter larger than the first portion **22**. Thereby, in the extended state, since the second portion **26** and the first portion **22** have different shapes, by obtaining the bent state, a space is easily formed between the first portion

22 and the second portion **26**. Accordingly, it is possible to appropriately maintain the gaps **21**A of the expansion portion **20** and to effectively collect the thrombus **301** by the expansion portion **20** by suppressing the clogging.
(96) Moreover, the first portion **22** and the second portion **26** are separately located without coming into contact with each other in the bent state. Thereby, since a space is formed between the first portion **22** and the second portion **26** when it is brought into the bent state, it is possible to appropriately maintain the gaps **21**A of the expansion portion **20** and to effectively collect the thrombus **301** by the expansion portion **20** by suppressing the clogging.
(97) Moreover, in the boundary state at the time when entire second portion **26** is pulled out from the inside of the first portion **22** in the bent state, the axes of the linear bodies **21** located in the second portion **26** have the inflection points P on a plane seen from the axial direction of the expansion portion **20**. Thereby, it is possible to turn back the expansion portion **20** using the portion having the inflection points P of the linear bodies **21**. Accordingly, the shape of the expansion portion **20** in the bent state is stabilized, and the bent state can be easily obtained.
(98) Moreover, in the bent state, the relative axial position of the second portion **26** with respect to the first portion **22** can be changed by the expansion portion **20**. Thereby, when the gaps **21**A are clogged in the biological lumen, the second portion **26** is moved with respect to the first portion **22**, and it is possible to increase a portion having the gaps **21**A of the expansion portion **20** which are not clogged.
(99) Moreover, in the expansion portion **20** in the extended state, the length from the portion **27** having the maximum outer diameter of the expansion portion **20** to the distal end portion is longer than the length from the portion **27** having the maximum outer diameter of the expansion portion **20** to the proximal end portion. Thereby, since the axial length of the second portion **26** is shorter than the first portion **22**, a space is easily formed between the first portion **22** and the second portion **26** by obtaining the bent state. Accordingly, it is possible to appropriately maintain the gaps **21**A of the expansion portion **20** and to effectively collect the thrombus **301** by the expansion portion **20** by suppressing the clogging.
(100) Moreover, in the extended state, the maximum inclination angle of the second portion **26** with respect to the axial direction is larger than the maximum inclination angle of the first portion **22** with respect to the axial direction. Accordingly, the second portion **26** tends to be bent in the axial direction and to be located in the inside of the first portion **22**. Furthermore, since the first portion **22** and the second portion **26** have different shapes by obtaining the bent state, a space is easily formed between the first portion **22** and the second portion **26**. Accordingly, it is possible to appropriately maintain the gaps **21**A of the expansion portion **20** and to effectively collect the thrombus **301** by the expansion portion **20** by suppressing the clogging.
(101) Moreover, in the bent state, the curvature radius r**1** of the portion convex toward the distal side of the first portion **22** is larger than the curvature radius r**2** of the portion convex toward the distal side of the second portion **26**. Accordingly, the second portion **26** tends to be bent in the axial direction and to be located in the inside of the first portion **22**. Furthermore, since the first portion **22** and the second portion **26** have different shapes by obtaining the bent state, a space is easily formed between the first portion **22** and the second portion **26**. Accordingly, it is possible to appropriately maintain the gaps **21**A of the expansion portion **20** and to effectively collect the thrombus **301** by the expansion portion **20** by suppressing the clogging.
(102) Moreover, the present invention also includes a procedure or method for aspirating and removing the thrombus **301** (object) formed in the lesion area in the blood vessel (biological lumen) using the aforementioned medical device **1**. The procedure method includes step S**10** of inserting the sheath **30** in which the expansion portion **20** is accommodated into the blood vessel, step S**11** of pushing out the expansion portion **20** from the sheath **30** in the blood vessel and expanding the expansion portion **20** by the elastic force of the expansion portion to be brought into contact with the blood vessel, step S**12** of causing the expansion portion **20** into the bent state, and

step S**14** of collecting the thrombus **301** in the blood vessel by the expansion portion **20**. In the procedure configured as described above, when the expansion portion **20** is set in the bent state, the first portion **22** and the second portion **26** hardly contact each other so that a space is formed between the first portion **22** and the second portion **26**. Accordingly, it is possible to appropriately maintain the gaps **21**A of the expansion portion **20** and to effectively collect the thrombus **301** by the expansion portion **20** by suppressing the clogging.

(103) The present invention is not limited only to the embodiments described above, and various modifications are possible by those skilled in the art within the technical idea of the present invention. For example, in the present embodiment, the medical device **1** has a structure to be accessed from the upstream side of the target lesion, but it may have a structure to be accessed from the downstream side of the target lesion.

(104) Moreover, in the present embodiment, the device inserted into the blood vessel along the shaft portion **24** is the aspiration device **100** including the breaking member **140**. However, the configuration of the device to be inserted is not limited as long as the object can be aspirated from the blood vessel. Moreover, the device for aspirating an object in the blood vessel may be configured separated from the device for dropping the object from the blood vessel. Therefore, the device for aspirating an object in the blood vessel may be a pipe body capable of performing aspiration without a breaking member. For example, only the sheath **30** may be a device for aspirating an object. Moreover, the sheath **30** is used in both the medical device **1** and the aspiration device **100**, but a separated sheath may be used for each device. Moreover, an aspiration device and a breaking device may not be provided.

(105) Moreover, the biological lumen into which the medical device **1** is inserted is not limited to the blood vessel, and may be, for example, a vessel, a ureter, a bile duct, an oviduct, a hepatic duct, and the like.

(106) Moreover, the configuration of the auxiliary expansion portion is not particularly limited. Moreover, the medical device may not include an auxiliary expansion portion.

(107) Moreover, in the modification example as shown in FIG. **18**, the expansion portion **20** may have a straight portion **23** having a constant outer diameter in the axial direction in the boundary state. The straight portion **23** is located in the first portion **22**. Thereby, the straight portion **23** may come into contact with the intravascular wall surface in a wide range (i.e., the length or area of contact between the straight portion **23** of the expansion portion **20** and the intravascular wall surface is enlarged). Accordingly, the expansion portion **20** is hardly inclined in the blood vessel, and a good position can be maintained.

(108) Moreover, in another modification example shown in FIG. **19**, the shaft portion **24** may pass through the expansion portion **20** from the hand and extend up to the auxiliary expansion portion **80**. The shaft portion **24** slidably passes through the proximal side interlock portion **60**. The shaft portion **24** is interlocked with the distal side interlock portion **50**. Furthermore, the distal end portion of the shaft portion **24** is interlocked with the fixing portion **82** of the auxiliary expansion portion **80**. Being interlocked with the shaft portion **24** is not limited to being fixed to the shaft portion **24**, and includes being interlocked to be relatively rotatable and movable.

(109) Moreover, a flexible film member for restricting blood flow may be fixed at the portion of the expansion portion **20**.

(110) Moreover, as shown in FIG. **20**, as another method of use (procedure) using the medical device **1**, the medical device **1** may be used with device **400** which ejects liquid to destroy the thrombus **300**. The device **400** includes a release port **401** for discharging liquid, an aspiration port **402** aspirating the liquid, and a guide wire lumen **403**. The aspiration port **402** is provided on the distal side of the release port **401**, but may be provided on the proximal side. The release port **401** can release liquid supplied from the proximal portion of the device **400**. The aspiration port **402** can aspirate liquid or an object by the negative pressure supplied from a syringe and the like connected to the proximal portion of the device **400**.

(111) When using the medical device **1**, similarly to the aforementioned using method, the expansion portion **20** is expanded on the distal side from the thrombus **300** in the blood vessel and brought into the bent state (see FIGS. **9** and **10**). Next, the sheath **30** and the pressing shaft **40** are removed. Next, the proximal end of the shaft portion **24** is inserted into the guide wire lumen **403** of the device **400**. Next, the device **400** is made to reach the vicinity of the thrombus **300** along the shaft portion **24**. Thereafter, the liquid is released from the release port **401**. The released liquid destroys the thrombus **300**. The destroyed thrombus **301** is aspirated and discharged from the aspiration port **402** with the released liquid and the blood. There are cases in which the destroyed thrombus **301** is not aspirated by the aspiration port **402**. The not aspirated thrombus **301** flows with the blood and is collected by the expansion portion **20**. The collected thrombus **301** is finally aspirated by the aspiration port **402** of the device **400** that reaches the vicinity of the expansion portion **20**. After the thrombus **300** is destroyed, aspirated, and removed, the device **400** is removed from the blood vessel. Next, the sheath **30** is inserted into the blood vessel, and the expansion portion **20** is contracted and accommodated in the sheath **30**. Thereafter, the expansion tool **10** is removed from the blood vessel with the sheath **30**, and the procedure is completed. Note that, the device **400** may include a balloon or mesh-like tubular member that can be expanded radially outward.

(112) In the bent state, at least one of the release port **401** and the aspiration port **402** of the device **400** may be located at the inner space **29** on the inner side of the concave-shaped second portion **26**. In this case, the thrombus **301** collected by the inner space **29** is floating in the inner space **29** by the liquid released from the release port **401**. Thereafter, as the thrombus **301** floats, it becomes easier for the aspiration port **402** to aspirate the thrombus.

(113) The detailed description above describes embodiments of a medical device and procedure representing examples of the inventive medical device and procedure disclosed here. The invention is not limited, however, to the precise embodiments 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.

Claims

1. A medical device to be inserted into a biological lumen for collecting an object in the biological lumen, the medical device comprising: an elongated shaft possessing a distal end portion; an expansion portion that includes an elastically deformable body, the elastically deformable body possessing a proximal portion and a distal portion, the elastically deformable body including a plurality of through gaps that pass through the elastically deformable body; the proximal portion of the elastically deformable body being interlocked with a proximal side interlock portion, the proximal side interlock portion including a lumen extending throughout the proximal side interlock portion, the proximal side interlock portion being fixed to the distal end portion of the elongated shaft so that the elongated shaft and the proximal side interlock portion move together as a unit whereby movement of the elongated shaft results in movement of the proximal side interlock portion, the elongated shaft extending away from the elastically deformable body in a proximal direction; the proximal side interlock portion including an inner tube and an outer tube, the distal portion of the elongated shaft being fixed to at least one of the inner tube of the proximal side interlock portion and the outer tube of the proximal side interlock portion; the expansion portion including, when the expansion portion is in a bent state, a radially outwardly located annular-shaped portion that is bent toward the proximal direction; the expansion portion being changeable between the bent state and an extended state, the expansion portion in the bent state including a first portion and a second portion, the second portion being located inside the first portion when the

expansion portion is in the bent state, and the second portion moving in the proximal direction with respect to the first portion and being pulled out from the inside of the first portion when the expansion portion changes from the bent state to the extended state.

2. The medical device according to claim 1, wherein the distal end portion of the elongated shaft is positioned between the inner tube of the proximal side interlock portion and the outer tube of the proximal side interlock portion.

3. The medical device according to claim 1, wherein the lumen passing through the proximal side interlock portion is a centrally located guide wire lumen into which a guide wire is insertable.

4. The medical device according to claim 1, wherein the distal portion of the elastically deformable body is interlocked with a distal side interlock portion.

5. A medical device to be inserted into a biological lumen for collecting an object in the biological lumen, the medical device comprising: an elongated shaft possessing a distal end portion; an expansion portion that includes an elastically deformable body, the elastically deformable body possessing a proximal portion and a distal portion, the elastically deformable body including a plurality of through gaps that pass through the elastically deformable body; the proximal portion of the elastically deformable body being interlocked with a proximal side interlock portion; the distal end portion of the elongated shaft being fixed in place relative to the elastically deformable body by way of the proximal side interlock portion so that the elongated shaft and the proximal side interlock portion move together as a unit whereby movement of the elongated shaft results in movement of the proximal side interlock portion, the elongated shaft extending away from the elastically deformable body in a proximal direction; the expansion portion including, when the expansion portion is in a bent state, a radially outwardly located annular-shaped portion that is bent toward the proximal direction; the expansion portion being changeable between the bent state and an extended state, the expansion portion in the bent state including a first portion and a second portion, the second portion being located inside the first portion when the expansion portion is in the bent state, and the second portion moving in the proximal direction with respect to the first portion and being pulled out from the inside of the first portion when the expansion portion changes from the bent state to the extended state; and the elongated shaft being the only elongated shaft that is fixed in place relative to the elastically deformable body and that also extends away from the elastically deformable body in the proximal direction.

6. The medical device according to claim 5, wherein the elongated shaft is a first elongated shaft, and further comprising a second elongated shaft having a proximal end portion, the proximal end portion of the second elongated shaft being fixed in place relative to the elastically deformable body, the second elongated shaft extending away from the elastically deformable body in a distal direction that is opposite the proximal direction.

7. The medical device according to claim 5, wherein the distal portion of the elastically deformable body is interlocked with a distal side interlock portion.

8. The medical device according to claim 7, wherein the elongated shaft is a first elongated shaft, and further comprising a second elongated shaft having a proximal end portion, the proximal end portion of the second elongated shaft being fixed in place relative to the elastically deformable body by way of the distal side interlock portion so that the second elongated shaft and the distal side interlock portion move together as a unit.

9. The medical device according to claim 5, wherein the distal end portion of the elongated shaft is a distal-most end of the elongated shaft that is fixed to the proximal side interlock portion.

10. The medical device according to claim 5, wherein the distal portion of the elastically deformable body is interlocked with a distal side interlock portion, the proximal side interlock portion and the distal side interlock portion being axially spaced apart by a first axial distance when the expansion portion is in the extended state and being axially spaced apart by a second axial distance when the expansion portion is in the bent state, the first axial distance being greater than the second axial distance.

11. The medical device according to claim 5, wherein the proximal side interlock portion includes an inner tube and an outer tube.
12. The medical device according to claim 11, wherein the distal end portion of the elongated shaft is positioned between the inner tube of the proximal side interlock portion and the outer tube of the proximal side interlock portion.
13. A medical device to be inserted into a biological lumen for collecting an object in the biological lumen, the medical device comprising: an elongated shaft possessing a distal end portion; an expansion portion that includes an elastically deformable body having a plurality of through gaps that pass through the elastically deformable body, the expansion portion possessing a proximal portion and a distal portion; the proximal portion of the expansion portion being interlocked with a proximal side interlock portion, the proximal side interlock portion including an outer tube and an inner tube, the inner tube being positioned inside the outer tube; the distal end portion of the elongated shaft being fixed to at least one of the inner tube of the proximal side interlock portion and the outer tube of the proximal side interlock and extending away from the expansion portion in a proximal direction; the expansion portion being changeable from an extended state to a bent state by a restoring force of the expansion portion and without application of any forces external to the expansion portion so that as the expansion portion changes form from the extended state to the bent state, the expansion portion expands radially outwardly and an axial distance between the distal portion of the expansion portion and the proximal portion of the expansion portion is reduced; the expansion portion including, when the expansion portion is in the bent state, a radially outwardly located annular-shaped portion that is bent toward the proximal direction; and the expansion portion in the bent state including a first portion and a second portion, the second portion being located inside the first portion when the expansion portion is in the bent state, the expansion portion being changeable from the bent state to the extended state, and the second portion moving in the proximal direction with respect to the first portion and being pulled out from the inside of the first portion when the expansion portion changes from the bent state to the extended state.
14. The medical device according to claim 13, wherein the distal end portion of the elongated shaft is positioned between the inner tube of the proximal side interlock portion and the outer tube of the proximal side interlock portion.
15. The medical device according to claim 13, wherein the proximal side interlock portion incudes a lumen passing through the proximal side interlock portion.
16. The medical device according to claim 13, wherein the distal portion of the expansion portion is interlocked with a distal side interlock portion.