

[54] **INSTRUMENT FOR LIGATING
SUTURING AND DIVIDING ORGANIC
TUBULAR STRUCTURES**

3,584,628	6/1971	Green.....	128/305
3,675,688	7/1972	Bryan.....	140/93 D
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[22] Filed: **Dec. 29, 1971**

[21] Appl. No.: **213,574**

Related U.S. Application Data

[62] Division of Ser. No. 32,247, April 27, 1970, Pat. No.
3,675,688.

[52] U.S. Cl.....**128/305, 29/243.5, 140/93 D**

[51] Int. Cl.**A61b 17/12, A61b 17/32, B21f 15/00**

[58] Field of Search.....**128/305, 318, 334;**
29/243.57; 140/93 D

[56] **References Cited**

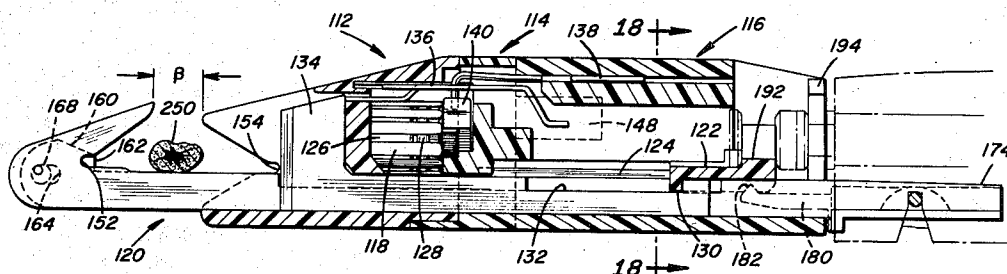
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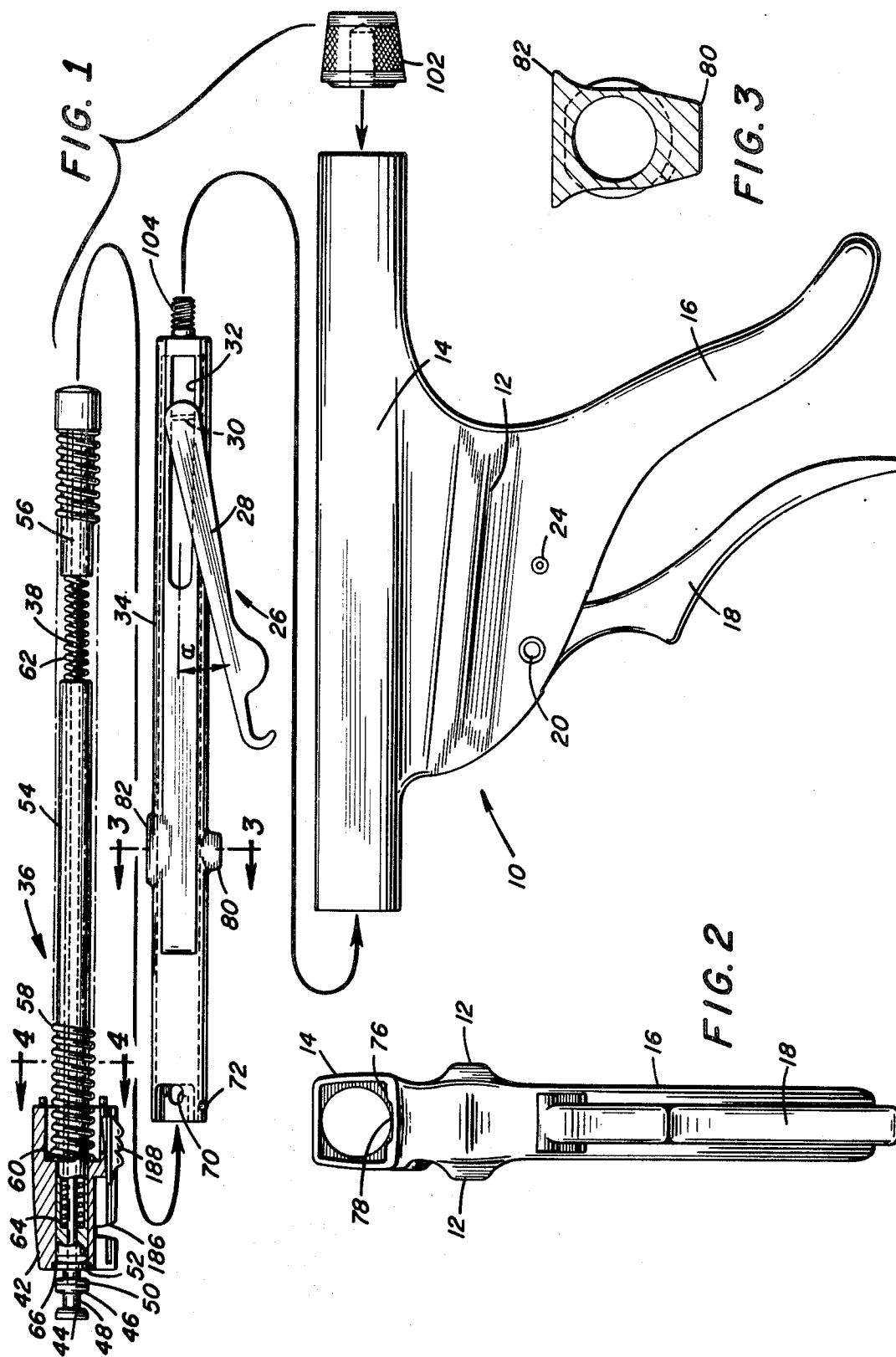
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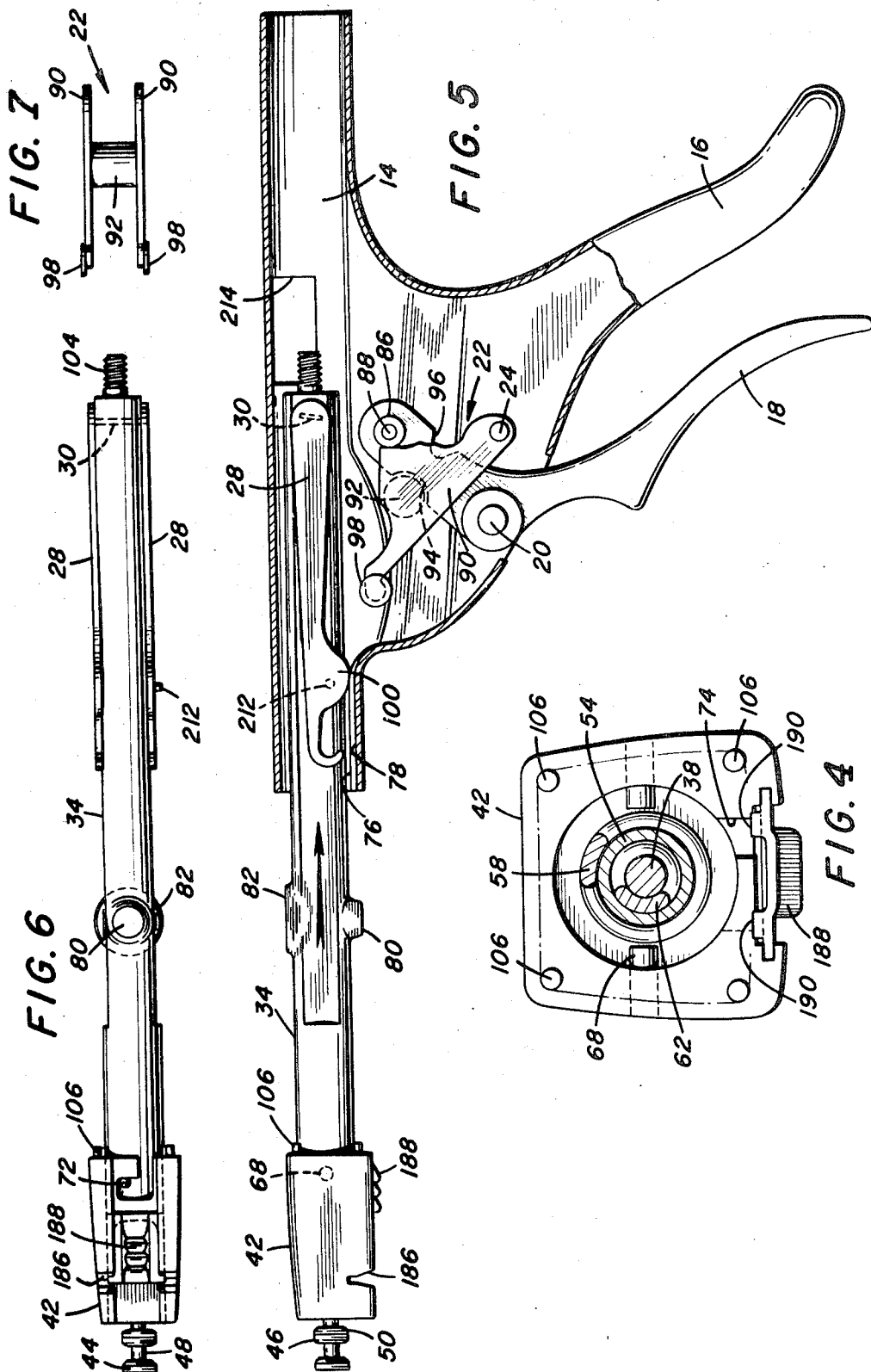
[57] **ABSTRACT**

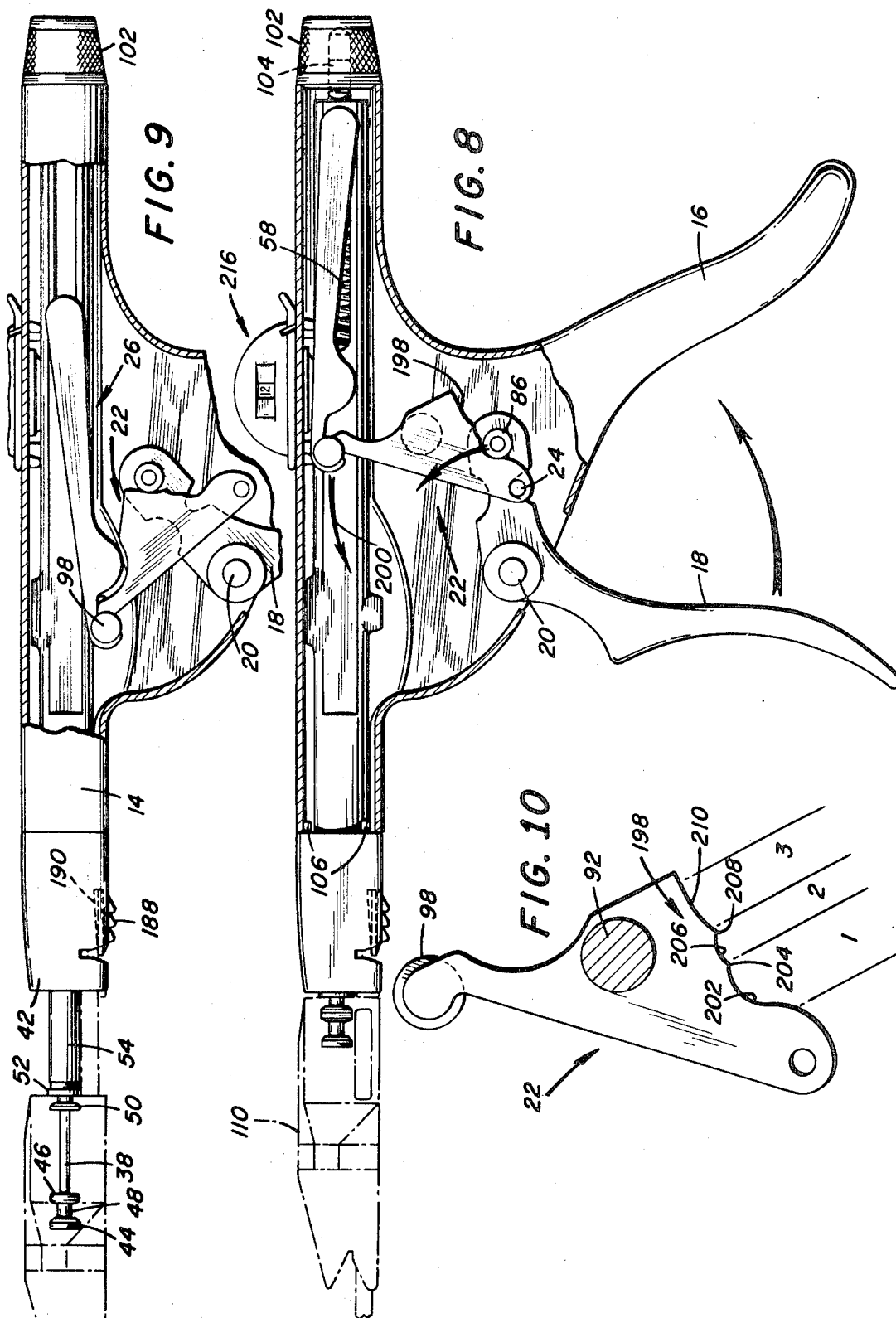
A medical instrument and associated cartridge for ligating an organic tubular structure, for suturing this structure in two places with a pair of sterilized staples and for dividing the tubular structure intermediate the suturing staples. The instrument is provided with a variable cam so that the ligating, suturing and dividing stages are all performed with uniform effort from the operating surgeon. The instrument is also provided with a counter for indicating the number of staples remaining in the cartridge. The novel cartridge ensures that the stapled and severed tubular structures are ejected from the instrument after the operation, operates smoothly without binding, and includes a lock which holds the elements of the cartridge in fixed positions during all stages of transit.

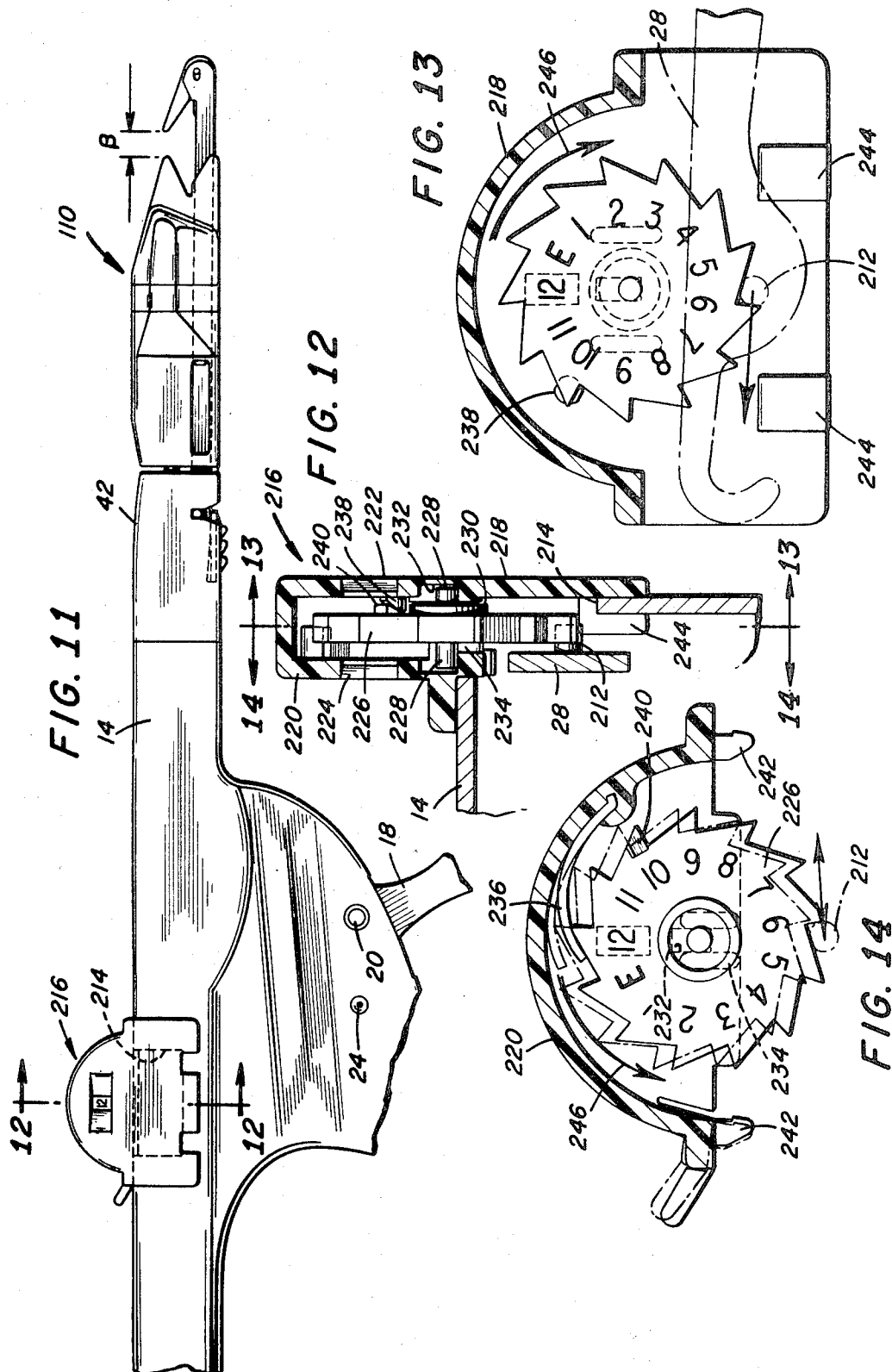
7 Claims, 26 Drawing Figures

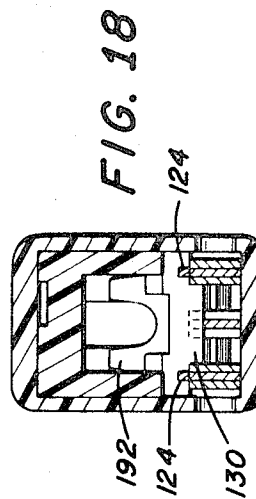
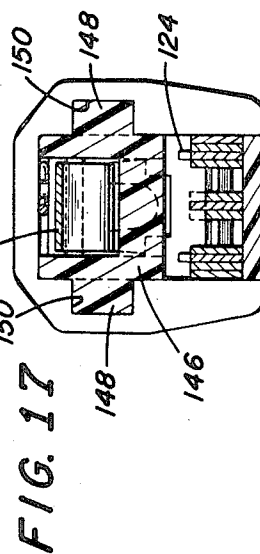
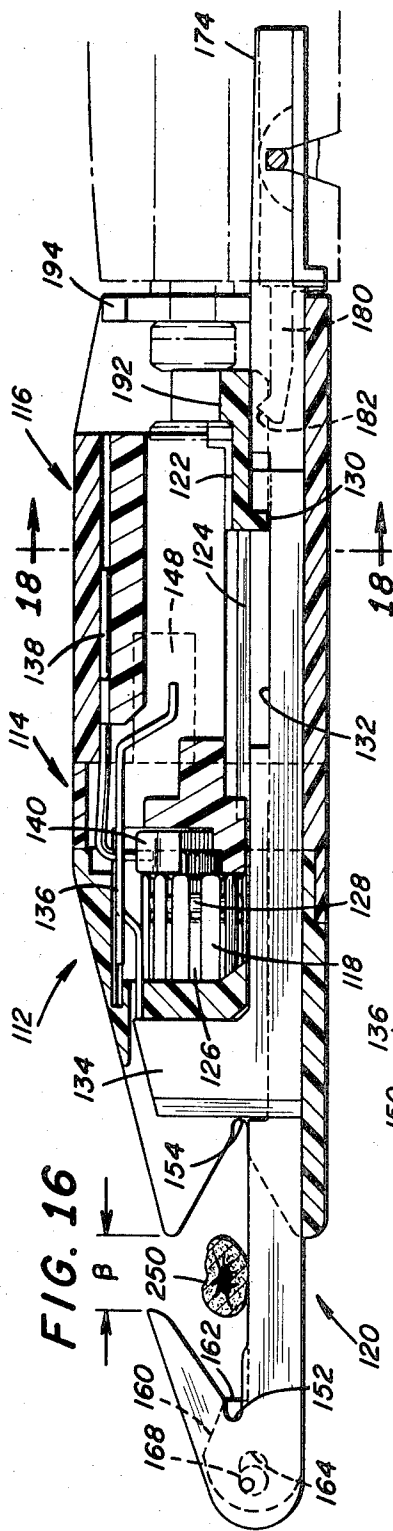
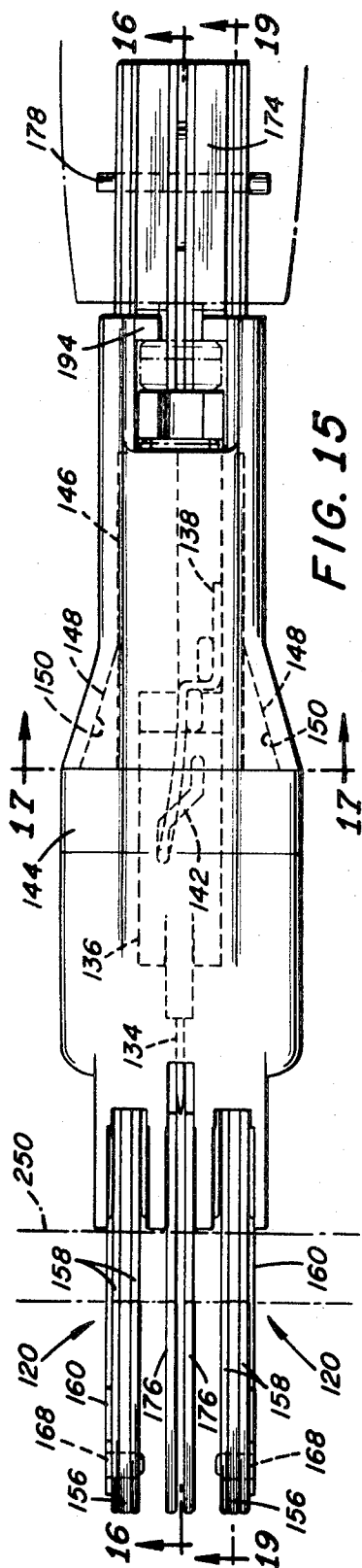












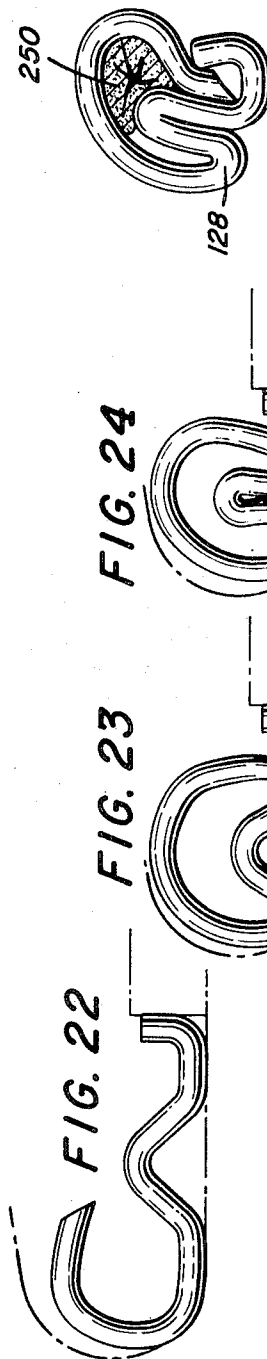
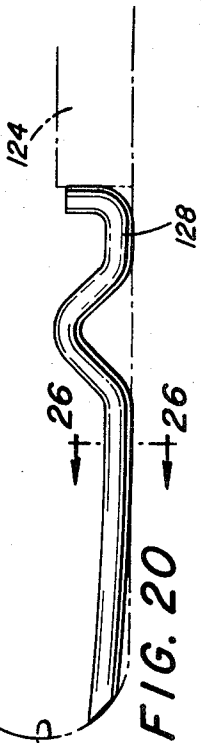
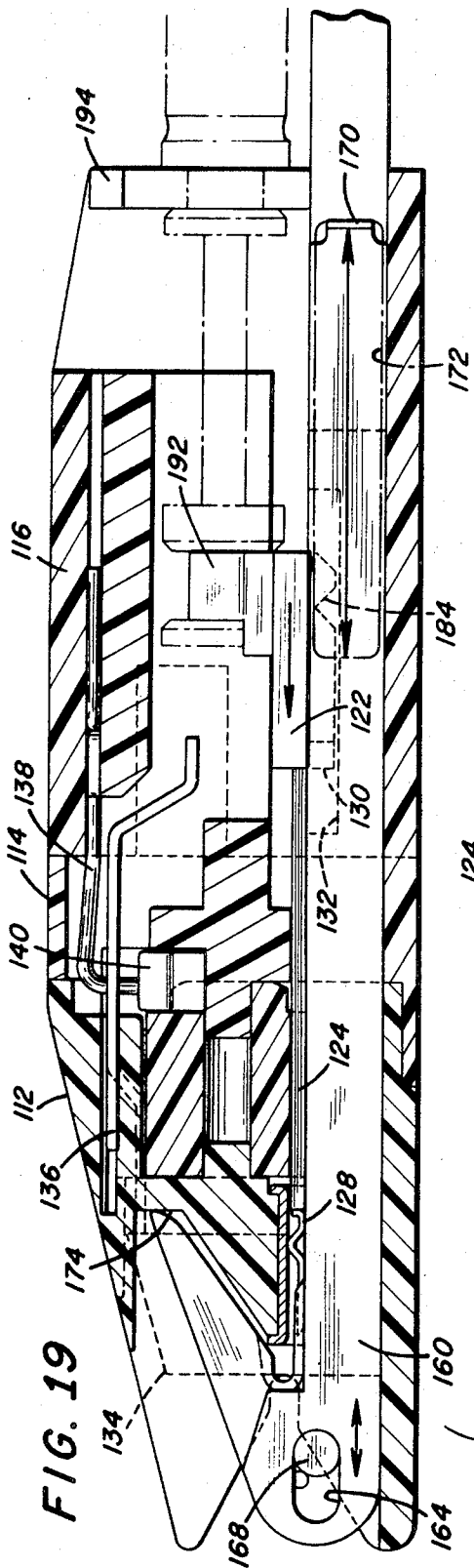


FIG. 22

FIG. 23

FIG. 24

FIG. 25

FIG. 26



INSTRUMENT FOR LIGATING SUTURING AND DIVIDING ORGANIC TUBULAR STRUCTURES

This is a division of application Ser. No. 32,247, filed Apr. 27, 1970, now Pat. No. 3,675,688.

BACKGROUND OF THE INVENTION

Medical instruments for clamping an organic tubular structure, sealing same with the use of surgical staples and dividing the structure after stapling, are not novel. See, for example, U.S. Pat. application Ser. No. 672,372, filed Oct. 2, 1967, and U.S. Pat. application Ser. No. 766,680, filed Oct. 11, 1968, now U.S. Pat. No. 3,684,628, each assigned to the present assignee.

In these copending patent applications, medical instruments capable of performing the above-outlined operations are described. In the first of these copending patent applications, such an instrument is described as a first concept, the instrument accordingly being of somewhat primitive form and having a number of potential drawbacks. In the second of these copending patent applications, a more sophisticated and workable instrument is described. Still, however, there exist a number of areas wherein improvement and simplification can be made. It is toward the improvement and simplification of the medical instruments described in these copending patent applications, that the present invention is directed.

SUMMARY OF THE INVENTION

The present invention relates to an efficient and simplified medical instrument for ligating an organic tubular structure, for suturing the structure at two positions with a pair of sterilized staples and for dividing the structure intermediate the two suturing staples. The base instrument is adapted to mate with a disposable and sterilized staple-carrying cartridge housing a number of staple pairs.

The inventive surgical instrument operates in several stages, each separate stage requiring a different input force for its practice. The instrument of the present invention includes a novel cam arrangement intermediate the surgeon-held trigger mechanism and the output drive shaft operating the cartridge. With the inventive cam, the different stages of operation are each carried out by the application of a uniform input force. That is, due to the novel cam arrangement forming a part of the present invention, the surgeon is able to practice the ligating, suturing and dividing operations without being made aware of the fact that the instrument is carrying out a series of independent operations.

As noted previously, the cartridge associated with the inventive instrument houses a plurality of staple pairs; the particular cartridge described herein houses twelve staple pairs. Because of the importance of keeping the surgeon aware of the number of staples remaining in his cartridge, the inventive instrument is adapted to mate with a novel lapse counter providing ready information as to the number of staples remaining in the cartridge. Then, when the surgeon sees that the cartridge is empty, he can immediately change to a new cartridge, thus avoiding an attempted operation with an exhausted cartridge.

It is required to compress the organic tubular structure in order to carry out the stapling and dividing operations. Because of this requirement, there is a tendency for the tubular structures to become lodged within the jaws of the instrument. To ensure that the

stapled tubular structure is properly ejected from the inventive instrument after the dividing operation, a pair of positive acting tissue ejecting plates are provided.

As noted previously, the staple-carrying cartridge of the present invention is disposable. The cartridge is therefore filled with staples, sterilized, packaged and shipped to its ultimate use location. To be sure that the disposable cartridge is always ready for insertion into an instrument, it is important that the relative positions between the individual components of the cartridge are maintained during all stages of transit. In this way, the necessity of carrying out alignment procedures at the time of each cartridge change is avoided. The cartridge forming a part of the present invention is provided with means for positively locking the moveable elements of the cartridge in their loading positions during transit.

Accordingly, it is the main object of the present invention to provide a surgical instrument capable of clamping an organic tubular structure in its jaws, sealing the tubular structure at two locations with staples, and dividing the structure at a location intermediate the two sealing staples.

It is another object of the present invention to provide such an instrument which operates with a constant input force.

Still a further object of the present invention is to provide such a medical instrument having means for indicating the number of staple remaining in its associated cartridge.

Yet another object of the present invention is to provide a staple-carrying cartridge which positively locks an organic tubular structure in its jaws, carries out stapling and dividing operations and which ensures the ejection of the structure after the dividing operation.

Another object of the present invention is to provide a novel staple-carrying cartridge having a locking device integral therewith to ensure that the moving parts of the cartridge are maintained in insertion alignment during all stages of transit.

A further object of the present invention is to provide a staple-carrying cartridge whose individual elements are maintained in proper alignment thereby avoiding binding contact therebetween.

These and other objects of the present invention, as well as many of the attendant advantages thereof, will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded side view of the medical instrument forming a part of the present invention;

FIG. 2 is a front view of the instrument housing showing in FIG. 1;

FIG. 3 is a cross-section through line 3—3 of FIG. 1;

FIG. 4 is a cross-section through line 4—4 of FIG. 1;

FIG. 5 is a side view, partially in section, of the instrument shown in FIG. 1 during assembly;

FIG. 6 is a bottom view of the drive mechanism of the medical instrument shown in FIG. 1;

FIG. 7 is a bottom view of the cam shown in FIG. 5;

FIG. 8 is a view similar to FIG. 5 but showing the instrument fully assembled and with a cartridge positioned thereon;

FIG. 9 is a view similar to FIG. 8 during a staple driving operation;

FIG. 10 is an enlarged cross-section of the cam shown in FIG. 7;

FIG. 11 is a side view of the forward region of the inventive medical instrument including a cartridge and a lapse counter;

FIG. 12 is a cross-section through line 12—12 of FIG. 11;

FIG. 13 is a cross-section through line 13—13 of FIG. 12;

FIG. 14 is a cross-section through line 14—14 of FIG. 13;

FIG. 15 is a top view of the staple-housing cartridge forming a part of the present invention;

FIG. 16 is a cross-section through line 16—16 of FIG. 15;

FIG. 17 is a cross-section through line 17—17 of FIG. 15;

FIG. 18 is a cross-section through line 18—18 of FIG. 16;

FIG. 19 is a cross-section through line 19—19 of FIG. 15;

FIGS. 20 through 25 illustrate a staple undergoing a formation sequence; and

FIG. 26 is a cross-section through line 26-26 of the staple shown in FIG. 20.

DETAILED DESCRIPTION OF THE DRAWINGS

With reference first to FIGS. 1 through 4, a basic description of the inventive medical instrument will be given. A hollow casing forms the main body of the medical instrument and is indicated generally at 10. The casing 10 may be conveniently divided into a cam housing section 12, a drive housing section 14 and a fixed handle section 16. Positioned on the casing 10 is a trigger 18 pivotable about a pin 20 and a cam 22 (FIG. 5) pivotable about a pin 24.

The trigger 18 is connected, through the cam 22, to a cam-engaging hook 26 (FIG. 9). The cam engaging hook 26 is defined by a pair of arms 28 rigidly connected together by an alignment bar 30, the bar 30 adapted to slide in a slot 32 carved into an elongated guide sleeve 34. The sleeve 34 serves as a housing, support member and guide for a series of biasing springs and driving rods which act on the associated cartridge to bring about the ligating, suturing, and dividing operations of the instrument.

A driving assembly 36 is adapted to slide and lock into place in the guide sleeve 34, thereby providing a positive link between the trigger 18 and the disposable cartridge associated with the instrument. An inner rod 38 extends from a shoulder element 40, through a cartridge mount 42 and terminates in a pair of spaced collars 44 and 46 which are united by a recess 48.

A second pair of spaced collars 50 and 52 are carried by a hollow outer rod 54 which outer rod extends from the collar 52 through the cartridge mount 42 and terminates at a preset distance from the shoulder element 40. A hollow spacing rod 56, of the same diameter as the rod 54, is located intermediate the end of the rod 54 and the shoulder element 40, the space between the rods 54 and 56 being calculated so as to equal the differential stroke between collars 46 and 50 (this differential stroke to be explained below). If desired the spacing rod 56 could be eliminated by increasing the size of the outer rod 54 accordingly.

The cartridge mount 42 is biased away from the shoulder element 40 by means of a biasing spring 58 ex-

tending from an abutment surface 60 in the cartridge mount 42 to the shoulder element 40. A differential spring 62 surrounds the inner rod 38, extends through the rods 54 and 56, and abuts both the shoulder element 40 and an abutment wall 64 integral with the hollow outer rod 54. From FIG. 1 it can therefore be seen that the biasing spring 58 serves to maintain the spacing between the cartridge mount 42 and the shoulder element 40. The differential spring 62, on the other hand, exerts a constant force tending to maintain the shoulders 46 and 50 in contact with one another. A shoulder 66 is defined in the cartridge mount 42 and serves as a stop when engaging the shoulder 52. In this manner, the relative positions of the elements of the driving assembly 36 are maintained.

As noted previously, the driving assembly 36 is adapted to be fit within the guide sleeve 34. For this reason, the cartridge mount 42 is provided with a pair of locking pins 68 extending into the hollow central region thereof. Each of the locking pins 68 on the cartridge mount 42 is adapted to slide within and positively engage one of a pair of locking grooves 70 defined in the body of the guide sleeve 34. And, to ensure that the driving assembly 36 is properly aligned with the guide sleeve 34, an alignment pin 72 is provided on the body of the cartridge mount 42. The biasing spring 58 serves to maintain the locking pins 68 in their respective locking grooves 70.

When the driving assembly 36 is secured in the guide sleeve 34, the shoulder element 40 abuts the alignment bar 30 integral with the cam-engaging hook 26. The bar 30 is, in this manner, urged toward its rearwardmost position in the slot 32. The hook 26 is held in this position due to the force exerted by the biasing spring 58. Because of the fixed alignment between the arms 28 of the cam engaging hook 26 and the alignment bar 30, the arms 28 of the hook 26 are urged into rest positions defining an angle α with the central axis of the guide sleeve 34. The reason for this predetermined rest position will be explained below.

Insertion of the guide sleeve 34 into the casing 10 will now be described. As seen best in FIG. 2, the lower wall 76 of the drive housing 14 contains a depressed region 78. And, as seen in FIGS. 1 and 3, the lower region of the guide sleeve 34 is provided with a projection 80. The projection 80 on the guide sleeve 34 is adapted to comfortably slide in the depression 78 in the drive housing 14. The upper region of the guide sleeve 34 is fit with a projection 82 having a width dimension substantially greater than the projection 80. The width of the projection 82 is made to approximate the internal width of the uppermost region of the drive housing 14. In this manner, the guide sleeve 34 cannot be improperly inserted into the drive housing 14.

In FIG. 5, the relationship between the trigger 18 and the cam 22 can be seen. The trigger 18, pivoting about pin 20, is integral with an extension 84 supporting a cylindrical roller 86 which is adapted to roll about a pin 88. The cam 22 (the bottom of which is shown in FIG. 7) is defined by a pair of cam arms 90 rigidly connected to one another by a tubular member 92. The section 84 of the trigger 18 is provided with a first depression 94 and a second depression 96. The depression 94 is adapted to mate with the tubular member 92, and the depression 96 is adapted to mate with the pin 24. The first mating occurs when the trigger is fully depressed,

and the second mating occurs when the trigger is released.

When the trigger 18 is in its fully contracted position (as shown in FIG. 5) the roller 86 has moved along the surface of the cam 22 and the depression 94 has mated with the tube 92. It is when the trigger 18 is in this position, that the guide sleeve 34 is ready to be inserted into its drive housing 14.

When viewing FIGS. 6 and 7, it will be evident that the distance between the arms 28 of the cam engaging hook 26 is approximately equal to the distance between the cam pairs 90. This distance is actually slightly greater than the distance between the cam pairs 90 due to the placement of an engagement disc 98 on each of the cam pairs 90. The cam engaging hooks are adapted to encounter and grasp the engagement discs 98 when in proper alignment.

As mentioned previously, the arms 28 of the cam-engaging hook 26 define an angle α with the body of the guide sleeve 34. The biasing spring 58 exerts a force on the alignment bar 30 and maintains this predetermined angle unless the hook 26 is acted upon by the external environment.

In FIG. 5, the guide sleeve 34 is shown partially inserted into the drive housing 14. A protrusion 100 on each of the arms 28 rotates the arms about the alignment bar 30, this protrusion being of such dimensions to ensure that when the same encounters the lower wall of the drive housing 14, the hook is lifted above and avoids the forwardmost section of the housing.

When the guide sleeve 34 is moved a greater distance into the housing 14, the protrusion 100 comes out of engagement with the lower wall of the drive housing 14. And, when the hook leaves the surface defined by this wall of the housing, the arms 28 return to their angled rest position. With the arms 28 in their rest positions and with the trigger 18 in its fully contracted position, the hooks on the arms 28 are calculated to be in exact alignment with the engaging discs 98. Therefore, when the guide sleeve 34 is further inserted into the drive housing 14, the cam engaging hook 26 carries with it and pivots the cam 22 about its pivot pin 24.

When the guide sleeve 34 nears its rearwardmost position in the drive housing 14, a knurled restraining knob 12 is mated with a threaded extension 104 on the rear portion of the guide sleeve. A set of four alignment pins 106 extend from the rear of the cartridge mount 42 and ensure proper alignment between the cartridge mount and the drive housing 14. With the elements then in their rest positions, the instrument takes the form shown in FIG. 8.

As disclosed in the later filed of the two above-noted copending U.S. patent applications, the ligating, suturing and dividing operations are done in stages. Each stage requires its own input force for its performance and, for this reason, the novel camming arrangement forming a part of the present invention is employed. The precise operation of the novel cam will be more fully described below; however, for ease of understanding, the configuration of the staple-housing cartridge will first be explained. This will be done with reference to FIGS. 8, 11 and 15 through 19.

The cartridge forming a part of the present invention is shown generally at 110 and is similar, in most respects, to the cartridge disclosed in the later filed of the two above-noted copending U.S. patent applications. Accordingly, stress will be put only on the differences

between the present cartridge and that already known. The cartridge 110 comprises, basically, a body made up of three sections, a forward barrel-housing section 112, a thin intermediate support section 114 and a rear cover section 116. Each of these sections is made of plastic, the sections being adapted to unite by heat sealing or gluing.

As was the case in the last of the above-noted copending patent applications, the forwardmost section of 112 of the cartridge 110 houses a pair of staple-carrying barrels 118. However, unlike the previously described cartridge, each barrel 118 houses only 12 staples rather than 12 sets of two staples each. It has been found that the tubular organic structures may be properly sutured with only two staples. Accordingly, the cartridge 110 is provided with but two anvils 120, each anvil being adapted to carry a single staple and to form same around the tubular organic structure to be sutured.

As seen best in FIGS. 15 and 19, the cartridge 110 is provided with a staple-pusher similar, in most respects to the pusher already known. A main body 122 slides in the rear housing section 116 and has embedded therein a pair of pusher rails 124. Each of the pusher rails 124 is adapted to slide into the grooves 126 in its associated barrel 118 and to cause the ejection and formation of a staple 128 following the shape of the forwardmost region of the anvil 120.

The main body 122 of the pusher has a downwardly projecting flange 130. This flange slides within notch 132 and controls the movement of a knife blade 134 integral with the notch. The rest position of the main body 122 is shown in FIG. 15. In this position, the flange 130 engages the rearwardmost portion of the slot 132 and holds the knife blade 134 away from the area wherein cutting occurs. When, however, the main body portion 122 is moved toward the anvil, the projection 130 engages the forwardmost part of the slot 132 and urges the knife 134 into the cutting area. Therefore, first a staple is ejected and formed around the tubular structure and then the knife blade moves forward and severs the structure. The length of the slot determines the time delay between the completion of the stapling operation and the initiation of the severing operation.

At the upper region of the cartridge 110 is a camming plate 136 associating with a biasing spring 138 and a camming bar 140. The camming plate 136 has a cam groove 142 cut therethrough. In operation, the camming plate 136 is moved in a direction parallel to the longitudinal direction of the cartridge 110. When this occurs, the forwardmost end of the spring 138, projecting through the slot 142 and associating with the camming bar 140, moves in a direction transverse to the longitudinal dimension of the cartridge. When this occurs, the camming bar 140 simultaneously indexes both of the staple-carrying barrels 118. This indexing operation is similar to that described in the above-noted copending patent application.

To be sure that the spring 138 properly controls the operation of the camming bar 140 and maintains the teeth of the camming bar 140 in engagement with the gears 142 of the barrels 118, it is necessary that the downwardly projecting region of the spring 138 be biased toward the camming bar 140. Because of this downward bias on the forward region of the spring 138, there is a resulting upward bias on the rearward region

of the spring. And, because the cartridge 110 is constructed with three-piece construction, the spring 138 tends to urge the individual pieces of the cartridge 110 out of longitudinal alignment.

The inventive cartridge 110 is provided with means for maintaining proper alignment between the individual elements of the cartridge. These means can best be seen in FIGS. 15 through 17 and FIG. 19.

The centrally located support section 114 of the cartridge 110 is in the form of a U-shaped member 144 having a rearwardly extending portion 146 (see FIGS. 16 and 17). The projection 146 has integral therewith a pair of triangular wedges 148 extending and tapering into the rear housing section 116. In the walls of the housing section 116, there are cut a pair of wedge-like depressions 150 adapted to mate with the wedges 148. Because of the wedge shape of these elements, the manufacture of the cartridge is facilitated, and because the wedges 148 mate with the depressions 150 in a direction parallel to the longitudinal dimension of the cartridge 110, the tension of the spring 138 is unable to cause relative motion between the central support section 114 and the rear housing section 116. Therefore, the moving elements of the cartridge 110 are able to freely move without binding.

As in the later filed of the two above-noted copending patent applications, the cartridge of the present invention employs a pair of anvil assemblies 120 moveable with respect to the main body of the cartridge 110. The forwardmost part of each anvil 120 has a curved staple-forming section 152 adapted to unite with a similarly curved section 154 on the forward barrel housing section 112. In this manner, when the barrel housing section 112 abuts the anvil sections 120, a tissue gap is defined between the curved region 152 on the anvil sections 120, and the curved region 154 on the barrel housing section 112. It is in this position that the organic tubular structure is sutured and divided.

Naturally, it is important that the tubular structure be ejected from the curved section 152 after the ligating, suturing and dividing operations are completed. The cartridge forming a part of the present invention is, therefore provided with means for ensuring tissue ejection after each complete operation.

As seen best in FIG. 15, each anvil section 120 is defined by a series of laminated metallic elements. The central element 158 can be termed a staple-forming element since it is on this element that the staple rides and it is this element which defines the final shape of the staple. Then, positioned on each side of the element 156, is a pair of guide elements 158 ensuring that the staple is maintained in proper alignment with the staple-forming element 156.

A fourth element 160, which may be termed a tissue-ejecting plate, is positioned on each of the two anvil assemblies 120 at the outermost regions thereof. As seen best in FIG. 16, the tissue-ejecting plate 160 defines a vertical wall 162. It is this wall which forces the tissue out of the depression defined by the curved surface 152 on the anvil assembly 120. A slot 164 in the plate 160 extends in a direction parallel to the longitudinal dimension of the cartridge 110 and mates with a pin 168, extending entirely through the laminate and maintaining the elements integral. The slot 164 thus defines a forward and a rear position for the tissue-ejecting plate 160.

The tissue-ejecting plate 160 extends substantially the full length of the cartridge 110. The rearwardmost end of the tissue-ejecting plate 160 terminates in a tab 170 extending out of a slot 172 defined in the rear housing section 116 of the cartridge 110. It is the interaction between the slot 172 and the tab 170 which controls both the forward and the rearward movement of the tissue-ejecting plate 160. That is, when the anvil assembly 120 abuts the forward barrel-housing section 112, at wall 174 (see FIG. 19), the tab 170 is put in contact with the rear wall of the slot 172. In this way, the tissue-ejecting plate 160 is urged out of the depression in the anvil assembly 120. When, on the other hand, the anvil assembly 120 is at its farthest distance from the main body of the cartridge 110, the tab 170 engages the forwardmost wall of the slot 172 causing the tissue-ejecting plate 160 to force the tissue out of the depression defined by the curved surface 152.

As explained previously, the cartridge forming a part of the present invention includes means for locking the moving parts during all stages of transit in positions whereby the cartridge 110 is always ready to be loaded into the basic surgical instrument. The locking means takes the following form.

As seen best in FIGS. 15 and 16, the rearwardmost part of the anvil assembly 120 associates with a mounting block 174. This mounting block is made of plastic, and maintains a proper alignment between the laminated elements forming a part of the anvil assembly 120, the knife member 134 and the knife guiding plates 176. A mounting pin 178 passes through the mounting block 174 and holds the metallic laminate elements in place.

Integral with the forwardmost part of the mounting block 174 are a pair of projections 180 having tapered extensions 182 biased into the plane of the pusher block 122. The pusher block 122, on the other hand, has defined therein a pair of grooves 184 adapted to mate with the tapered extensions 182. When the individual elements of the cartridge 110 are in the positions shown in FIG. 16, the tapered extensions 182 on the mounting block 174 mate with the depressions 184 in the pusher block 122. In this manner, the relative positions of the moveable elements in the cartridge 110 are maintained so as to ensure positive insertion of the cartridge in the medical instrument. The projections 180 are resilient and, therefore, when the cartridge is fired by the instrument, the pointed elements 182 easily come out of engagement with the depressions 184.

The cartridge 110 is inserted in the body of the instrument as follows. The mounting block 174 of the cartridge 110 is moved into engagement with the cartridge mount 42 so that the mounting pin 178 slides into a notch 186 defined in the mount 42. Then, a sliding locking element 188 is moved from the position shown in FIG. 1 into the position shown in FIG. 9. The top surface of the locking member 188 defines a ramp 190 which is adapted to frictionally engage the bottom portion of the mounting plate 174 and to therefore ensure positive locking of the cartridge 110 into the instrument.

The pusher block 122 defines, at its rearwardmost region, a saddle 192 which, when the cartridge is mounted on the instrument, mates with the recess 48 and is secured therein by the collars 44 and 46. Similarly, the rearwardmost part of the cartridge 110 defines a saddle 194 which is adapted to sit in the depres-

sion between the collars 50 and 52. In this manner, and again referring to FIG. 1, the main body of the cartridge 110 is made integral with the outer rod 54 (being locked between collars 50 and 52), while the pusher assembly, responsible for ejecting and forming the staples around the tubular structure, is made integral with the inner rod 38 (being locked between collars 44 and 46).

The operation of the instrument is as follows. The rest position of the instrument is shown in FIG. 8 and the fully fired position of the instrument is shown in FIG. 9. Starting from its rest position, the initial thrust of the trigger 18 moves the main body of the cartridge 110 toward the stationary anvil assembly 120. Before this, the organic tubular structure to be ligated, sutured and divided is positioned within the jaws of the cartridge (the jaws being separated, as shown in FIG. 11, by a distance which corresponds to the maximum allowable diameter of a tubular structure to be used with the instrument).

When the trigger 18 is depressed a given amount, the body of the cartridge 110 contacts the anvil assembly 120 and the organic tubular structure is securely ligated between the jaws of the cartridge. Then, further motion of the trigger 18 overcomes the force of the differential spring 62 and causes relative motion between the inner rod 38 and the outer rod 54. When this occurs, the pusher assembly is moved in the body of the cartridge 110 and causes the ejection of a pair of staples from the barrels 118 and, ultimately, the formation of the staples around the tubular structure to be sutured. Further compression of the trigger 18 moves the knife blade 134 forward thus dividing the organic tubular structure intermediate the pair of staples.

The different operations described above require different forces for their performance. During the initial movement of the main body of cartridge 110, toward the anvil assembly 120, only the force of the biasing spring 58 must be overcome. When, however, the anvil assembly 120 abuts the forward barrel-housing section 112, the added force exerted by the differential spring 62 comes into play. Then, still a greater force becomes necessary when the staple is bent around the anvil bar 168. It has been found that the transmission of these differential forces to the hand of the surgeon is an annoyance to the surgeon during a stapling operation. It was with this in mind that the novel camming arrangement forming a part of the present invention was devised.

With reference then to FIGS. 8 through 10, the operation of the novel camming arrangement forming a part of the present invention will be described. As will be seen in FIGS. 8 and 9, depression of the trigger 18 causes the trigger to pivot about its pivot pin 20. And, due to the action of the camming roller 86, bearing against the camming surface 198 on the cam 22, the cam 22 rotates in the direction of arrow 200, thus acting against the force exerted by the biasing spring 58. As mentioned previously, the initial operation of the trigger 18 moves the main body of the cartridge 110 toward the anvil 120. During this operation, the cam roller 86 moves along the region 202 of the cam surface 198.

The cam roller 86 rolls, first in a "downhill" direction and then rolls "uphill". The peak of the first uphill journey of the cam roller 86 is shown at 204. Then, very shortly after the roller 86 passes over the peak 204, the

anvil assembly 220 meets the barrel housing section 112 of the cartridge 110. At this instance, the force exerted by the differential spring 62 is added to the force of the biasing spring 58, the combination force opposing the depression of the trigger. The distance along the cam surface 198 corresponding to the time between the initial movement of the main body of the cartridge 110 and the initial contact between the anvil assembly 120 and the main body of cartridge 110, is shown, in FIG. 10, at area 1. It will be noted that this area ends shortly after the roller 86 encounters the peak 204 and at a time when the roller 86 is travelling in a downhill direction along the region 206 of the cam surface 198.

The roller 86 then travels downhill while the pusher moves forward, begins an uphill climb while the pusher ejects a pair of staples from the barrels, and encounters and travels over a second peak 208. This interval is shown as area 2 and represents the time interval between the initial travel of the pusher and the instant when the pusher brings about the first bending of the staple pair. As seen in FIG. 10, the initial bending of the staple pair occurs shortly after the roller 86 encounters the peak 208 and while the roller travels downhill along the region 210 of the cam surface 198.

The area designated 3 represents the interval during which the staple pair bends around the anvil assembly and sutures the organic tubular structure. During the end of this interval, the knife blade divides the tubular structure.

When the cam roller 86 rolls downhill, after encountering a peak in the cam surface 198, the force required to cause movement in the drive assembly is reduced. That is, the input force necessary to develop a given output force decreases when the cam roller 86 rolls downhill along the cam surface 198. Conversely, the input force required to develop a given output force increases when the cam roller 86 rolls uphill along the surface 198. The cam 22 is shaped in such a manner that the required input force is substantially complementary to the necessary output force. That is, when the output force is required to be high, the cam roller 86 is made to roll downhill, thereby reducing the necessary input force to develop the required output force. Then, when the required output force is low, the cam roller 86 is made to roll uphill so as to increase the required input force to bring about the necessary output force. In this manner, the surgeon is unaware of the changing output demands of the instrument which he uses. The surgeon feels that he exerts a given and constant input force over the entire multi-stage operation.

The cam and timing sequence forming parts of the present invention are actually designed in such a manner that the required input force is gradually increased to "ready" the surgeon for the force transition which is to come. The surgeon is delivered a surge of power when the roller passes a peak and, shortly thereafter (when the surge of power is actually required), the surgeon is unable to recognize this excess demand. That is, while theoretically the cam roller 86 should pass over the peaks 204 and 208 at the instant when the added output force is required, the transition is moved slightly after the peak so that the surgeon encounters, in practice, what is desired by theory.

As can be seen in FIG. 6, one of the arms 28 of the cam engaging hook 26 is provided with a pin 212. And, as can best be seen in FIGS. 5, 11 and 12, one wall of the drive housing 14 is provided with an opening 214.

A lapse counter 216 fits on the drive housing of the casing 10, engages the pin 212, and serves to indicate the number of staple pairs remaining in the barrels of the cartridge 110.

The lapse counter 216 comprises a main body having the body halves 218 and 220. The body half 218 has an inspection window 222 and the body half 220 has an inspection window 224. A rotating gear 226, having the numerals 1 through 12 and the letter "E" engraved on both sides thereof, is mounted on the main body so that one of the numbers or the letter "E" is always visible through both of the inspection windows 222 and 224.

Each side of the gear 226 is provided with a centrally located pin 228 serving as an axis of rotation for the gear; and one side of the gear is provided with a centrally located projecting cylinder 230. And each of the body halves has, near its center, a depression 232 adapted to mate with a respective pin 228 on the gear 226. The body half 220, remote from the side of the gear 226 provided with the cylindrical projection 230, is equipped with a pair of upstanding projections 234. The centrally located cylindrical projection 230 on the gear 226, and the upstanding projections 234 on the internal wall of the body half 220 serve to ensure that the gear 226 is oriented properly in the housing of the lapse counter 216.

As seen clearly in FIG. 12 through 14, each of the pin engaging indentations 232 is elongated in a vertical direction. This allows the gear 226 to move from the position shown in solid lines to the position shown in phantom (see FIG. 14). A spring 236 embedded in the body half 220 biases the gear 226 toward the bottom of the indentations 232.

On the body half 218, located internally, is a beveled stop 238; and a corresponding stop 240 is mounted on the side of the gear 226 adjacent the stop 238. The relative positions of the stops 238 and 240 are designed so as to prevent further rotation of the gear 226 when the letter "E", indicating that the cartridge is empty, appears in the inspection window 222.

In constructing the lapse counter 216, the gear 226 is initially oriented so that the numeral 12 is visible through both of the inspection windows 222 and 224. At this time, the two body halves are heat sealed or glued together; and the integral lapse counter 216 is then fit on the casing 10. For this purpose, the body half 220 is provided with a pair of locking arms 242 and the body half 218 is provided with a pair of alignment tabs 244. The locking arms 242 are adapted to mate with corresponding openings in the top of the casing 10 and the alignment tabs 244 are adapted to fit within the casing 10, projecting through the opening 214.

When the trigger 18 is depressed, the arms of the drive mechanism are pulled toward the cartridge 110 through the action of the cam 22. When this occurs, the pin 212 engages one of the teeth of the gear 226 and causes rotation of the gear in the direction of arrows 246. Such rotation causes the next lowest number to appear through the inspection windows. On the release of the handle 18, the arms 28 return to their rest positions, under the action of the biasing spring 58, and the pin 212 again passes the gear 226. Upon its rearward passage, the pin 212 urges the gear 226 upwardly against the force exerted by the spring 236, without further rotation of the gear. The free arm of the spring 236 serves as a stop to the backward rotation of the gear 226. Such operation continues through 12 strokes of

the trigger 18 and, on the thirteenth stroke (one stroke after the cartridge is emptied) the stops 238 and 240 come into engagement with one another, thus preventing further operation of the instrument.

With reference now to FIG. 20 through 25, the shaping of the staples 128 will be explained. The initial shape of the staples 128 is shown in FIG. 20, illustrated in cross-section in FIG. 26. The pusher bars 124 urge two staples 128 out of their respective barrels and into the track of the anvil bar 156. As the force exerted by the pusher bars increases, the staples reach a point where they "break" and begin to bend around the anvil bar. This breaking point is shown in FIG. 21. Then, the forward part of each staple continues to wrap around the respective curved surface 12 on the anvil assembly, then taking the form shown in FIG. 22. In FIG. 23, the staple has continued its travel around the anvil and is shown just as the "hump" of the staple begins to collapse. In FIG. 24, the hump has fully collapsed; and, in FIG. 25, the forwardmost part of the staple is locked in place by the collapse of the tail thereof. A tubular organic structure 250 is shown, in FIG. 25, as it would appear when sutured by a staple.

Above, there has been described a single embodiment of the present invention. It should be appreciated, however, that this embodiment is described for the purpose of illustration only and that numerous alterations and modifications may be practiced by those skilled in the art without departing from the spirit and scope of the invention. Accordingly, it is the intent that the invention not be limited by the above but be limited only as defined in the appended claims.

We claim:

1. A staple-carrying cartridge for ligating, suturing and dividing an organic tubular structure, the cartridge comprising: a rail assembly including a pair of parallel spaced anvil parts and knife guide means extending between said anvil parts and parallel thereto; at least one wire suture associated with each of said anvil parts, said wire sutures being slidable with respect to said anvil parts; a pusher element cooperating with said wire sutures and serving to eject same in pairs from said cartridge and to drive same against said anvils, thereby causing said wire sutures to become wrapped about said organic tubular structure held against said anvils; a knife cooperating with said pusher for severing said tubular structure held against said anvils; and means for ejecting the tubular structure halves from said anvils after the dividing operation is completed.

2. The cartridge defined in claim 1, wherein said means for ejecting tissue is in the form of at least one tissue ejecting plate lying parallel to and slidably mounted with respect to at least one of said parallel spaced anvil parts.

3. The cartridge defined in claim 2, wherein each of said anvil parts has an indentation defined therein, said indentation serving to house said organic tubular structure during the ligating, suturing and dividing operations; and wherein said at least one tissue ejecting plate has first and second positions, the first position being remote from said indentations defined in said anvil parts and said second position extending into and blocking the passage to said indentations.

4. The cartridge defined in claim 3, and further comprising means for moving at least one tissue ejecting plate out of the region of said indentations during a su-

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turing operation and into the region of said indentations after a suturing operation.

5. The cartridge defined in claim 1, and further comprising locking means for maintaining the relative positions between the moveable elements of said cartridge, during all stages of transit, in positions ready to be inserted into its associated surgical instrument.

6. The cartridge defined in claim 5, wherein said locking means maintains the relative positions between said rail assembly and said pusher.

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7. The cartridge defined in claim 6, wherein said pusher is provided with a locking indentation; and said rail assembly is provided with a locking projection; said projection and said indentation adapted to mate when the relative positions of said moveable elements are ready for insertion into the associated surgical instrument, and wherein said locking means may be easily disengaged from one another after insertion of said cartridge into said surgical instrument.

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