



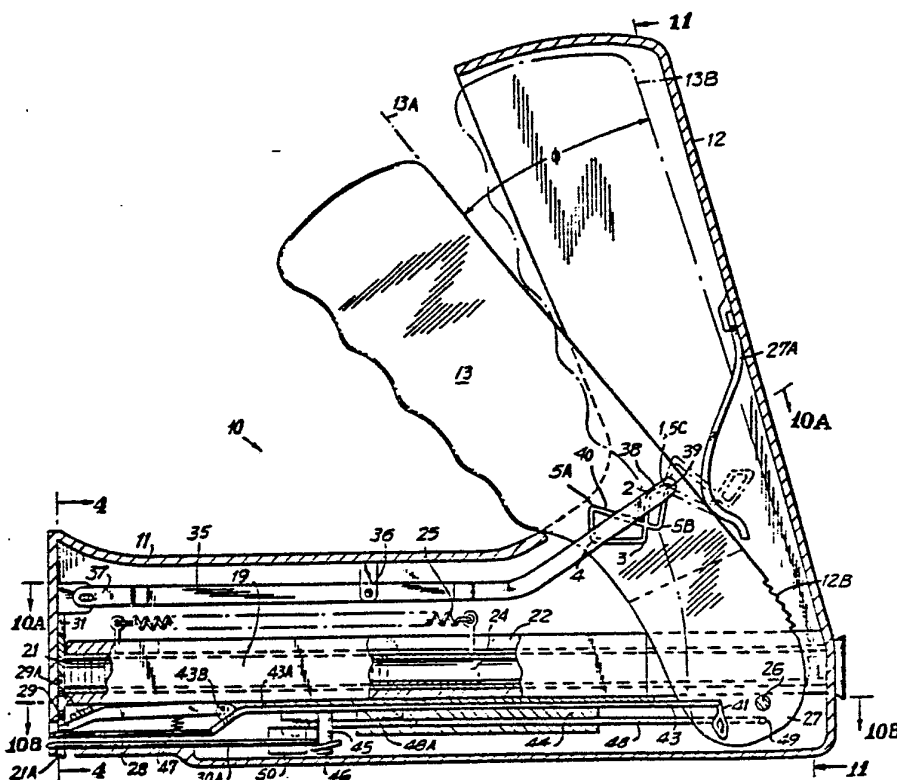
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(54) Title: A SURGICAL STAPLING SYSTEM AND APPARATUS

(57) Abstract

A surgical stapling system, apparatus and staple wherein a resilient staple (21) has a relaxed closed configuration, is expanded into an open crescent shape, and finally is allowed to return to its closed configuration while simultaneously piercing and drawing together adjacent edges (33A) of an open incision or wound. The stapling apparatus (10) contains a plurality of staples (21) and includes projections (28, 29, 30) which engage and secure each staple to the apparatus until its closure to tissue is complete and separation from the apparatus is desired. Further mechanism (2, 3, 4 & 5) is provided to control the staple as it closes and optionally to re-open a closed or partially closed staple.



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A SURGICAL STAPLING SYSTEM
AND APPARATUS

Technical Field

5 This invention concerns closure of incisions at the conclusion of many typical surgical procedures. Such closures can involve the rejoining of a wide variety of tissue types and bones, such as the rib cage, fascia, muscle skin and fat.

Background Art

10 Primary objectives of these closure procedures are to affect rapid and proper healing with a minimum of discomfort and scarring and to ensure that the wound remains securely closed. A related objective is that the closure not interfere with subsequent bandages and change of
15 dressing.

Closure generally involves joining various layers of tissue, each in a special and correct manner. For instance, in abdominal surgery the severed peritoneum layer must be joined, followed by the layers of muscle, fascia, fat and skin. Additionally, retention sutures which pass
20 through all layers may be used or required as insurance that the closure will not open. To accomplish these sutured closures typical materials include silk, gut and a wide variety of synthetics including Dacron^R, Teflon^R and various new disposable materials. Depending on strength
25 required, the materials may be monofilament or braided and the caliber may be varied. Also there are metal sutures which are usually made from non-reactive stainless steel. Each material has characteristics which make its
30 use appropriate for a specific purpose.

In all these techniques an important consideration is scar formation, the manner in which the human body reacts to suture materials which behave, for the most part, as foreign bodies and cause the body's defense mechanisms to
35 seal them off with connective tissue. When the body's reaction is greater, more scar tissue will be formed.

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Obviously, sutures cannot be passed without a delivery system which for these sutures consists of a large assortment of needles. Each type of needle is designed to provide a particular function, such as ease of handling, ease of passage, ease of release, minimal trauma, etc. The surgeon will generally either thread a needle or use pre-threaded suture-needle combinations and secondary instruments such as suture holders.

Wound closure is thus a major concern among surgeons whose primary objectives include: (a) to minimize time required to close, (b) to reduce surgeon fatigue and patient anesthesia time, (c) to reduce tissue trauma and accelerate wound healing, (d) to minimize blood loss, (e) to achieve optimum cosmetic results, and (f) to control and reduce overall costs.

It is these objectives which led to the development of a relatively new method of closure, namely joining adjacent tissue with metal staples delivered and secured by a staple gun. These metal staples which have partially replaced traditional sutures, have become popular for both external and internal closures, including joining cut ends of blood vessels, hollow organs and various layers of tissue within the body. Dozens of stapling devices for surgery have been developed by Americans and foreigners, especially those of the Soviet Union.

One aspect of virtually all of these known stapling devices is the characteristic way in which they function and the use of bendable but non-resilient metal staples. Force is applied to change the initially open, generally U-shape configuration of each metal staple to a final, closed configuration, whereby the staple will hold two adjacent edges of tissue together. The staple devices are held and operated by the surgeon's hand, with force applied either manually by the surgeon or by a power-assisted mechanical force incorporated into the stapler. The force required to bend or crush the ends of the non-elastic metal staples is substantial, and is typically applied by

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an anvil which drives each staple into position and then forcibly bends the legs of the staple. Once placed, the staples cannot be removed without the use of a separate device which forcibly returns the staple to its generally open configuration, so that removal is possible without tearing the tissue.

It is the broad purpose of this present invention to provide a surgical stapling instrument for joining with staples two opposing layers of tissue, skin/or fascia of a patient. This device is to utilize a new type of elastic or spring staple and a unique delivery system, and to have a mode of increased control including reversible operation for removing an emplaced staple with the same device and without even moving the device from the site of placement. Another object of the present invention is to achieve a reduction in overall size and weight of the stapler in order to provide more exacting control for the surgeon, especially in difficult-to-reach places. A further objective is to reduce the amount of manual force and motion applied to the device when it is at the site or delivery point of the staple.

The new invention disclosed and claimed in subsequent sections of this application is fundamentally different from all known prior art stapling systems and devices, with typical of such prior devices being disclosed in the U.S. patents listed in the Appendix I attached hereto, and all relating to non-elastic staples which are crushed from open to closed condition.

Disclosure of the Invention

The present invention is a hand-held and hand operated multi-stage surgical instrument that carries a plurality of new spring staples, preferably in a cartridge, and delivers and closes one staple at a time to the adjacent edges of an incision being closed or adjacent tissue or other substances being joined. Although the new staples are similar in size to standard non-elastic staples of



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known staple-guns, the new staples are different in many important ways. The new staples are flexible and resilient with sufficient memory to permit rather extensive alteration of the staple's shape when force is applied to open the staple for emplacement, while allowing the staple to return to its original closed configuration in a state of rest. Each of the staples has a shape which is the ideal for its final position in place in the body when it joins two layers of tissue. The staples are initially loaded in a cartridge or magazine, wherein they have the same configuration that they will be assuming when finally placed in an incision.

Because of these structural characteristics the staple itself provides a large portion of the force required to return to its closed shape and thereby pull adjacent tissues together and achieve proper closure. Accordingly, less force is required by the operator than with prior art staples and stapling devices, where each staple must be forcibly bent beyond its elastic limit for each step of closure. The new delivery system therefore may be smaller and lighter which permits better control, better visibility, and less fatigue on the part of the surgeon.

This device is operated by squeezing and pivoting a trigger a selected distance toward or into the handle, and subsequently releasing the trigger to automatically return to its normal position. This motion of the trigger activates a multi-stage operation that includes the following steps: (a) loading a staple from the staple magazine into the placement section; (b) opening or expanding the staple within the placement section; (c) delivering the open staple so that its ends contact the adjacent edges of tissue of the incision; (d) releasing the staple on a fully controlled basis into the tissue; (e) providing a modest amount of force to guarantee that the staple fully closes, i.e. returns to its original configuration, (f) releasing the staple from the device; and (g) re-loading



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a new staple into the placement section.

The advantages of this device over the known prior art devices are many. As mentioned above the staple's own resilient force urging it to a closed configuration reduces to a minimum any additional manual force required of the surgeon. Also the distance the surgeon's fingers must depress the squeeze-action trigger is very short. Thus the new device is essentially "easy" to operate, requires little effort, and has no jolt or comparable motion upon closure or release of each staple.

Another major and significant improvement provided by this invention is its ability to remove a staple after such has been placed, if the surgeon determines the staple has not been placed properly or the surgeon decides for any other reason to immediately remove the staple. This is permitted by the creation of an indicator or other signal in the trigger assembly that tells the surgeon when the staple has been placed and fully closed in the incision and inserted. If he is satisfied with the placement he merely continues to squeeze the trigger beyond the indicator point and the placement and release are concluded. If, however, he wishes to withdraw the staple, he simply releases the trigger, which is spring-biased to return to its open or start condition; the staple remains tied to the device, is opened and removed from the tissue, and is ready to be re-positioned on the incision and inserted.

In all other known prior art stapling devices, once the staple has been placed, correctly or incorrectly, it may only be removed by a secondary or separate device. The reversibility capability of the new stapler permits a margin for error and enables instant correction or change of plan on the part of the surgeon.

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Another important feature is the jam-free mechanism which prevents loading of a new staple until the previous staple has been fully released from the instrument. The loading function is accomplished during the return phase of the trigger and cannot therefore be activated until
5 the indicator point has been passed by the trigger during the staple-displacement phase.

All functions of the device (loading, opening, placement, closure and release) are accomplished as part of a continuous mechanical action, namely squeezing and
10 then releasing the trigger. This device has very few moving and stationary parts, which assures simplicity and problem-free operation and low production costs to create the possibility for this system to be a single-use disposable product.

15 Because there is no requirement for converging jaws or for a crushing force to close non-elastic staples around an anvil as in the prior art, the width of the new device may be very small, approximately the width of one new staple in its open position. This narrow configuration is most useful, of course when skin stapling is re-
20 quired in relatively inaccessible areas.

Removal of the new staple requires a simple opening or expansion of the resilient staple. Above and below the mid-section of the staple are locking and safety pins
25 respectively which engage and secure the staple to the device until final release. While these two pins remain engaged to an otherwise emplaced staple, a pair of expansion pins adjacent the safety pin at the lower surface of the staple are caused to diverge and thereby expand the
30 generally oval shape of the staple, causing the legs thereof to separate. In this way the staple is changed from a generally oval shape to a generally U-shape, so that it can be easily and safely withdrawn from the incision tissue.

35 A semi-automatic nature of the device is provided by three springs or spring members. A first main spring urges the trigger outward from the handle, the force of

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this spring being overcome relatively easily by manual squeezing of the trigger by the surgeon. A second spring, such as a constant tension coil Negator^R spring, urges the staples in the magazine toward the discharge end, where a single staple is discharged periodically and driven by an anvil to a "ready" position to be subsequently expanded, emplaced in the incision, and finally released. A third spring is inherent in the expansion pin member whereby a resilient member has a pair of adjacent pin-like parts which are normally in closed position, and may be forced apart by a wedge movable between the pins. These pins will resiliently converge when the wedge is removed.

To cause proper movement of the anvil and the safety, lock and expansion pins, two cams are provided on the trigger which actuate drive levers when the trigger is squeezed clockwise and subsequently released to spring back counterclockwise. The first cam establishes the motion pattern for the anvil to deliver staples and later to apply the final closing force on each staple. The second cam establishes the motion pattern for the safety, lock, and expansion pins to move forward and rearward together at the proper time. A separate wedge is driven by a direct linkage with the trigger to open and close the expansion pins. Accordingly, squeezing of the trigger automatically operates the device through its various stages for loading a staple from the magazine into the placement section, expanding the staple, delivering the open staple to the wound, allowing the staple to engage and close the wound, and final releasing of the staple, or optionally re-opening and removing the staple.

The new stapler as disclosed herein has many features which are significant and useful when used in the combination described above or in various other combinations. The new invention comprises first, a new elastic staple that is resiliently expanded to engage adjacent edges of tissue and subsequently released to close and secure the tissue. The invention further comprises a

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delivery system or apparatus to contain the staples, and to expand, deliver, and release them as required, without having to use a crushing force. The next and most significant feature is the ability to easily, quickly, and safely reverse the staple emplacement process and thus to remove the staple with the same device. In the preferred embodiment of this invention the staple remains secured to the staple gun by a safety pin even while the staple has penetrated the tissue and closed, thus affording the surgeon constant and total control of the stapling procedure and apparatus.

To produce the proper movement patterns of parts for delivery, opening, closing etc. of the staples many different mechanisms may be devised; however, the preferred embodiment disclosed herein is not only remarkably simple to manufacture and use, it is designed to be extremely inexpensive to produce, while still meeting all the objectives described in earlier paragraphs. This preferred embodiment is illustrated in the appended drawings and described in the following paragraphs.

Brief Description of the Drawings

Fig. 1 is a front perspective of the new invention;

Fig. 2 is a top plan view thereof;

Fig. 3 is a side elevation view thereof taken in section along lines 3-3 in Fig. 2;

Fig. 3A is a fragmentary front perspective view of the staple magazine;

Fig. 4 is a front end elevation view thereof taken in section along line 4-4 in Figs. 2 and 3;

Figs. 5A, 6A, 7A, 8A and 9A are front end elevation views similar to Fig. 4 and showing with Fig. 4 the sequential stages of operation of the invention.

Figs. 5B, 6B, 7B 8B, and 9B are fragmentary side elevation views corresponding to Figs. 5A-9A respectively;



Figs. 10A and 10B are generally horizontal sections taken along lines 10A-10A and 10B-10B respectively in Fig. 3;

Fig. 11 is a generally vertical section taken
5 along line 11-11 in Fig. 3;

Fig. 12 is a top plan view of the expansion pin of Fig. 3;

Fig. 13 is a top plan view of another embodiment of the expansion pin;

10 Fig. 14 is a schematic side elevation view showing the handle and expansion pin lever in different positions;

Fig. 15 is a graph showing a cam configuration for the sequential movement of the trigger and corresponding
15 anvil movement;

Fig. 16 is a graph showing a second cam configuration for the sequential movement of the trigger and corresponding movement of the pin sub-assemblies;

20 Fig. 17 is a schematic drawing showing a cam groove and follower corresponding to the cam movement of Fig. 15;

Fig. 18 is a schematic drawing showing a cam groove and follower corresponding to the cam movement of Fig. 16;

25 Fig. 19 is a fragmentary elevation view in section showing the staple retainer clip;

Fig. 20 is a fragmentary perspective view of the discharge end of the stapler;

Fig. 20A is a perspective view of the anvil and staple retainer clip in its high unflexed condition;

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Fig. 20B is a fragmentary view of the top end of the retainer clip in its flexed condition;

Fig. 21 is a fragmentary side elevation of the stapler's discharge end;

5 Fig. 22 is a fragmentary bottom plan view of the stapler's discharge end;

Fig. 23 is a front elevation view of a stapler showing its closed and open conditions;

Fig. 24 is a similar view to Fig. 23; and

10 Figs. 25-28 are fragmentary front elevation views of the anvil and a staple in a succession of positions.

Best Mode for Carrying Out the Invention
and

15 Industrial Applicability

Fig. 1 is a perspective representation and Fig. 2 is a top plan view of the new stapler 10 which includes a main housing or body 11, a handle portion 12 which extends generally upward and at a slightly forward angle from the body portion, a rear part 12A of the handle, a movable trigger part 13 which can be squeezed and compressed into handle 12, and curved finger-receiving portions 14 of the trigger 13 for more securely gripping this device. The basic housing 11 has a front end or face

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plate 15, a rear end 16, a lower portion 17 of the front end, and an upper portion 18 of the front end.

Fig. 3, as a sectional view of Fig. 2, illustrates the basic internal parts of the new staple delivery system for delivering, closing or opening staples as desired by the surgeon. Within the housing is a magazine 19, also shown in Fig. 3A, which can contain and carry approximately 100 staples in its approximately 4 inch length, the magazine comprising a bar 20 extending horizontally on which the staples 21 are aligned side by side. A hood or outer sleeve 22 is used to guide the staples as they move along the bar toward the forward end 23 thereof, and a pusher 24 aligned with the staples on bar 20 is driven by spring 25 which urges staples along the bar for delivery whenever the staple device is actuated.

Additional operational elements contained within the housing 11 and partially within the handle 12 are illustrated in Fig. 3. The trigger 13 pivots on axle 26 with a lower section of the trigger 27 extending below the pivot axle. The trigger is pivotable between a first open position 13A to a fully closed position 13B shown in dotted line which defines therebetween about 30° of movement. This same movement obviously occurs below the pivot axle as above. A spring symbolized by item 27A constantly urges trigger 13 counterclockwise into its open position 13A. In use the surgeon grips the handle 12 with his palm on the back part 12A and his fingers on the front part around finger grip portions 14. Squeezing and releasing the trigger is the only requirement for all operations of this device.

First we will describe what happens to each staple as it is expanded and delivered, directed to engage and close an incision, and then becomes released from the device; in later paragraphs we will describe what internal sub-assemblies of the mechanism are responsible for this

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sequence of operations. The various steps or positions of operation of the device and the corresponding changes of the staples configuration will be designated positions 1, 2, 3, 4, 5, 5A, 5B, 5C, which are illustrated in Figs. 409B. In position 1 a staple 21A is already expanded and positioned for delivery to an open wound. This staple is secured and stabilized by lock and safety pins 29 and 28 respectively above and below the mid-portion of the staple as indicated in Fig. 4; the staple is held open and expanded by expansion pins 30. Also in this first position anvil 31 is in its mid-height position whereby it covers the end of magazine 19 and prevents additional staples 21 from being discharged from the magazine. It can be seen in Figs. 6A and 9A that the anvil has low positions, and in Figs. 7A and 8A the anvil has high positions. A notch 31A in the center portion of the anvil provides clearance space when the anvil descends, for the lock pin 29 as indicated in Fig. 6A.

Now proceeding to Figs. 5A and 5B it can be seen that the expansion pins 30 have moved together to their closed position, the staple 21A has resiliently started to return to its naturally closed position; the anvil 31 has remained in its mid-position and the four pins, namely the lock pin 29, the safety pin 28 and the expansion pins 30 have remained in their extended position which means they are fully to the left in the corresponding Fig. 5B and also in Fig. 3.

Now moving to position 3 illustrated in Fig. 6A, it is seen that the anvil 31 has descended further, has engaged the staple 21A and forced it into a fully closed loop wherein the leg portions 21L of the staple are almost co-linear. In this position 3 the four pins mentioned above continue to remain in their fully extended state.

In moving from positions 3 to 4, the anvil 31 begins to rise and simultaneously the pin assembly begins to move backward, which is to the right in Fig. 7B. More particularly the lock pin 29 begins to rise away from the



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safety pin 28, whereby the staple which was closed in Fig. 6A, is then free to be separated from the stapling device 10. When position 4 is fully reached, the pin assemblies are fully retracted and the anvil 31 has risen to the point where it almost exposes the next staple 21B in the magazine to be discharged; however an edge 32 of the anvil jaw still covers the next staple 21B and prevents it from moving forward until the proper time.

In the next phase of operation as indicated in Figs. 8B and 8A, the anvil 31 is moved to its highest position, thus exposing the magazine to deliver one staple 21B into the space 31B between the end 23 of the magazine and the face plate 15 of the housing. Also during this step the pin assemblies remain retracted. The next position 5B as illustrated in Figs. 9A and 9B shows that the anvil 31 has descended and in so doing has driven the staple 21B downward to its waiting position, and simultaneously the pin assemblies have moved forward with the locking pin 29 and safety pin 28 fully engaging and gripping the staple, and with the expansion pins 30 also moved forward but remaining in their closed positions beneath the center section of the staple. Thus the staple has been delivered in its fully closed, natural and relaxed state. The final position 5C is also the beginning position 1, where the anvil has risen slightly, the pin assemblies remain extended, and most significantly, the expansion pins 30 have diverged thereby opening the staple to its ready condition.

Now we will explain what parts of the trigger and drive mechanisms cause the anvil and the pin assemblies to move in the motion paths described, and cause the staples to be opened and closed.

As indicated in Figs. 3 and 14 the trigger 13 is movable from its first and open/^{position} 13A in a clockwise direction to position 13B. It is intended that when the trigger is in this open position, the anvil will be up and the

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staple will be expanded and ready for delivery to an incision as shown in Fig. 4. The logical sequence in the operation of this device is for the surgeon to slowly squeeze the trigger into the handle when he wishes to deliver a single staple which is to engage and pierce the adjacent layers of tissue and close that portion of the wound. Accordingly, the discharge opening 33 (Fig. 7B and 8B) is placed near and directly above the adjacent and closely approximated edges of the tissue 33A, as shown in Figs. 5A and 6A. Slowly squeezing the trigger will cause the expansion pins 30 to converge and allow the staple to begin to close according to its own resilience which urges it toward its naturally closed position as indicated in Fig. 5A. If the resistance of the tissue is not too great the points of the staple will pierce the tissue and continue to penetrate the tissue as the staple finds its natural totally closed position.

As the surgeon continues to squeeze on the trigger the anvil will begin to descend until it engages the top surface of the staple as indicated in Fig. 6A and urges the final closure of any staple which has not found its own fully closed position. At this time of final closure when the trigger is approaching position 4, the device will emit a signal such as (a) a sound caused by a ratchet 12B engaging spring 27A within the handle, or (b) a higher trigger resistance caused by a spring-biased detent or other device. The indicator will warn the surgeon that the staple is fully closed, that the pin assemblies are still forward and still engaging and locked to the staple, and that further compression of the trigger will release the pins from the staple. The signal furthermore tells the surgeon that if at this time he decides the staple should be removed for any reason, he can simply relax his grip on the trigger and the initial steps described above will operate in reverse, namely that the pin assemblies will remain engaged and locked to the staple, except that the expansion pins will start to diverge and slowly open the staple, carrying it from positions 4 to 3 to 2 to 1,

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until the staple is fully open and removed harmlessly from the wound. Such removal will occur without damaging tissue, without requiring the surgeon to move the stapling device away from the wound, and without requiring any separate and/or additional device for the removal of the staple.

If the surgeon, upon sensing the signal indication mentioned above, decides the staple is properly placed and satisfactory, then he would simply continue to squeeze the trigger to its final compressed condition 13B, whereby the pin assembly will have reached position 4 indicated in Figs. 7A and 7B, the staple will be released, and the anvil will begin to rise. After the trigger is fully squeezed and the staple is released and separated from the staple gun, the surgeon begins to relax his grip on the trigger which is spring-biased to return to first position 13A while the anvil moves through position 5A, 5B and 5C (same as 1) as indicated in Figs. 8A, 9A and 4. When the trigger has fully returned to its initial position 13A, a new staple will be opened and ready as indicated in Fig. 4.

What has happened during the return of the trigger phase, is that the anvil has risen to its highest position shown in Fig. 8A exposing the next lead staple 21B; the anvil then descends as indicated in Fig. 9A driving the staple down to its ready position, and simultaneously the pin assemblies move forward and grip the staple 21B with the expansion pins in their closed position. In the last degrees of motion by the trigger returning to position 13A, the expansion pins open while the safety and lock pins remain tightly gripped at the mid-point of the staple and this ready position is shown in Fig. 4 which is the same as position 1.

The drive assemblies for the anvil and the pins are quite simple and require few parts, as shown in Fig. 3, 10A, 10B, and 11. For driving the anvil there is a lever arm 35 which is pivotable about pivot joint 36, has a remote end 37 pivotally engaging the anvil 31 and

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a near end 38 which includes at its end a follower 39 which moves in cam groove 40 defined in a portion of the trigger 13. It should be obvious that movement of the trigger in one direction or another will cause the follower 5 39 to traverse a path defined by the cam groove 40; this in turn will drive the near end arm 38 of lever 35 about pivot 36 and cause a similar but opposite motion to the remote end 37 and the same motion to anvil 31.

A second cam 41 is also shown at the bottom 10 right portion of Fig. 3, this cam also being situated in or on some portion of the trigger 13. A cam follower 42 rides in the cam groove 41, this follower being carried by lever 43 which moves axially in guide 44. Accordingly, as the trigger pivots, the follower 42 is driven to follow 15 the shape of cam 41 and cause a corresponding motion of projection 45 extending downward from lever 43 into the rear loop 46 of the expansion pin body 30A, see Fig. 12. Link 43 has a front portion 43A that includes pivot 43B and a forward extension forming safety pin 28. Coupled 20 to pivot 43B is lock pin 29, with a spring 47 urging pins 28 and 29 apart, and a guide 29A directing lock pin 29 diagonally downward whenever it is urged forward by lever 43.

The purpose of this last sub-assembly is to link 25 together the lock pin 29, the safety pin 28, and the expansion pins 30 into a unit that moves forward or rearward depending upon the guiding control of cam 41. This explains why, in the sequence of positions 1-5 described earlier, the four pins always move forward and rearward 30 together, and why the lock pin in its upper position can permit passage of the staple from above to below the lock pin as shown in Figs. 7B and 8B, while the lock pin later descends down on top of the staple and locks it with the safety pin as indicated in Fig. 9B. Below lever 35 43 is a generally parallel lever 48 coupled at 49 to the lower part 27 of the trigger and movable axially to drive wedge 50 which appears also in Figs. 10B, 12 and

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14. The wedge is driven forward directly by pivoting of the trigger. In Fig. 14 positions 1-4 correspond to the same positions in Figs. 4-7B, so that with open position of the trigger the wedge is rearward at position 1 in Figs. 12 and 14, thus causing the expansion pin member 30A to open and pins 30 to diverge for opening a staple as shown in Fig. 4. Squeezing the trigger drives wedge 50 forward to positions 2, 3, and 4, according to Fig. 12; in these forward positions the expansion pins 30 remain closed and inactive, as shown in Figs. 6A-9A. In Figs. 3 and 10B the lever 48 that drives wedge 50, includes a slot 48A that allows clearance for projection 45 to extend through while lever 48 reciprocates.

The precise motion pattern of the anvil 31 and the four pins is established by cams 40 and 41, explained more fully as follows. Fig. 15 is a graph illustrating the coordinated action of the trigger and anvil, as indicated in "Positions of Operation" 1, 2, 3, and 4 across the top from left to right, and positions 5A, 5B, and 5C from right to left. The vertical direction indicates the movement of the anvil from its bottom position to its top position with intermediate 1/4, 1/2 and 3/4 positions. At successive points in the figure "8" shape in Fig. 15 representing the cam groove 40 of Fig. 3, there are the positions 1 through 4, and 5A through 5C repeated for clarification. An examination of this graph indicates that as the trigger moves from position 1 to position 2, namely moving clockwise as it is being squeezed, the anvil is intended to follow the pattern of the cam, and accordingly it moves from position 1 to 2 in the graph and does not change its elevation from the half-way position. Next the trigger moves from position 2 to 3 and the cam shape and anvil position moves from 2 to 3 which indicates that the anvil descends from its half-elevated position to its down position 3. Further, compression of the trigger from 3 to 4 causes the anvil to move back up to its half-position as indicated in line 3-4 of the cam groove.

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Next is the return movement of the trigger forward toward its initial position; the first forward movement from position 4 to 5A causes the cam to rise to its highest position. Further relaxation of the trigger to open to position 5B causes the cam to drop all the way to its 5B position or its lowest position. Finally, complete return of the trigger from 5B to 5C or 1, in its fully open position, causes the anvil to rise back to its half-way position. It is assumed that standard techniques for cam design would be used to establish the mathematical details of this cam shape which are symbolically indicated and represented by the figure "8" cam groove 40 in Fig. 3 and similarly represented by the diagram in Fig. 15. In going from position 2 to 3 for example, the anvil drops; to cause this descent the near end 38 of lever 35 must rise. The cam 40 illustrated in Fig. 15 shows a drop from position 2 to 3 which is symbolic for clarity since the actual cam groove should rise.

Fig. 16 is another graph which represents the coordinated movements of the trigger and pins, and correspondingly numbered steps of operation across the top, indicated as steps 1-4 to the right and steps 5A through 5C to the left. Vertical indicia indicate the movement of the four pins from their fully extended position shown at the top of the graph to their fully retracted position shown at the bottom. The explanation for this cam shape is generally similar to that presented above regarding Fig. 15. The movement of the trigger from position 1 to 2 shows that the cam line 1-2 is horizontal, so the pins remain in their fully extended state. Further squeezing of the trigger from positions 2-3 results in continued non-movement of the pins as indicated by the straight line of the cam 2-3. Additional squeezing of the trigger causes the pins to retract along the diagonal line shown in the diagram from positions 3-4. Now upon releasing the trigger to move counterclockwise toward its open position, the pins follow the path indicated from point 4 to 5A, and

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further expansion of the trigger causes the pins to quickly extend, along lines 5A to 5B. The final extension of the trigger in the handle from 5B to 5C or 1 does not change the fully extended position of the pins.

5 It should be noted that the expansion pins, while they move forward and backward with the safety and lock pins, also converge or diverge according to a specific program which is partly indicated in Fig. 16. When the trigger moves initially from position 1 to 2, the pins
10 remain extended but they converge or close. Correspondingly when the trigger makes its final move from position 5B to 5C the pins, which are already extended, diverge or open and expand a staple which is in the ready position. This is further indicated by the difference between diagrams
15 from Figs. 9A and 4.

Opening and closing of the expansion pins was explained earlier with regard to wedge 50 and lever 48 as shown in Figs. 12, 13, and 14. The pin member 30A in Fig. 12 and its alternate embodiment 30B in Fig. 13 are made of
20 highly resilient material. In each case the natural state is closed, which corresponds to the natural state of the staples 21. The dotted configurations in these figures merely show the diverged or open condition when the wedge 50 or 50B respectively is in position 1. The wedge 50
25 does not need to be driven by a cam with a precisely defined pattern of movement, because it is sufficient to merely open or close the expansion pins; at all other times the wedge can be in clear space engaging nothing, while the trigger moves through its various other positions.
30

Figs. 17 and 18 show details of the cam follower and cam groove associated with Figs. 15 and 16 respectively. As was discussed earlier, when the trigger is pulled from positions 1 through 3 and approaches 4, it
35 will emit a signal or provide some indication that the staple has fully closed as shown in Fig. 6A, and that further squeezing of the trigger will release the staple and

-20-

disengage the device from the staple. Once the decision is made to continue squeezing the trigger and release is affectuated, a safety feature is provided so that the trigger must be fully released back to its original position before it can be compressed again, so that jamming with extra staples will be avoided. In order to prevent the follower from taking the wrong path on the cam, when it enters the intersection, a safety feature is provided in Fig. 17 by an elongated follower 50. Once this follower enters the intersection 51 of the grooves of the cam 40, the cam's nose part 52 will cross the intersection and enter the path toward position 5B before its tail section 53 has left the prior path. Accordingly, it is impossible for the follower to head for position 2 or 3 before first going to 5B, 5C(1), 2, etc.

A corresponding set of safety features are provided in the cam groove 41 in Fig. 18 which corresponds to cam groove 41 in Fig. 3. At points 2 and 4 are gates 54 and 55 each being spring-biased to remain closed. Accordingly, a follower 42 corresponding to follower 42 in Fig. 3 can move from position 1 to 3 in Fig. 18, but cannot move from position 1 to 5; also this follower could move from 5 to 4 to 3 past the gate 55. Finally of course the follower could move from position 5 through the gate 54 to position 2 and then back down to position 1. Obviously many alternative forms of gates are possible.

The apparatus shown in Figs. 1-18 is preferably made of high quality materials suitable for use in a hospital operating room. The handle, trigger, housing, and certain internal parts are plastic, while the cams, followers, springs and staples and associated parts are appropriate metal. The staples 21 shown in Figs. 3-9 obviously require very high strength along with very high resilience, properties which may be provided by various spring materials including the material Elgeloy®. These staples have the natural, un-flexed state shown in Figs. 3A and 5B, each staple being about one fourth the size



-21-

illustrated herein, and each having sharp points on the opposing legs 21L indicated in Figs. 5A and 6A. It is contemplated that the entire device could be manufactured so economically in view of its unusually small number of parts, and pre-loaded with a magazine full of staples, that it could be distributed as a disposable unit.

The staples in their closed state may have various configurations wherein a wire is bent to circumscribe a space which may be oval, square, rectangular, circular, semi-circular, and elliptical, for example. These staples in their open and flexed state will be described as generally crescent shaped even though they will have various actual shapes corresponding to their closed shapes. The crescent concept simply means that in open configuration the pointed ends are spaced apart and directed generally transversely of the base of the staple, in contrast to the ends being directed toward each other in closed configuration. One example of the new staple is approximately 0.006 inch thick, 0.040 inch wide, and made of ELGELOY® spring material made by the Elgeloy Corp. of America.

Fig. 20, 20A, 20B, 21, and 22 illustrate the following features: (a) high visibility of the staple 60 before and during discharge from the stapling gun 61; (b) a retainer spring 62 for coupling the staple 60 to the anvil 63 until the safety and lock pins 64, 65 engage and secure the staple between them; and (c) a shield 66 to prevent the exposed staple tips 60A from hooking onto tissue or anything else while the stapler 61 is being moved about and before the exact location for stapling has been selected.



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The purpose of the retainer clip 62 is to engage and secure the staple from falling downward and possibly out of the gun immediately after it leaves the magazine to a position immediately below the anvil, and before the anvil drives the staple downward to the location where it is engaged by the safety's lock pins. Accordingly this retainer clip has spring arm 7 at its top end and a loop or tip 68 at its bottom end. When the anvil rises, generally as disclosed in Figs. 7A and 8A, its arms 67 strike and are deflected by the housing part 69 as shown in Figs. 21 and 20B this causes the intermediate part of the clip and its bottom tip 68 to move slightly downward, thereby providing a small space for the next staple from the magazine 70 to fit directly below the anvil. Fig. 21 shows the anvil before it has risen, with tip 68 closely adjacent to the bottom 71 of the anvil. Obviously the staple will be resiliently held between said tip 68 and the anvil until subsequent release to be described below.

Fig. 21 corresponds generally to Fig. 9B wherein the anvil is down, the safety pin 64 and lock pin 65 are extended and holding staple 60, and the expansion pins 72 are extended forward but not diverged. Fig. 21 further illustrates how lock pin 65 will move forward so that its tip 65A pushes tip 68 of the clip away while simultaneously tip 68 of the clip away while simultaneously tip 65A takes its position above staple 60 and safety pin 64 takes its position below the staple. Fig. 22 illustrates a bottom view of the tip 68 engaging the center of staple 60 while the pins 64 and 72 are yet to be extended forward. Thus, the retainer clip device 60 prevents each staple from falling before the various

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pins engage, capture and expand such staple.

Also to be noted in Figs. 19-22 is slot 73 in the face plate 74. One function of this slot is to provide space or relief for tip 68 of the retainer clip to deflect as shown particularly in dotted line Fig. 21. A second function is to provide a bearing surface 75 at the bottom of slot 74 against which the end 76 of safety pin 64 will rest. This support is helpful at a later phase when the anvil may press downward as shown in Fig. 26 pressing a staple into an "over-closed" condition, i.e. closed more tightly than its original or nominal shape shown in Fig. 25 for example.

Also illustrated in Figs. 19-21 is a shield feature 66 intended to prevent the exposed tips 60A of a "ready" staple held by the safety and lock pins from catching on clothing, equipment or tissue. The shield is a movable plate whose movement is automatically controlled by a cam-follower element 76, 77. The shield remains in closed "up" position shown in solid line until the mechanism arrives at conditions 5A-5B-5C-1 as shown on cam 76 and further indicated in Fig. 16 where the expansion pins diverge, the staple is opened, and the staple tips become exposed. More particularly the shield 66 has a vertical blade 78 in which is defined the cam groove 76. The rear end of the shield connects via pivot pin 79 to the housing to permit the shield to pivot downward to position 66A shown in dotted line, wherein the shield extends downward farther than the tips of the staple. A wire spring 79 resiliently urges the shield to stay in its up-closed condition; the shield is driven to pivot downward when a cam pin 77 moves in cam 76 inclined zone 5A-5B in Fig. 19. Such cam pin



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will be carried by the expansion pin sub-assembly corresponding to post 45 and pins 30A in Fig. 3. Accordingly, during the trigger motion and expansion pin movement 5A-5B-5C/1, i.e. while the staple is in descended position, the shield will be operative, until the arrival at position 1 where the staple is ready for insertion. According to the cam 76 in Fig. 19, the shield will have returned to up-closed condition by the time the pins and staple are at position 1 for insertion, i.e. the shield will be retracted from its extended position where it interferes with the staple tips from contacting tissue. An additional feature of the cam 76 is a gate 80 which directs a pin 77 to move from points 3-2-5A and prevents the pin from traveling from 3-2-1. However the pin can freely move from 1-2-3, by merely deflecting the gate upward to the adjacent dotted line position. Fig. 19A shows a variation of cam 76 to provide the same general action as in Fig. 19, wherein the pin moves from 7A to 5A to 6A then past a gate to 7A.

As discussed earlier, the staples herein are flexible and resilient and will return to their nominal shape when the expansion pins return to the converged position. It is possible that certain staples will be less flexible and/or resilient than others due to the material selected, the thickness of the material, or the general configuration, which alterations may be selected to produce staples which are stronger, stiffer, or have other specific properties. It is further possible with such less flexible staples, that they will be driven slightly beyond their elastic limit when flexed to fully open condition. Upon return to the closed condition,

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such staples will have a new nominal closed condition that is slightly less closed than the original closed condition.

5 There are various ways to overcome the above-described situation where a staple does not fully close. Figs. 23-28 illustrate an anvil 81 with a notch 82 which cooperates with safety pin 83 and lock pin 84 on staple 85. By gripping and supporting the top of the staple at 85A while pressing downward with the anvil 81 as shown in 10 Figs. 25 & 26, the shoulders 86 of the anvil will drive the staple into an over-flexed condition. Upon withdrawal of the anvil the staple 85 will expand to its original nominally closed shape as shown in Fig. 27.

15 An alternative technique is shown in Fig. 28, where the safety pin 87 has a width dimension greater than that of the lock pin 88. Upon forced closing of staple 89 by anvil shoulders 86 the staple shape will be altered at two points 90 spaced apart from the apex at 91. In this manner the overflexing (i.e. beyond 20 elastic limit) during opening of the staple that occurred at 91, is not again overflexed on closing as shown in Fig. 26, but two different adjacent areas 90 are overflexed for closing. By this arrangement there is less weakening of the staple's basic strength in the important 25 apex area.

To allow the anvil to overflex a staple in its closed condition, the expansion pins 92 must converge to a position shown in Fig. 26, which is closer together than the nominal position shown in Figs. 23-25. When 30 the anvil descends with force, indicated in Fig. 26, the safety pin 83 is supported by the front plate bearing surface 75 shown in Figs. 19-21.



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A typical staple consists of a wire strip or other shape of metal or other suitable material bent to circumscribe a space. The staple has a central body part with opposite ends or legs terminating in points. In closed condition the ends are directed generally toward each other, generally defining a closure line, but not necessarily being co-linear. In open configuration the legs of the staple are directed generally transversely of said closure line.

Obviously many variations of the staple and apparatus of this invention are possible within the scope and spirit of the disclosure and the claims appended hereto.



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APPENDIX I

3,078,465	3,499,591	3,935,981	3,638,847
3,080,564	3,581,551	3,949,923	3,638,652
3,144,654	3,589,589	3,949,924	3,618,842
3,176,896	3,592,377	3,973,709	3,601,302
3,244,342	3,593,903	4,014,492	3,584,628
3,252,643	3,683,927	4,043,504	3,545,444
3,269,630	3,692,224	4,047,654	3,955,581
3,269,631	3,717,294	4,101,063	3,082,426
3,275,211	3,732,719	4,109,844	3,551,987
3,278,107	3,740,994	4,122,989	3,795,034
3,314,581	3,790,057	4,127,227	3,646,801
3,315,863	3,819,100	Re. 28,932	3,606,888
3,351,191	3,822,818	4,164,225	3,604,561
3,482,428	3,837,555	3,675,688	3,973,709
3,489,330	3,858,783	3,662,939	3,889,683
3,490,675	3,873,013	3,650,453	4,162,678
3,494,533	3,875,648	3,643,851	4,111,206
			4,076,162

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Claims

1. A stapling device for delivering staples to an incision or wound to be closed and causing each of said delivered staples (i) to engage adjacent edges of tissue of the incision, (ii) to close and secure said edges together, and (iii) to separate from said device, where each of said staples is a resilient wire having pointed ends and bent to circumscribe a space, each staple having a relaxed closed configuration with said ends of the wire directed toward each other, each staple when flexed from said relaxed closed configuration to its open configuration defining a generally crescent shape, said flexed staple tending to return to its closed configuration, the device comprising:

- (a) a housing,
- (b) a handle,
- (c) a trigger movable between an open first position and a closed second position,
- (d) a magazine in said housing for containing a plurality of said staples,
- (e) first means for moving one staple at a time from said magazine to a discharge area of said device,
- (f) second means for releasably engaging said staple in the discharge area,
- (g) third means for controllably allowing a flexed staple in its open configuration to resiliently return to its closed configuration for joining adjacent edges of tissue to the extent that said staple closes itself, and
- (h) control means operable by moving said trigger between said first and second positions, thereby causing said first, second, and third means to operate as described and in the sequence listed in paragraphs e, f and g above, said control means subsequently causing said second means to disengage and discharge said closed staple from the device.

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2. A surgical stapling device comprising a housing for containing at least one staple in a closed state, and control means for releasably engaging said staple, opening said staple such that the legs are outside of said housing, returning said staple to about its closed state and releasing said staple from said device, the improvement to said control means comprising means for forcibly returning said staple to its closed state.

3. A device of claim 2, the improvement to said control means comprising means for forcibly opening and returning said staple by bending said staple beyond its elastic limit.

4. A device of claim 2 or 3, the improvement to said control means comprising means for opening said staple in at least one first location, and means for returning said staple in one or more locations, each being different from said first location.

5. A device of claim 4, wherein the opening means flexes said staple at two places.

6. A device of claim 4 or 5, wherein the returning means flexes said staple at two places.

7. A device of claim 4, wherein said one or more locations comprise points on said staple.

8. A surgical staple comprising in a closed state a top part, two approximately equal side parts, and two leg parts terminating in ends in opposing relationship, the improvement comprising two angular bends equally distant from the top center of the staple and located either in said top part or in said side parts respectively.

9. A method of using a surgical stapling device comprising holding together two adjacent edges of an opening, placing said device containing at least one staple in a closed state adjacent said edges, opening said staple, causing the two ends of said staple to contact said adjacent edges, respectively, closing said staple to pierce said edges, and releasing said staple from said device whereby the closed staple holds together said adjacent edges, the improvement comprising forcibly closing said staple.



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10. A method of claim 9, the improvement comprising forcibly opening and returning said staple by bending said staple beyond its elastic limit.

11. A method of claim 9 or 10, the improvement comprising opening said staple in at least one first location, and closing said staple in one or more locations, each being different from said first location.

12. A method of claim 11, wherein the opening steps flexes said staple at two places.

13. A method of claim 11 or 12, wherein the closing step flexes said staple at two places.

14. A method of claim 11, wherein said one or more locations in said closing step are points.

15. A method of claim 9 or 14, wherein said closed staple has a top part, two approximately equal side parts and two leg parts terminating in ends in opposing relationship, the improvement comprising two angular bends equally distant from the top center of the staple and located either in said top part or in said side parts respectively.



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FIG. 1

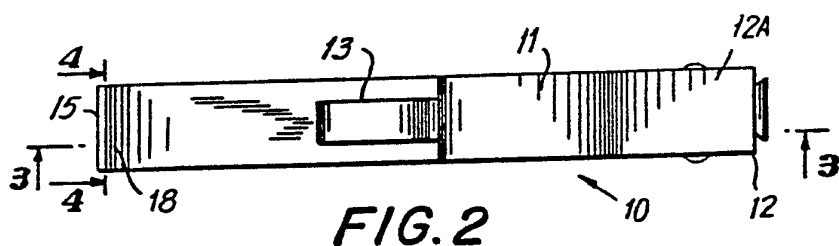
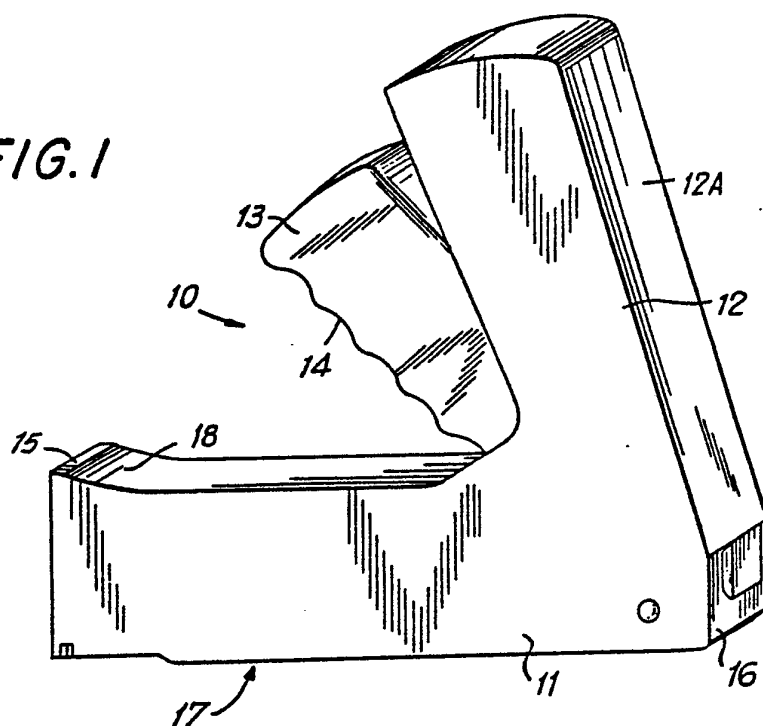
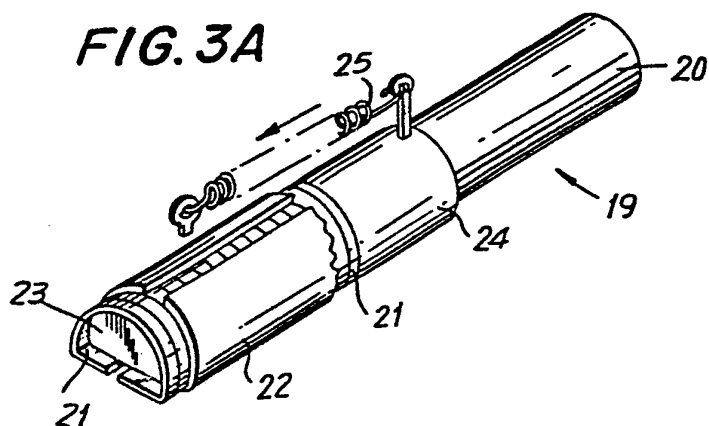
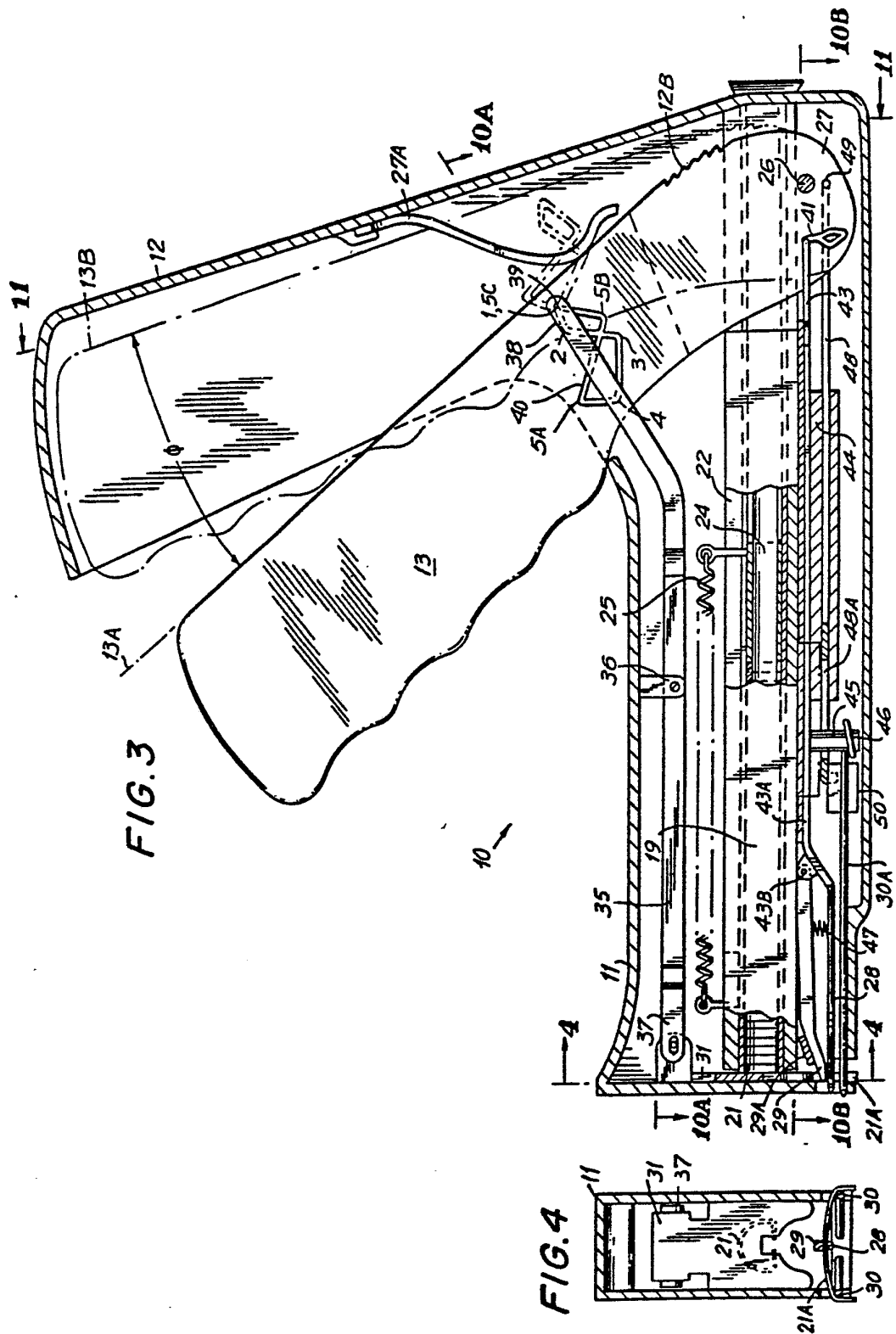


FIG. 2

FIG. 3A



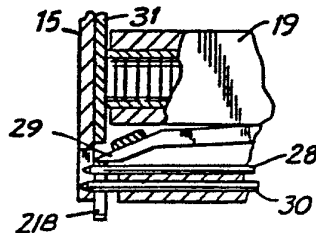
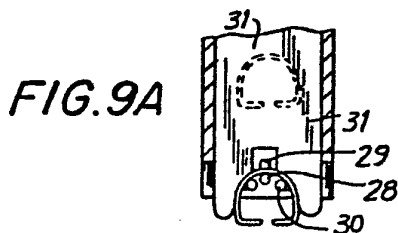
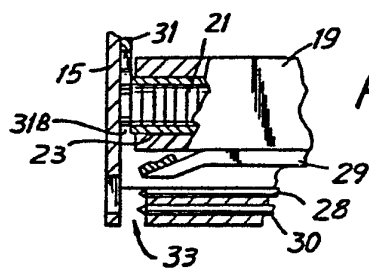
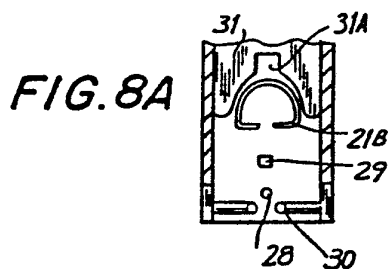
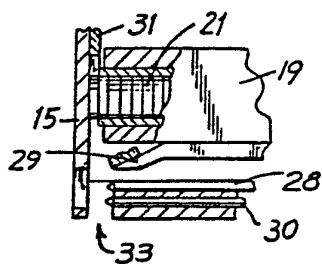
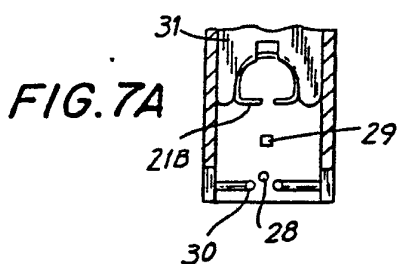
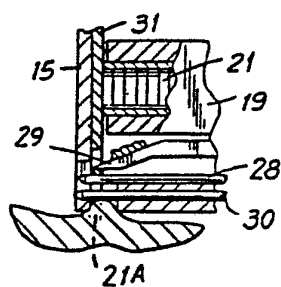
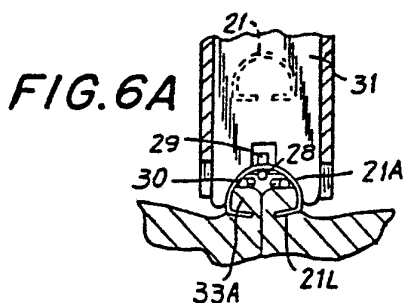
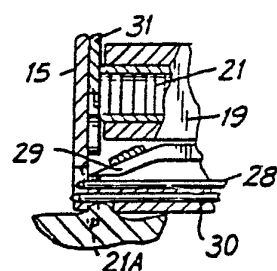
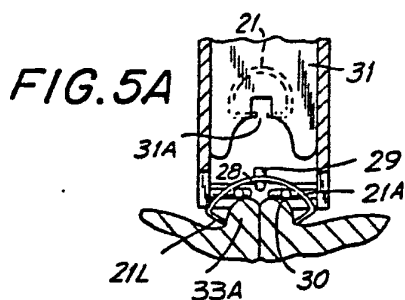
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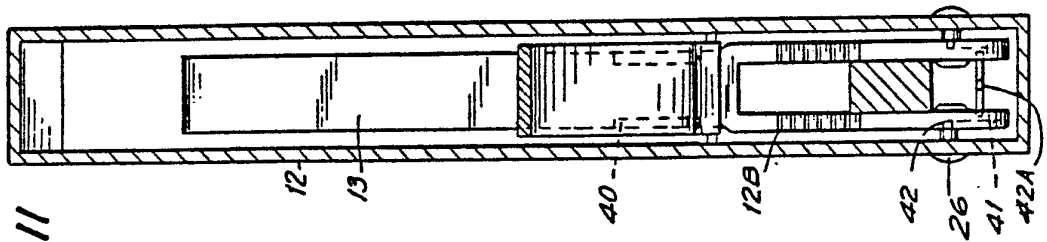


FIG. 11

FIG. 10A

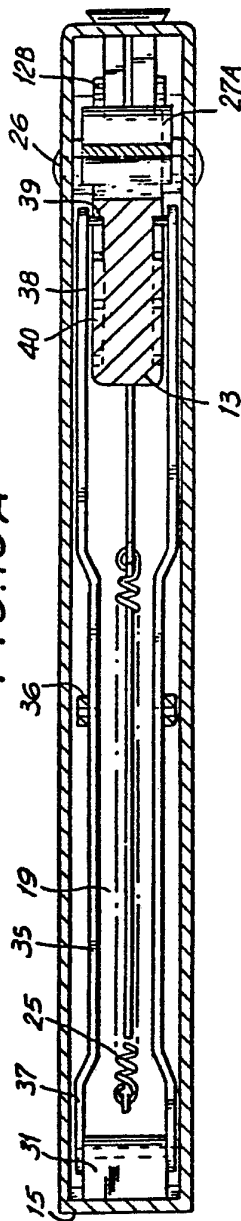
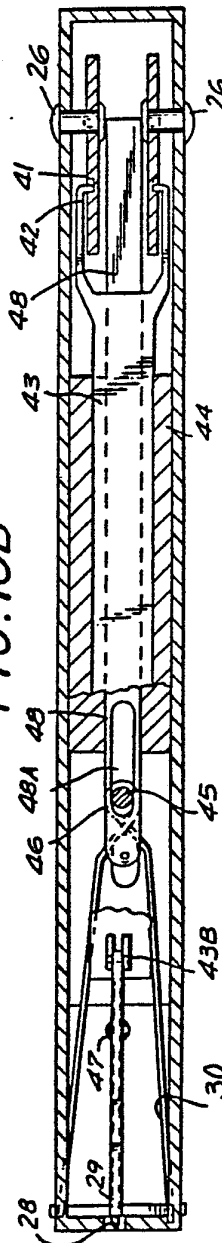


FIG. 10B



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FIG. 12

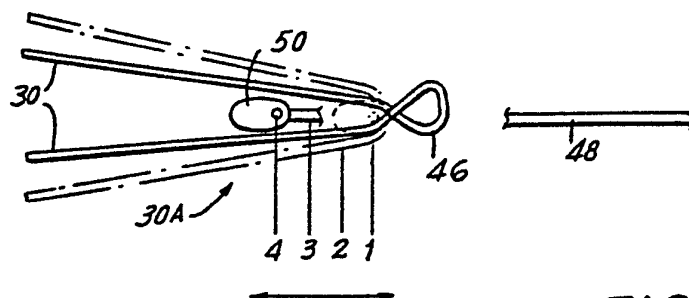


FIG. 13

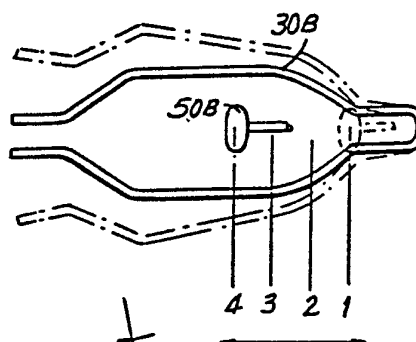
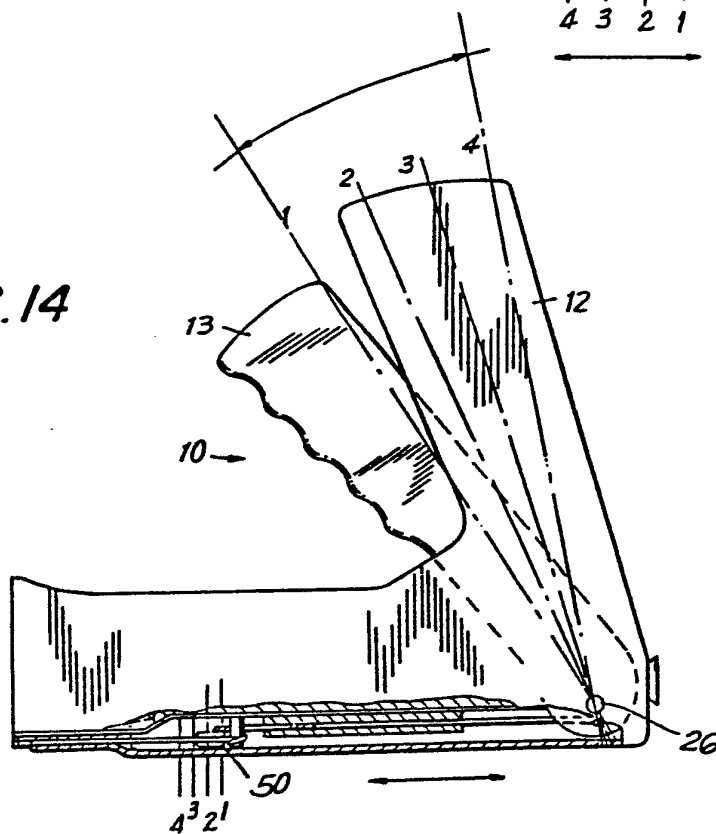
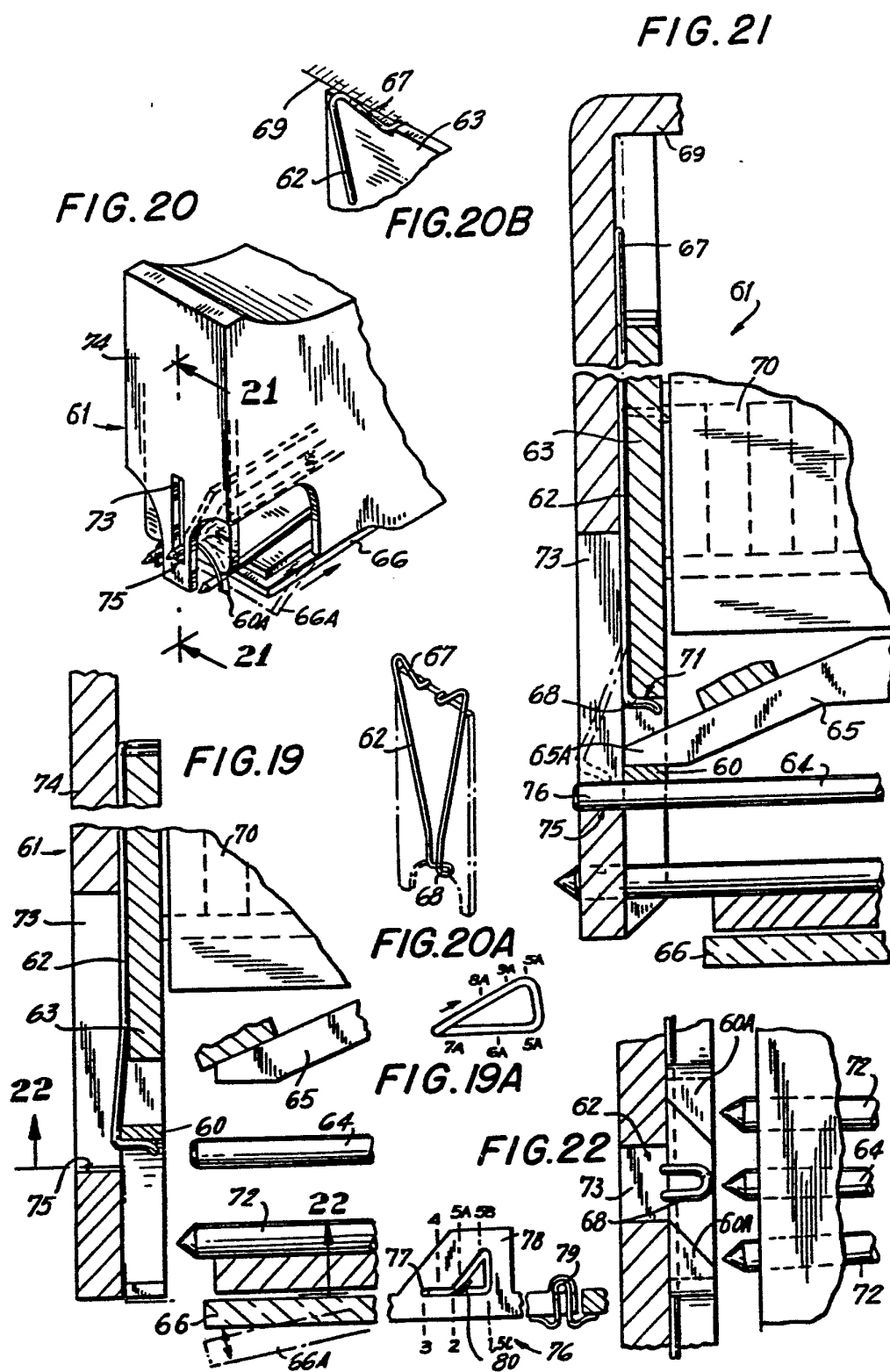


FIG. 14



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8/8

FIG. 23

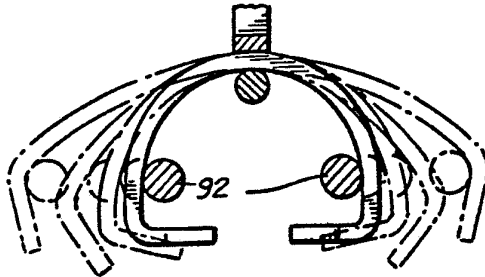


FIG. 24

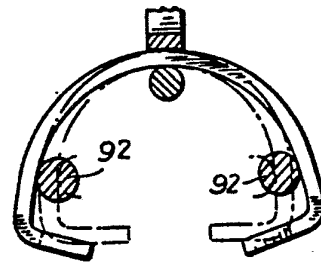


FIG. 25

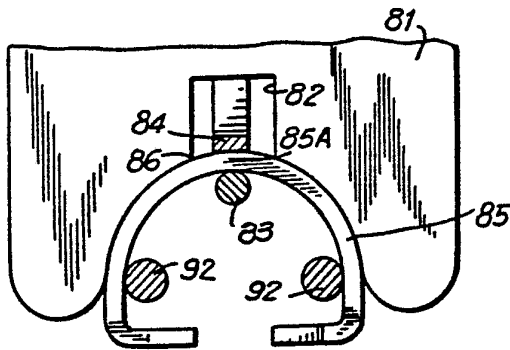


FIG. 26

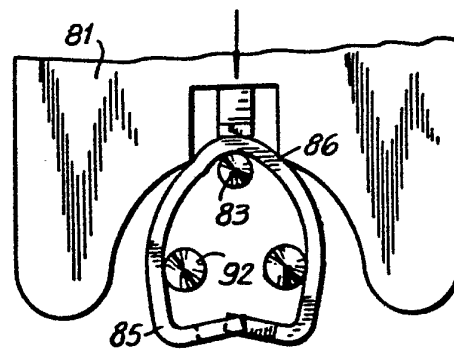


FIG. 27

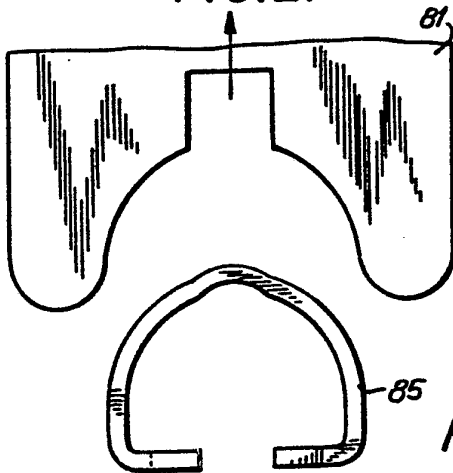
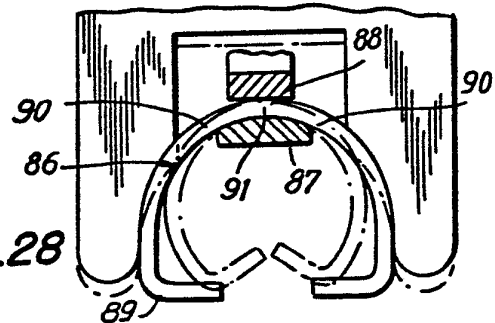


FIG. 28



INTERNATIONAL SEARCH REPORT

International Application No PCT/US82/01137

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³ According to International Patent Classification (IPC) or to both National Classification and IPC INT. CL. ³ A 61 B 17/04 U.S. CL. 227/19																							
II. FIELDS SEARCHED Minimum Documentation Searched ⁴ <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <th style="width: 20%;">Classification System</th> <th style="width: 80%;">Classification Symbols</th> </tr> <tr> <td style="vertical-align: top; padding: 5px;">U.S.</td> <td style="padding: 5px;"> 24/67.3/67.5/67.9/259R/259FS/261R 72/409/410 128/325/330/334R/335/337 227/19/82/83/120/156/Dig 1 411/457/458/459/460/461 </td> </tr> </table> Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵			Classification System	Classification Symbols	U.S.	24/67.3/67.5/67.9/259R/259FS/261R 72/409/410 128/325/330/334R/335/337 227/19/82/83/120/156/Dig 1 411/457/458/459/460/461																	
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴ <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <th style="width: 10%;">Category [*]</th> <th style="width: 70%;">Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷</th> <th style="width: 20%;">Relevant to Claim No. ¹⁸</th> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">U S, A, 3,231,976 Published 01 February 1966 Wallshein</td> <td style="text-align: center; vertical-align: top; padding: 5px;">8</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">F R, A, 989,416 Published 10 September 1951 Moreau</td> <td style="text-align: center; vertical-align: top; padding: 5px;">8</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">U S, A, 3,446,212 Published 27 May 1969 Le Roy</td> <td style="text-align: center; vertical-align: top; padding: 5px;">8</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">U S, A, 3,958,576 Published 25 May 1976 Komiya</td> <td style="text-align: center; vertical-align: top; padding: 5px;">8</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">U S, A, 3,873,016 Published 25 March 1975 Fishbein</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1 - 7</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">U S, A, 3,945,238 Published 23 March 1976 Eckert</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1 - 7</td> </tr> </table>			Category [*]	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸	X	U S, A, 3,231,976 Published 01 February 1966 Wallshein	8	X	F R, A, 989,416 Published 10 September 1951 Moreau	8	X	U S, A, 3,446,212 Published 27 May 1969 Le Roy	8	X	U S, A, 3,958,576 Published 25 May 1976 Komiya	8	A	U S, A, 3,873,016 Published 25 March 1975 Fishbein	1 - 7	A	U S, A, 3,945,238 Published 23 March 1976 Eckert	1 - 7
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A	U S, A, 3,873,016 Published 25 March 1975 Fishbein	1 - 7																					
A	U S, A, 3,945,238 Published 23 March 1976 Eckert	1 - 7																					
[*] Special categories of cited documents: ¹⁵ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "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) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "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. "&" document member of the same patent family																							
IV. CERTIFICATION <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="width: 50%; padding: 5px;"> Date of the Actual Completion of the International Search ² 23 November 1982 </td> <td style="width: 50%; padding: 5px;"> Date of Mailing of this International Search Report ² 01 DEC 1982 </td> </tr> <tr> <td style="padding: 5px;"> International Searching Authority ¹ RO/US </td> <td style="padding: 5px;"> Signature of Authorized Officer ²⁰ PAUL A. BELL EXAMINER </td> </tr> </table>			Date of the Actual Completion of the International Search ² 23 November 1982	Date of Mailing of this International Search Report ² 01 DEC 1982	International Searching Authority ¹ RO/US	Signature of Authorized Officer ²⁰ PAUL A. BELL EXAMINER																	
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FURTHER INFORMATION CONTINUED FROM THE FIRST SHEET
(Not for publication)

I. (continued) Claims 9 - 15 are drawn to a surgical method and as such are unsearchable under PCT Rule 39 (PCT Rule 39.1(iv))

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹⁰

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☒ Claim numbers 9-15 because they relate to subject matter ¹² not required to be searched by this Authority, namely:

PCT Rule 39 (Rule 39.1(iv))

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹³, specifically:

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ¹¹

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.