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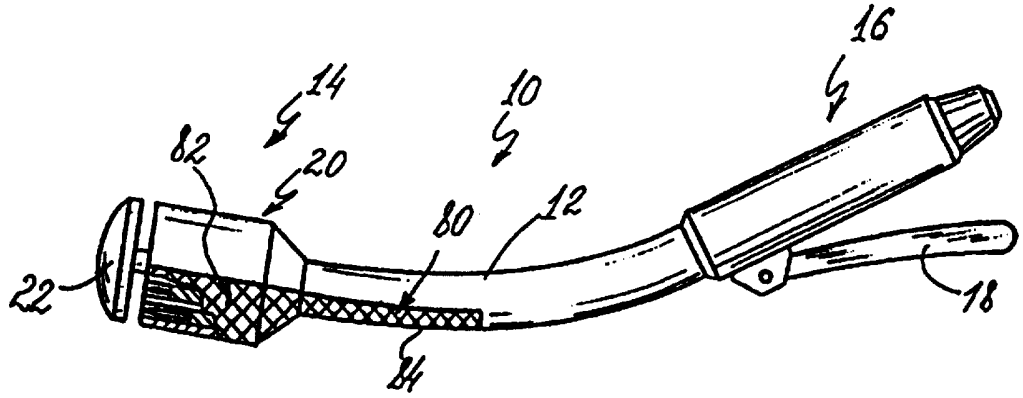

(57) Abstract

This invention is a suturing device (10) and a method of using the device (10), for providing anastomosis of first and second hollow organ portions (120, 122) each having an open end for suturing together with each other across a common interface (131), wherein the device (10) includes an elongated tubular housing (12) having a first free end (14), and a second end (16), the housing (12) being configured for insertion through the first hollow organ portion such that the second end is associated with the open end thereof; a suturing apparatus, associated with the second end of the tubular housing (12), for suturing together the open ends of the first and second organ portions (120, 122) by insertion of suture elements (40, 44, 48) therethrough along the entire length of the common interface (131) and thereacross; a suturing apparatus that includes an apparatus for inserting a single row of suture elements through the organ tissue along a portion of the common interface; and an apparatus for inserting a double row of suture elements through the organ tissue along the remainder of the common interface.

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SURGICAL STAPLER AND METHOD OF SURGICAL FASTENING

FIELD OF THE INVENTION

The present invention relates to apparatus for surgically connecting two portions of a hollow organs of the digestive system.

BACKGROUND OF THE INVENTION

Surgical staplers, providing either one row, or two concentric rows, of sutures are known for achieving anastomosis - or connection - between two generally tubular portions of hollow organs of the digestive system.

By way of example, USSR Patent No. 264612 describes circular anastomosis by use of a single row staple suture, while US Patent No. 4198982 describes double row staple suturing.

Generally, surgical staplers of the sort which provide anastomosis of hollow organs are formed of a suturing head which is attached to an elongate body, and an anvil. The elongate body is inserted via an opening in one side of the hollow organ, and the anvil is placed in the other. The ends of the organ portions to be connected are placed together and positioned between the suturing head and the anvil. Anastomosis is provided by operating the suturing head such that the staples therein are ejected through the organ tissue and against the anvil, thereby to be plastically deformed and to provide a desired connection of the organ portions. The entire stapler, including the anvil, which is removably connected to the suturing head, is subsequently withdrawn from the hollow organ.

Hollow bowel organs are characterized by having a mesentery along one side. As known, the side of a bowel connected to the mesentery has a very high density of blood vessels compared to the blood vessel density in the distal side of the organ. It has been found, due to the non-uniform distribution of blood vessels in digestive system organs, that neither the single row stapler, nor the double row stapler, fulfills all the requirements of anastomosis of these organs.

Single row staple suturing is characterized by low traumatization to the sutured tissue, anastomosis that is sufficiently elastic so as to facilitate relatively easy extraction of the stapler from the organ, and by not significantly obstructing blood supply to the sutured

tissue. It is also characterized, however, by applying insufficient pressure to organ tissue connected to the mesentery. Accordingly, due to the greater density of blood vessels in the organ tissue connected to the mesentery, the tissue to be connected is not fixated properly, and it is thus difficult to achieve anastomosis.

While double row suturing might be expected to overcome the above problems of single row suturing, the additional pressure provided at the tissue that is not adjacent to the mesentery causes the blood supply thereto to be blocked. This causes the formation of scar tissue thereat, leading to stenosis of the organ.

SUMMARY OF THE INVENTION

The present invention seeks to provide a novel method of surgical suturing of hollow organs to as to provide anastomosis thereof, and a novel surgical stapler for performing this method, which overcomes disadvantages of known art.

More particularly, the present invention seeks to provide reliable haemostasis and fixation of connected ends of sutured hollow organs, while also providing good conditions for tissue regeneration, minimal traumatization of sutured tissue, and a reduced probability of post-operative suture stenosis.

A further object of the invention is to optimize haemostasis of sutures while maintaining a sufficient blood supply to the sutured tissue.

Yet a further object of the present invention is to provide a method of suturing of hollow organs, and a means of performing the method of suturing, which take account of the varying cross-sectional shapes of these organs.

There is thus provided, in accordance with a preferred embodiment of the invention, a suturing device for providing anastomosis of first and second hollow organ portions each having an open end for suturing together with each other across a common interface, wherein the device includes:

an elongate tubular housing having a first free end, and a second end, the housing being configured for insertion through the first hollow organ portion such that the second end is associable with the open end thereof; and

suturing apparatus, associated with the second end of the tubular housing, for suturing together the open ends of the first and second organ portions by insertion of suture elements therethrough along the entire length of the common interface and thereacross, and wherein the suturing apparatus includes:

apparatus for inserting a single row of suture elements through the organ tissue along a portion of the common interface, and

apparatus for inserting a double row of suture elements through the organ tissue along the remainder of the common interface.

Additionally in accordance with a preferred embodiment of the invention, the apparatus for inserting a single row of the suture elements includes apparatus for inserting through the organ tissue a first row of suture elements having a first predetermined spacing, and the apparatus for inserting a double row of the suture elements includes apparatus for inserting a double row of the suture elements having other predetermined spacings, different from the first predetermined spacing,

wherein the spacings are predetermined to apply to the suture tissue a varying force along the entire suture predetermined so as to facilitate adequate blood supply to the suture tissue while not preventing haemostasis, thereby to facilitate optimal healing of the tissue.

Further in accordance with a preferred embodiment of the invention, the apparatus for inserting a double row of suture elements includes apparatus for inserting a second row of suture elements, having a second predetermined spacing, and apparatus for inserting a third row of suture elements generally parallel to the second row, and having a third predetermined spacing, different from the first and second predetermined spacings.

Additionally in accordance with a preferred embodiment of the invention, the first, second and third rows of suture elements include deformable suture elements.

Further in accordance with a preferred embodiment of the invention, each suture element is a deformable suture element which has a pair of legs extending generally parallel to the longitudinal axis of the housing, and arranged for transverse insertion through the organ tissue. Each suture element also has a transverse portion connecting the pair of legs, and the suturing device further includes

an anvil constructed for placement in the open end of the second hollow organ portion, and having formed on a rear face thereof a single row of recesses extending along a portion of the anvil periphery, and a double row of recesses extending along the remainder of the anvil periphery, for receiving and cooperating with the single and double rows of suture elements , respectively, after insertion thereof through the organ tissue; and

apparatus for selectably connecting the anvil to the housing.

Additionally in accordance with a preferred embodiment of the invention, the apparatus for inserting a single row of the suture elements includes apparatus for inserting

through the organ tissue a first row of suture elements having a first predetermined leg length and a first predetermined spacing, and

the apparatus for inserting a double row of the suture elements includes:

apparatus for inserting through the organ tissue a second row of suture elements having a second predetermined leg length and a second predetermined spacing, and

apparatus for inserting through the organ tissue a third row of suture elements, parallel to the second row, and having a third predetermined leg length and a third predetermined spacing,

wherein the leg lengths and the spacings are predetermined to apply to the suture tissue a varying force along the entire suture predetermined so as to facilitate adequate blood supply to the suture tissue while not preventing haemostasis, thereby to facilitate optimal healing of the tissue.

Further in accordance with a preferred embodiment of the invention, the apparatus for selectably connecting also includes apparatus for aligning the anvil with the suturing apparatus such that the single and double rows of the recesses are aligned in registration with the single and double rows of suture elements.

There is also provided, in accordance with a further preferred embodiment of the invention, a method of surgical stapling of first and second hollow organ portions so as to provide anastomosis thereof, wherein each organ portion has a first tissue portion and each organ portion further has a second tissue portion, and wherein at least one of the organ portions to be connected has a mesentery and the first tissue portion of the at least one organ portion is distal from the mesentery and the second tissue portion of the at least one organ portion is adjacent to the mesentery, and wherein the method includes the following steps:

holding together the ends of the organ portions sought to be stapled together;

a first step of stapling, including stapling together the first tissue portions of the two organ portions under a first pressure that facilitates adequate blood supply, and which also facilitates haemostasis thereat; and

a second step of stapling, including stapling together the second tissue portions under a second pressure, greater than the first pressure, that also facilitates adequate blood supply and facilitates haemostasis thereat. These steps are preferably performed simultaneously.

Additionally in accordance with the method of the invention, the first step of stapling includes inserting through the first tissue portions a single row of suture elements, and the second step of stapling includes inserting through the second tissue portions a double row of suture elements.

Further in accordance with the method of the invention, each suture element has a pair of legs arranged for transverse insertion through the organ tissue, and each step of stapling includes forcibly inserting the suture elements through the tissue and bending the legs down so as to cause them to become fastened to the tissue.

Additionally in accordance with the method of the invention, the first step of stapling includes inserting through the first tissue portions a first row of suture elements having a first predetermined leg length and a first predetermined spacing, and the second step of stapling includes:

inserting through the second tissue portions a second row of suture elements having a second predetermined leg length and a second predetermined spacing, and

inserting through the third tissue portions a third row of suture elements, parallel to the second row, and having a third predetermined leg length and a third predetermined spacing.

Preferably, the method further includes the step of predetermining the required leg lengths and spacings so as to apply a varying force along the entire suture while facilitating adequate blood supply to the suture tissue while not preventing haemostasis, thereby to facilitate optimal healing of the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more fully understood and appreciated form the following detailed description, taken in conjunction with the drawings, in which:

Fig. 1 is a side view of a suturing device, constructed and operative in accordance with a preferred embodiment of the present invention;

Fig. 2A is cross-sectional view of the head portion and anvil of the suturing device of Fig. 1;

Fig. 2B is a side-sectional view of the rear end of the suturing device of Fig. 1;

Fig. 2C is a cross-sectional view of a portion of the device seen in Fig. 2B, at line C-C therein;

Fig. 3A is a perspective view of a piston head forming part of the head portion of Fig. 2A;

Fig. 3B is a diagrammatic view of the three sizes of suture element seen in Fig. 2A;

Fig. 4A is a cross-sectional view of the head portion of Fig 2A, taken along line A-A therein;

Fig. 4B is a part-sectional view of the anvil of Fig. 2A, taken along line B-B therein;

Fig. 5 is a view corresponding to that of Fig. 4B, but showing a construction according to an alternative embodiment of the invention;

Fig. 6 is a view corresponding to that of Fig. 3A, but showing a construction according to yet a further alternative embodiment of the invention; and

Figs. 7A, 7B and 7C are schematic side views showing the suturing device of the present invention in various stages of use.

DETAILED DESCRIPTION OF THE INVENTION

Reference is now made to Fig. 1, in which there is seen a suturing device, also known as a surgical stapler, referenced generally 10, constructed and operative in accordance with a preferred embodiment of the present invention. The terms "suturing device" and "surgical stapler" are used interchangeably throughout the description and claims. Stapler 10 has an elongated tubular housing, referenced 12, which has a front end 14, which is inserted into a hollow organ to be sutured, and a rear end 16. Typically, operation of the stapler is provided via a squeeze-type trigger handle 18, which causes ejection of suturing elements or staples from the front end 14 and embedding of the staples in organ tissue, thereby to provide suturing thereof in accordance with the present invention.

Referring now also to Fig. 2A, front end 14 of stapler 10 is formed of a staple ejection head 20, referred to also as a suture head, and an anvil 22. As will be appreciated form the following description, staple ejection head 20 and anvil 22 cooperate so as to provide optimal anastomosis of organ portions in accordance with the present invention.

Ejection head 20 has a cylindrical casing 24, which constitutes a widened end portion of tubular housing 12. As seen in Figs. 2A and 3A, an elongate, hollow piston rod 26 extends generally axially along housing 12, terminating in a hollow piston head 27. Piston head 27, which is also illustrated in Fig. 4A, defines a first, generally cylindrical, wall-shaped pusher member 28, and a second wall-shaped pusher member 30, which extends only along a predetermined angular sector. Casing 24 has formed therein inner and outer partitions 32 and 34. Inner partition 32 is generally cylindrical and, at a first portion thereof, forms, together with an inward facing surface 36 of casing 24, a first chamber 38 for a plurality of first suturing elements 40 (Fig. 2A), which are provided as a single row. Outer partition 34 is disposed between a major portion of casing 24 and inner partition 32. A second chamber 42 for a second plurality of suturing elements 44 is thus formed between the inner and outer partitions 32 and 34, and a third chamber 46 for a third plurality of suturing elements 48 is formed between outer partition 34 and casing 24. It will thus be appreciated that the second and third pluralities of suturing elements 44 and 48 are provided as a double row. A circular blade 50, is also mounted onto piston head 27, and is provided for automatically cutting excess organ tissue at the time of suturing.

Pusher members 28 and 30 are disposed, as seen, within the first, second and third chambers. Activation of the handle 18 of the device 10, described below in conjunction with Figs. 2B and 2C, is operative to cause piston rod 26 to project pusher members 28 and 30

forwardly with respect to casing 24, thereby to cause ejection of the suturing elements from the chambers.

Anvil 22 has a rear-facing surface, referenced 52, which, as seen in Figs. 2A and 4B, has a plurality of recesses formed therein. In accordance with the present embodiment of the invention, the recesses are provided as first, second and third pluralities, respectively referenced 40', 44' and 48', and are distributed so as to be in registration with the first, second and third pluralities of suture elements, and thereby to cooperate with them when the device is activated.

Referring now particularly to Fig. 2A, there is provided an activating rod 54, which is operatively connected to handle 18, and which extends through tubular housing 12 and ejection head 20. Rod 54 has a front end portion 56 which is constructed for a snap-type connection with a rear end portion 58 of a stem element 60 formed on rear surface 52 of anvil 22. In particular, front end portion 56 is shown in the drawings as a female connecting portion, having a pair of splayed arms 62 having inward-facing protrusions 64 formed at the free ends thereof. Rear end portion 58 of stem element 60 is shown as a male portion, having a thickened head portion 66, beyond which is a neck portion 68 which has formed therein elongate grooves 69 which are adapted for engagement by inward-facing protrusions 64 of the female connecting portion.

Due to the elongate grooves 69 and protrusions 64, connection of the rod 54 to anvil 22 is possible in a single, unique position, predetermined such that the chambers for the first, second and third pluralities of suture elements 40, 44 and 48 are in registration with the corresponding first, second and third pluralities of recesses 40', 44' and 48', formed on anvil 22. Prior to operation of the device 10, rod 54 is connected to anvil 22, as shown and described below in conjunction with Fig. 7B, via the described connector portions, thereby enabling rearward removal of the entire device 10, including the anvil 22, after suturing.

Referring now to Fig. 2B, it is seen that both piston rod 26 and activating rod 54 extend rearwardly into rear end portion 16 of the suturing device 10, whereat they are enclosed by rear housing 150. As seen in Fig. 2C, activating rod 54 has a non-circular, typically rectangular, configuration along most of its length, and is disposed within piston rod 26, such that rotation of the activating rod 54 within the piston rod 26 is not possible. A rear end portion 152, however, of activating rod 54, is disposed within an elongate nut member 154 having a front portion 156 having an inward-facing screw thread 158. Rear end portion 152 of the activating rod 54 has a generally rounded cross-sectional configuration, and has formed thereon an outward-facing screw thread 160, which is

arranged for screwing engagement with screw thread 158. Nut member 154 terminates in a handle portion 162, via a narrowed neck portion 164 which is engaged by rear wall 166 of rear housing 150, thereby to be prevented from axial translation.

It will thus be appreciated that rotation of handle 162 is operative to cause a corresponding axial translation of activating rod 54 and thus of front end portion 56 (Fig. 2A) thereof, so as to facilitate engagement of rear end portion 58 of stem element 60 of anvil 22 by front end portion 56. Subsequently, the clearance between ejection head 20 and anvil 22 can be adjusted as desired by appropriate rotation of handle portion 162.

Handle 18 is mounted for rotation about an axis 168, and is formed with an inward-projecting tooth, referenced 170. Piston rod 26 has a recess 172, formed therein, and is arranged such that recess 172 is positioned in registration with tooth 170. Accordingly, depression of handle 18, achieved by squeezing it such that it rotates towards housing 150, as shown by arrow 174, causes a corresponding rotation of tooth 170 which, in turn, engages a rear-facing edge 176 of piston rod 26, thereby to causes a forward axial movement thereof, shown by arrow 178.

Referring now once again to Fig. 2A, stem element 60 preferably has a hook 61 formed thereon. Hook 61 is provided for fastening threads of a purse-string suture. An additional hook (not shown), for a similar purpose, is also provided adjacent to front end portion 56 of rod 54.

It is further seen that the respective axes 70 and 72 of rod 54 and blade 50, do not coincide. This is due to the fact that it is necessary to provide a greater pushing force to the second and third pluralities 44 and 48 of suture elements, than to the single, first plurality of suture elements 40.

As seen with reference to Figs. 2A and 4B, both the frequency and length of the suture elements are varied so as to take account of the suturing requirements of the different portions of tissue of the organ portions to be connected. In particular, it is seen that the lateral spacing between suture elements in the first, second and third pluralities varies directly with the distance between the portions of pusher members 28 and 30 in registration with the first, second and third pluralities of suture elements.

As stated above, the present invention provides suturing of hollow organs so as to provide optimal anastomosis of both the organ tissue adjacent the mesentery - which has a high density of blood vessels, - and of the tissue distal from the mesentery, which is less thick and which has a lower density of blood vessels. Accordingly, while the first plurality of suture elements 40 (Fig. 3B) are spaced apart and have legs 41 of length L2 so as to

provide proper fixation, haemostasis, and thus proper anastomosis of the tissue distal from the mesentery, the second and third pluralities 44 and 48 of suture elements, which are provided in a double row, are of different lengths and spacing.

As seen in Fig. 3B, the suture elements in the third plurality 48 are required to provide, first and foremost, proper fixation of the tissue adjacent to the mesentery, while the second plurality of suture elements 44, located inwardly of the third plurality, primarily provides the required pressure so as to prevent bleeding, and thereby to allow haemostasis. Accordingly, the suture elements 48 in the outside row have legs 49 which are relatively long, having a length L3, such that they can easily be inserted through the mesenteric tissue, and can provide the required fixation of this tissue; while the inner plurality of suture elements 44, while having shorter legs 45 of length L1, are more densely spaced, thereby to provide required sealing of the blood vessels.

Referring once again to Fig. 1, it is seen that housing 12 has a generally bent configuration, and the second and third chambers 42 and 46 are provided on the concave side of the housing. Preferably, housing 12 has provided thereon exterior markings along surface portions 80 and 82, including lines 84 and 86. These markings face towards the concave side of the housing 12, and, as the anvil 22 will already have been positioned such that the recesses for the second and third pluralities of suture elements face inwards, or towards the mesentery, the surface markings and lines provide a visual indication as to the orientation of the remainder of the device required so as to place the suture element pluralities in registration with their respective recesses. Similar markings are also provided on surface portion 88 of the stem element 60.

Referring now to Fig. 5, it is seen that, in accordance with an alternative embodiment of the invention, the anvil 93, and thus the entire front end of the suturing device of the invention, has a generally oval profile, and, further, has first, second and third pluralities of suture element recesses, respectively referenced 92, 94 and 96, which are, in part, rectilinear. The function of rod 54 (Figs. 1-4B) is provided by a pair of parallel rod members 98 and 100. Rod members 98 and 100 are disposed along a longitudinal axis 102 which is offset from the axis 103 which connects the geometric centers of the semi-circular end portions, referenced generally 104 and 106, of the oval front end portion of the suturing device.

Referring now to Fig. 6, it is seen that, in accordance with yet a further embodiment of the invention, the anvil 110, and thus the entire front end of the suturing device of the invention, has a generally oval profile, and, further, has first, second and third pluralities of

suture element recesses, respectively referenced 112, 114 and 116, which are, in part, rectilinear. The function of rod 54 (Figs. 1-4B) is provided by a single, generally flattened rod member 118.

Use of the suturing device of the present invention in suturing first and second bowel portions, respectively referenced 120 and 122, is now described in conjunction with Figs. 7A, 7B and 7C.

Referring now to Fig. 7A, prior to suturing of bowel portions 120 and 122, head portion 20 is inserted into first bowel portion 120, through an incision 124, such that the concave side, in general, of housing 12, and such that the markings 84 and 86 (Fig. 1), in particular, face towards the mesentery 126. Head portion 20 is further positioned such that front end 56 of rod 54 protrudes through an opening 128 of first bowel portion 120, thereby to be in axial registration with opening 130 of the second bowel portion 122. Anvil 22 is inserted through opening 130 into the second bowel portion 122, such that stem 60 protrudes rearwardly towards front end 56 of rod 54, and such that marking 88 (Fig. 2A) is in registration with the mesentery 126.

Referring now to Fig. 7B, the bowel ends 128' and 130' are partially closed about the suturing head 20 and anvil 22, respectively, by purse-string sutures, such that end portion 56 of rod 54 and stem 60 of anvil 22 remain protruding from the bowel portions. The ends of the threads are attached to their respective hooks, of which only one, namely, hook 61, is seen in the drawing.

Subsequently, after adjusting nut member 154 (Fig. 2B) as required, as described above in conjunction with Fig. 2B, rod 54 and anvil 22 are connected, also as described above, such that the chambers for the first, second and third pluralities of suture elements 40, 44 and 48 are in registration with the corresponding first, second and third pluralities of recesses 40', 44' and 48', formed on anvil 22. It will be appreciated that the unique positioning of the anvil 22 relative to the rod member 54, and thus relative to the suturing head 20, is required due to the different pluralities of suture elements whose position is determined by their function in the suture.

Referring now to Fig. 7C, nut member 154 (Fig. 2B) is rotated so as to cause an axial retraction retract rod 54, thereby to bring head portion 20 and anvil 22 together, such that the bowel ends 128' and 130' are pressed therebetween, defining a common interface 131. Subsequently, handle 18 is rotated, as described above in conjunction with Fig. 2B, so as to extend piston rod 26 and thus pusher members 28 and 30, and blade 50 forwardly of casing 24. This causes the suture elements 40, 44 and 48 to be extended across interface

131, through the bowel tissue and into recesses 40', 44' and 48' on anvil 22, such that the legs of the suture elements are bent inwards, thereby to connect the two bowel portions together. The described extension of blade 50 is operative to cut off the excess tissue connected to device 10 by the purse-string sutures.

It will thus be appreciated that the double row of suturing elements, constituted by second and third pluralities 44 and 48, used to suture the bowel tissues adjoining the mesentery, provide good fixation of the tissue portions, and apply enough pressure so as to provide good haemostasis thereat. In particular, the pressure applied via the inner or second plurality of suture elements 44, is greater, due to the fact that the portion of pusher member 28 is relatively long, and the elements themselves are relatively short. This provides improved haemostasis thereby. The greater length of the outermost row of suture elements 48, ensures that the pressure applied to the sutured bowel tissue thereby, while being sufficient to fixate the tissue properly, does not overly reduce the blood supply to these tissue portions. Accordingly, the tissue is permitted to heal properly with sufficient haemostasis, but without stenosis ands thus undesired formation of scar tissue.

In the tissue portion distal from the portion adjacent to the mesentery, only a single row of suture elements, in the form of plurality 40, is used. As opposed to the prior art use of a double row suture, the single row suture of the present invention facilitates a desired elasticity of the anastomosis and of the bowel lumen, thereby facilitating extraction of the entire surgical stapler 10, and, in particular, of the anvil 22. Furthermore, suture traumatization and the possibility of post-operative suture stenosis, are reduced. In order to ensure the required haemostasis, healing and strength of the suture, the length of the suture elements in first plurality 40 is selected to be between the length of the suture elements of the second and third pluralities 44 and 48, and the frequency of the first plurality 40 is selected to be greater than that of the third plurality of suture elements 48.

The various configurations of the suture elements shown in Figs. 4B, 5 and 6, are intended for suturing of predetermined types of hollow organ. For example, the generally circular arrangement of Figs. 4B and 5 is best suited for the connection of bowel portions, as described above in conjunction with Figs. 7A-7C. The various oval configurations shown in Figs. 5 and 6, however, are more suited to connection of the colon to the jejunum, or of a bowel portion to the stomach.

It will be appreciated by persons skilled in the art that the scope of the present invention is not limited by what has been shown and described above, merely by way of example. The scope of the invention is limited, rather, solely by the claims, which follow.

CLAIMS

1. A suturing device for providing anastomosis of first and second hollow organ portions each having an open end for suturing together with each other across a common interface, wherein said device comprises:

an elongate tubular housing having a first free end, and a second end, said housing being configured for insertion through the first hollow organ portion such that said second end is associable with the open end thereof; and

suturing means, associated with said second end of said tubular housing, for suturing together the open ends of the first and second organ portions by insertion of suture elements therethrough along the entire length of the common interface and thereacross, and wherein said suturing means comprises:

means for inserting a single row of suture elements through the organ tissue along a portion of the common interface, and

means for inserting a double row of suture elements through the organ tissue along the remainder of the common interface.

2. A suturing device according to claim 1, wherein said means for inserting a single row of said suture elements comprises means for inserting through the organ tissue a first row of suture elements having a first predetermined spacing, and

said means for inserting a double row of said suture elements comprises means for inserting a double row of said suture elements having other predetermined spacings, different from said first predetermined spacing,

wherein said spacings are predetermined to apply to the suture tissue a varying force along the entire suture predetermined so as to facilitate adequate blood supply to the suture tissue while not preventing haemostasis, thereby to facilitate optimal healing of the tissue.

3. A suturing device according to claim 2, wherein said means for inserting a double row of suture elements comprises:

means for inserting a second row of suture elements, having a second predetermined spacing, and

means for inserting a third row of suture elements generally parallel to said second row, and having a third predetermined spacing, different from said first and second predetermined spacings.

4. A suturing device according to claim 3, wherein said first, second and third rows of suture elements comprise deformable suture elements.

5. A suturing device according to claim 1, wherein each said suture element is a deformable suture element which has a pair of legs extending generally parallel to the longitudinal axis of said housing, and arranged for transverse insertion through the organ tissue, each said suture element also having a transverse portion connecting said pair of legs, and wherein said suturing device further comprises:

an anvil constructed for placement in the open end of the second hollow organ portion, and having formed on a rear face thereof a single row of recesses extending along a portion of the anvil periphery, and a double row of recesses extending along the remainder of the anvil periphery, for receiving and cooperating with said single and double rows of suture elements , respectively, after insertion thereof through the organ tissue; and

means for selectably connecting said anvil to said housing.

6. A suturing device according to claim 5, wherein said means for inserting a single row of said suture elements comprises means for inserting through the organ tissue a first row of suture elements having a first predetermined leg length and a first predetermined spacing, and

said means for inserting a double row of said suture elements comprises:

means for inserting through the organ tissue a second row of suture elements having a second predetermined leg length and a second predetermined spacing, and

means for inserting through the organ tissue a third row of suture elements, parallel to said second row, and having a third predetermined leg length and a third predetermined spacing,

wherein said leg lengths and said spacings are predetermined to apply to the suture tissue a varying force along the entire suture predetermined so as to facilitate adequate blood supply to the suture tissue while not preventing haemostasis, thereby to facilitate optimal healing of the tissue.

7. A suturing device according to claim 5, wherein said means for selectably connecting also comprises means for aligning said anvil with said suturing means such that

said single and double rows of said recesses are aligned in registration with said single and double rows of suture elements.

8. A suturing device according to claim 7, wherein said means for selectably connecting comprises:

a rod member, also located within said tubular housing, and having a front end portion protruding from said second end of said housing; and

a stem protruding rearwardly from said anvil and connected thereto and having a rear end portion; and

means for fastening said front end portion of said rod member to said rear end portion of said stem.

9. A suturing device according to claim 5, and wherein said recesses are operative to receive and plastically deform said legs of said suture elements, thereby to bend said legs about and fasten them to the organ tissue.

10. A suturing device according to claim 1, and also including means for cutting excess organ tissue from the open ends of the organ portions to be sutured together.

11. A suturing device according to claim 1, and also comprising means for activating said suturing means to insert said single and double rows of suture elements into the organ tissue.

12. A suturing device according to claim, 1 wherein said means for activating comprises a piston rod extending through said tubular housing, and said suturing means comprises a piston head, wherein said piston head has formed therein a plurality of pusher members for ejecting said suture elements from said second end of said tubular housing, thereby to insert said suture elements into the organ tissue.

13. A suturing device according to claim 1, wherein said tubular housing has a curved configuration, thereby to ease placement thereof into the first organ portion.

14. A suturing device according to claim 13, wherein said tubular housing has a concave portion, and said means for inserting a double row of suture elements is located adjacent to said concave portion.

15. A suturing device according to claim 1, wherein said means for inserting a single row of suture elements comprise means for inserting a single row of suture elements along a first portion of a predetermined geometric pattern, and said means for inserting a double row of suture elements comprise means for inserting a single row of suture elements along a second portion of said predetermined geometric pattern.

16. A suturing device according to claim 15, wherein said predetermined geometric pattern approximates to a circle.

17. A suturing device according to claim 15, wherein said geometric pattern is oval.

18. A method of surgical stapling of first and second hollow organ portions so as to provide anastomosis thereof, wherein each said organ portion has a first tissue portion and each said organ portion further has a second tissue portion, and wherein at least one of the organ portions to be connected has a mesentery and the first tissue portion of the at least one organ portion is distal from the mesentery and the second tissue portion of the at least one organ portion is adjacent to the mesentery, and wherein said method includes the following steps:

holding together the ends of the organ portions sought to be stapled together;

a first step of stapling, comprising stapling together the first tissue portions of the two organ portions under a first pressure that facilitates adequate blood supply, and which also facilitates haemostasis thereat; and

a second step of stapling, comprising stapling together the second tissue portions under a second pressure, greater than said first pressure, that also facilitates adequate blood supply and facilitates haemostasis thereat.

19. A method according to claim 18, wherein said steps of stapling are performed simultaneously.

20. A method according to claim 18, wherein said first step of stapling comprises inserting through the first tissue portions a single row of suture elements, and said second step of stapling comprises inserting through the second tissue portions a double row of suture elements.

21. A method according to claim 20, wherein each suture element has a pair of legs arranged for transverse insertion through the organ tissue, and each said step of stapling comprises forcibly inserting the suture elements through the tissue and bending the legs down so as to cause them to become fastened to the tissue.

22. A method according to claim 21, wherein said first step of stapling comprises inserting through the first tissue portions a first row of suture elements having a first predetermined leg length and a first predetermined spacing, and

said second step of stapling comprises:

inserting through the second tissue portions a second row of suture elements having a second predetermined leg length and a second predetermined spacing, and

inserting through the third tissue portions a third row of suture elements, parallel to the second row, and having a third predetermined leg length and a third predetermined spacing,

and wherein said method further comprises the step of predetermining the required leg lengths and spacings so as to apply a varying force along the entire suture while facilitating adequate blood supply to the suture tissue while not preventing haemostasis, thereby to facilitate optimal healing of the tissue.

23. A method according to claim 20, and also comprising, prior to said first step of stapling, the following additional steps:

placing a stapling head in the end of one of the organ portions so as to face the other organ portion, wherein the single and double rows of suture elements are held within the stapling head prior to said steps of stapling;

placing an anvil in the end of the other organ portions so as to face the stapling head, wherein the anvil has having suture element receiving recesses formed in single and double rows for respectively receiving the single and double rows of suture element during said steps of stapling;

fixating the anvil within the organ end such that the single and double rows of recesses are respectively located distally from and adjacent to the mesentery; and

aligning the stapling head with the anvil such that the single and double rows of suture elements are positioned in registration with the single and double rows of recesses, respectively.

24. A method according to claim 23, wherein said step of fixating comprises:

positioning the anvil within the organ end such that the single and double rows of recesses are respectively located distally from and adjacent to the mesentery; and

attaching the anvil to the organ tissue by means of purse-string sutures.

25. A method according to claim 18, also including the step of cutting excess organ tissue from the open ends of the organ portions being sutured together.

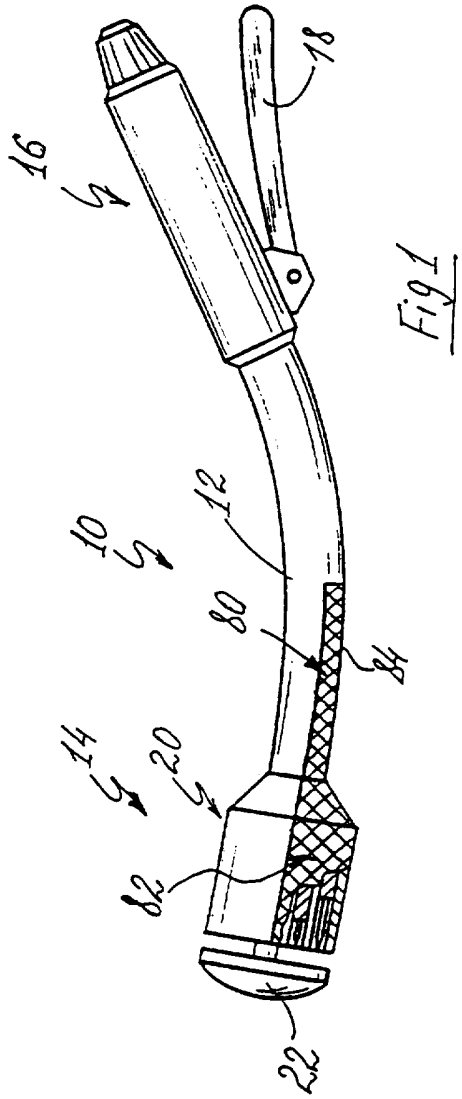
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Fig 1

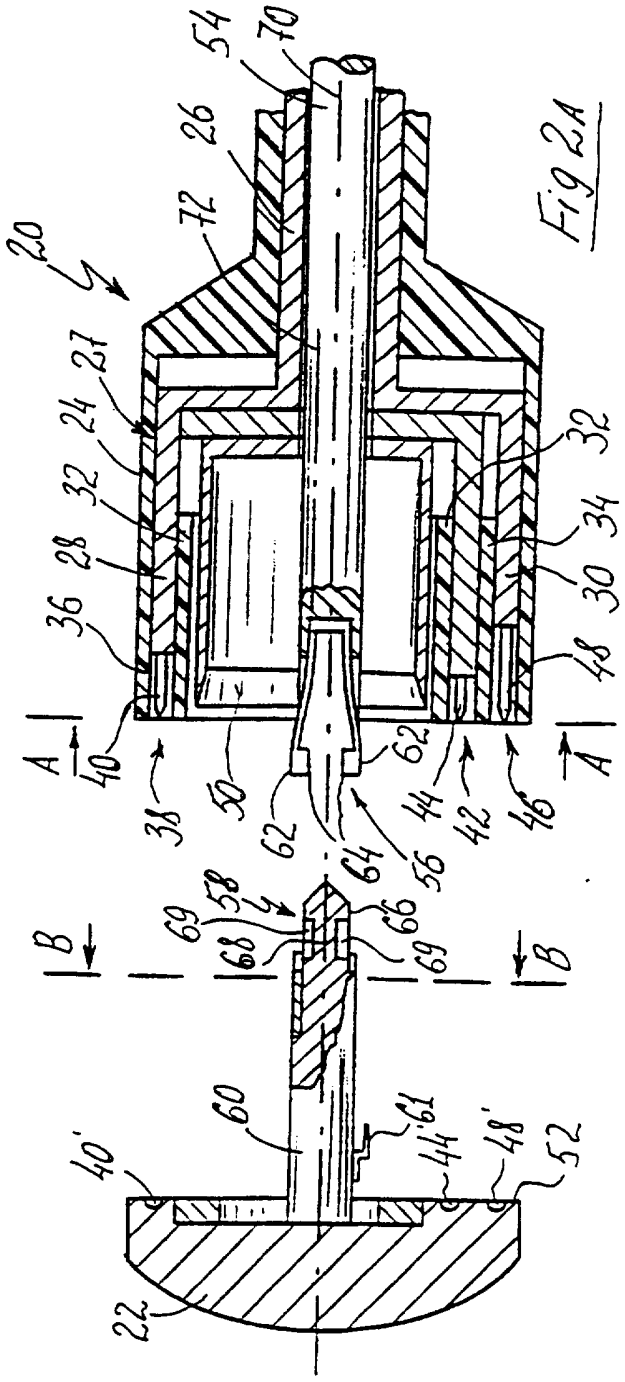
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Fig 2A

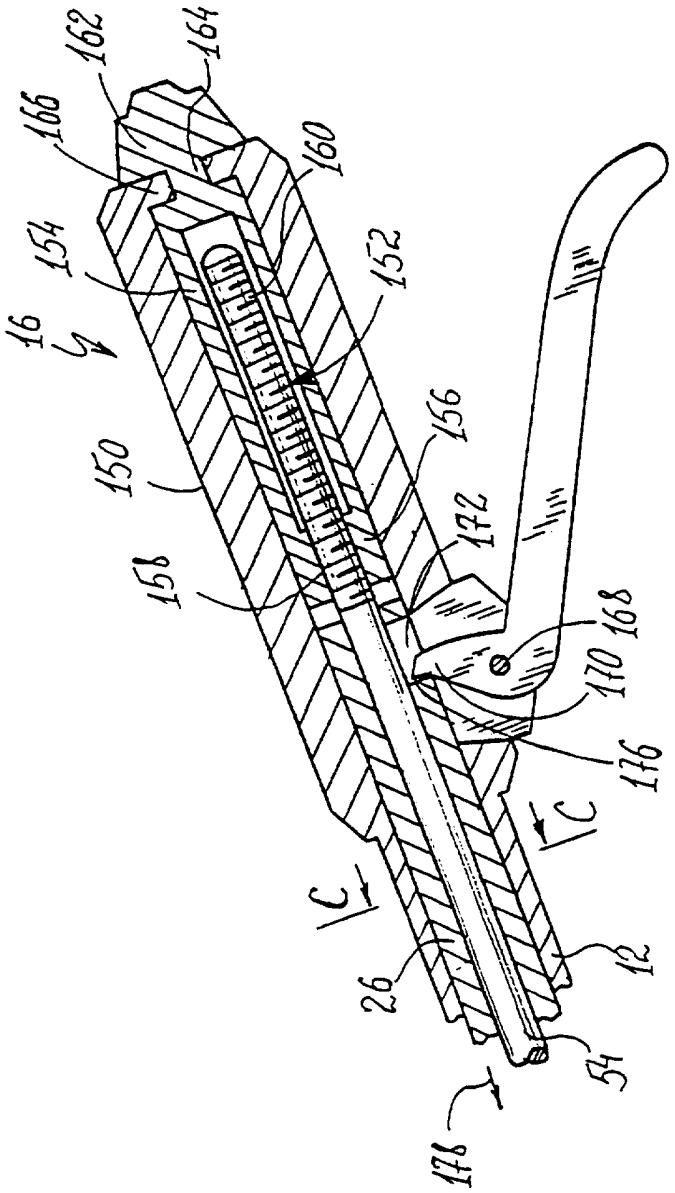
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Fig 2B

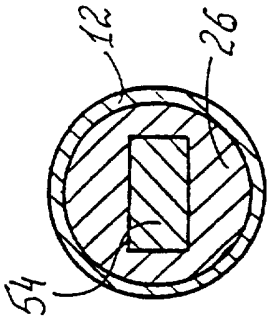
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Fig 2C

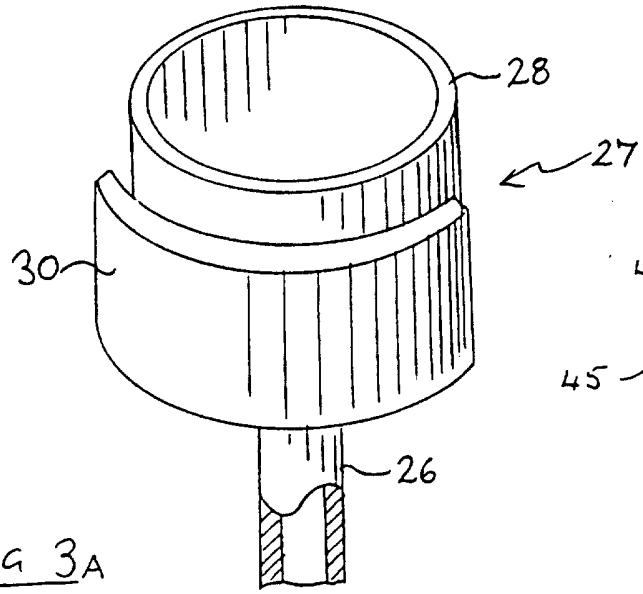

FIG 3A

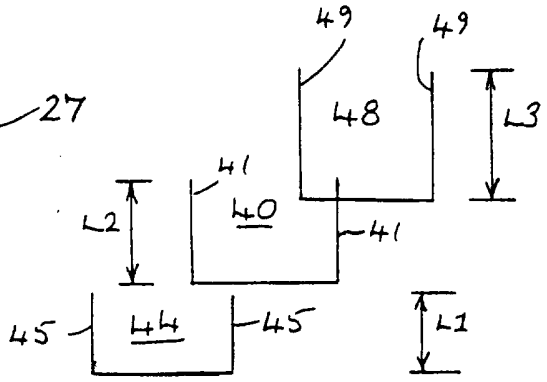

FIG 3B

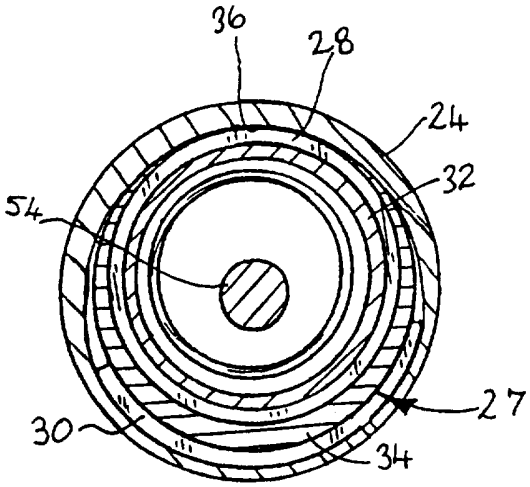

FIG 4A

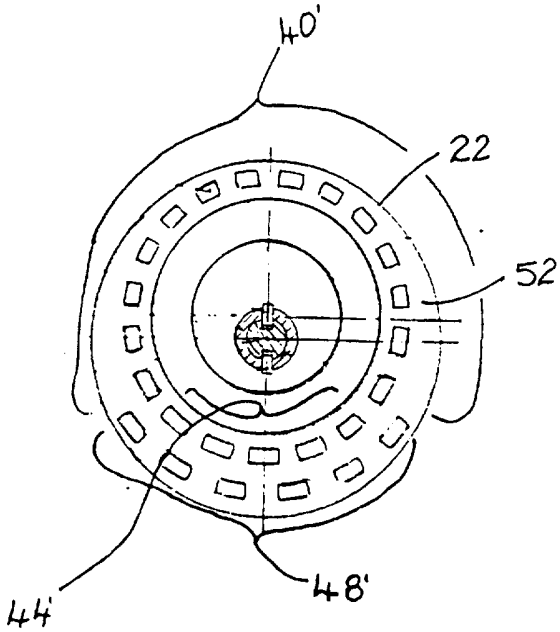

FIG 4B

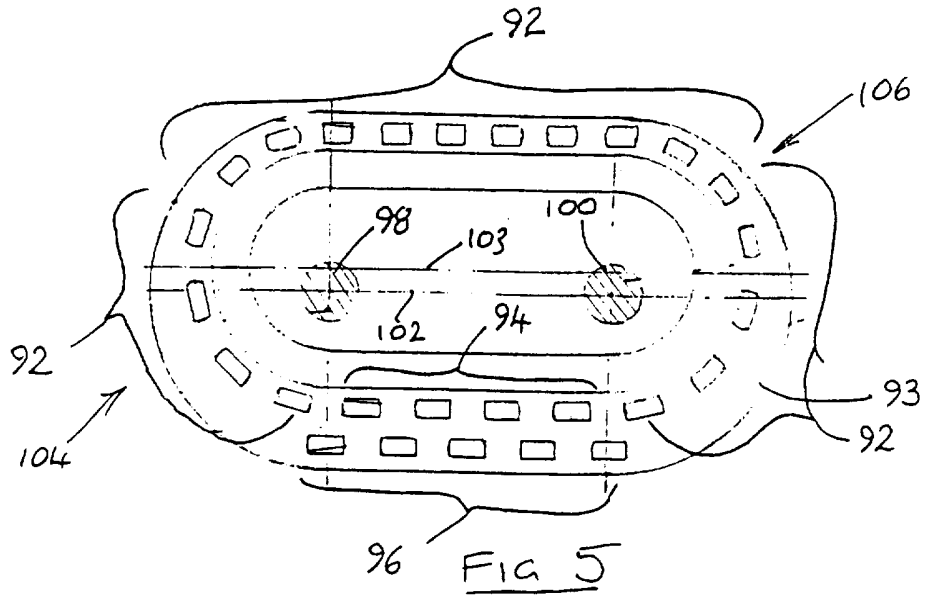
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Fig 5

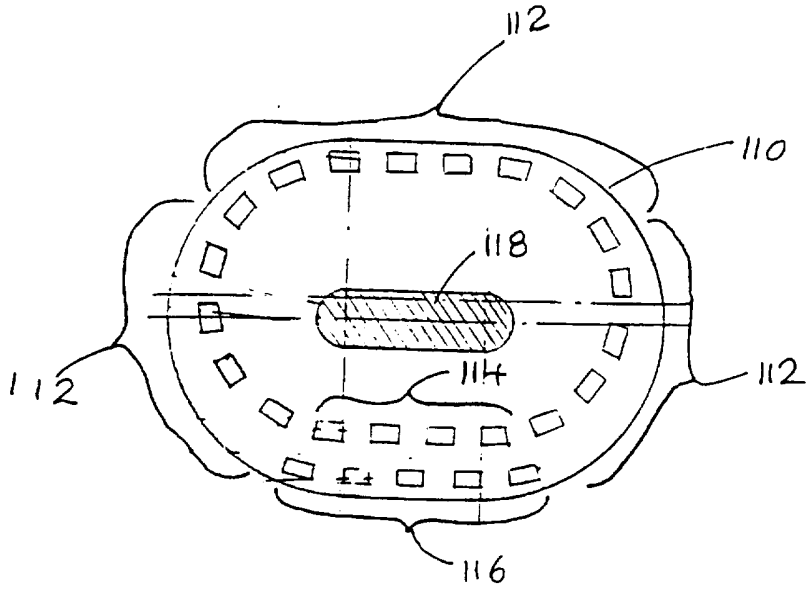
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Fig 6

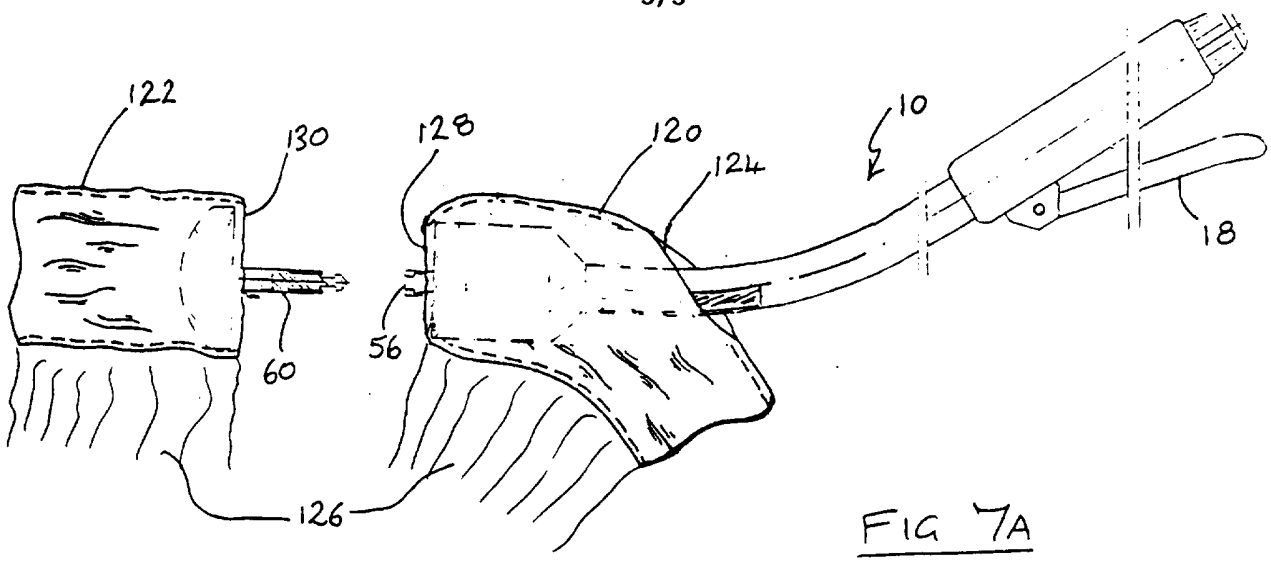

FIG 7A

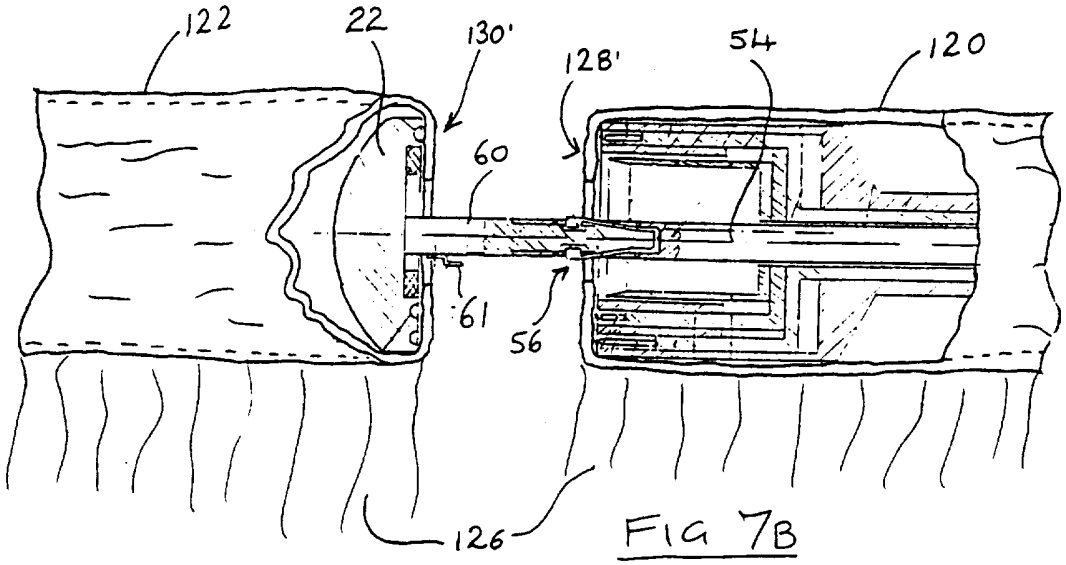

FIG 7B

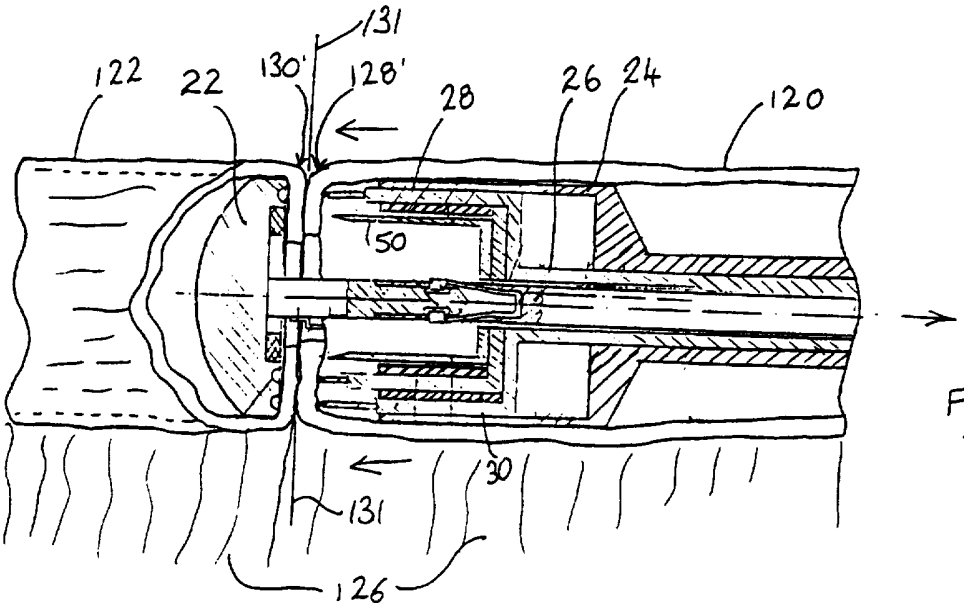

FIG 7C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL97/00104

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/10
US CL :606/139
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)

U.S. : 606/139, 142-144, 148, 151-153, 157

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,445,644 A (PIETRAFITTA et al) 29 August 1995.	1-25
A	US 5,027,834 A (PRUITT) 02 July 1991.	1-25
A	US 4,930,503 A (PRUITT) 05 June 1990.	1-25

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; 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
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search	Date of mailing of the international search report
07 JULY 1997	18 JUL 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Diane Smith for TINA T. D. PHAM Telephone No. (703) 308-0824

Form PCT/ISA/210 (second sheet)(July 1992)*