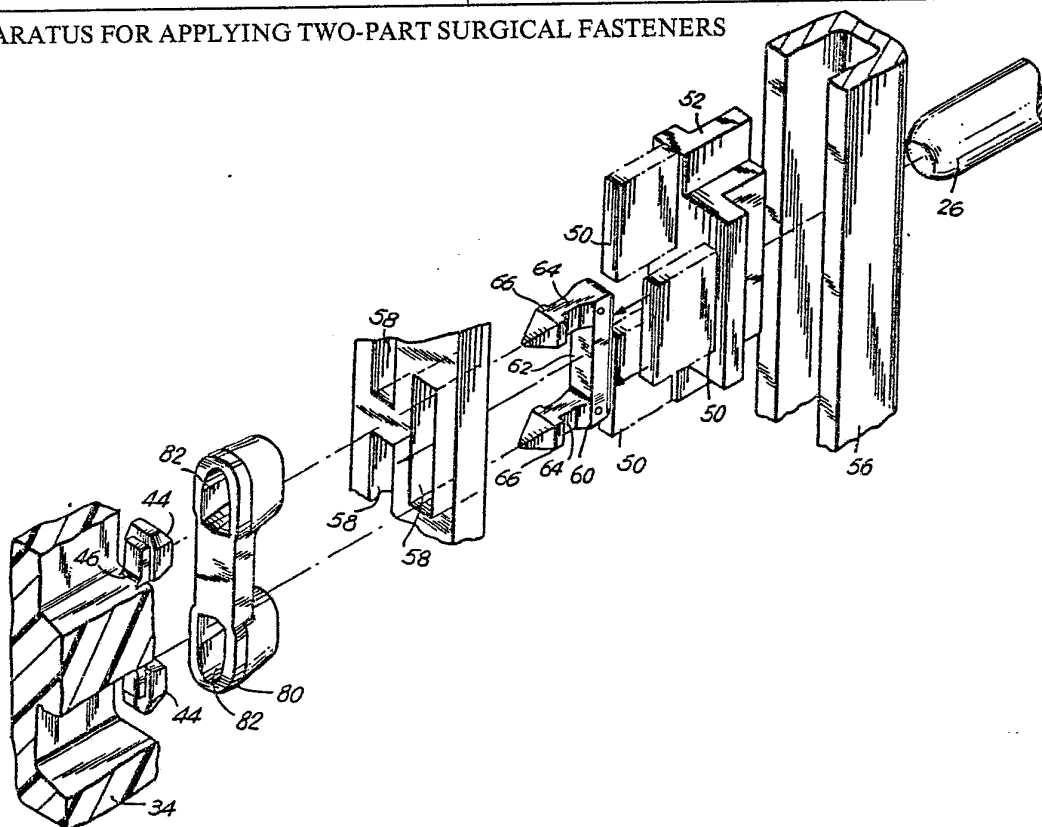




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ³ : A61B 17/04; A41H 37/04 B31B 1/00	A1	(11) International Publication Number: WO 84/ 03825 (43) International Publication Date: 11 October 1984 (11.10.84)
(21) International Application Number: PCT/US84/00337 (22) International Filing Date: 5 March 1984 (05.03.84) (31) Priority Application Number: 480,566 (32) Priority Date: 30 March 1983 (30.03.83) (33) Priority Country: US (71) Applicant: UNITED STATES SURGICAL CORPORATION [US/US]; 150 Glover Avenue, Norwalk, CT 06850 (US). (72) Inventor: GREEN, David, T. ; 251 Wolfpit Avenue, Norwalk, CT 06851 (US). (74) Agent: BROOKS, Robert, B.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06850 (US). (81) Designated States: BR, DE, GB, JP.		Published With international search report.

(54) Title: APPARATUS FOR APPLYING TWO-PART SURGICAL FASTENERS



(57) Abstract

In apparatus (10) for applying a two-part surgical fastener (60, 80) including a fastener part (60) having at least one prong (64) and a retainer part (80) having an aperture (82) for receiving and retaining the distal end of the prong (64), the retainer part (80) is initially held securely to the apparatus (10) by contact with a lug (44) extending into the aperture (82). When the two parts (60, 80) of the fastener are forced together, the distal end of the prong (64) pushes the lug out of the aperture (82), thereby releasing the retainer part (80) from the apparatus (10).

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APPARATUS FOR APPLYING
TWO-PART SURGICAL FASTENERS

Background of the Invention

This invention relates to surgical fastening apparatus, and more particularly to apparatus for applying surgical fasteners comprising two interlocking parts.

Surgical fasteners have been developed which comprise a fastener part having one or more prongs and a retainer part having a corresponding number of apertures for respectively receiving and engaging the ends of the prongs of the fastener part (see, for example, Noiles U.S. patent 4,060,089). Both parts of the fastener are typically made of a plastic or plastic-like material which may be biologically absorbable. In use, the fastener and retainer parts are respectively positioned on opposite sides of the tissue to be fastened. The fastener part is then driven toward the tissue so that the prongs pass through the tissue and interlock with the retainer part. The retainer part prevents the prongs from being withdrawn from the tissue.

In applying surgical fasteners of this type it is important for the retainer part to be held securely prior to engaging the fastener part. This is required to prevent the retainer part from becoming loose and possibly lost in the operating site and to assure that each fastener part mates with a retainer part to provide the intended surgical fastening. Once the fastener and retainer parts have interlocked, however, it is equally important for



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the structure which supports the retainer part to readily release the retainer part so that the fastened tissue can be easily removed from the fastener applying apparatus.

In view of the foregoing, it is an object of this invention to improve and simplify apparatus for applying two-part surgical fasteners of the type described above.

It is a more particular object of this invention to provide apparatus for applying two-part surgical fasteners of the type described above in which the retainer part is held firmly in the apparatus until the two parts of the fastener are joined, after which the retainer parts are released from the apparatus.

Summary of the Invention

These and other objects of the invention are accomplished in accordance with the principles of the invention by providing a support structure for the retainer part of a two-part surgical fastener, the support structure including means for releasably engaging the retainer part until the prong or prongs of the fastener part have interlocked with the retainer part, at which time the prong or prongs contact the means for releasably engaging the retainer part and cause that means to release the retainer part.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawing and the following detailed description of the invention.

Brief Description of the Drawing

Figure 1a is a perspective view of an illustrative embodiment of surgical fastener applying apparatus constructed in accordance with this invention. Figure 1a shows the permanent actuator and disposable cartridge of this apparatus separate from one another.

Figure 1b is similar to Figure 1a but shows the cartridge mounted in the actuator and the apparatus in use.



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Figure 2 is an enlarged view of the cartridge portion of the apparatus shown in Figure 1b with portions cut away to reveal the interior components.

Figure 3 is a sectional view taken along the line 3-3 in Figure 2.

Figure 4 is a view similar to Figure 2 but showing the apparatus after the two parts of the fasteners have been joined.

Figure 5 is a sectional view taken along the line 5-5 in Figure 4.

Figure 6 is an enlarged elevational view of a portion of the apparatus of Figures 1-5.

Figure 7 is a sectional view taken along the line 7-7 in Figure 6.

Figure 8 is a view similar to Figure 7 but showing the apparatus after the two parts of the fasteners have been joined.

Figure 9 is a sectional view taken along the line 9-9 in Figure 8.

Figure 10 is a perspective, exploded view of a portion of the apparatus of Figures 1-9.

Detailed Description of the Invention

The surgical fastener applying apparatus shown in the accompanying drawing is only one possible environment of the present invention. As shown in Figure 1a, this apparatus includes reusable actuator 10 and a replaceable and disposable fastener-carrying cartridge 30. Although not necessary to an understanding of the present invention, full details regarding the construction and operation of actuator 10 are provided in commonly assigned, co-pending Green United States patent application Serial No. 267,080, filed May 26, 1981. Similarly, additional details regarding the construction and operation of a fastener-carrying cartridge similar to cartridge 30 are provided in Green United States patent 4,354,628.

Actuator 10 includes proximal handle 12, distal cartridge holder 14, and intermediate shaft assembly 16.



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Cartridge 30 includes proximal fastener-holding assembly 32 and distal retainer-holding assembly 34. Assemblies 32 and 34 are pivotally connected to one another by pivotal connection 36. Cartridge 30 slides into actuator 10 as shown in Figure 1b with retainer-holding assembly 34 firmly but releasably engaged in the distal leg of cartridge holder 14 and with fastener-holding assembly 32 freely movable on pivotal connection 36 between the parallel spaced sides of the proximal leg of cartridge holder 14.

Tissue 18 to be fastened is positioned between fastener-holding assembly 32 and retainer-holding assembly 34. Clamp actuator 20 on actuator 10 is pivoted parallel to shaft assembly 16. This causes clamping assembly 22 to translate toward fastener-holding assembly 32, thereby pivoting the fastener-holding assembly into parallel relationship with retainer-holding assembly 34. As clamping assembly 22 translates toward fastener-holding assembly 32, it first contacts leaf spring 38 which is fixedly mounted near the bottom of fastener-holding assembly 32 and which projects proximally outward from the proximal side of assembly 32. The upper end of leaf spring 38 engages alignment pin 40. When clamping assembly 22 contacts leaf spring 38 as described above, it both pivots assembly 32 toward assembly 34 and substantially flattens leaf spring 38 against the proximal side of assembly 32. This drives alignment pin 40 in the distal direction so that the distal end of pin 40 projects out of assembly 32 and into aperture 42 near the top of assembly 34. This helps to align assemblies 32 and 34 during application of the fasteners to the tissue.

When the tissue 18 has been clamped in the apparatus as described above, fastener actuator 24 is squeezed toward handle 12. This causes elements in assemblies 20 and 22 (the distal-most of these elements being rod 26, Figures 2 and 3) to translate in the distal direction. Rod 26 enters the proximal side of fastener-holding assembly 32 as shown in Figures 4 and 5 and drives



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fastener pushers 50 in the distal direction. Each of fastener pushers 50 pushes a U-shaped surgical fastener part 60 in the distal direction. As best seen in Figure 8, each fastener part 60 includes a base 62 and two parallel prongs 64, each prong being perpendicular to the base at a respective one of the opposite ends of the base.

When fastener parts 60 are thus driven in the distal direction, prongs 64 pass through the clamped tissue. After passing through the tissue, the distal end of each prong enters an aligned aperture 82 in a retainer part 80 associated with the fastener part. Retainer parts 80 are supported by and releasably retained in retainer-holding assembly 34 as will be described in greater detail below. As best seen in Figure 9, the distal end of each prong 64 has an enlarged head 66 which interlocks with interior surfaces 84 of the retainer member aperture to prevent prongs 64 from being withdrawn from the retainer member apertures after the two parts of the fastener have been forced together. Each retainer part 80 thus prevents the associated fastener part 60 from pulling out of the tissue. Fastener part 60 and retainer part 80 cooperate to apply pressure to the fastened tissue as is necessary for such purposes as tissue approximation and hemostasis. In the particular embodiment shown in the drawing, the apparatus applies two parallel rows of fasteners, the rows being longitudinally offset from one another.

When the fasteners have been applied to the tissue as described above, fastener actuator 24 is released. This retracts pin 26 from fastener-holding assembly 32. Clamp actuator 20 is then pivoted out to its original position by depressing release 28. The outward pivoting of clamp actuator 20 retracts clamping assembly 22 and allows cartridge 30 to pivot open. The fastened tissue is removed from cartridge 30. The apparatus is readied for reuse by removing and discarding expended cartridge 30 and reloading actuator 10 with a new cartridge. Between surgical procedures actuator 10 must be cleaned and sterilized, but



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no such cleaning and sterilization is required for disposable cartridges 30.

Before surgical fasteners 60, 80 are applied to the tissue as described above, retainer parts 80 are held on retainer-holding assembly 34 by deformable holder members or lugs 44 (Figures 6 and 7) which project into the distal side of retainer part apertures 82. In their initial or first positions, lugs 44 fit tightly into apertures 82 so that retainer parts 80 are held securely on retainer-holding assembly 34 by the frictional fit between lugs 44 and the retainer parts. Like retainer parts 80, lugs 44 and the adjacent nondeformable supporting structure are preferably made of a plastic or plastic-like material. Most preferably, lugs 44 and the adjacent nondeformable supporting structure are integral.

Each lug 44 projects far enough into the associated retainer part aperture 82 so that, when the associated fastener prong 64 enters aperture 82, the distal end of the prong contacts the lug and deflects or deforms it to a second position as shown in Figures 8 and 9. In the embodiment shown in Figures 6-10, each lug 44 is basically a block which is connected along only one edge 46 to the nondeformable body of retainer-holding assembly 34. The other edges of each lug 44 are unsupported. Thus when the distal end of the associated prong 64 contacts each lug 44, the edge 46 of the lug by which it is connected to the body of retainer-holding assembly 34 acts as a deformable flexural hinge having a pivotal axis substantially perpendicular to the longitudinal axis of prong 64. Each lug 44 pivots about this hinge 46 when contacted by the distal end of the associated prong 64. Prongs 64 force lugs 44 substantially out of apertures 82, thereby breaking the frictional contact between lugs 44 and retainer parts 80. This releases retainer parts 80 from retainer-holding assembly 34 so that the fastened tissue is easily removed from the apparatus. Lugs 44 remain connected to the body of retainer-holding assembly 34 by hinges 46.



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As mentioned above, two-part surgical fasteners of the type described herein are usually made of a plastic or plastic-like material. Such material may be preferred because it does not scatter X-rays the way metal surgical staples do. In some applications, however, it may not be possible for plastic prongs 64 to penetrate the tissue to be fastened unaided. If that is the case, metal piercers or guides may be provided in fastener-holder assembly 32 as shown, for example, in commonly-assigned, co-pending Green United States patent application Serial No. 310,065, filed October 9, 1981. In general, one such metal piercer is provided adjacent each prong. The sharp distal end of each piercer passes through the tissue just ahead of the distal end of the associated prong. If such piercers are used with the apparatus of the present invention, it will be apparent that the distal ends of the piercers rather than the distal ends of the fastener prongs may contact lugs 44 and deflect those lugs out of retainer part apertures 82. It will therefore be understood that the term "prong" as used herein and in the appended claims includes both the actual fastener part prong 64 and/or any associated metal piercer. This definition of the term "prong" applies even though the metal piercers may be withdrawn from proximity to the fasteners after the fastening has been completed.

When, as in the embodiment depicted in the accompanying drawing, multiple fasteners are driven simultaneously, especially without metal piercers or guides, it has been found desirable to connect pushers 50 rigidly together in a plurality of small groups which are mutually exclusive and collectively exhaustive of the totality of pushers. In the particularly preferred embodiment shown in Figure 10, three pushers 50 are formed integrally on each pusher mounting 52. All of pusher mountings 52 are driven simultaneously by channel member 56 which is loosely associated with pusher mountings 52 so that channel member 56 does not constitute a rigid connection between pusher mountings 52. If each pusher 50 were separate, the pushers



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might have a tendency to become misaligned and therefore bind in their respective pusher channels 58. On the other hand, if all the pushers 50 were integral, any cocking of the pusher structure might again cause the pusher structure to bind relative to pusher channels 58. It has been found that joining pushers 50 together in small groups is preferable to either of the two extremes mentioned above. In particular, the integral structure of three pushers shown in Figure 10 has been found especially desirable. This structure consists of two adjacent pushers 50 in one row of fasteners and one intermediate pusher 50 in the adjacent row of fasteners. The two pusher structures 52a and 52b adjacent to pusher structure 52 (portions of which are visible in Figure 2) are identical but reversed (i.e., with two pushers 50 in the row of fasteners having only one pusher 50 in fully depicted pusher structure 52). Providing three pushers integrally in this manner helps to stabilize the individual pushers without introducing into the apparatus a long, rigid structure which might tend to bind even if slightly cocked.

It will be understood that the foregoing is merely illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, metal piercers can be provided to assist the fastener prongs in passing through the tissue if desired. As another example of modifications within the scope of the invention, actuator 10 and cartridge 30 could be made as one integral disposable unit.



CLAIMS

1. In apparatus for applying a surgical fastener made up of two interlocking parts, the fastener including a fastener part having a prong which passes through the tissue to be fastened and a retainer part for interlocking with the end of the prong after it has passed through the tissue to prevent the prong from being subsequently withdrawn from the tissue, the improvement comprising a structure for releasably supporting the retainer part prior to interlocking of the prong and the retainer part, the supporting structure including a deformable part for releasably engaging the retainer part, the deformable part being contacted and deformed by the prong as the prong interlocks with the retainer part, the deformable part releasing the retainer part when thus deformed.

2. The apparatus defined in claim 1 wherein the deformable part engages the retainer part by frictional contact between the deformable part and the retainer part.

3. The apparatus defined in claim 1 wherein the retainer part includes an aperture extending through the retainer part substantially parallel to the longitudinal axis of the prong, wherein, prior to deformation, the deformable part extends into the aperture from the side of the retainer part which faces away from the prong, and wherein the prong enters the aperture in order to interlock with the retainer member and to substantially displace the deformable part from the aperture.

4. The apparatus defined in claim 3 wherein the supporting structure further includes a nondeformable part, and wherein the deformable part comprises:

a lug which, prior to deformation, extends into the aperture from the side of the retainer part which faces away from the prong; and

a hinge connection between one side of the lug and the nondeformable part.

5. The apparatus defined in claim 4 wherein the pivotal axis of the hinge connection is substantially perpendicular to the longitudinal axis of the prong.



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6. The apparatus defined in claim 4 wherein the lug is unsupported relative to the nondeformable part except for the hinge connection.

7. The apparatus defined in claim 4 wherein the nondeformable part, the lug, and the hinge connection are integral, and wherein the hinge connection is a flexural hinge.

8. Apparatus for simultaneously driving a plurality of surgical fasteners from a fastener-holding assembly, each fastener including a longitudinal base substantially parallel to the surface of the tissue to be fastened and two prongs substantially perpendicular to the surface of the tissue to be fastened, each prong being attached to the base adjacent a respective one of the ends of the base, the apparatus comprising:

a plurality of fastener pushers disposed in the fastener-holding assembly, each pusher being substantially perpendicular to the surface of the tissue to be fastened and each pusher acting on the base of a respective one of the fasteners to drive the associated fastener from the fastener-holding assembly;

means for rigidly connecting adjacent fasteners together in a plurality of groups which are mutually exclusive and collectively exhaustive of the totality of pushers; and

means for simultaneously pushing all of the groups of pushers toward the fasteners to drive the fasteners from the fastener-holding assembly without forming a rigid connection between any of the groups.

9. The apparatus defined in claim 8 wherein each group of rigidly connected pushers consists of three pushers.

10. The apparatus defined in claim 9 wherein the fasteners are disposed in two parallel rows which are longitudinally offset from one another, and wherein each group of pushers consists of two pushers respectively



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associated with two adjacent fasteners in one of the rows
and one pusher associated with the intermediate fastener
in the other row.



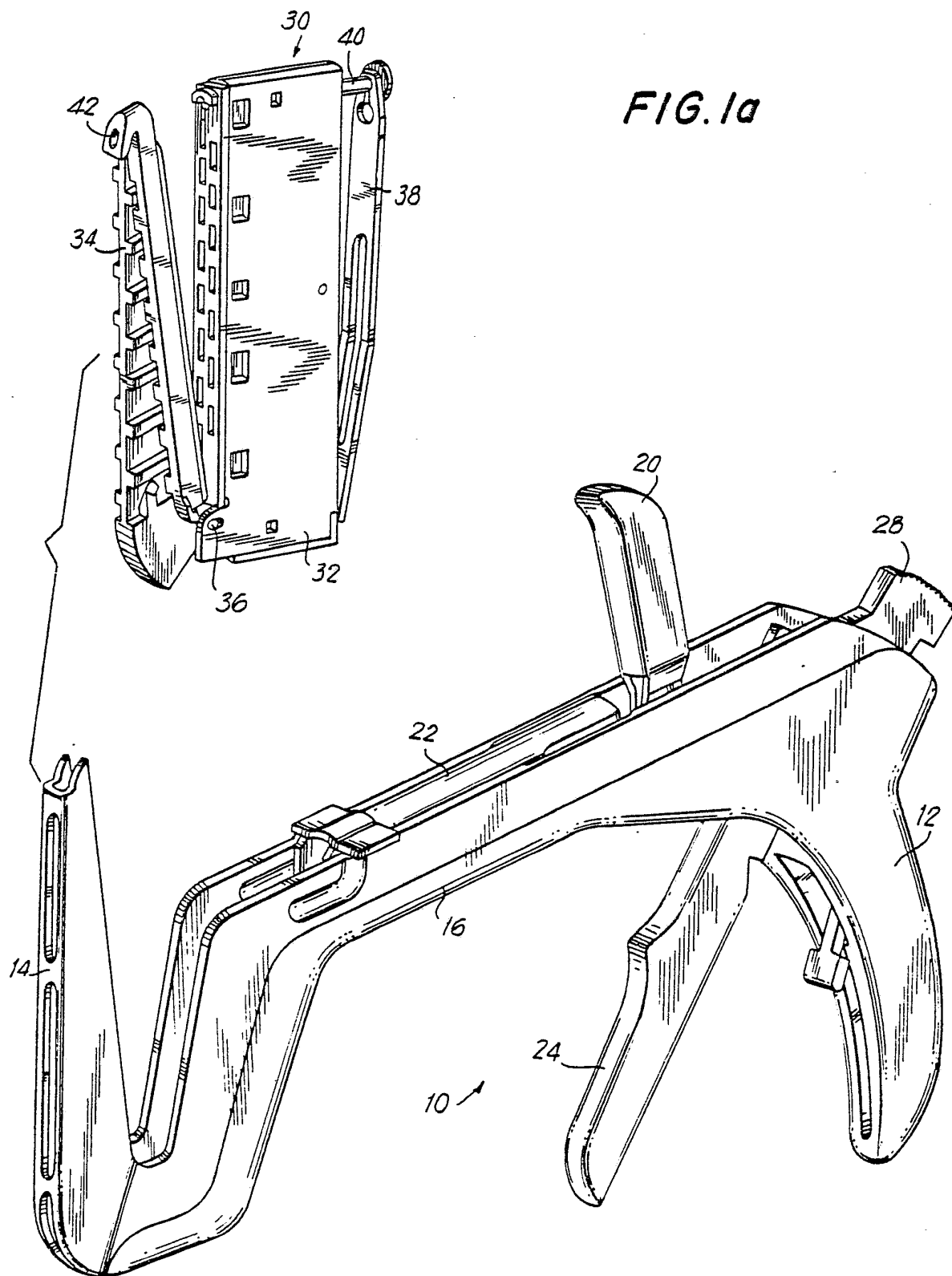
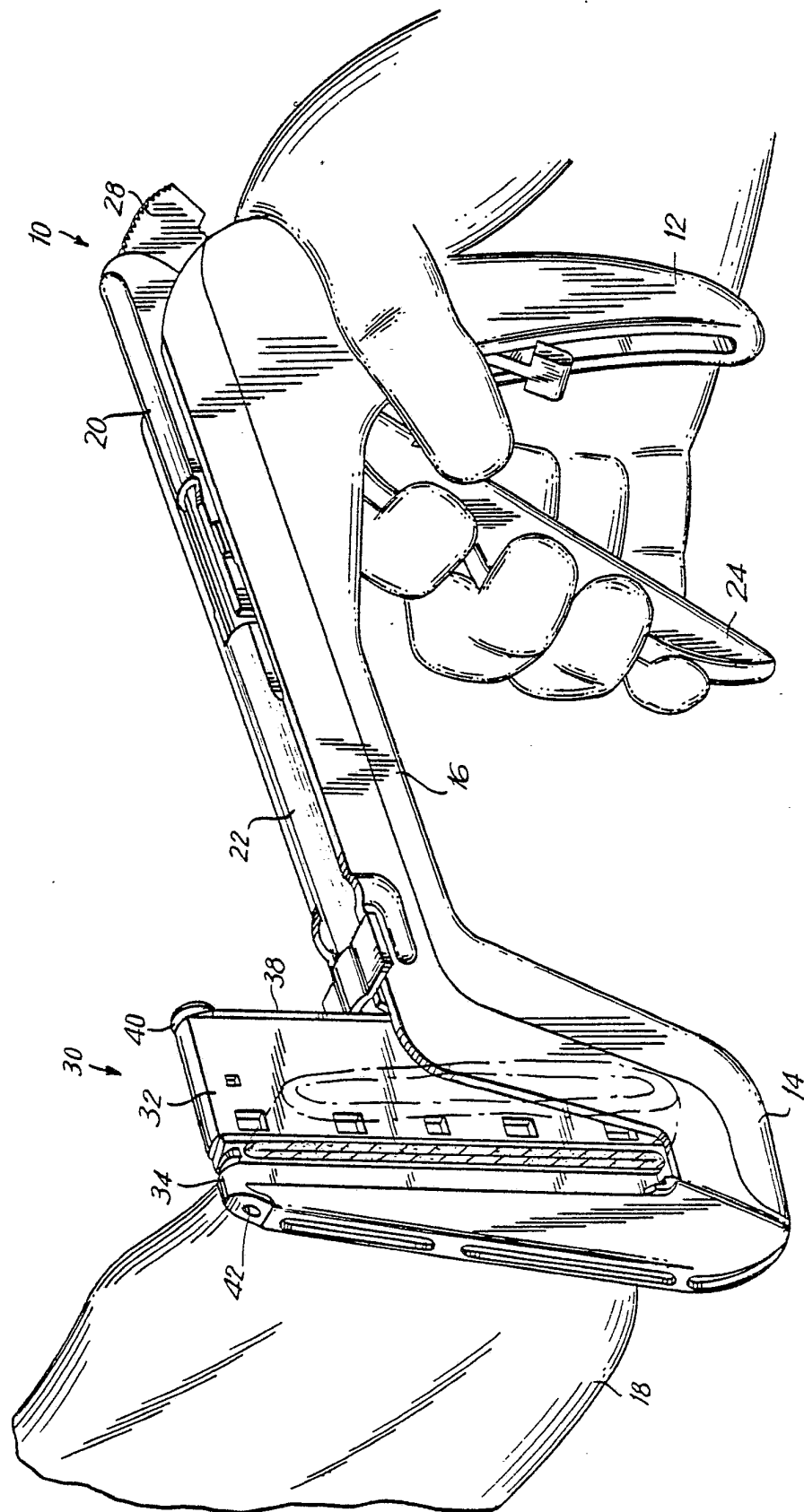
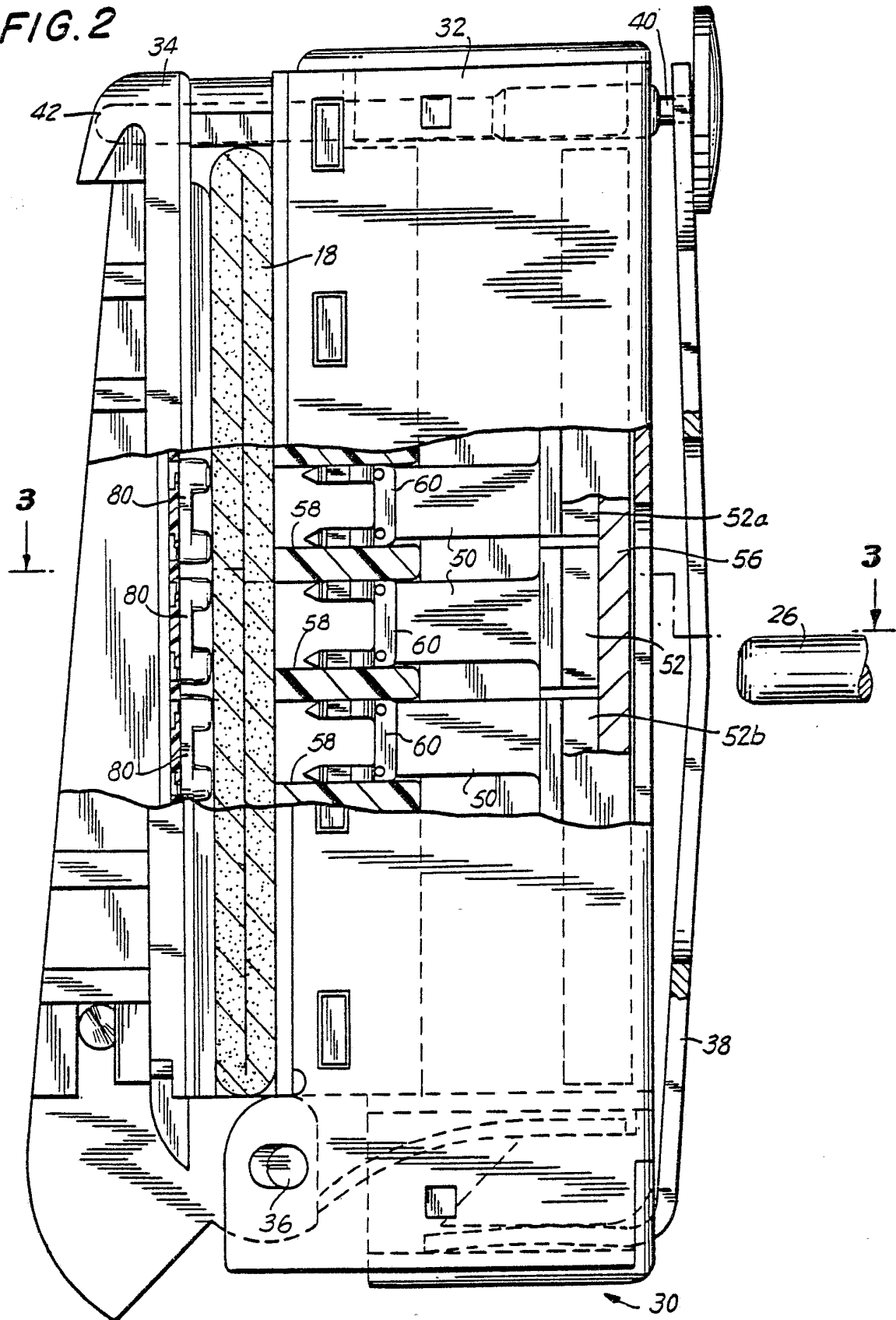


FIG. 1b

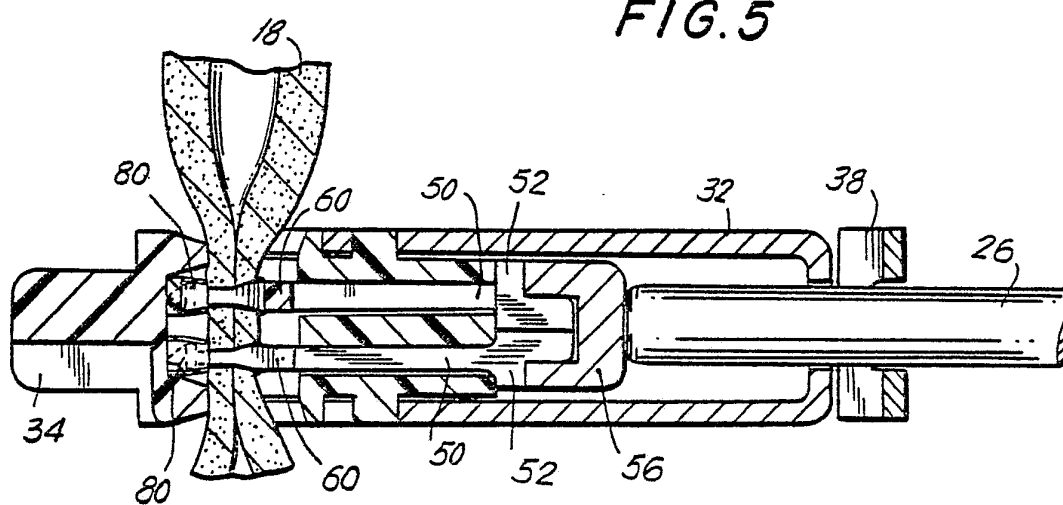
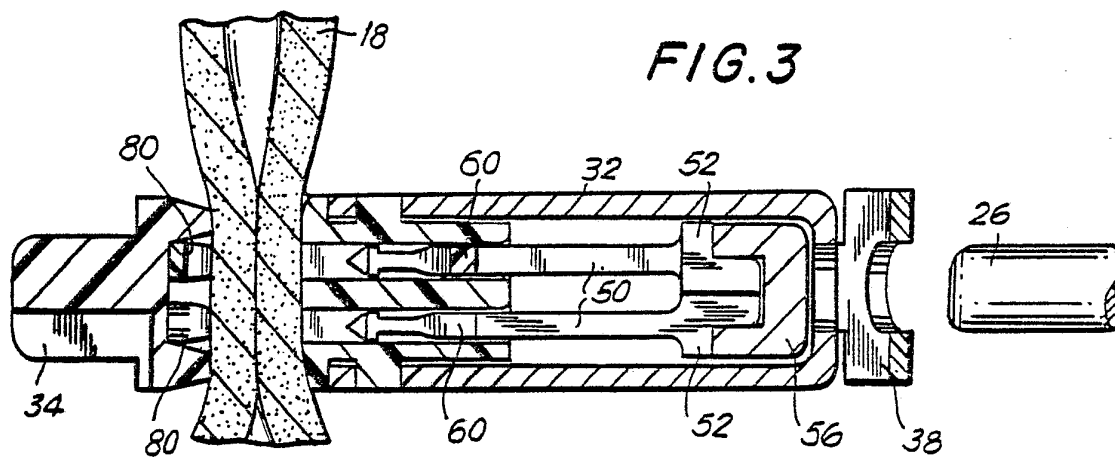


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FIG. 2



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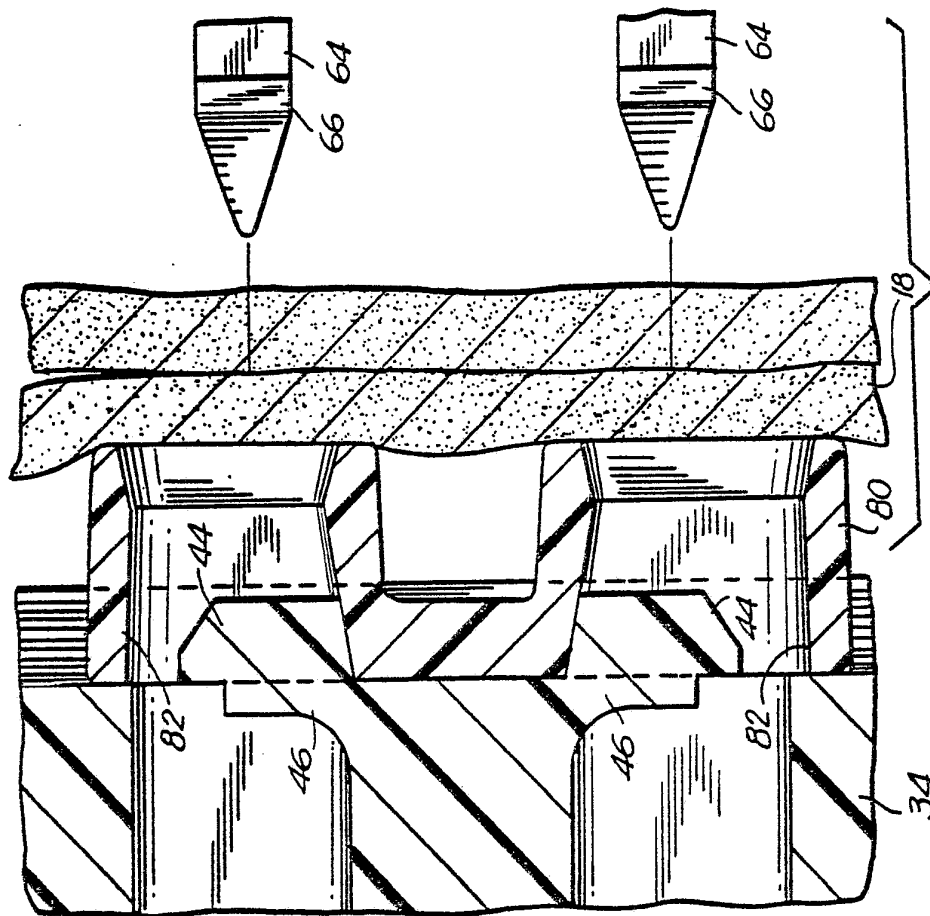


FIG. 7

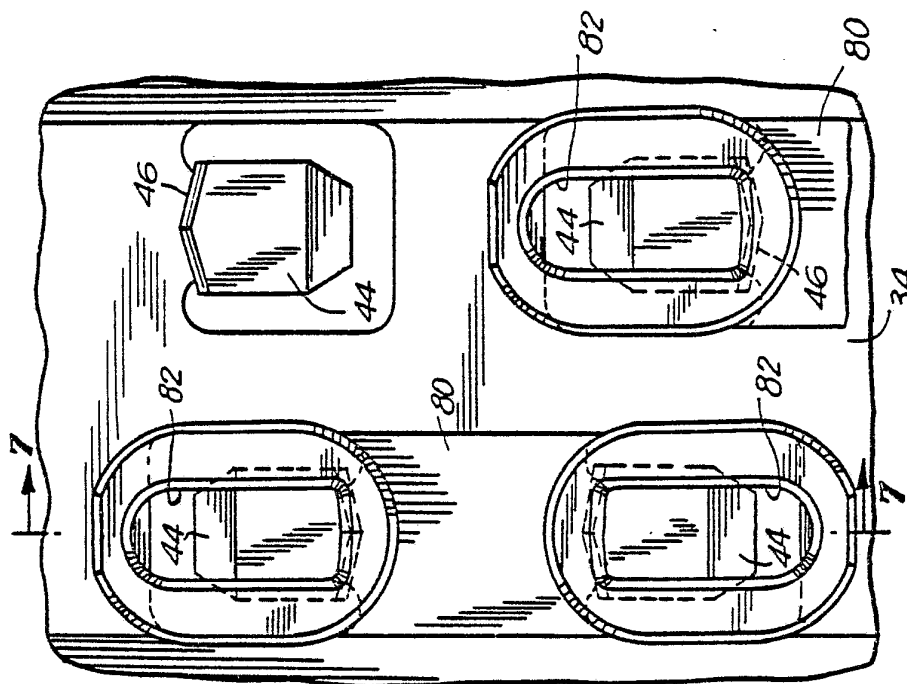


FIG. 6

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FIG. 8

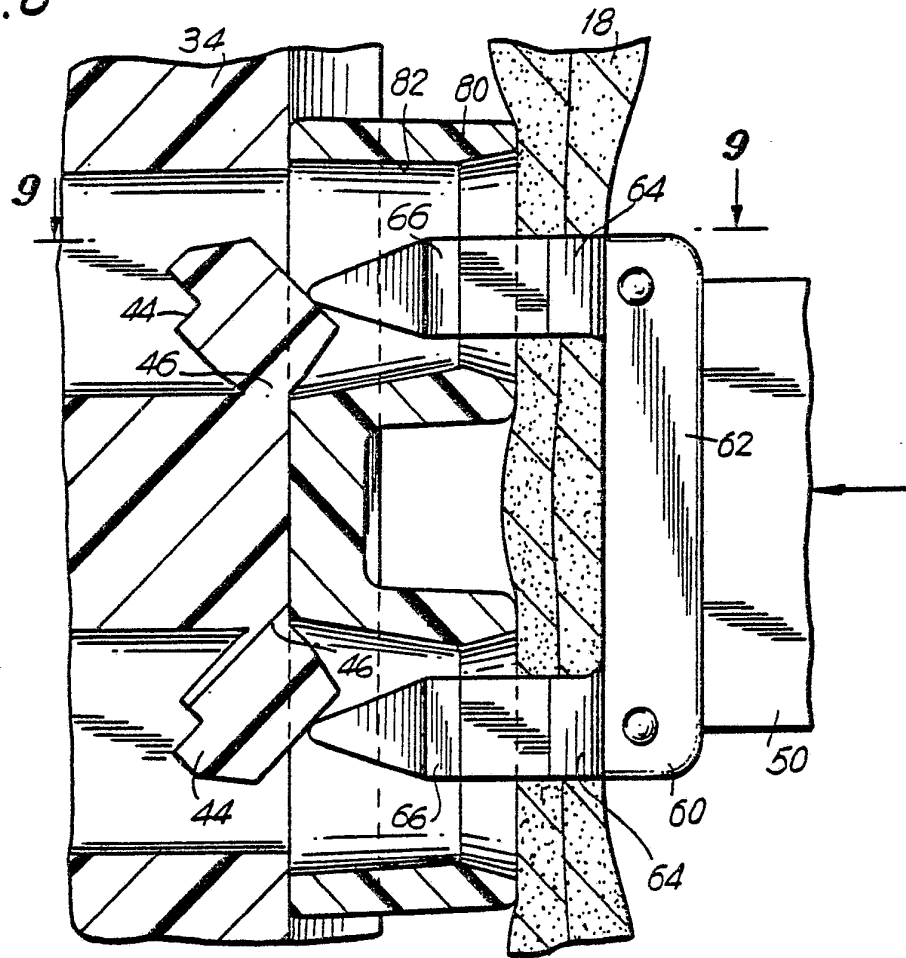
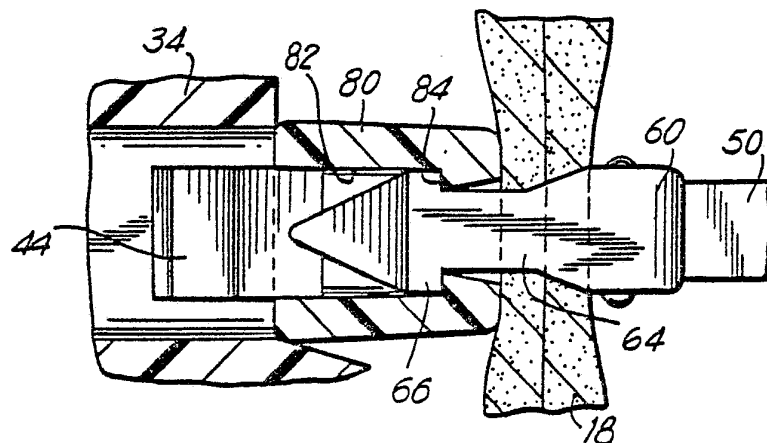


FIG. 9



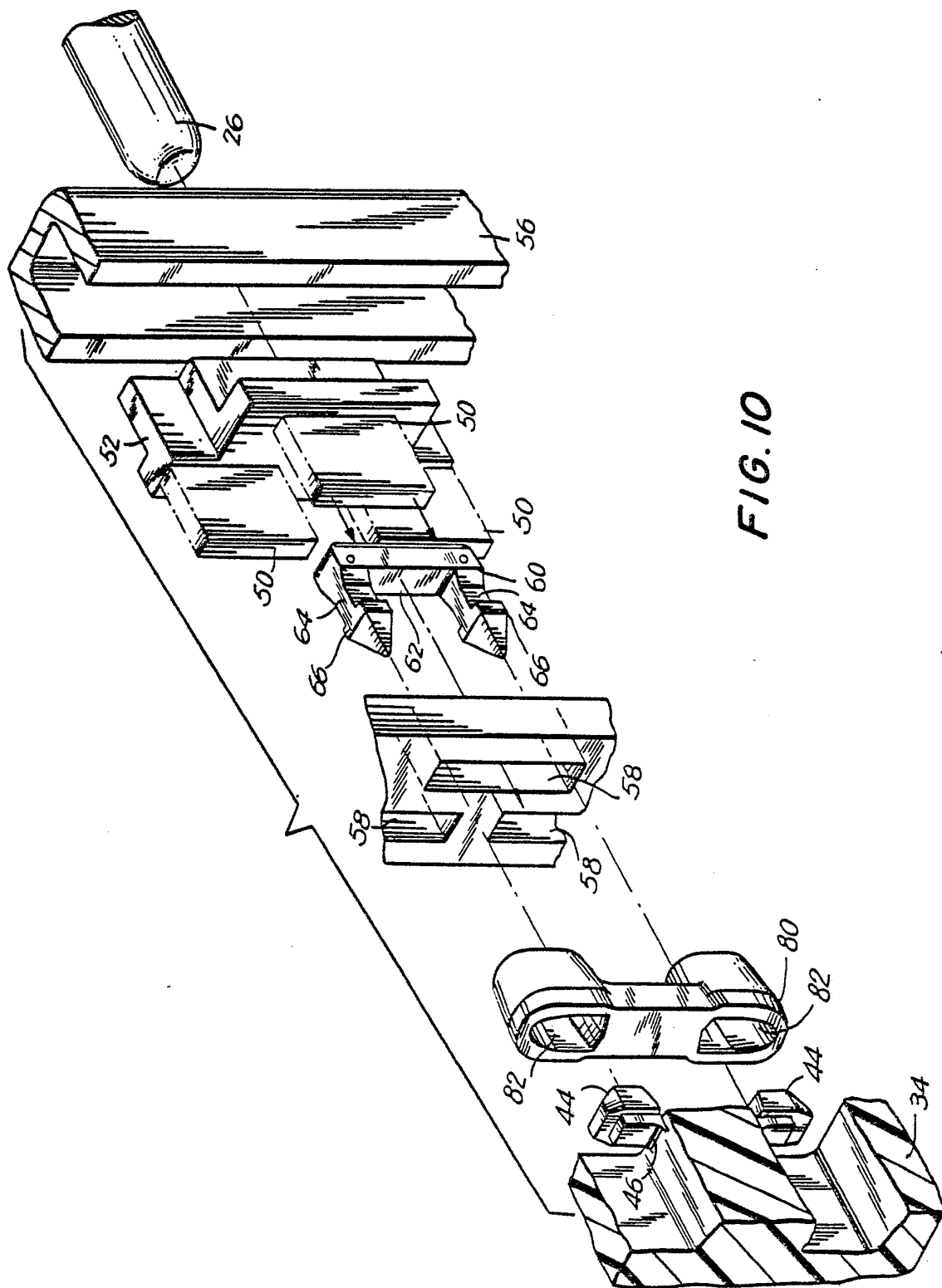


FIG. 10

INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US 84/00337**

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. A61B 17/04; A41H 37/04; B31B 1/00 U.S. CL. 128/334C; 227/15, 19		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
U.S.	128/325, 334R, 334C, 346 227/ D1G1A-C, 15, 19 411/469, 475, 476	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category [*]	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X, P	US, A, 4402445 (GREEN) 06 Sept. 1983	(3-10)
A	SU, A, 0906540 (KANSHIN) 23 Feb. 1982	
Y	US, A, 4310115 (INOUE) 12 Jan. 1982	(3-10)
A	US, A, 4305539 (KOROLKOU) 15 Dec. 1981	
A	US, A, 4198982 (FORTNER) 22 Apr. 1980	
A	US, A, 3494533 (GREEN) 10 Feb. 1970	
A	US, A, 3357296 (LEFEVER) 12 Dec. 1967	
X	US, A, 3166072 (SULLIVAN) 19 Jan. 1965	(1-7)
Y	US, A, 2940451 (VOGELFANGER) 14 Jan. 1960	(8-10)
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>[*] Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²	Date of Mailing of this International Search Report ²	
07 JUN 1984	08 JUN 1984	
International Searching Authority ¹	Signature of Authorized Officer ²⁰	
ISA/US		

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 _____, because they relate to subject matter ¹² not required to be searched by this Authority, namely:

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:

I. Claims 1-7 drawn to therretainer support structure.

II. Claims 8-10 drawn to the fastener pusher assembly.

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.