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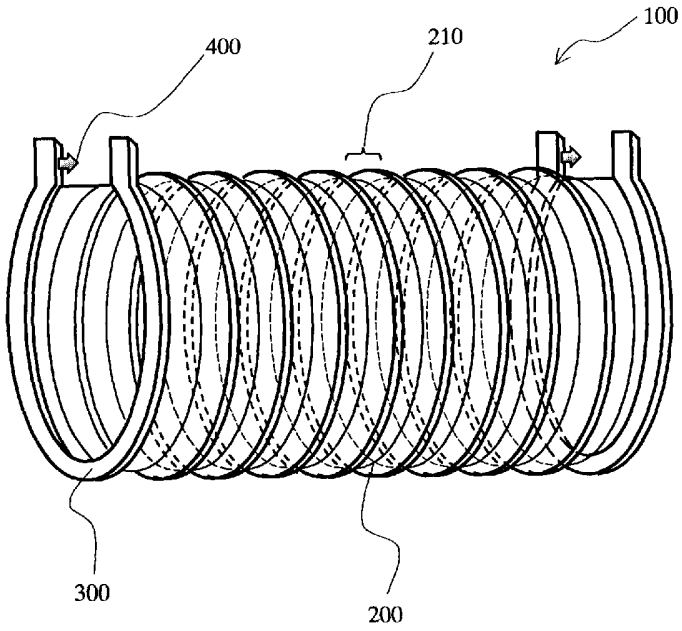
(54) Title: NERVE ANASTOMOSIS DEVICE



(57) Abstract: Disclosed is a nerve anastomosis device comprising an extensible body member of having a circular cross-section, and being hollow, and capable of being easily extended by a small pulling force; fastening members of being open, and being attached to both ends of the extensible body, and capable of wrapping the outer surface of an injured nerve, joint members of being formed on the open upper ends of the fastening member to join these open ends to each other. The nerve anastomosis device of the present invention can be used to anastomose a severed nerve by easy handling, thereby reducing the operative time largely. Moreover, the device is very small in the folded state and thus can be easily inserted in an injured site through a small incision, which also reduces a patient's pain.

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NERVE ANASTOMOSIS DEVICE

TECHNICAL FIELD

The present invention relates to a medical device useful for the anastomosis of injured nerves, and more particularly the nerve anastomosis device being placed between both ends of a severed nerve and then being simply joined.

BACKGROUND ART

When a nerve in the human body is severed, the relevant organs are paralyzed with respect to sense and movement. The nerve has a further lower generation rate than other body organs so that it is not easy to cure the severed nerve to the state before severance.

Once a nerve is severed, fibers in a proximal nerve being the nerve toward the brain, i.e., the proximal nerve fibers, remain unchanged, whereas the distal nerve fibers being in a peripheral nerve toward muscles are decomposed and then absorbed, that is, the distal nerve fibers undergo a series of processes called Wallerian degeneration. Moreover, as times are elapsed, a nerve tube in which the nerve fibers were decomposed/absorbed withers (being collapsed) and, when such collapse starts before new nerve fibers growing newly at the end of the proximal nerve arrive, the regeneration becomes impossible.

Generally, the proximal nerve fibers grow into the decimal nerve by 0.3 mm per day in the state that a severed nerve is sutured, and before the nerve fibers are regenerated completely, a nerve near to organs such as muscles undergoes the collapse

already.

As prior methods for suturing a severed nerve, there are methods of overlapping a silicon ring, blood vessel (vein), artificial nerve tube (so called, N-tube), etc. on the severed nerve. The method of using the silicon ring has the problem that the blood circulation is blocked by an impermeable silicone and resultantly the collapse occurs. The method of using the vein has the problem that a vein in other organ of a patient should be harvested and said collapse also occurs. The method of using the N-tube has the problem that the severed portion should be sutured in the fully exposed state, thereby causing a long operation time and a patent's pain.

Meanwhile, in order to solve these problems, a plurality of apparatus and methods were developed for carrying out the nerve suture effectively, and some of examples are illustrated as below.

U.S. Pat. No. 4,534,349 discloses an absorbable sutureless nerve repair device being longitudinally-opened, porous, rough-surfaced tubes of a body-absorbable polymer. In operation, the opened device is placed on a severed nerve and then is interlocked. However, for using this device, the operational site surrounding a severed nerve should be fully opened, thereby causing a long operation time and a patient's pain.

U.S. Pat. No. 4,920,962 discloses a splint-like element for use in end-to-end nerve suture, comprising two elongated bodies made of a material that is rigid and slightly resilient and pieces of reinforcing material placed along the body. However, the bodies may be easily separated from the nerve because the attachment is achieved at a part of nerve. Further, for reinforcement of suture, more than two pairs of elements should be used, which however makes the operation time longer.

U.S. Pat. No. 6,102,921 discloses a sling formed of breathable flexible porous semipermeable membrane material having a plurality of tabs spaced thereon. For suture, both ends of a severed nerve are placed on the sling and then the sling is rolled and

fastened. Therefore, the severed nerve should be fully exposed and several procedures should be carried out in serial, which is very cumbersome to a surgeon.

Korean Patent Laid-open Gazette No. 2000-57129 discloses an artificial neural canal comprising tubes made of a material decomposable and absorbable in vivo and covered on the inner and outer sides thereof with coating layers made of gelatin or collagen, and collagen parts disposed in the lumens of the tubes, each of them having a space extending through the tube in almost parallel with the axis of the tube, in which each space is filled with a matrix gel. However, in spite of a high regeneration rate, this neural canal should be sewed with a suture (stitching fiber) by a surgeon, which is time-consuming and cumbersome.

SUMMARY OF INVENTION

Therefore, the objects of the present invention are to solve the problems described above for once and all.

A first object of the present invention is to provide a device capable of anastomosing lacerated, severed or grafted nerves by a simple method.

A further object of the present invention is to provide a device capable of anastomosing an injured nerve by an endoscopic operation without opening fully the injured nerve.

A further other object of the present invention is to provide a device capable of anastomosing even an injured nerve being of the form of curve by nature.

Another object of the present invention is to provide a device of preventing an injured nerve from collapsing by accelerating the regeneration rate, in which the collapse of nerve causes the regeneration to be impossible.

In accordance with the present invention, the above objects are archived with a

nerve anastomosis device which comprises an extensible body member having the circular cross-section, and being hollow, and capable of being easily extended by a small pulling force; fastening members being opened, and being attached to both ends of the body member, and capable of being fastened on outer surface of an injured nerve; and joint members formed on the open ends of the fastening member to joint these open ends to each other in operation.

Accordingly, one of the fastening members is fastened (or connected) to the proximal end (or the distal end) of an injured nerve, and then, with the extensible body pulled, the other of the fastening members is fastened to the distal end (or the proximal end) of the injured nerve. Resultantly, the body member is easily extended to be deformed into a cylindrical form.

When a severed nerve is wrapped with a cylindrical tube as in the present invention, nerve fibers thereof generally grow along the tube in the original direction prior to severance, which has been known as the regeneration characteristic of nerve fiber. To the contrary, when a severed nerve is sutured directly, the regeneration directions of nerve fibers are apt to be changed randomly.

A nerve is a further less resilient tissue than a blood vessel. Therefore, when a severed nerve is sutured by extending it, the regeneration becomes impossible because the scar tissue appears. As such, the conventional direct-suture method using a stitching fiber is also carried out under the condition the severed nerve is maintained to be unsuspended with the utmost attention. In consideration of this characteristic of nerve, the extensible body member in the device of the present invention has the configuration capable of being easily extended by a small pulling force.

A preferred configuration of the extensible body member is that extension units, consisting of a ridge and a trough, are connected continuously and repeatedly along the outer surface of the cylindrical body member. Accordingly, when the body is

compressed, ridges of the extension units adjoin to each other so that the size of the body member becomes small. To the contrary, when the body member is extended by a pulling force, the extension units are unfolded to the utmost so that the body member is largely extended to become nearly cylindrical. Such configuration is similar to that of the accordion. The number of extension units is not specifically limited but it may depend upon the length of anastomosis. Preferably, the extension length of body member is around 1 cm in consideration of the regeneration rate of nerve fibers and the collapse phenomenon of nerve.

Materials of the extensible body member are preferably ones having pores penetrating between the internal and the external thereof in the extended state. In an embodiment, they may be natural or artificial absorbable polymers which are dissolved and absorbed in vivo as certain times elapse. Such polymers have been known and include polyamino acid such as partially-oxidated cellulose, chitin derivative, collagen, polyglycolic acid, polylactic acid, partially-esterificated poly-L-glutamic acid; polyester such as diol, succinic acid; polyhydroxybutylate, polyglycolic acid, etc. These materials or their derivates are disclosed in U.S. Pat. No. 3,225,766, U.S. Pat. No. 3,364,200, U.S. Pat. No. 3,371,069, U.S. Pat. No. 4,032,993, U.S. Pat. No. 4,074,366 and U.S. Pat. No. 4,118,470, which are incorporated with the present invention as the references but the present invention is not restricted to them.

The fastening members, which are attached to both ends of the extensible body, are made of rather rigid materials and are fastened to the ends of an injured nerve. They are opened at the time before being jointed. Accordingly, the fastening members are easily wrapped on the nerve and then closely attached to the outer surface of nerve in the jointed state of the joint members. The inner diameter of the fastening member in the jointed state is the same or a little larger than that of the nerve.

In an embodiment, in order for the fastening member to be fastened to the

nerve further strongly, a plurality of small protrusions are formed along the inner surface of the fastening member. Alternatively, the stronger fastening may be achieved by the rough inner surface of the fastening member, thereby causing the stronger frictional force between the inner surface of the fastening member and the outer surface of the nerve. The fastening members can be also made of biologically acceptable materials and, in another embodiment, the same materials with those of the extensible body member.

The joint members formed on the open upper portion of the fastening member serve as joining the open upper portion of the fastening member to close it in operation, whereby the fastening member is connected to the nerve. Any other configurations can be acceptable if they carry out such function, but the configuration capable of being joined by a small force at one time is preferable in considering the anastomosis procedure of connecting the nerve being a fine tissue. A preferred embodiment of such joint member is a pair of male-female parts, the male part being of an arrow form and the female part being of a recess form for the male part to able to be inserted.

Meanwhile, as mentioned above, the nerve growth factor (NGF) of accelerating the regeneration is secreted during the regeneration of nerve in vivo. According to the preferred configuration of the present invention, said NGF is coated on the inner surface of extensible body member. The NGF may be produced from microorganisms by the gene manipulation technology or from non-cellular protein synthesis systems being tried recently. In an embodiment, the NGF is coated on a portion of the inner surface of extensible body, e.g., on the troughs of extension units. When the extensible body member is compressed, the troughs adjoin to each other and thus the NGF can be coated only on the troughs of extensible body.

As shown below, the description refers to the drawing in order to describe the present invention more in detail, thereby, the scope of the invention is however not to be

interpreted as a limitation of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIGS. 1A, 1B and 2 show one exemplary nerve anastomosis device 100 comprising an extensible body member 200, fastening members 300 and joint members 400. FIG. 1A shows the compressed state (folded state) of the nerve anastomosis device 100, and FIG. 1B shows the a little extended state of the nerve anastomosis device 100. The extensible body member 200 comprises a plurality of successively extension units 210 of which each consists of a ridge 212 and a trough 214. FIG. 2 shows the further extended state of the nerve anastomosis device 100 in which the extensible body member 200 is further extended than that in FIG. 1B. For such structural characteristic, the nerve anastomosis device 100 of the present invention can be inserted in the folded state through a small incision around an injured nerve, whereby it is possible to reduce a patient's pain and operative time.

FIGS. 3A and 3B show fastening members 300, 302 in the nerve anastomosis device of the present invention. Referring to FIG. 3A, the upper portion of fastening member 300 is opened at the time before joint members joins to each other, and the overall shape of the fastening member 300 is near an ellipse. On both ends of the upper portion facing each other, joint members 400 are formed. When the joint members 400 join to each other, the fastening member 300 is deformed to a circular shape corresponding to the cross-sectional shape of a nerve. In FIG. 3B, disclosed is another fastening member 302 which has a plurality of small protrusions 330 along the inner surface thereof. The small protrusions 330 make the fastening member attached to the nerve 300 further strongly.

FIGS. 4A to 4D show the procedure of anastomosing a severed nerve by

employing the nerve anastomosis device 100 of FIG. 1.

In the step of FIG. 4A, the nerve anastomosis device 100 is put on an end 510 of a severed nerve 500. The end 510 of the severed nerve 500 may be the proximal nerve or the distal nerve. In this step, an extensible body member 200 is maintained folded.

In the step of FIG. 4B, the nerve anastomosis device 100 is affixed to the end 510 of the severed nerve 500 by joining a fastening member 310. The joining of the fastening member 310 can be accomplished by merely interlocking joint members (not shown) formed on the open upper portion of the fastening member 310.

In the step of FIG. 4C, the other fastening member 320 is pulled backward and then put on the corresponding end 520 of the severed nerve 500. Herein, an extensible body member 200 is stretched, whereby the body member 200 is deformed to a cylindrical hollow shape. Since the body member 200 is bendable, even when severed nerves 510 and 520 are not in the linear position, the anastomosis of such nerves can be achieved.

The present invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention and all such modifications would be obvious to one skilled in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A and 1B are lateral views of the nerve anastomosis device, according to an embodiment of the present invention, in the folded state and a little extended state.

FIG. 2 is a perspective view of the nerve anastomosis device in the further extended state.

FIGS. 3A and 3B are front views of fastening members of other shapes in the

nerve anastomosis device.

FIGS. 4A to 4D are procedure views of anastomosing a severed nerve by employing the nerve anastomosis device of FIG. 1A.

DESIGNATION OF THE REFERENCE NUMBERS

100: nerve anastomosis device

200: extensible body member

300: fastening member

400: joint member

510, 520: severed nerve

INDUSTRIAL APPLICABILITY

The nerve anastomosis device according to the present invention can be used to anastomose a severed nerve by easy handling, thereby reducing the operation time largely. Moreover, the device is very small in the folded state and thus can be easily inserted in an injured site through a small incision, which also reduces a patient's pain. Even in the case that a severed nerve is not in a linear position, it is possible to anastomose it with the device, and in another embodiment, the nerve regeneration rate can be accelerated by NGF being coated on the inner surface of extensible body member in the device.

WHAT IS CLAIMED IS:

1. A nerve anastomosis device comprising an extensible body member of having a circular cross-section, and being hollow, and capable of being easily extended by a small pulling force; fastening members of being opened, and being attached to both ends of the extensible body member, and capable of being fastened on the outer surface of an injured nerve; and joint members of being formed on the open upper ends of the fastening member to join these open ends to each other in operation.

2. The nerve anastomosis device according to Claim 1, wherein the extensible body member comprises a plurality of extension units, the extension unit consisting of a ridge and a trough connected continuously and repeatedly along the outer surface of the cylindrical body member, whereby, when the extensible body member is folded, a ridge of the extension unit adjoin to a ridge of the neighbor unit so that the dimension of the body member becomes small, whereas, when the body member is stretched by a pulling force, ridges are unfolded to the utmost so that the body member is largely extended to be deformed to a nearly cylindrical shape.

3. The nerve anastomosis device according to Claim 1 or 2, wherein materials of the extensible body member are biologically acceptable and are ones having pores penetrating between the internal and the external thereof in the extended state.

4. The nerve anastomosis device according to Claim 1 or 2, wherein the fastening member has a plurality of small protrusions along the inner surface thereof or has the rough inner surface to enforce the friction force between the fastening member and the nerve.

5. The nerve anastomosis device according to Claim 1 or 2, wherein the nerve growth factor (NGF) is coated on a part or the whole of the inner surface of extensible body member.

DRAWINGS

Fig. 1A

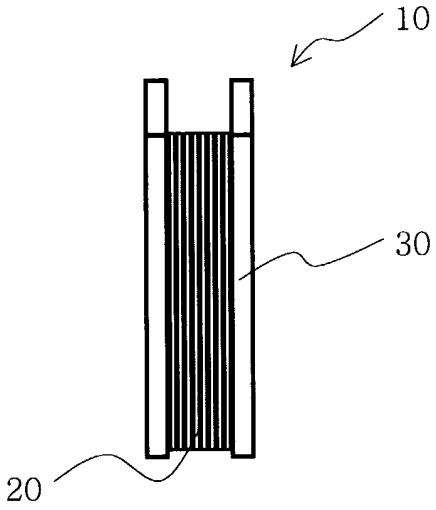


Fig. 1B

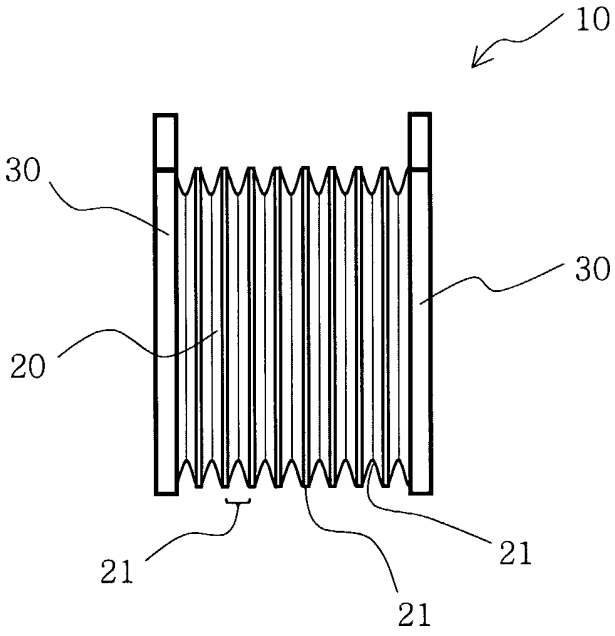


Fig. 2

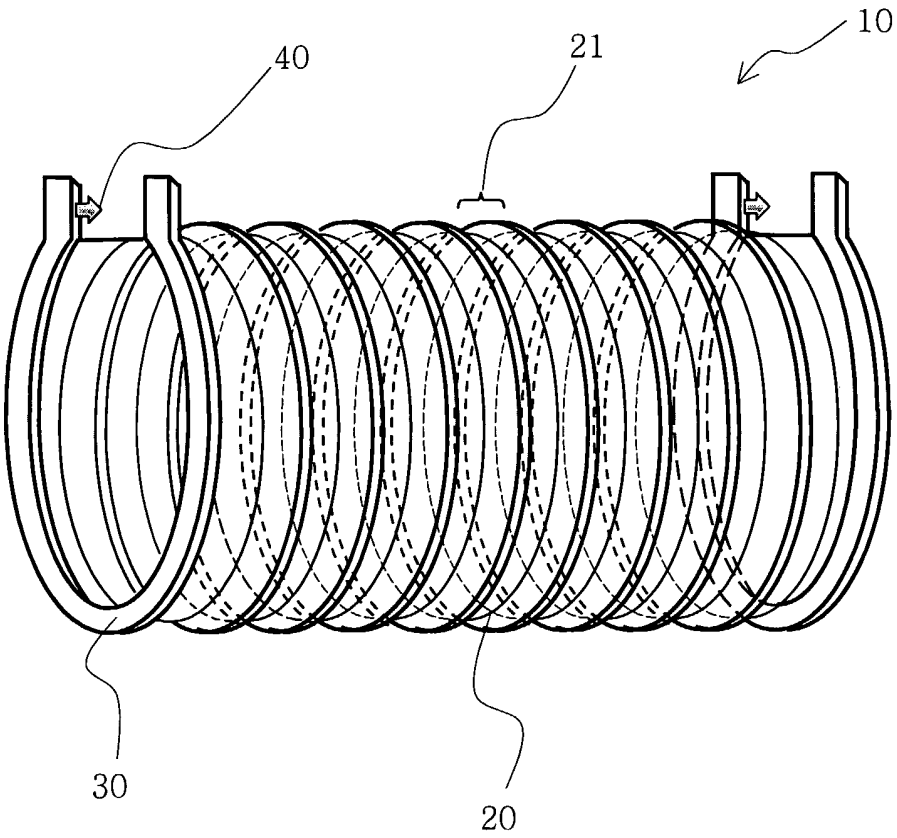


Fig. 3A

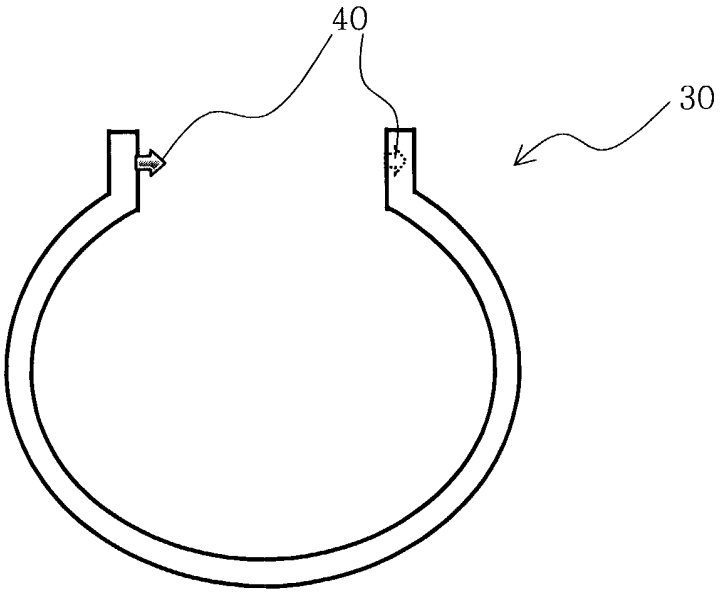


Fig. 3B

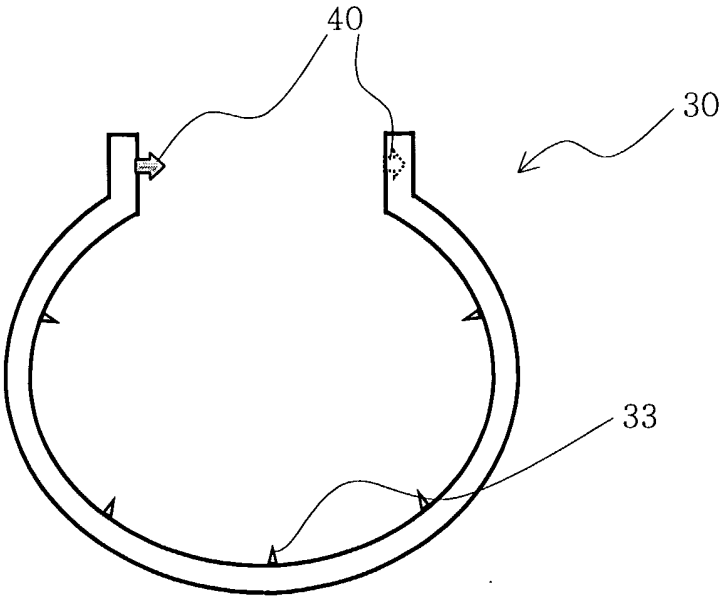


Fig. 4A

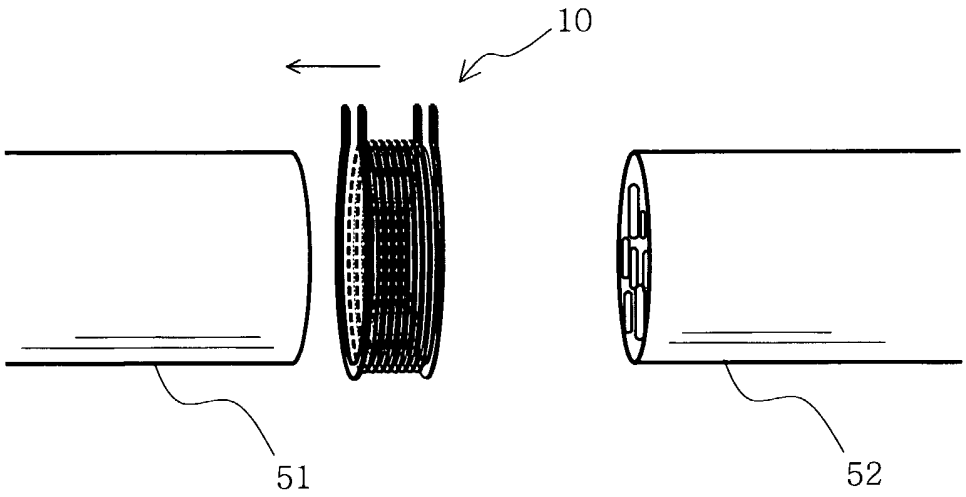


Fig. 4B

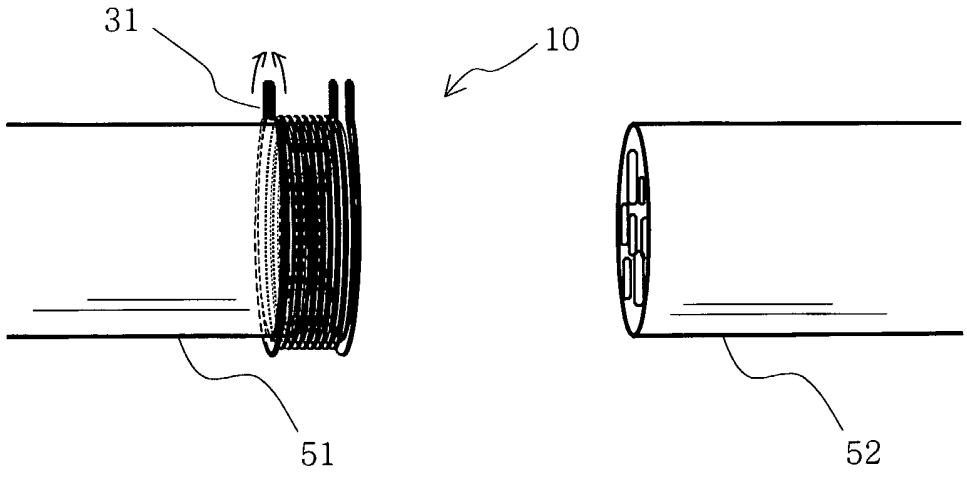


Fig. 4C

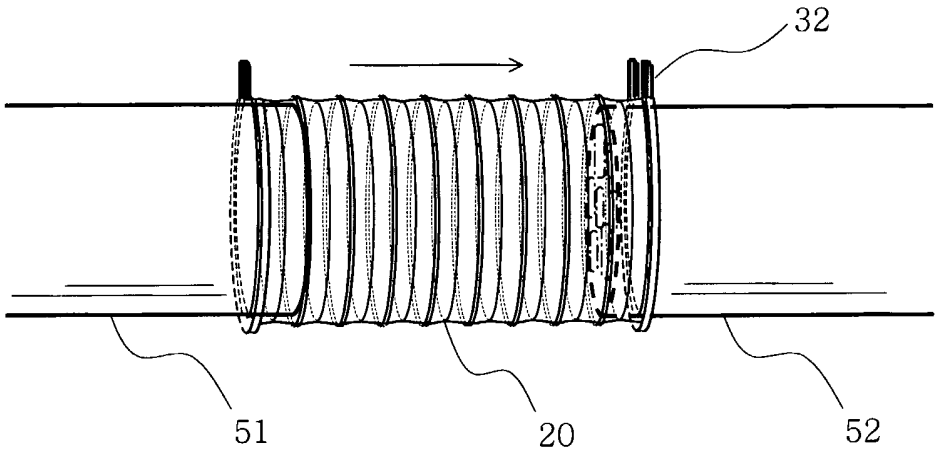
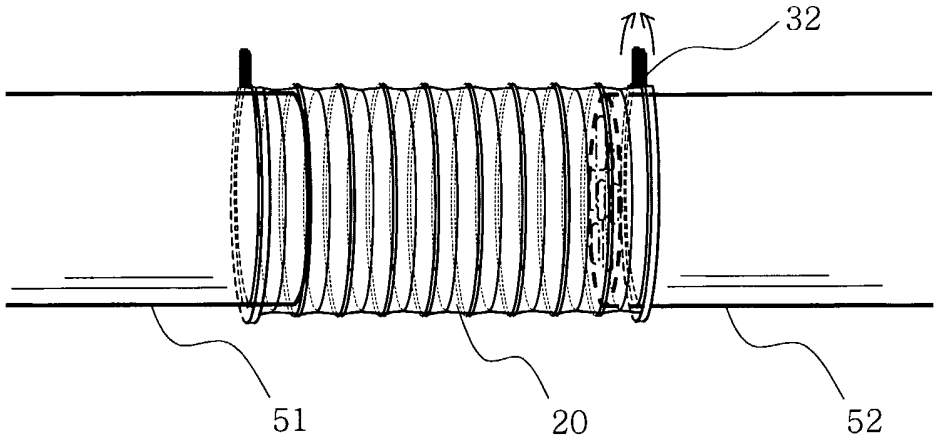


Fig. 4D



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR02/00966

A. CLASSIFICATION OF SUBJECT MATTER

IPC7 A61B 17/115

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC7 A61B17*

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
KOREAN PATENTS AND UTILITY MODELS

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US5030225A(PATRIK AEBISCHER) 9. JULY 1991(09.07.1991), SEE ENTIRE DOCUMENT	1-5
A	US5011486A(PATRIK AEBISCHER) 30 APRIL 1991 (30.04.1991), SEE ENTIRE DOCUMENT	1-5
A	US4669474A(THOMAS H. BARROWS) 2 JUNE 1987 (02.06.1987), SEE ENTIRE DOCUMENT	1-5
A	US5122151A(LUIS DE MEDINACELI))10. JUNE 1992 (10.06.1992), SEE ENTIRE DOCUMENT	1-5

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevence
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevence; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevence; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 JUNE 2002 (27.06.2002)	28 JUNE 2002 (28.06.2002)

Name and mailing address of the ISA/KR	Authorized officer
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Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/KR02/00966

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