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Medical device

Abstract

A medical device is disclosed capable of reducing risk factors of an anastomotic leakage after a surgical operation is performed. The medical device includes an adhesion promotion sheet configured to include an adhesion promotion portion promoting adhesion of biological tissues and a frame portion provided outside the adhesion promotion portion in a plane direction and a pulling unit connected to the adhesion promotion sheet and configured to deform a second region so as to cover at least a portion of an outer peripheral surface of a biological organ to be joined with a pulling operation.

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Background/Summary

CROSS-REFERENCES TO RELATED APPLICATIONS (1) This application is a continuation of International Application No. PCT/JP2020/014286 filed on Mar. 27, 2020, which claims priority to Japanese Patent Application No. 2019-065048 filed on Mar. 28, 2019, the entire content of both of which is incorporated herein by reference.

FIELD OF THE DISCLOSURE

(1) The present disclosure generally relates to a medical device.

BACKGROUND DISCUSSION

(2) In the medical field, a medical procedure (for example, anastomosis for a digestive tract) of joining biological organs to each other by performing a surgical operation is known. In a case where the medical procedure as described above is performed, as a prognosis determinant after surgery, it is important that there is no delay in adhesion in a joint portion joined between the biological organs.

(3) In the medical procedure of joining the biological organs, various methods and various medical instruments are used. For example, a method of suturing the biological organs by using a biodegradable suture, or a method of using a mechanical joint device (refer to Japanese Patent Application Publication No. 2007-505708 A) for performing anastomosis by using a stapler has been proposed. In particular, in a case where anastomosis is performed using the mechanical joint device, compared to a method of using the suture, a joining force between the biological organs can be improved in the joint portion. Accordingly, risk factors of an anastomotic leakage can be reduced.

(4) However, a degree of progress of adhesion in the joint portion depends on a state of biological tissues in a joint object site (joint target site) of a patient. Therefore, for example, even in a case where the joint device as disclosed in Japanese Patent Application Publication No. 2007-505708 A is used, depending on the state of the biological tissues of the patient, there is a possibility that the risk factors of the anastomotic leakage cannot be sufficiently reduced.

SUMMARY

(5) A medical device is disclosed, which is capable of reducing risk factors of an anastomotic leakage after a surgical operation is performed.

(6) A medical device is disclosed, which includes an adhesion promotion sheet configured to include a first region promoting adhesion of biological tissues and a second region provided outside the first region in a plane direction and a pulling unit connected to the adhesion promotion sheet and configured to deform the second region so as to cover at least a portion of an outer peripheral surface of a biological organ to be joined with a pulling operation.

(7) According to the medical device according to the present disclosure, the adhesion of the biological tissues of the biological organs can be promoted by interposing the adhesion promotion sheet between the joint target sites of the biological organs to be joined. In addition, the operator can deform the second region of the adhesion promotion sheet so as to cover at least a portion of the outer peripheral surface of the biological organs to be joined by pulling the pulling unit. As a result, the operator can stably hold the adhesion promotion sheet in the biological organs, and can help prevent the adhesion promotion sheet from being distorted or misaligned during the medical procedure. Therefore, the risk of anastomotic leakage of the biological organs can be effectively reduced.

(8) A medical device is disclosed that promotes adhesion between biological tissue, the medical device comprising: an adhesion promotion sheet made of a biodegradable sheet that promotes adhesion of the biological tissue, the adhesion promotion sheet including a first region having a plurality of through-holes that pass through the first region and a second region provided outside

the first region in a plane direction; a pulling unit connected to the adhesion promotion sheet and configured to deform the second region so as to cover at least a portion of an outer peripheral surface of a biological organ to be joined with a pulling operation; and wherein the pulling unit includes a connection section connected to the second region and a non-connection section, the non-connection section is not connected to the second region and is configured to be pulled out of the adhesion promotion sheet.

(9) A method is disclosed of promoting adhesion between biological tissue comprising: disposing a medical device at one joint target site, the medical device comprising an adhesion promotion sheet including a first region that promotes adhesion of biological tissues and a second region provided outside the first region in a plane direction, and a pulling unit connected to the adhesion promotion sheet; pulling the pulling unit to deform the adhesion promotion sheet of the medical device to deform the second region; fixing the adhesion promotion sheet of the medical device to the one joint target site; and joining the one joint target site and an other joint target site in a state where at least a portion of the adhesion promotion sheet is disposed between the one joint target site and the other joint target site.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

- (1) FIG. 1A is a perspective view illustrating a form of a medical device of the present invention.
- (2) FIG. 1B is a perspective view illustrating a usage example of the medical device in FIG. 1A.
- (3) FIG. 2 is an enlarged cross-sectional view illustrating a portion of a cross section taken along line 2A-2A in FIG. 1A.
- (4) FIGS. 3A-3C are plan views illustrating a shape example of a pulling unit including a string-shaped member.
- (5) FIG. 4A is a perspective view illustrating Modification Example 1 of the medical device of the present disclosure.
- (6) FIGS. 4B-4G are plan views illustrating a shape example of a pulling unit including a strip-shaped member.
- (7) FIG. 5A is a perspective view illustrating a usage example of Modification Example 2 of the medical device of the present disclosure.
- (8) FIG. 5B is a perspective view illustrating a usage example of Modification Example 3 of the medical device of the present disclosure.
- (9) FIG. 6A is a perspective view illustrating Modification Example 4 of the medical device of the present disclosure.
- (10) FIG. 6B is a perspective view illustrating Modification Example 5 of the medical device of the present disclosure.
- (11) FIG. 7 is a flowchart illustrating each procedure of a treatment method using the medical device.
- (12) FIG. 8 is a flowchart illustrating a procedure of an embodiment of the treatment method (pancreatic parenchyma-jejunum anastomosis).
- (13) FIG. 9 is a schematic perspective view for describing the pancreatic parenchyma-jejunum anastomosis.
- (14) FIG. 10 is a schematic perspective view for describing the pancreatic parenchyma-jejunum anastomosis.
- (15) FIG. 11 is a schematic perspective view for describing the pancreatic parenchyma-jejunum anastomosis.
- (16) FIG. 12 is a schematic perspective view for describing the pancreatic parenchyma-jejunum anastomosis.

- (17) FIG. **13** is a schematic cross-sectional view for describing the pancreatic parenchyma-jejunum anastomosis.
- (18) FIG. **14** is a schematic perspective view for describing the pancreatic parenchyma-jejunum anastomosis.
- (19) FIG. **15** is a schematic perspective view for describing the pancreatic parenchyma-jejunum anastomosis.
- (20) FIG. **16** is a schematic perspective view for describing the pancreatic parenchyma-jejunum anastomosis.
- (21) FIG. **17** is a plan view illustrating a pulling unit according to another modification example.
- (22) FIG. **18** is a diagram schematically illustrating a usage example of a medical device provided with the pulling unit according to another modification example.
- (23) FIG. **19** is a diagram schematically illustrating a usage example of the medical device provided with the pulling unit according to another modification example.
- (24) FIG. **20** is a diagram schematically illustrating a usage example of the medical device provided with the pulling unit according to another modification example.
- (25) FIG. **21** is a diagram schematically illustrating a usage example of the medical device provided with the pulling unit according to another modification example.
- (26) FIG. **22** is a diagram schematically illustrating a usage example of the medical device provided with the pulling unit according to another modification example.

DETAILED DESCRIPTION

(27) Set forth below with reference to the accompanying drawings is a detailed description of embodiments of a medical device representing examples of the inventive medical device disclosed here. In the description of the drawings, the same elements are designated by the same reference numerals, and duplicate description will be omitted. In addition, dimensional proportions in the drawings are exaggerated and different from actual proportions for convenience of description, in some cases.

(28) FIG. **1A** is a perspective view illustrating a form of a medical device **100**. FIG. **1B** is a perspective view illustrating a usage example of the medical device **100** in FIG. **1A**. FIG. **2** is an enlarged cross-sectional view illustrating a portion of the cross section taken along line **2A-2A** in FIG. **1A**. FIGS. **3A** to **3C** are plan views illustrating a shape example of a pulling unit **120**.

(29) Medical Device **100**

(30) As illustrated in FIG. **1A**, the medical device **100** includes an adhesion promotion sheet **110** disposed between biological organs to be joined, and the pulling unit **120** provided on the adhesion promotion sheet **110**.

(31) As illustrated in FIGS. **9** to **16**, the medical device **100** can be applied to a medical procedure of joining predetermined biological organs (for example, anastomosis for a digestive tract). As will be described later, in the description of the present specification, pancreatic parenchyma-jejunum anastomosis will be described as an example of the medical procedure using the medical device **100**.

(32) Adhesion Promotion Sheet **110**

(33) As illustrated in FIG. **1A**, the adhesion promotion sheet **110** includes an adhesion promotion portion (corresponding to a “first region”) **110A** that promotes adhesion of biological tissues formed from a biodegradable sheet having a plurality of through-holes **112**. The adhesion promotion portion **110A** is formed in a predetermined range including a central portion **C** in a plane direction of the adhesion promotion sheet **110**.

(34) The adhesion promotion sheet **110** has a frame portion (corresponding to a “second region”) **110B** provided more outside (i.e., peripherally of) the adhesion promotion sheet **110** in the plane direction than the adhesion promotion portion **110A**. The frame portion **110B** is formed in a certain range including an outer peripheral edge **O** of the adhesion promotion sheet **110** so as to surround the periphery of the adhesion promotion portion **110A**. In the present embodiment, the through-

hole **112** is not formed in the frame portion **110B**.

(35) Adhesion Promotion Portion **110A**

(36) As illustrated in FIG. **1A**, the through-holes **112** formed in the adhesion promotion portion **110A** can be regularly and periodically provided in the plane direction of the adhesion promotion sheet **110**. However, each through-hole **112** may be randomly provided at each portion in the plane direction of the adhesion promotion sheet **110**.

(37) As illustrated in FIG. **2**, each through-hole **112** extends substantially vertically between a front surface **113** and a rear surface (i.e., back surface) **114** along the thickness direction of the adhesion promotion sheet **110** (vertical direction in FIG. **2**). Each through-hole **112** may be bent or curved, for example, in a zigzag shape between the front surface **113** and the rear surface **114** in a cross section along the thickness direction of the adhesion promotion sheet **110**.

(38) In accordance with an exemplary embodiment, each through-hole **112** has a substantially circular planar shape (shape when the front surface **113** of the adhesion promotion sheet **110** or the rear surface **114** of the adhesion promotion sheet **110** is viewed in a plan view). However, the planar shape of each through-hole **112** is not particularly limited, and may be, for example, an ellipse or a polygon (for example, a rectangle or a triangle). In addition, the plane shape and the cross-sectional shape may be different for each through-hole **112**.

(39) In accordance with an exemplary embodiment, the adhesion promotion sheet **110** has a substantially circular planar shape. However, the planar shape of the adhesion promotion sheet **110** is not particularly limited, and may be, for example, an ellipse or a polygon (for example, a rectangle or a triangle).

(40) The thickness of the adhesion promotion sheet **110** (dimension T illustrated in FIG. **2**) is not particularly limited, and the thickness of the adhesion promotion sheet **110** can be 0.05 mm to 0.3 mm, preferably 0.1 mm to 0.2 mm. In a case where the thickness of the adhesion promotion sheet **110** is 0.05 mm or more (particularly, for example, in a case of 0.1 mm or more), the adhesion promotion portion **110A** can be provided with such strength that the adhesion promotion portion **110A** is not damaged when the adhesion promotion sheet **110** is handled. In a case where the thickness of the adhesion promotion sheet **110** is 0.3 mm or less (particularly, for example, in a case of 0.2 mm or less), the adhesion promotion portion **110A** can be in close contact with the biological tissue to which the adhesion promotion sheet **110** is applied and can be provided with sufficient flexibility to follow the biological tissue.

(41) In the adhesion promotion portion **110A**, a ratio value of the hole diameter D (distance D illustrated in FIG. **2**) of the through-hole **112** to the pitch P (distance P illustrated in FIG. **2** and the distance between the through-holes **112** adjacent to each other) of the through-hole **112** is preferably 0.25 or more and less than 40. In a case where the planar shape of the through-hole **112** is a perfect circle, the hole diameter D of the through-hole **112** is equal to the diameter of the perfect circle. In a case where the planar shape of the through-hole **112** is not a perfect circle, the diameter of a perfect circle (equivalent circle diameter) having the same area as an area of an opening portion of the through-hole **112** (portion of the through-hole **112** facing the front surface **113** or the rear surface **114**) can be defined as the hole diameter D of the through-hole **112**.

(42) Since the adhesion promotion portion **110A** includes a plurality of through-holes **112**, there are a plurality of values of the hole diameter D corresponding to each through-hole **112**. Therefore, in the present embodiment, in calculating the above-described ratio value, an arithmetic average value of two or more values of the hole diameter D corresponding to each of the plurality of through-holes **112** is used as a representative value of the hole diameter D. The pitch P of the plurality of through-holes **112** means a shortest distance between the opening portions of the two through-holes **112**. However, with regard to the value of the pitch P, there are a plurality of values of the pitch P corresponding to a combination of the through-holes **112** adjacent to each other. Therefore, according to the present embodiment, in calculating the above-described ratio value, the arithmetic average value of two or more values of the pitch P corresponding to each combination of the

through-holes **112** adjacent to each other is used as a representative value of the pitch P.

(43) The pitch P of the above-described through-holes **112**, the hole diameter D, and the ratio of the hole diameter D to the pitch P are merely examples, and the present disclosure is not limited to the examples of the pitch P of the through-holes **112**, the hole diameter D, and the ratio of the hole diameter D to the pitch P as disclosed.

(44) The adhesion promotion portion **110A** can be made of a biodegradable material. The constituent material of the adhesion promotion portion **110A** is not particularly limited, and examples of the material of the adhesion promotion portion **110A** can include a biodegradable resin. As the biodegradable resin, for example, it is possible to use a known biodegradable (co)polymer such as those disclosed in Japanese Patent Application Publication No. 2011-528275 A, Japanese Patent Application Publication No. 2008-514719 A, Pamphlet of International Publication No. 2008-1952 (i.e., WO 2008/001952), and Japanese Patent Application Publication No. 2004-509205 A. Specifically, the biodegradable resin can include (1) a polymer selected from a group formed of aliphatic polyester, polyester, polyanhydride, polyorthoester, polycarbonate, polyphosphazene, polyphosphate ester, polyvinyl alcohol, polypeptide, polysaccharide, protein, and cellulose; or (2) copolymer formed of one or more monomers forming the above-described materials (1). That is, it is preferable that the biodegradable sheet includes at least one biodegradable resin selected from a group formed of the polymer selected from a group formed of aliphatic polyester, polyester, polyanhydride, polyorthoester, polycarbonate, polyphosphazene, polyphosphate ester, polyvinyl alcohol, polypeptide, polysaccharide, protein, and cellulose, and the copolymer formed of one or more monomers forming the polymer.

(45) A manufacturing method of the adhesion promotion portion **110A** is not particularly limited. For example, the manufacturing method includes a method of preparing a fiber formed of the above-described biodegradable resin and manufacturing a mesh-shaped sheet by using the fiber. A method of preparing the fiber formed of the biodegradable resin is not particularly limited. For example, the method can include an electrospinning method (electric field spinning method and electrostatic spinning method) or a melt blowing method. For the method for the adhesion promotion portion **110A**, only one of the above-described methods may be selected and used. Alternatively, two or more methods may be selected in appropriate combination with each other for preparing the adhesion promotion **110A**. As still another example of the manufacturing method of the adhesion promotion portion **110A**, a fiber formed of the above-described biodegradable resin may be spun in accordance with a usual method, and the obtained fiber may be knitted into a mesh shape to manufacture the biodegradable sheet according to the present disclosure.

(46) The adhesion promotion portion **110A** causes a biological reaction by using the constituent materials such as the biodegradable resin constituting the adhesion promotion portion **110A**. Due to this action, the adhesion promotion portion **110A** induces expression of biological components such as fibrin. The biological components induced in this manner can promote adhesion by accumulating in the spaces of the through-holes **112** of the adhesion promotion portion **110A**. Therefore, the adhesion promotion portion **110A** is disposed between the biological organs to be joined, thereby promoting the adhesion by using the above-described mechanism.

(47) The material of the adhesion promotion portion **110A** may not be biodegradable as long as it is possible to promote the adhesion of the biological organs. In addition, the adhesion promotion portion **110A** may not have the through-hole **112** regardless of the material, as long as it is possible to promote the adhesion of the biological organs.

(48) Frame Portion **110B**

(49) As illustrated in FIG. 1A, the frame portion **110B** is formed on the adhesion promotion sheet **110** so as to surround the periphery of the adhesion promotion portion **110A**. The frame portion **110B** is preferably formed to have a higher rigidity (i.e., greater rigidity) than that of the adhesion promotion portion **110A** so that the frame portion **110B** is not easily deformed when an external force is applied. The frame portion **110B** can be made of, for example, a biodegradable sheet in

which a hole portion such as a through-hole **112** is not formed, a resin sheet having a higher rigidity than that of the adhesion promotion portion **110A**, or a non-woven fabric.

(50) In addition, the through-hole **112** is not formed in a certain region including the outer peripheral edge O of the biodegradable sheet which is a constituent material of the adhesion promotion portion **110A**, so that the adhesion promotion sheet **110** may be provided with the frame portion **110B**. In addition, after forming the through-hole **112** in a certain region including the outer peripheral edge O of the biodegradable sheet which is a constituent material of the adhesion promotion portion **110A**, only the region is compressed or heated in the thickness direction to crush the through-hole **112**. Accordingly, a portion in which the constituent materials of the biodegradable sheet are densely assembled may be formed, and the portion may be used as the frame portion **110B**.

(51) In addition, the frame portion **110B** may be provided with a suppressing portion that suppresses a synechia with the biological organs at least in a part of the frame portion **110B**. The material constituting the suppressing portion of the frame portion **110B** is not particularly limited as long as it is possible to suppress the synechia with the biological organs. For example, the suppressing portion of the frame portion **110B** may be a non-woven fabric. In addition, the suppressing portion of the frame portion **110B** can be made of a biodegradable material, similarly to the adhesion promotion portion **110A**.

(52) The area ratio of the adhesion promotion portion **110A** and the frame portion **110B** in the adhesion promotion sheet **110**, the shapes of the adhesion promotion portion **110A** and the frame portion **110B** in a plan view, and the like are not particularly limited.

(53) Pulling Unit **120**

(54) As illustrated in FIGS. **1A** and **1B**, the medical device **100** can include the pulling unit **120** that is connected to the adhesion promotion sheet **110** and deforms the frame portion **110B** so as to cover at least a portion of the outer peripheral surface of the pancreatic parenchyma **B1** to be joined with the pulling operation.

(55) The pulling unit **120** can include a string-shaped member having a predetermined length. The pulling unit **120** includes a connection section **121** connected to the frame portion **110B** and a non-connection section **123** that is not connected to the frame portion **110B** and that can be pulled by an operator and extends outside of the frame portion **110b** of the adhesion promotion sheet **110**.

(56) The connection section **121** of the pulling unit **120** is inserted through the inside of the adhesion promotion sheet **110**. Inside the adhesion promotion sheet **110**, a space (not illustrated) into which the connection section **121** is slidably inserted is formed. In the present embodiment, as illustrated in FIG. **1B**, the pulling unit **120** is disposed on the adhesion promotion sheet **110** so that the frame portion **110B** of the adhesion promotion sheet **110** constitutes an opening portion of a bag (drawstring bag) having a space inside when the non-connection section **123** is pulled in the adhesion promotion sheet **110**. In accordance with an exemplary embodiment, the operator can adjust the opening area of the opening portion of the bag configured to include the adhesion promotion sheet **110** by adjusting the pulling amount of the non-connection section **123** of the pulling unit **120**.

(57) The method of attaching the pulling unit **120** to the adhesion promotion sheet **110** is not particularly limited. In addition, the pulling unit **120** may be configured so as to be separated from the adhesion promotion sheet **110**, or may be configured so as to be retrofitted with a member separate from the adhesion promotion sheet **110**.

(58) In accordance with an exemplary embodiment, the pulling unit **120** is disposed in the frame portion **110B** with a length equal to or more than half the adhesion promotion sheet **110** along the circumferential direction. In the present embodiment, as illustrated in FIG. **1B**, the connection section **121** is disposed at a corresponding portion on a posterior wall **B1c** (portion of the pancreatic parenchyma **B1** on a dorsal side in the circumferential direction) side of the pancreatic parenchyma **B1**. The non-connection section **123** can be disposed at a corresponding portion of an

anterior wall **B1d** (portion of the pancreatic parenchyma **B1** on a ventral side in the circumferential direction) of the pancreatic parenchyma **B1** of the adhesion promotion sheet **110**. However, the position where the connection section **121** of the pulling unit **120** is disposed on the adhesion promotion sheet **110** is not particularly limited.

(59) The medical device **100** can include an adjustment unit **150** that can adjust the amount of deformation of the frame portion **110B** by limiting the pulling operation of the pulling unit **120**. In the present embodiment, the adjustment unit **150** is configured to include an annular portion **123a** which is a portion of the non-connection section **123** and an insertion portion **123b** through which the annular portion **123a** is inserted. The pulling operation of the pulling unit **120** can be restricted by adding, for example, an uneven shape, a notch, or the like (for example, structures illustrated in FIGS. 3A-4G) to a portion of the non-connection section **123** and hooking the non-connection section **123** on the annular portion **123a** to fit the non-connection section **123**. In addition, by configuring the adjustment unit **150** as described above, the adjustment unit **150** also has a function as a lock mechanism **160** that automatically maintains a pulled state without maintaining the state where the operator pulls the pulling unit **120** with fingers or the like. The adjustment unit **150** and the lock mechanism **160** may include, for example, a fixing member made of a member separated from the pulling unit **120**. In addition, the non-connection section **123** may be configured so that at least a part of the non-connection section **123** cannot pass through the annular portion **123a**.

(60) For example, the pulling unit **120** can be made of a thermoplastic elastomer such as vinyl chloride, polyurethane elastomer, polystyrene elastomer, styrene-ethylene-butylene-styrene copolymer (SEBS), and styrene-ethylene-propylene-styrene copolymer (SEPS), a thermoplastic resin such as nylon and PET, or rubber, silicone elastomer, fiber material, and metals such as SUS wire (i.e., stainless steel wire), copper wire, titanium wire, and nitinol wire. In addition, the pulling unit **120** may be made of, for example, the same material as that of the adhesion promotion portion **110A**. By using the same material as that of the adhesion promotion portion **110A**, it is possible to manufacture at the same manufacturing site as that of the adhesion promotion portion **110A**, so that the manufacturing work is rather easy.

(61) FIGS. 3A and 3B illustrate an example of the shape of the pulling unit **120**. As illustrated in FIG. 3A, for example, a pulling unit **120A** can include a string-shaped member having a wavy outer shape. In addition, as illustrated in FIG. 3B, for example, a pulling unit **120B** can include a string-shaped member having a bump-like outer shape (shape in which a projection portion and a recessed portion are alternately formed along the extending direction). In addition, as illustrated in FIG. 3C, a pulling unit **120C** can include a string-shaped member having an outer shape in which one end side intersecting the extending direction is formed in a straight line and the other end side is formed in a wavy shape. For example, the pulling unit **120A** and the pulling unit **120B** are formed of an elastic material, so that the pulling unit **120A** and the pulling unit **120B** can be deformed in a straight line when the pulling operation is performed, and the pulling unit **120A** and the pulling unit **120B** can be configured to return to the original shape when the pulling operation is released. With this configuration, when each of the pulling units **120A** and **120B** is pulled, the friction between each of the pulling units **120A** and **120B** and the adhesion promotion sheet **110** can be reduced, and the adhesion promotion sheet **110** can be prevented from being damaged. In addition, in the pulling unit **120C** illustrated in FIG. 3C, one end side intersecting the extending direction is formed in a straight line, so that the friction with the adhesion promotion sheet **110** can be further reduced.

(62) As will be described later, a pulling unit **220** can also be configured to include a strip-shaped member (for example, as illustrated in FIGS. 4A-4G). In the present specification, the strip-shaped member can be defined as a member having a larger cross-sectional area than that of the string-shaped member. As an example of the strip-shaped member, a member having a long side and a short side formed in a cross-sectional shape can be cited, and the cross-sectional shape is not limited to the strip-shaped member.

(63) FIG. 1B illustrates a state when the adhesion promotion sheet **110** is disposed on the pancreatic parenchyma Ba. The operator disposes the adhesion promotion portion **110A** of the adhesion promotion sheet **110** so as to overlap a cut surface **B1a** of the pancreatic parenchyma Ba. At this time, the operator disposes the non-connection section **123** of the pulling unit **120** on the anterior wall **B1d** (portion of the pancreatic parenchyma **B1** on the ventral side in the circumferential direction) side of the pancreatic parenchyma **B1**. The operator deforms the frame portion **110B** by pulling the pulling unit **120** on the anterior wall **B1d** side of the pancreatic parenchyma **B1** in a direction separated from the pancreatic parenchyma **B1**. When the pulling unit **120** is pulled, the adhesion promotion sheet **110** is deformed into a bag shape so as to cover a portion of the outer peripheral surface of the pancreatic parenchyma **B1**. When the operator pulls the pulling unit **120** by a predetermined length, the subsequent pulling operation is limited by the adjustment unit **150**. As a result, it is possible to prevent the pancreatic parenchyma **B1** from being excessively tightened by the pulling unit **120**. By deforming the adhesion promotion sheet **110** so as to cover the pancreatic parenchyma **B1**, the adhesion promotion sheet **110** can be stably held by the pancreatic parenchyma **B1**.

(64) As described above, the medical device **100** according to the present embodiment includes the adhesion promotion sheet **110** provided with the adhesion promotion portion **110A** promoting adhesion of the biological tissues formed of the biodegradable sheet having the plurality of through-holes **112**, and the frame portion **110B** provided outside the adhesion promotion portion **110A** in the plane direction, and the pulling unit **120** that is connected to the adhesion promotion sheet **110** and deforms the frame portion **110B** so as to cover at least a portion of the outer peripheral surface of the biological organ to be joined with the pulling operation.

(65) According to the medical device **100** configured as described above, the adhesion of the biological tissues of the biological organs can be promoted by interposing the adhesion promotion sheet **110** between the joint target sites of the biological organs to be joined. In addition, the operator can deform the frame portion **110B** of the adhesion promotion sheet **110** so as to cover at least a portion of the outer peripheral surface of the biological organs to be joined by pulling the pulling unit **120**. As a result, the operator can stably hold the adhesion promotion sheet **110** in the biological organs, and can help prevent the adhesion promotion sheet **110** from being distorted or misaligned during the medical procedure. Therefore, the risk of anastomotic leakage of the biological organs can be effectively reduced.

(66) In addition, the pulling unit **120** can include the connection section **121** connected to the frame portion **110B**, and the non-connection section **123** that is not connected to the frame portion **110B** and is pulled out of the adhesion promotion sheet **110**. Therefore, the operator can deform the frame portion **110B** so as to cover the outer peripheral surface of the biological organ by a simple operation of pulling the non-connection section **123**.

(67) In addition, the connection section **121** is connected to the frame portion **110B** with a length equal to or more than half the adhesion promotion sheet **110** along the circumferential direction. Therefore, the operator can more reliably deform the adhesion promotion sheet **110** into a desired shape by pulling the pulling unit **120**.

(68) In addition, the pulling unit **120** can include a string-shaped member having a predetermined length. Therefore, the operator can rather easily deform the adhesion promotion sheet **110** into a desired shape by pulling the pulling unit **120**.

(69) In addition, the medical device **100** can include the adjustment unit **150** that can adjust the amount of deformation of the frame portion **110B** by limiting the pulling operation of the pulling unit **120**. Therefore, the operator can help prevent the biological organs from being excessively tightened by the pulling unit **120**.

(70) In addition, the frame portion **110B** can help prevent the frame portion **110B** from performing the synechia with the biological organs other than the biological organs to be joined by the suppressing portion that suppresses the synechia with the biological organs.

(71) Next, a modification example of the above-described embodiment will be described. In the description of the modification example, detailed description of the constituent members and the like already described in the above-described embodiment will be omitted. In addition, the contents not particularly described in the description of the modification example can be the same as those in the above-described embodiment.

Modification Example 1

(72) FIG. 4A is a perspective view of a medical device **200** according to Modification Example 1, and FIGS. 4B-4G is a diagram for describing a shape example of the pulling unit **120** of the medical device **200** according to the modification example 1.

(73) As illustrated in FIG. 4A, the pulling unit **220** included in the medical device **200** according to Modification Example 1 includes a strip-shaped member. The pulling unit **220** includes a connection section **221** connected to the frame portion **110B** and a non-connection section **223** pulled out outside the adhesion promotion sheet **110**. The non-connection section **223** is provided with the adjustment unit **150** configured to include an annular portion **223a** and an insertion portion **223b** inserted through the annular portion **223a**.

(74) As illustrated in FIG. 4B, the pulling unit **220** can include a strip-shaped member extending linearly with a substantially constant width. In addition, as illustrated in FIG. 4C, the pulling unit **220A** can include a strip-shaped member formed in a substantially central portion in the extending direction and having a projection portion **225** projecting in the width direction intersecting the extending direction. The pulling unit **220A** can increase a holding force for holding the adhesion promotion sheet **110** on the biological organs as compared with the pulling unit **220**. In addition, as illustrated in FIG. 4D, the pulling unit **220B** can include a strip-shaped member formed in a shape in which the width gradually increases toward the substantially central portion in the extending direction. In a case where the pulling unit **220B** is configured to be removable from the adhesion promotion sheet **110**, the pulling unit **220B** is likely to be released from the insertion (connection) with respect to the adhesion promotion sheet **110**. In addition, as illustrated in FIGS. 4E and 4F, the rigidity may be configured to be different between the both end portions **226** and the central portion **227** in the width direction of each of the pulling units **220C** and **220D**. In accordance with an exemplary embodiment, the rigidity of a portion of each of the pulling units **220C** and **220D** can be made higher than that of the other portions, thus it is possible to help prevent each of the pulling units **220C** and **220D** from being damaged during the pulling operation. In addition, as illustrated in FIG. 4G, the pulling unit **220E** may be provided with slits **228a** and **228b** extending in the width direction and a hole portion **229** formed in the central portion in the width direction and extending in the extending direction. The operator can regulate the pulling operation of the pulling unit **220E** by passing the pulling unit **220E** through the hole portion **229** and hooking the side surface portion of the pulling unit **220E** into the slits **227a** and **228b**. Each pulling unit including the strip-shaped member may be formed in the same planar shape as the shape example of the string-shaped member illustrated in FIGS. 3A and 3B.

(75) In the medical device **200**, since the pulling unit **220** includes the strip-shaped member, the contact area between the pulling unit **220** and the pancreatic parenchyma **B1** is larger than that in the case where the pulling unit **220** includes the string-shaped member. Therefore, the medical device **200** can increase the holding force of the adhesion promotion sheet **110** with respect to the pancreatic parenchyma **B1**.

Modification Example 2

(76) FIG. 5A is a perspective view for describing a usage example of a medical device according to Modification Example 2.

(77) A connection section **321** of a pulling unit **320** can be configured to have a first site **321a** having a rigidity higher than that of the non-connection section **123** and a second site **321b** having a rigidity lower than that of the first site **321a**. As illustrated in FIG. 5A, the first site **321a** and the second site **321b** can be alternately disposed along the circumferential direction of the adhesion

promotion sheet **110**. By including the first site **321a**, the pulling unit **320** can increase the holding force for holding the adhesion promotion sheet **110** on the pancreatic parenchyma **B1** on the posterior wall **B1c** (portion of the pancreatic parenchyma **B1** on a dorsal side in the circumferential direction) side of the pancreatic parenchyma **B1**.

Modification Example 3

(78) FIG. **5B** is a perspective view for describing a usage example of a medical device according to Modification Example 3.

(79) The medical device may include, for example, a holding member **180** that can be attached to the adhesion promotion sheet **110**. The holding member **180** can include, for example, a member having a higher rigidity than that of the pulling unit **320**. In addition, the holding member **180** can be configured to have a C-shaped outer shape that can be disposed along a portion of the outer peripheral surface on the posterior wall **B1c** (portion of the pancreatic parenchyma **B1** on a dorsal side in the circumferential direction) side of the pancreatic parenchyma **B1**. The holding member **180** is disposed so as to be hooked on the pancreatic parenchyma **B1**, so that the operator can hold the adhesion promotion sheet **110** more stably on the pancreatic parenchyma **B1**.

Modification Example 4

(80) FIG. **6A** is a perspective view of a medical device **400** according to Modification Example 4.

(81) A frame portion **410B** of an adhesion promotion sheet **410** included in the medical device **400** according to Modification Example 4 includes a plurality of protruding portions **411a**, **411b**, and **411c** disposed in the circumferential direction of the adhesion promotion sheet **410**. Each of the protruding portions **411a**, **411b**, and **411c** includes a hole portion **412** through which the pulling unit **120** can be inserted. A predetermined space (gap) **g** is formed between the protruding portions **411a**, **411b**, and **411c**. In accordance with an exemplary embodiment, each of the protruding portions **411a**, **411b** and **411c** has a substantially triangular planar shape.

(82) The operator can deform each of the protruding portions **411a**, **411b** and **411c** along the outer peripheral surface of the pancreatic parenchyma **B1** by pulling the pulling unit **120**. In addition, each of the protruding portions **411a**, **411b** and **411c** is disposed so as to cover at least a portion of the outer peripheral surface of the pancreatic parenchyma **B1**. Each of the protruding portions **411a**, **411b**, and **411c** may be rather easily deformed when the pulling operation is performed, as compared with the frame portion **110B** (refer to FIG. **1A**) described above. Therefore, each of the protruding portions **411a**, **411b** and **411c** can be more reliably deformed along the outer peripheral surface of the pancreatic parenchyma **B1**.

Modification Example 5

(83) FIG. **6B** is a perspective view of a medical device **500** according to Modification Example 5.

(84) A frame portion **510B** of an adhesion promotion sheet **510** included in the medical device **500** according to Modification Example 5 includes four protruding portions **511a**, **511b**, **511c**, and **511d**. Each of the protruding portions **511a**, **511b**, **511c**, and **511d** includes a hole portion **512** through which the pulling unit **120** can be inserted. A predetermined space (gap) **g** is formed between the protruding portions **511a**, **511b**, **511c**, and **511d**. In accordance with an exemplary embodiment, each of the protruding portions **511a**, **511b** and **511c** has a substantially rectangular planar shape. Similarly to the medical device **400** according to Modification Example 4, since each of the protruding portions **511a**, **511b**, **511c**, and **511d** is rather easily deformed when the pulling unit **120** is pulled, the medical device **500** according to Modification Example 5 can be reliably deformed along the outer peripheral surface of the pancreatic parenchyma **B1**. The shape, number, and the like of the protruding portions illustrated in Modification Examples 4 and 5 are not particularly limited.

Embodiment of Treatment Method (Biological Organs Anastomosis)

(85) Next, a treatment method using the medical device will be described.

(86) FIG. **7** is a flowchart illustrating each procedure of the treatment method using the medical device.

(87) The treatment method includes preparing a medical device including an adhesion promotion sheet provided with a pulling unit (S11), disposing the adhesion promotion sheet at one joint target site (S12), pulling the pulling unit to deform the adhesion promotion sheet (S13), fixing the adhesion promotion sheet to the one joint target site (S14), and joining the one joint target site and the other joint target site in a state where at least a portion of the adhesion promotion sheet is disposed between the one joint target site and the other joint target site (S15).

(88) The biological organs and the joint target site in the biological organs which are joined by using the treatment method are not particularly limited, and can be optionally selected. In the following description, pancreatic parenchyma-jejunum anastomosis will be described as an example. However, the above-described treatment method may be applied, for example, to large intestine anastomosis or gastric tube anastomosis. In addition, as the medical device used in each medical procedure described below, for example, it is possible to select any desired one from the medical devices described above. However, in the following description, as a representative example which can be used for each medical procedure, an example of using a specific medical device will be described. In addition, in each medical procedure described below, detailed description of known medical procedures, known medical devices, and medical instruments will be appropriately omitted.

(89) Hereinafter, in the description herein, “disposing the adhesion promotion sheet between the biological organs” means at least any one of disposing the adhesion promotion sheet in a state of being in direct or indirect contact with the biological organs, disposing the adhesion promotion sheet in a state where a spatial gap is formed with the biological organs, and disposing the adhesion promotion sheet in both the states (for example, disposing the adhesion promotion sheet in a state where the adhesion promotion sheet is in contact with one biological organ and the adhesion promotion sheet is not in contact with the other biological organ). In addition, in the description herein, a “periphery” does not define a strict range (region), and means a predetermined range (region) as long as a treatment purpose (joining the biological organs to each other) can be achieved. In addition, as long as the treatment purpose can be achieved, in the medical procedure described in the respective treatment methods, orders can be appropriately switched among the order of the respective treatment methods.

(90) Embodiment of Treatment Method (Pancreatic Parenchyma-Jejunum Anastomosis)

(91) FIG. 8 is a flowchart illustrating a procedure of an embodiment of the treatment method (pancreatic parenchyma-jejunum anastomosis), and FIGS. 9 to 16 are diagrams used for describing the pancreatic parenchyma-jejunum anastomosis.

(92) In the treatment method according to the present embodiment, the biological organs to be joined are the pancreatic parenchyma B1 after pancreaticoduodenectomy and the jejunum B2. In the following description, a procedure of joining the periphery of the cut surface B1a of the cut pancreatic parenchyma B1 (one joint target site) and a predetermined site of an intestinal wall of the jejunum B2 (the other joint target site) will be described. In addition, in the present embodiment, the usage example of the medical device 100 illustrated in FIG. 1A will be described.

(93) As illustrated in FIG. 8, the treatment method according to the present embodiment includes preparing the medical device 100 including the adhesion promotion sheet 110 provided with the pulling unit 120 (S101), disposing the adhesion promotion sheet 110 on the cut surface B1a of the pancreatic parenchyma B1 (S102), pulling the pulling unit 120 to deform the adhesion promotion sheet 110 (S103), fixing the adhesion promotion sheet with a fixing member (S104), interposing the adhesion promotion sheet 110 between the pancreatic parenchyma B1 and the jejunum B2 (S105), joining with the adhesion promotion sheet 110 interposed between the pancreatic parenchyma B1 and the jejunum B2 (S106), and indwelling the adhesion promotion sheet 110 between the pancreatic parenchyma B1 and the jejunum B2 (S107).

(94) Next, an example of the treatment method according to the present embodiment will be specifically described with reference to FIGS. 9 to 16. In FIG. 14, a plurality of both end needles

920a to **920e** described later are omitted.

(95) As illustrated in FIG. 9, the operator causes the rear surface **114** (or front surface **113**) of the adhesion promotion sheet **110** face the cut surface **B1a** of the pancreatic parenchyma **B1**. The operator disposes the non-connection section **123** so as to not to cover the cut surface **B1a** of the pancreatic parenchyma **B1** in the plane direction. The operator can deform the adhesion promotion sheet **110** so that the frame portion **110B** covers a portion of the outer peripheral surface of the pancreatic parenchyma **B1** by pulling the pulling unit **120**. The operator can hold the adhesion promotion portion **110A** in close contact with the cut surface **B1a** of the pancreatic parenchyma **B1** (refer to FIG. 1B) by performing such an operation.

(96) When disposing the adhesion promotion sheet **110** on the cut surface **B1a** of the pancreatic parenchyma **B1**, the operator can adopt the following work procedure. First, the operator forms a hole portion **130** in the adhesion promotion sheet **110** by pressing an end portion **911** (or end portion **912**) of a pancreatic duct tube **910** against the adhesion promotion sheet **110**. In addition, the operator inserts the pancreatic duct tube **910** into the jejunum **B2** so that the end portion **911** of the pancreatic duct tube **910** passes through the inside of the jejunum **B2** from the through-hole **B2a** at the planned anastomosis site of jejunum **B2** and exits the outside of the jejunum **B2** from the through-hole **B2b** of the jejunum **B2**.

(97) Next, the operator temporarily inserts the end portion **912** of the pancreatic duct tube **910** into the pancreatic duct **B1b** of the pancreatic parenchyma **B1** in a state where the pancreatic duct tube **910** inserts the hole portion **130** of the adhesion promotion sheet **110** and holds the adhesion promotion sheet **110**.

(98) As the pancreatic duct tube **910**, for example, a resin tube in which a bump (projection portion) for preventing falling off is formed at the end portion **912** can be used. The pancreatic duct tube **910** temporarily inserted into the pancreatic duct **B1b** suppresses the leakage of body fluid such as pancreatic juice from the pancreatic duct **B1b** during the medical procedure. According to such a procedure, the operator can dispose the adhesion promotion sheet **110** and temporarily insert the pancreatic duct tube **910** at the same time.

(99) In addition, the operator may use a device other than the pancreatic duct tube **910** when forming the hole portion **130** for inserting the pancreatic duct tube **910**. In addition, the hole portion **130** through which the pancreatic duct tube **910** is inserted may be formed in the adhesion promotion sheet **110** in advance in a state before use. In addition, the operator may temporarily insert the pancreatic duct tube **910** into the pancreatic duct **B1b** after disposing the adhesion promotion sheet **110** on the cut surface **B1a** of the pancreatic parenchyma **B1**.

(100) Next, the operator fixes the adhesion promotion sheet **110** to the pancreatic parenchyma **B1** with the fixing member. In the following description, an example of a procedure of fixing the adhesion promotion sheet **110** to the pancreatic parenchyma **B1** by using the plurality of the both end needles **920a** to **920e** with sutures as fixing members will be described. As the both end needles **920a** to **920e**, needles having a bioabsorbable absorbent thread (suture) and a biocompatible needle portion attached to both ends of the absorbent thread can be used. Both end needles **930** and **940a** to **940e** described later are also configured to include absorbent threads and needle portions.

(101) First, as illustrated in FIG. 10, the operator moves the both end needle **920a** from the posterior wall **B1c** of the pancreatic parenchyma **B1** (portion of the pancreatic parenchyma **B1** on a dorsal side in the circumferential direction) and the portion disposed on the posterior wall **B1c** in the adhesion promotion sheet **110** toward the anterior wall **B1d** of the pancreatic parenchyma **B1** and the portion disposed on the anterior wall **B1d** in the adhesion promotion sheet **110** in a state where the adhesion promotion sheet **110** is held on the pancreatic parenchyma **B1**. Next, the operator moves the both end needle **920a** so as to insert a jejunal serosal muscular layer at the planned anastomosis site of the jejunum **B2** (periphery of the through-hole **B2a**). The operator repeats such an operation, and as illustrated in FIG. 11, inserts the plurality of the both end needles

920a to **920e** into the plurality of the both end needles **920a** to **920e** on the adhesion promotion sheet **110**, the pancreatic parenchyma **B1**, and the jejunal serosal muscular layer of the jejunum **B2**. In this manner, the operator can fix the adhesion promotion sheet **110** to the pancreatic parenchyma **B1** by using the plurality of the both end needles **920a** to **920e** that suture the pancreatic parenchyma **B1** and the jejunum **B2**.

(102) The operator may appropriately separate the pulling unit **120** from the adhesion promotion sheet **110** after fixing the adhesion promotion sheet **110** to the cut surface **B1a** of the pancreatic parenchyma **B1**. The operator pulls the pulling unit **120** until the adhesion promotion sheet **110** is fixed to the cut surface **B1a** of the pancreatic parenchyma **B1** and maintains a state where the frame portion **110B** of the adhesion promotion sheet **110** is in close contact with the outer peripheral surface of the pancreatic parenchyma **B1**. Accordingly, it is possible to help prevent the adhesion promotion sheet **110** from misaligning or falling off from the pancreatic parenchyma **B1**.

(103) The number of both end needles to be inserted into the pancreatic parenchyma **B1** and the jejunal serosal muscular layer of the jejunum **B2** and the positions through which the both end needles are inserted are not particularly limited. In addition, the operator may fix the adhesion promotion sheet **110** to the pancreatic parenchyma **B1** by using a biodegradable stapler or the like as a fixing member instead of the plurality of the both end needles **920a** to **920e**.

(104) Next, as illustrated in FIG. **11**, the operator removes the end portion **912** of the pancreatic duct tube **910** from the pancreatic duct **B1b**.

(105) Next, as illustrated in FIG. **11**, the operator passes the both end needle **930** from a luminal side of the pancreatic duct **B1b** toward the anterior wall **B1d** side of the cut surface **B1a** of the pancreatic parenchyma **B1**. The both end needle **930** is held by a gripping instrument such as tweezers so as not to interfere with the medical procedure in a state where the jejunum **B2** is not inserted.

(106) Next, as illustrated in FIGS. **11** and **13**, the operator moves one end of the both end needle **940a** from the luminal side of the pancreatic duct **B1b** toward the cut surface **B1a** of the pancreatic parenchyma **B1**. Next, as illustrated in FIGS. **12** and **13**, the operator inserts the other end of the both end needle **940a** into the through-hole **B2a** of the jejunum **B2**, and moves the other end of the both end needle **940a** from the inside of the jejunum **B2** toward the outside of the jejunum **B2**. As illustrated in FIG. **14**, the operator inserts the plurality of both end needles **940a** to **940e** into different sites of the pancreatic duct **B1b** in the circumferential direction and the jejunum **B2**. FIG. **13** is a cross-sectional view schematically illustrating a portion of the pancreatic parenchyma **B1** and the jejunum **B2** before being anastomosed.

(107) Next, as illustrated in FIG. **14**, the operator brings the posterior wall **B1c** of the pancreatic parenchyma **B1** and the pancreatic duct **B1b** into close contact with the planned anastomosis site of the jejunum **B2**. Of the plurality of the both end needles **940a** to **940e**, the both end needles **940c** to **940e** that insert the dorsal side (posterior wall **B1c** side) of the pancreatic duct **B1b** in the circumferential direction are ligated.

(108) Next, as illustrated in FIG. **15**, the operator reinserts the end portion **912** of the pancreatic duct tube **910** into the pancreatic duct **B1b**. Next, the operator inserts a needle portion **931** extending from the inside of the pancreatic duct **B1b** in the both end needle **930** into the through-hole **B2b** formed in the jejunum **B2**, and moves the needle portion **931** from the inside of the jejunum **B2** toward the outside of the jejunum **B2**.

(109) Next, the operator ligates the both end needles **930**, **940a**, and **940b** (not illustrated). The number of both end needles to be inserted into the pancreatic duct **B1b** and the jejunum **B2** and the positions through which the both end needles are inserted are not particularly limited.

(110) Next, as illustrated in FIG. **16**, the operator ligates the both end needles **920a** to **920e** while pressing the jejunum **B2** against the pancreatic parenchyma **B1** with the operator's finger. As a result, the pancreatic parenchyma **B1** and the jejunum **B2** are sutured in a state where the adhesion promotion sheet **110** is interposed between the pancreatic parenchyma **B1** and the jejunum **B2**. The

jejunum **B2** is deformed by the tension generated at the time of suturing so as to enclose the cut surface **B1a** of the pancreatic parenchyma **B1** and the adhesion promotion portion **110A** of the adhesion promotion sheet **110**.

(111) The operator indwells the adhesion promotion sheet **110** in a state where the adhesion promotion portion **110A** of the adhesion promotion sheet **110** is interposed between the cut surface **B1a** of the pancreatic parenchyma **B1** and the intestinal wall of the jejunum **B2**. The adhesion promotion portion **110A** of the adhesion promotion sheet **110** is indwelled between the cut surface **B1a** of the pancreatic parenchyma **B1** and the intestinal wall of the jejunum **B2** while being in contact with the cut surface **B1a** of the pancreatic parenchyma **B1** and the intestinal wall of the jejunum **B2**. Accordingly, the adhesion of the biological tissue of the pancreatic parenchyma **B1** and the biological tissue of the intestinal wall of the jejunum **B2** is promoted.

(112) As described above, the treatment method according to the present embodiment is applied to the medical procedure of joining the pancreatic parenchyma **B1** and the jejunum **B2**. In addition, in the above treatment method, the periphery of the cut surface **B1a** of the cut pancreatic parenchyma **B1** and the intestinal wall (jejunal serosal muscular layer) of the jejunum **B2** are joined to each other. According to the treatment method, the adhesion promotion portion **110A** of the adhesion promotion sheet **110** interposed between the cut surface **B1a** of the pancreatic parenchyma **B1** and the intestinal wall of the jejunum **B2** can promote the adhesion of the biological tissue of the pancreatic parenchyma **B1** and the biological tissue of the intestinal wall of the jejunum **B2**, and can reduce the risk of anastomotic leakage after the pancreatic parenchyma-jejunum anastomosis.

(113) In addition, the operator can help prevent the adhesion promotion sheet **110** from being distorted or misaligned by deforming the frame portion **110B** of the adhesion promotion sheet **110** so as to cover at least a portion of the outer peripheral surface of the pancreatic parenchyma **B1** by the pulling unit **120**.

Another Modification Example

(114) Next, a pulling unit **620** according to another modification example will be described with reference to FIGS. **17** to **22**. In the description of the present modification example, the description of the content that overlaps with the content already described in the above-described embodiment will be omitted. In addition, the contents not particularly described in the description of the modification example can be the same as those in the above-described embodiment.

(115) FIG. **17** illustrates a plan view of a pulling unit **620** in a state before being connected to the adhesion promotion sheet **110**. FIGS. **18** to **22** illustrate a procedure example of the medical procedure using the medical device **100** provided with the pulling unit **620**.

(116) As illustrated in FIG. **17**, the pulling unit **620** includes a strip-shaped main body portion **621** having a predetermined width and length, a plurality of slit portions **623** formed on one end portion **621a** in the longitudinal direction of the main body portion **621**, and a first hole portion **625a** and a second hole portion **625b** formed on the other end portion **621b** in the longitudinal direction of the main body portion **621**.

(117) The one end portion **621a** of the main body portion **621** can be formed, for example, into a tapered shape that tapers toward the tip end side of the one end portion **621a**. By providing such a shape, the work of passing the one end portion **621a** of the main body portion **621** through each of the hole portions **625a** and **625b** can be rather easily performed (refer to FIGS. **19** and **20**).

(118) The first hole portion **625a** is disposed closer to the one end portion **621a** of the main body portion **621** than the second hole portion **625b**. The first hole portion **625a** and the second hole portion **625b** extend in directions orthogonal to each other. The first hole portion **625a** extends substantially parallel to the width direction (horizontal direction in FIG. **17**) of the main body portion **621**. The second hole portion **625b** extends substantially parallel to the longitudinal direction (vertical direction in FIG. **17**) of the main body portion **621**.

(119) The first hole portion **625a** can be formed, for example, in a substantially rectangular shape in which long sides are disposed along the width direction of the main body portion **621** in the plan

view illustrated in FIG. 17. The second hole portion **625b** can be formed, for example, in a substantially rectangular shape in which long sides are disposed along the longitudinal direction of the main body portion **621** in the plan view illustrated in FIG. 17. The shape, position, and size of each of the hole portions **625a** and **625b** are not particularly limited.

(120) The slit portion **623** is inclined and extends in a direction parallel to the longitudinal direction of the main body portion **621**. Specifically, the slit portion **623** is inclined from the center side of the main body portion **621** toward the outside. The number and shape of the slit portions **623**, the specific position provided in the main body portion **621**, and the like are not particularly limited.

(121) As illustrated in FIG. 18, a portion of the main body portion **621** constitutes a connection section **631a** connected to the frame portion (second region) **110B** of the adhesion promotion sheet **110**. The connection section **631a** can be slidably connected to, for example, the frame portion **110B**, similarly to the connection section **121** (refer to FIG. 1B) described in the above-described embodiment. In addition, as illustrated in FIG. 18, a portion of the main body portion **621** constitutes a non-connection section **631b** that is not connected to the frame portion **110B** of the adhesion promotion sheet **110**.

(122) As illustrated in FIG. 22, the slit portion **623** and each of the hole portions **625a** and **625b** disposed in the non-connection section **631b** have a function as an adjustment unit **650** that can adjust the amount of deformation of the frame portion **110B** of the adhesion promotion sheet **110**.

(123) Next, with reference to FIGS. 18 to 22, an example of the procedure of the medical procedure using the medical device **100** provided with the pulling unit **620** will be described. The procedure and the like already described in the above-described embodiment will be omitted as appropriate.

(124) As illustrated in FIG. 18, the operator disposes the adhesion promotion portion **110A** of the adhesion promotion sheet **110** on the cut surface **B1a** of the pancreatic parenchyma **B1**. The operator deforms the adhesion promotion sheet **110** by pulling both end portions **621b** and **621b** located at the non-connection section **631b** of the pulling unit **620**, and covers a portion of the outer peripheral surface of the pancreatic parenchyma **B1** with the frame portion **110B** of the adhesion promotion sheet **110**.

(125) As illustrated in FIGS. 19 and 20, the operator inserts a portion of the main body portion **621** on the one end portion **621a** side into each of the hole portions **625a** and **625b**. When inserting a portion of the main body portion **621** on the one end portion **621a** side into each of the hole portions **625a** and **625b**, the operator deforms a portion of the main body portion **621** on the other end portion **621b** side so as to be folded back. The operator can use, for example, a medical instrument **710** such as forceps when performing such an operation. Specifically, as illustrated in FIG. 20, the operator operates to lift the medical instrument **710** while grasping a portion of the main body portion **621** on the one end portion **621a** side with the medical instrument **710** passed through each of the hole portions **625a** and **625b**, as illustrated in FIG. 19. By performing such an operation, the operator can rather easily pass a portion of the main body portion **621** on the one end portion **621a** side together with the medical instrument **710** through each of the hole portions **625a** and **625b**.

(126) As illustrated in FIG. 21, the operator pulls the portion inserted through each of the hole portions **625a** and **625b** in the main body portion **621**, while pressing a portion where each of the hole portions **625a** and **625b** is disposed in the main body portion **621** and the peripheral portions thereof, by using a medical instrument **720** such as forceps. Accordingly, the adhesion promotion sheet **110** can be held on the pancreatic parenchyma **B1**.

(127) Even when the operator releases the pulling of the pulling unit **620**, the slit portion **623** is maintained in a state of being hooked by the first hole portion **625a** and the second hole portion **625b**. Therefore, the holding force for holding the adhesion promotion sheet **110** on the pancreatic parenchyma **B1** can be maintained.

(128) In the present modification example, the first hole portion **625a** disposed at a position closer to the pancreatic parenchyma **B1** than the second hole portion **625b** (position closer to the outer

peripheral surface of the pancreatic parenchyma B1) extends along the width direction of the pulling unit **620** (refer to FIG. 17). In addition, as illustrated in FIGS. 19 and 22, the first hole portion **625a** is disposed along the extending direction of the pancreatic parenchyma Ba. Therefore, the operator can help prevent the main body portion **621** of the pulling unit **620** from being deformed so that the width of the portion inserted through the first hole portion **625a** can be excessively reduced. Therefore, in the main body portion **621** of the pulling unit **620**, the load applied to the pancreatic parenchyma Ba by the portion inserted through the first hole portion **625a** can be suppressed to reduce the applied load. On the other hand, the second hole portion **625b** disposed at a position further separated from the pancreatic parenchyma B1 than the first hole portion **625a** (position separated from the outer peripheral surface of the pancreatic parenchyma B1) extends in a direction intersecting the width direction of the pulling unit **620** (refer to FIG. 17). Therefore, the portion inserted through the second hole portion **625b** in the main body portion **621** of the pulling unit **620** is deformed so that the width is reduced along the shape of the second hole portion **625b** having a smaller width. The main body portion **621** having a width larger than that of the second hole portion **625b** is inserted into the second hole portion **625b** having a smaller width. Accordingly, the hooking between the inner peripheral portion of the second hole portion **625b** and the main body portion **621** is increased. Therefore, the holding force of the adhesion promotion sheet **110** with respect to the pancreatic parenchyma B1 can be effectively increased.

(129) As illustrated in FIG. 22, the operator can wrap the one end portion **621a** side inserted through the first hole portion **625a** and the second hole portion **625b** in the main body portion **625** around the pancreatic parenchyma Ba. The above portion of the main body portion **625** may be excised.

(130) As described above, according to the medical device **100** provided with the pulling unit **620** according to the present modification example, the holding force of the adhesion promotion sheet **110** on the pancreatic parenchyma Ba can be effectively increased while reducing the load applied to the pancreatic parenchyma Ba.

(131) The detailed description above describes versions of a medical device representing examples of the inventive medical device disclosed here. The invention is not limited, however, to the precise embodiment 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 method of promoting adhesion between biological tissue comprising: disposing a medical device on a cut surface of one joint target site, wherein the one joint target site is a pancreatic parenchyma, the medical device comprising an adhesion promotion sheet including a first region that promotes adhesion of biological tissues and a second region provided outside the first region in a plane direction, and a pulling unit connected to the adhesion promotion sheet; pulling the pulling unit to deform the adhesion promotion sheet of the medical device to deform the second region; fixing the adhesion promotion sheet of the medical device to the one joint target site with a fixing member; interposing the adhesion promotion sheet between the one joint target and an other joint target site, wherein the other joint target site is a jejunum; joining the one joint target site and the other joint target site in a state where at least a portion of the adhesion promotion sheet is disposed between the pancreatic parenchyma and the jejunum; and indwelling the adhesion promotion sheet between the pancreatic parenchyma and the jejunum.
2. The method according to claim 1, wherein at least a portion of the connection section has a rigidity greater than a rigidity of the non-connection section.
3. The method according to claim 1, wherein the pulling unit includes a string-shaped member.

4. The method according to claim 1, wherein the pulling unit includes a strip-shaped member having a predetermined length, the strip-shaped member having a larger cross-sectional area than that of a string-shaped member.
5. The method according to claim 1, further comprising: adjusting an amount of deformation of the second region with an adjustment unit that limits the pulling operation of the pulling unit.
6. The method according to claim 1, wherein the second region includes a plurality of protruding portions disposed in a circumferential direction of the adhesion promotion sheet, and the method further comprises: inserting the pulling unit into a hole portion in each of the plurality of protruding portions.
7. A method of promoting adhesion between biological tissue comprising: disposing a medical device on a cut surface of one joint target site, the medical device comprising an adhesion promotion sheet including a first region that promotes adhesion of biological tissues, and a second region provided outside the first region in a plane direction, and a pulling unit connected to the adhesion promotion sheet, wherein the pulling unit includes a connection section connected to the second region and a non-connection section, the non-connection section is not connected to the second region and is configured to be pulled out of the adhesion promotion sheet, wherein the connection section of the pulling unit includes a first site having a rigidity higher than that of the non-connection section and a second site having a rigidity lower than that of the first site, and wherein the first site and the second site are alternately disposed along a circumferential direction of the adhesion promotion sheet; pulling the pulling unit to deform the adhesion promotion sheet of the medical device to deform the second region; fixing the adhesion promotion sheet of the medical device to the one joint target site; interposing the adhesion promotion sheet between the one joint target and an other joint target site; joining the one joint target site and the other joint target site in a state where at least a portion of the adhesion promotion sheet is disposed between the one joint target site and the other joint target site; and indwelling the adhesion promotion sheet between the one joint target site and the other joint target site.
8. The method according to claim 7, further comprising: connecting the connection to the second region with a length equal to or more than half the adhesion promotion sheet along a circumferential direction.
9. A method of promoting adhesion between biological tissue comprising: disposing a medical device on a cut surface of one joint target site, the medical device comprising an adhesion promotion sheet including a first region that promotes adhesion of biological tissues, wherein the first region is made of a biodegradable sheet having a plurality of through-holes that pass through the first region, and a second region provided outside the first region in a plane direction wherein the second region does not have any through-holes, and a pulling unit connected to the adhesion promotion sheet; pulling the pulling unit to deform the adhesion promotion sheet of the medical device to deform the second region; fixing the adhesion promotion sheet of the medical device to the one joint target site; interposing the adhesion promotion sheet between the one joint target and an other joint target site; joining the one joint target site and the other joint target site in a state where at least a portion of the adhesion promotion sheet is disposed between the one joint target site and the other joint target site; and indwelling the adhesion promotion sheet between the one joint target site and the other joint target site.
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