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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 :		(11) International Publication Number:
A61B 17/00	A1	WO 86/ 02254
		(43) International Publication Date: 24 April 1986 (24.04.86)

(21) International Application Number: PCT/US85/01982

(22) International Filing Date: 15 October 1985 (15.10.85)

(31) Priority Application Numbers: 662,679
782,732

(32) Priority Dates: 19 October 1984 (19.10.84)
4 October 1985 (04.10.85)

(33) Priority Country: US

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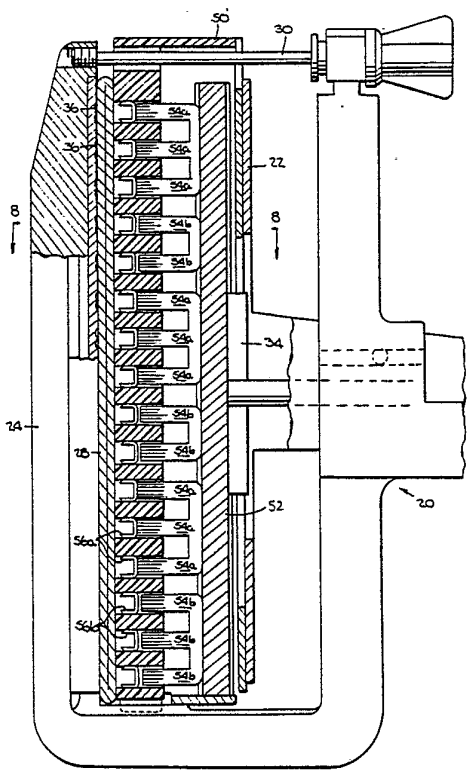
(81) Designated States: AT (European patent), BE (European patent), BR, CH (European patent), DE (European patent), FR (European patent), GB, IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.

(54) Title: SURGICAL FASTENER APPLYING APPARATUS

(57) Abstract

Apparatus (20) for substantially simultaneously applying a plurality of surgical fasteners to body tissue includes means (54a and 54b) for preventing all of the fasteners from reaching peak formation force at the same time in order to reduce the maximum force required to operate the apparatus.



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Apparatus which simultaneously or substantially simultaneously applies a plurality of surgical fasteners is therefore different from apparatus such as that shown in Green U.S. patent 4,429,695 which completes the application of some surgical fasteners before the application of other fasteners has begun. Apparatus of the type shown in the Green '695 patent is not of interest in relation to the present invention.

The fasteners applied by instruments of the types shown in the above-mentioned Hirsch et al. and Conta et al. patents need not be metal surgical staples. For example, Green U.S. patent 4,506,671 shows two-part surgical fasteners made of resinous materials which can be used as an alternative to metal surgical staples. Such two-part fasteners typically have a fastener part and a retainer part. The prongs of the fastener part are driven part way through the tissue to be fastened, whereupon the ends of the prongs interlock with the associated retainer part to secure the tissue. As used herein, the term "surgical fastener" is generic to metal staples, two-part resinous fasteners, and the like.

Most of the known surgical fasteners are characterized by a relatively sharp peak force requirement during application. For example, relatively little force is required to push the sharply pointed legs of metal surgical staples through tissue. However, when the ends of the staple legs reach the anvil of the stapler, a relatively large force is required to begin to bend or crimp the staple legs. Once the staple legs have begun to bend, the force required to continue bending the staple legs is substantially less than the force required to initiate bending. Similarly, the force required to push the prongs of two-part fasteners through tissue is typically substantially less than

SURGICAL FASTENER APPLYING APPARATUS

Background of the Invention

This application is a continuation-in-part of application Serial No. 662,679, filed October 19, 1984.

This invention relates to surgical fastener applying apparatus, and more particularly to surgical fastener applying apparatus of the type that applies a plurality of surgical fasteners simultaneously or substantially simultaneously.

Among the known types of surgical fastener applying instruments are several that apply a plurality of surgical fasteners simultaneously or substantially simultaneously. For example, Hirsch et al. U.S. patent 3,275,211 shows apparatus for simultaneously applying a plurality of metal surgical staples in a linear array. As another example, Conta et al. U.S. patent 4,304,236 shows apparatus for simultaneously applying a plurality of metal surgical staples in a circular array.

In the present context, a surgical fastener applying instrument is said to apply a plurality of surgical fasteners "simultaneously" or "substantially simultaneously" if, during at least some portion of the fastener applying stroke of the apparatus, all of the fasteners are simultaneously in motion relative to the fastener holding portion of the apparatus.

the force required to cause the ends of the prongs to interlock with the retainer part of the fastener.

As used herein, the term "formation force" refers to the force required to apply a surgical fastener, and the term "peak formation force" refers to the maximum force required during application of a surgical fastener. In general, a surgical fastener reaches its peak formation force when it first contacts or engages the associated "fastener forming means", i.e., the anvil of the stapler in the case of metal staples or the retainer part of the fastener in the case of two-part resinous fasteners.

Several of the known surgical fastener applying instruments simultaneously apply approximately 30 surgical fasteners. For some surgical procedures, there is interest in simultaneously applying even more than 30 fasteners (e.g., 60 or more fasteners). Because all of these fasteners are applied simultaneously, all of the fasteners reach their peak formation force simultaneously, thereby requiring the surgeon to apply a very large force to the fastener applying apparatus. This may make the apparatus relatively difficult to operate. In addition, the need to provide structures which can receive and transmit such large forces may increase the size, cost, and complexity of the fastener applying apparatus. The size of the apparatus may also undesirably increase as a result of the application of an increased number of fasteners.

In view of the foregoing, it is an object of this invention to improve surgical fastener applying apparatus of the type which simultaneously applies a large number of surgical fasteners.

It is another object of this invention to reduce the maximum force required to operate surgical fastener applying apparatus of the type which

simultaneously applies a plurality of surgical fasteners.

It is still another object of this invention to reduce the size of the apparatus required to apply a large number of surgical fasteners.

Summary of the Invention

These and other objects of the invention are accomplished in accordance with the principles of the invention by including in surgical fastener applying apparatus of the type described above means for causing at least one of the fasteners to reach peak formation force before at least one other fastener reaches peak formation force. In general, this is accomplished by including in the apparatus means for causing at least one fastener to engage the fastener forming means before at least one other fastener engages the fastener forming means. For example, in apparatus for substantially simultaneously applying a plurality of metal surgical staples, the above-mentioned means causes at least one staple to contact the anvil of the stapler before at least one other staple contacts the anvil. The staples may contact the anvil successively, or the staples may be grouped in two or more groups so that the groups contact the anvil successively. In the case of apparatus which substantially simultaneously applies a plurality of two-part resinous fasteners, the above-mentioned means causes at least one fastener part to interlock with its associated retainer part before at least one other fastener part interlocks with its associated retainer part. Once again, the fastener and retainer parts may interlock successively, or the fasteners may be grouped in two or more groups so that the groups interlock successively.

The invention reduces the maximum force required to apply a given number of surgical

fasteners because it prevents all of the fasteners from reaching their peak formation force at the same time.

Various embodiments of the invention have been developed. In a first embodiment, some of the fastener pushers are shorter than other pushers so that the fasteners associated with the shorter pushers are retarded relative to the other fasteners. In a second embodiment, the structure which drives the pushers is stepped so that some pushers are retarded relative to other pushers. In a third embodiment, the anvil structure associated with some fasteners (staples) is recessed relative to the anvil surface associated with other fasteners so that the fasteners associated with the more recessed anvil surface reach that surface after the other fasteners reach the less recessed anvil surface. In the two-part fastener equivalent of the third embodiment, the retainer parts associated with some fastener parts are recessed relative to the retainer parts associated with the other fastener parts. In a fourth embodiment, the fasteners themselves vary in size so that they do not all reach peak formation force at the same time. In the case of metal staples, for example, the legs of some staples are shorter than the legs of other staples so that the staples with longer legs contact the anvil before the staples with shorter legs. Similarly, the legs of the fastener parts of some two-part fasteners can be made shorter than other fastener part legs so that the fastener parts with longer legs interlock with their associated retainer parts before the fastener parts with shorter legs interlock with their associated retainer parts. In a fifth embodiment, the structure that pushes the fasteners toward the fastener forming means (i.e., the anvil or retainer

parts) is angled slightly so that some fasteners are pushed slightly ahead of other fasteners.

In accordance with another aspect of the invention, the size of apparatus for applying a large number of surgical fasteners can be reduced by placing two fasteners in each fastener holding aperture in the apparatus. The apertures are shaped to keep the fasteners in each aperture separate from one another and to prevent them from becoming entangled with one another as they are driven from the aperture and thereby applied to tissue.

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

Brief Description of the Drawings

Figures 1 and 2 are force diagrams useful in explaining the principles of the invention.

Figure 3 is a perspective view of a first illustrative embodiment of the invention.

Figure 4 is an elevational view of a portion of the apparatus of Figure 3 showing an early stage in the operating cycle of that apparatus.

Figures 5-7 are views similar to Figure 4 showing successive stages in the operating cycle of the apparatus of Figure 3.

Figure 8 is a cross sectional view taken along the line 8-8 in Figure 5.

Figures 9 and 10 are views similar to Figure 8 corresponding, respectively, to the operating cycle stages shown in Figures 6 and 7.

Figures 11-16 are detailed sectional views showing successive stages in the formation of representative staples in the apparatus of Figure 3.

Figure 17 is an elevational view of the front of the staple holding cartridge in the apparatus of Figure 3.

Figure 18 is an enlargement of a portion of Figure 17.

Figure 19 is a cross sectional view taken along the line 19-19 in Figure 17.

Figure 20 is an elevational view of the anvil in the apparatus of Figure 3.

Figures 21 and 22 are cross sectional views taken respectively along the lines 21-21 and 22-22 in Figure 20.

Figure 23 is a view similar to Figure 5 showing an alternative embodiment of the invention.

Figure 24 is a view similar to Figure 8 showing another alternative embodiment of the invention.

Figure 25 is another view similar to Figure 8 showing yet another alternative embodiment of the invention.

Figure 26 is another view similar to Figure 8 showing still another alternative embodiment of the invention.

Figure 27 is another view similar to Figure 8 showing yet another alternative embodiment of the invention.

Figure 28 is a view generally similar to Figure 5 showing still another alternative embodiment of the invention.

Detailed Description of the Invention

In Figure 1, the force required to apply a typical metal surgical staple is plotted as a function of the displacement of the associated staple pusher. (See also Figure 59 of Green et al. U.S. patent 3,494,533.) The initial force requirement (region A) is relatively low as the pusher pushes

the sharply pointed legs of the staple through the tissue. As soon as the ends of the staple legs contact the anvil of the stapler, however, the force requirement increases very rapidly (region B) to the peak formation force C, i.e., the force required to initiate bending of the staple legs. Once bending has been initiated, the force requirement decreases rapidly again (region D).

The formation force requirement for the typical two-part resinous surgical fastener (Figure 2) is generally similar to that described above. Initially (region A), relatively little force is required to push the sharply pointed ends of the fastener part prongs through the tissue. However, when the latches on the fastener part prongs contact the latches on the associated retainer part, the formation force requirement increases very rapidly (region B) to the peak formation force C, i.e., the force required to cause the latches on the fastener and retainer parts to interlock. Thereafter (region D), the force requirement drops off rapidly again.

In accordance with this invention, apparatus for substantially simultaneously applying a plurality of surgical fasteners characterized by formation force curves like those shown in Figures 1 and 2 is constructed so that all of the fasteners do not reach their peak formation force C at the same time. In particular, the surgical fastener applying apparatus of this invention is constructed so that at least some of the fasteners reach their peak formation force C while at least some other fasteners are still at their relatively low initial formation force A, and so that the fasteners that are first to reach peak formation force have returned to relatively low formation force D when the fasteners that are last to reach peak formation force reach their peak

formation force C. In this way, the maximum force required to operate the fastener applying apparatus of this invention is substantially less than it would be if all of the fasteners reached peak formation force at the same time.

A first illustrative embodiment of the invention is shown in Figures 3-22 in the context of surgical fastener applying apparatus of the type shown in commonly assigned, co-pending Green U.S. patent application Serial No. 598,461, filed April 9, 1984 (Docket No. USSC 1047 CIP II), which is hereby incorporated by reference herein for background information not essential for understanding or practicing the present invention. As shown in Figure 3, this apparatus includes a reusable actuator 20 for removably receiving and actuating a disposable staple holding cartridge 50. When cartridge 50 is placed in cartridge holder 22, cartridge holder 22 can be moved toward anvil 24 by rotation of clamp actuator 26 (compare Figures 4 and 5). The tissue 28 to be fastened is thereby clamped between cartridge 50 and anvil 24. Alignment pin 30 is pushed through cartridge 50 into anvil 24 to help register and align elements 50 and 24 and to help confine tissue 28 between those elements.

When tissue 28 is fully clamped as shown in Figure 5, handle 32 (Figure 3) is pivoted to the rear to drive fastener actuator bar 34 in the distal direction as shown in Figure 6. Fastener actuator bar 34 enters the rear of cartridge 50 and pushes pusher driver 52 in the distal direction. This in turn pushes all of pushers 54a and 54b in the distal direction. Some of pushers 54 (i.e., those designated 54a) are slightly longer than the other pushers (i.e., those designated 54b). (Pushers 54a and 54b are joined together in groups of two or three

for reasons (such as reduction of the number of separate parts in the apparatus) having nothing to do with the present invention.) The difference in length of pushers 54a and 54b is typically relatively small (e.g., .008-.012 inches) and is exaggerated in the accompanying drawings to better illustrate the invention.

When pushers 54 are pushed in the distal direction as described above, they push staples 56 toward anvil 24 as shown progressively in Figures 11-16. Anvil 24 has pockets 36 for clinching staples 56 in the conventional manner. (In order to facilitate comparison of the progress of staples 56a (associated with relatively long pushers 54a) with the progress of staples 56b (associated with relatively short pushers 54b), a staple 56b is superimposed on a staple 56a in Figures 11-16, although in that respect Figures 11-16 are not true views of the apparatus.) As shown in Figure 11, the ends of the legs of staples 56a reach the surface of anvil 24 before the ends of the legs of staples 56b reach that surface. Accordingly, staples 56a reach peak formation force C (Figure 1) while staples 56b are still in relatively low initial formation force region A. As pushers 54 continue to move in the distal direction, the ends of the legs of staples 56a begin to bend inwardly as shown in Figure 12, and the ends of the legs of staples 56b continue to move toward the surface of anvil 24. Accordingly, staples 56a pass peak formation force C and enter reduced formation force region D before staples 56b reach peak formation force C.

Continued distal motion of pushers 54 causes staples 56a to continue to bend, and causes staples 56b to reach peak formation force C and to begin to

bend as shown in Figure 13. Accordingly, when staples 56b reach peak formation force C, staples 56a are already well past peak formation force and into reduced formation force region D.

Still further distal motion of pushers 54 causes staples 56a and 56b to continue to bend as shown in Figures 14-16. Because pushers 54a are slightly longer than pushers 54b, staples 56a are clinched slightly more than staples 56b at the end of the staple applying stroke of the apparatus as shown in Figure 16. This does not adversely affect the resulting staple array.

When all of staples 56 have been fully clinched as shown in Figure 16, the stapling operation is complete. Handle 32 is accordingly released and clamp actuator 26 is rotated to proximally retract cartridge holder 22 and cartridge 50. This releases the clamping pressure on tissue 28 as shown in Figure 7. The apparatus can be removed from the tissue when alignment pin 30 is proximally retracted.

Because staples 56a pass through peak formation force C before staples 56b, the maximum force required to operate the apparatus is substantially less than it would be if all of staples 56 passed through peak formation force C at the same time.

In accordance with another aspect of the invention illustrated by the embodiment of Figures 3-22, the width W (Figure 8) of cartridge 50 and anvil 24 can be kept relatively small even though a large number of fasteners is applied by the apparatus by using two staples 56 in each cartridge slot 58 instead of one staple in each slot as is customary. The structure facilitating the use of two staples 56 in each cartridge slot 58 is best seen in Figures 8-10 and 17-22. As shown in Figure 18, the opposite ends of each cartridge slot 56 have two laterally spaced

grooves 60 parallel to the axis along which staples 56 are driven. Each groove 60 receives and guides one leg of one of the two staples 56 in the slot. The distal end of each pusher 54 also has two parallel, laterally spaced grooves 62 (see Figures 8-10). Each groove 62 receives the backspan of a respective one of the two staples in the associated slot 58. Each of anvil pockets 36 also has two laterally spaced grooves 38 parallel to grooves 62 (see Figures 8-10 and 20-22). Each of grooves 38 receives and guides the end of one leg of one of the two staples driven into pocket 36 in order to clinch the staples. Thus although two staples 56 are provided in each slot 58, the foregoing structure keeps the staples in each slot separate from one another and prevents them from becoming entangled with one another as they are driven.

Although two staples 56 are employed in each slot 58 in the embodiment shown in Figures 3-22, those skilled in the art will appreciate that this is not necessarily the case, and that a single staple 56 could be used in each slot 58 if desired. See also the embodiments shown in Figures 24-27 (discussed below) in which the same number of fasteners are employed as in the embodiment of Figures 3-22, but in which each fastener has its own slot 58.

Those skilled in the art will also recognize that two-part resinous surgical fasteners of the type shown, for example, in Green U.S. patent 4,506,671 can be substituted for metal surgical staples 56 in the embodiment shown in Figures 3-22. This is illustrated by Figure 23, which is similar to Figure 5 but shows the apparatus with two-part resinous fasteners 70 in place of metal surgical staples 56. The fastener parts 72 of fasteners 70 replace

staples 56. The retainer parts 74 of fasteners 70 replace anvil pockets 36. In other respects the construction and operation of the apparatus of Figures 23 can be generally similar to the construction and operation of the apparatus of Figures 3-22. Because pushers 54a are slightly longer than pushers 54b, fastener parts 72a interlock with retainer parts 74a before fastener parts 72b interlock with retainer parts 74b. Accordingly, fasteners 70a reach peak formation force C (Figure 2) while fasteners 70b are still in relatively low formation force region A, and fasteners 70b do not reach peak formation force C until fasteners 70a have passed through peak formation force C into reduced formation force region D. The maximum force required to operate the apparatus is therefore substantially less than it would be if all of fasteners 70 reached peak formation force C at the same time.

Figure 24 shows another embodiment of the invention in which all of pushers 54 are the same length, but in which pusher driver 52 is notched, grooved, or otherwise stepped so that it begins to push some of pushers 54 (i.e., those designated 54c) before it begins to push other pushers (i.e., those designated 54d). Figure 24 is similar to Figure 8, but with the following differences: First, there is only one staple 56 in each cartridge slot 58. Second, there are four rows of cartridge slots 58 instead of only two rows as in Figure 8. Third, all of pushers 54 are the same length. And fourth, pusher driver 52 contains a shallow central groove 64 so that when pushed in the distal direction, it contacts outer pusher rows 54c before it contacts inner pusher rows 54d. Accordingly, outer staple rows 56c are pushed slightly ahead of inner staple rows 56d and staples 56c pass through peak formation force C

before staples 56d reach that force level. As in the embodiment of Figures 3-22, the maximum force required to operate the apparatus of Figure 24 is substantially less than it would be if all of staples 56 reached peak formation force C at the same time. The depth of groove 64 can be similar to the difference between the lengths of pushers 54a and 54b in the embodiment of Figures 3-22. Those skilled in the art will appreciate that two-part resinous surgical fasteners of the type shown in Figure 23 can be substituted for metal staples 56 in the embodiment of Figure 24 if desired.

Figure 25 shows yet another embodiment of the invention in which some of anvil pockets 36e are deeper than other anvil pockets 36f. In other respects the embodiment of Figure 25 is similar to the embodiment of Figure 24 except that pusher driver 52 is not grooved in Figure 25. Because inner anvil pockets 36e are deeper than outer anvil pockets 36f, staples 56f contact anvil 24 before staples 56e. Accordingly, staples 56f pass through peak formation force C before staples 56e reach that force level. The maximum force required to operate the apparatus is therefore substantially less than it would be if all of staples 56 reached peak formation force C at the same time. The difference in depth between anvil pockets 36e and 36f can be similar to the difference between the lengths of pushers 54a and 54b in the embodiment of Figures 3-22.

Once again, those skilled in the art will appreciate that two-part resinous fasteners of the type shown in Figure 23 can be substituted for metal staples 56 in the apparatus of Figure 25 if desired. This is illustrated in Figure 26. Inner retainer parts 74e are recessed relative to outer retainer parts 74f so that outer fasteners 70f interlock

before inner fasteners 70e. In this way all of fasteners 70 do not pass through peak formation force C at the same time and the maximum force required to operate the apparatus is accordingly reduced.

Still another embodiment of the invention is shown in Figure 27. In this embodiment (which is similar to the embodiment of Figure 25 except that all of anvil pockets 36 are of the same depth), the legs of inner staples 56g are slightly shorter than the legs of outer staples 56h. Accordingly, outer staples 56h pass through peak formation force C before inner staples 56g pass through that force level. The result again is to reduce the maximum force required to operate the apparatus. The difference in staple leg length in this embodiment can be similar to the difference between the lengths of pushers 54a and 54b in the embodiment of Figures 3-22.

As in the case of the previously described embodiments, those skilled in the art will recognize that two-part resinous fasteners can be substituted for metal staples 56 in the embodiment of Figure 27. In that event, the legs of the fastener parts of some of those fasteners are made longer than the legs of the fastener parts of the other fasteners in order to achieve operation similar to that described above in relation to Figure 27.

Yet another alternative embodiment of the invention is shown in Figure 28. This Figure is identical to Figure 13 in commonly assigned, co-pending U.S. patent application Serial No. 662,679, filed October 19, 1984 (Docket No. USSC 1054), which is hereby incorporated by reference herein for background information not essential for understanding or practicing the present invention. As described in detail in the 662,679 application, staples 202 are driven in the distal direction when the proximal

end of cable 112 is pulled in the proximal direction. This causes cam bar 230 to move down relative to pusher actuator member 240. As cam bar 230 moves down, it is also forced to move in the distal direction by cam follower pins 232 traversing cam slots 354 and 454. Because cam slots 354 and 454 have different shapes, the lower end of cam bar 230 initially moves more rapidly in the distal direction than the upper end of cam bar 230. This causes lower staples 202 to reach peak formation force C before upper staples 202 reach that force level. Although all of staples 202 are in motion at the same time relative to fastener holding part 210 (thereby satisfying the above definition of substantially simultaneous staple application), the staples reach and pass through peak formation force C progressively, from the bottom of the apparatus to the top as viewed in Figure 28. Accordingly, at least some of staples 202 pass through peak formation force C before other staples reach that force level and the maximum force required to operate the apparatus is substantially less than it would be if all of staples 202 reached peak formation force C at the same time.

As in the previously described embodiments, two-part resinous fasteners of the type shown in Figure 23 can be substituted for metal staples 202 in the embodiment of Figure 28 if desired.

It will be understood that the embodiments shown and described herein are only 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, other structures for angling or inclining elements such as fastener

actuator bar 34, pusher driver 52, and/or cam bar 230 to achieve a result similar to that described above in relation to Figure 28 will be apparent to those skilled in the art.

Claims

1. Apparatus for substantially simultaneously applying a plurality of surgical fasteners to body tissue characterized by means for causing at least one fastener to reach peak formation force before at least one other fastener reaches peak formation force.

2. The apparatus defined in claim 1 wherein each of the fasteners is applied by being pushed by a pusher, and wherein the pusher associated with said one fastener is longer than the pusher associated with said one other fastener.

3. The apparatus defined in claim 1 wherein each of the fasteners is applied by being pushed by a pusher, wherein all of said pushers are pushed by a pusher driver, and wherein the pusher driver pushes the pusher associated with said one fastener ahead of the pusher associated with said one other fastener.

4. The apparatus defined in claim 1 wherein the fasteners are applied by clinching them against the surface of an anvil, and wherein the portion of the anvil surface associated with said one other fastener is more deeply recessed than the portion of the anvil surface associated with said one fastener.

5. The apparatus defined in claim 1 wherein the fasteners are applied by driving them into interlocking engagement with associated retainer parts, and wherein the retainer part associated with said one other fastener is more recessed relative to said one other fastener than the retainer part asso-

ciated with said one fastener is recessed relative to said one fastener.

6. The apparatus defined in claim 1 wherein each fastener has at least one leg having a free end portion which is operated upon to apply the fastener, and wherein the leg of said one fastener is longer than the leg of said one other fastener.

7. The apparatus defined in claim 1 wherein each of the fasteners is applied by being pushed by a pusher, wherein all of said pushers are pushed by a pusher driver, wherein said one fastener is associated with one portion of the pusher driver, wherein said one other fastener is associated with another portion of the pusher driver, and wherein said pusher driver is inclined from said one portion to said other portion so that said one fastener is pushed ahead of said one other fastener.

8. Apparatus for substantially simultaneously applying a plurality of surgical fasteners to body tissue comprising:

a unitary aperture containing two of said fasteners in parallel spaced relationship to one another;

means for substantially simultaneously ejecting said two fasteners from said aperture; and

surfaces in the interior of said aperture for maintaining said two fasteners in parallel spaced relationship to one another as said ejecting means ejects said two fasteners from said aperture.

9. The apparatus defined in claim 8 wherein said two fasteners are U-shaped fasteners disposed face to face in parallel spaced planes, and wherein said surfaces comprise two parallel

grooves at each end of said aperture, each of said grooves being respectively aligned with and partially receiving one leg of each of said fasteners.

10. The apparatus defined in claim 9 wherein the fasteners are metal staples which are applied by driving the ends of the staple legs against an anvil surface, and wherein the anvil surface has two parallel grooves, each of said grooves being aligned with the plane of a respective one of the staples for partially receiving the legs of the associated staple when the staples are driven against the anvil surface.

Fig. 1.

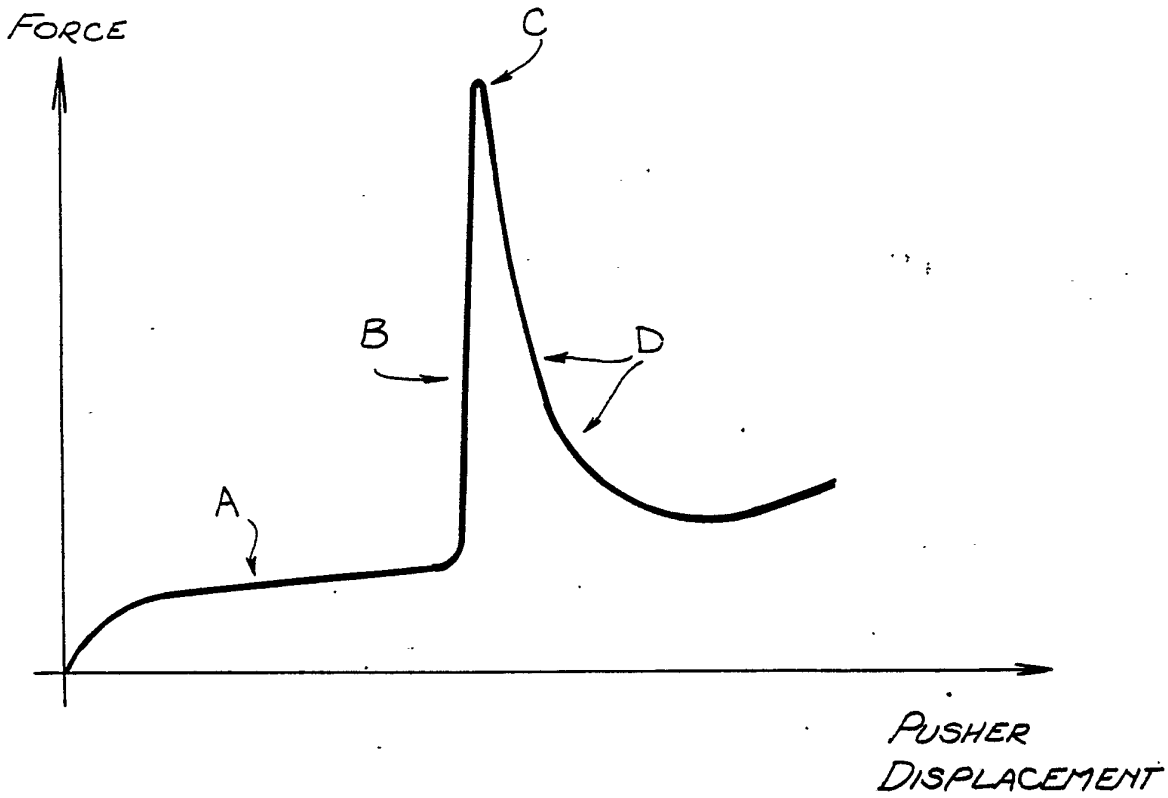
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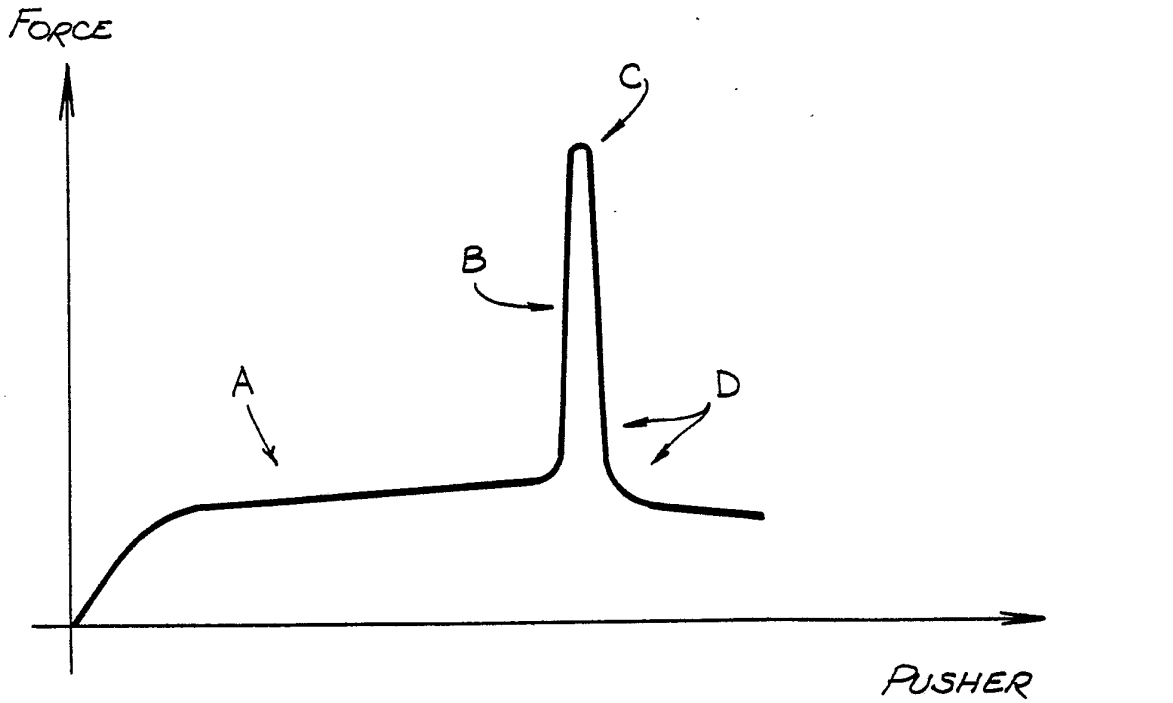
Fig. 2.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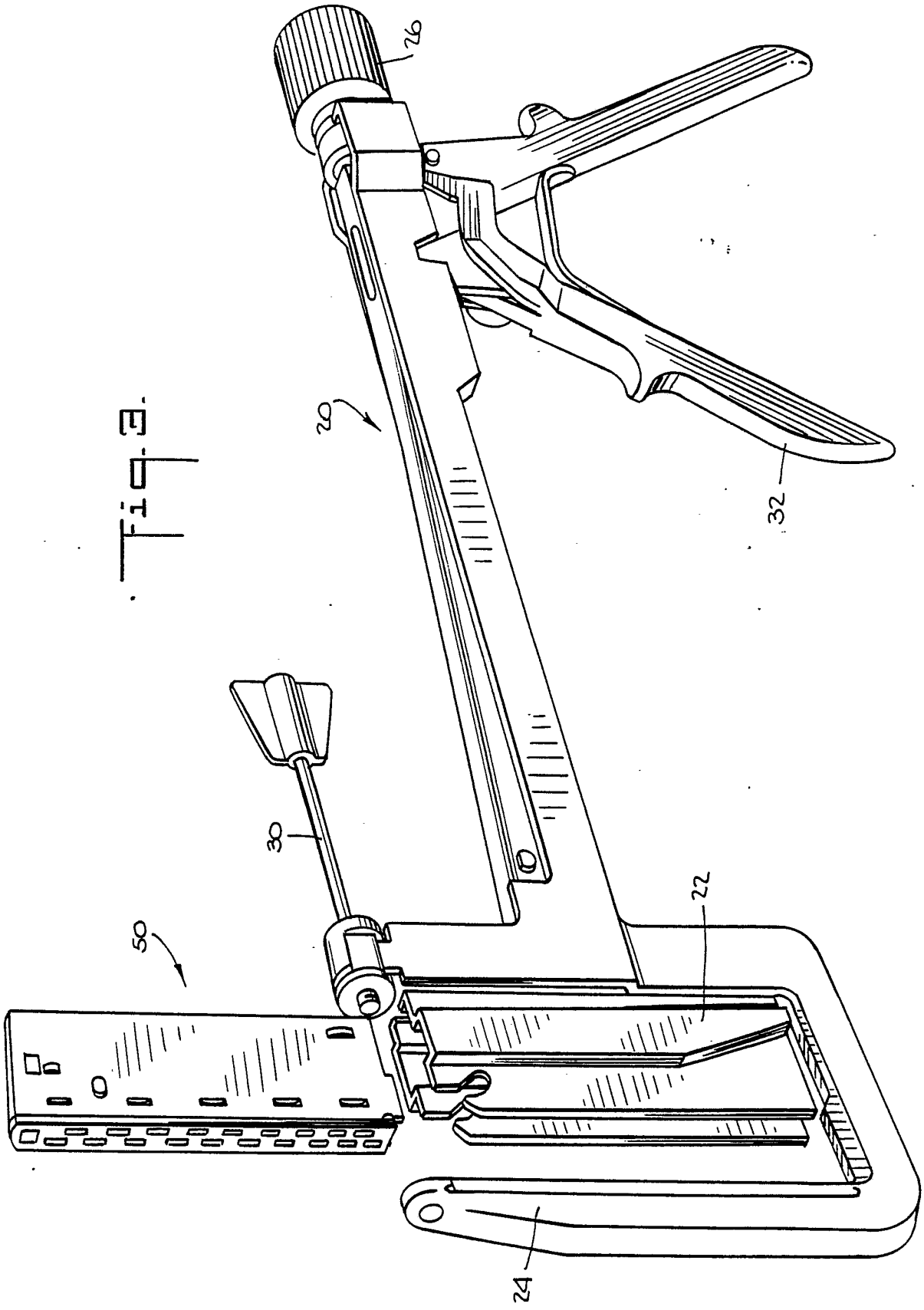

Fig. 3.

Fig. 4.

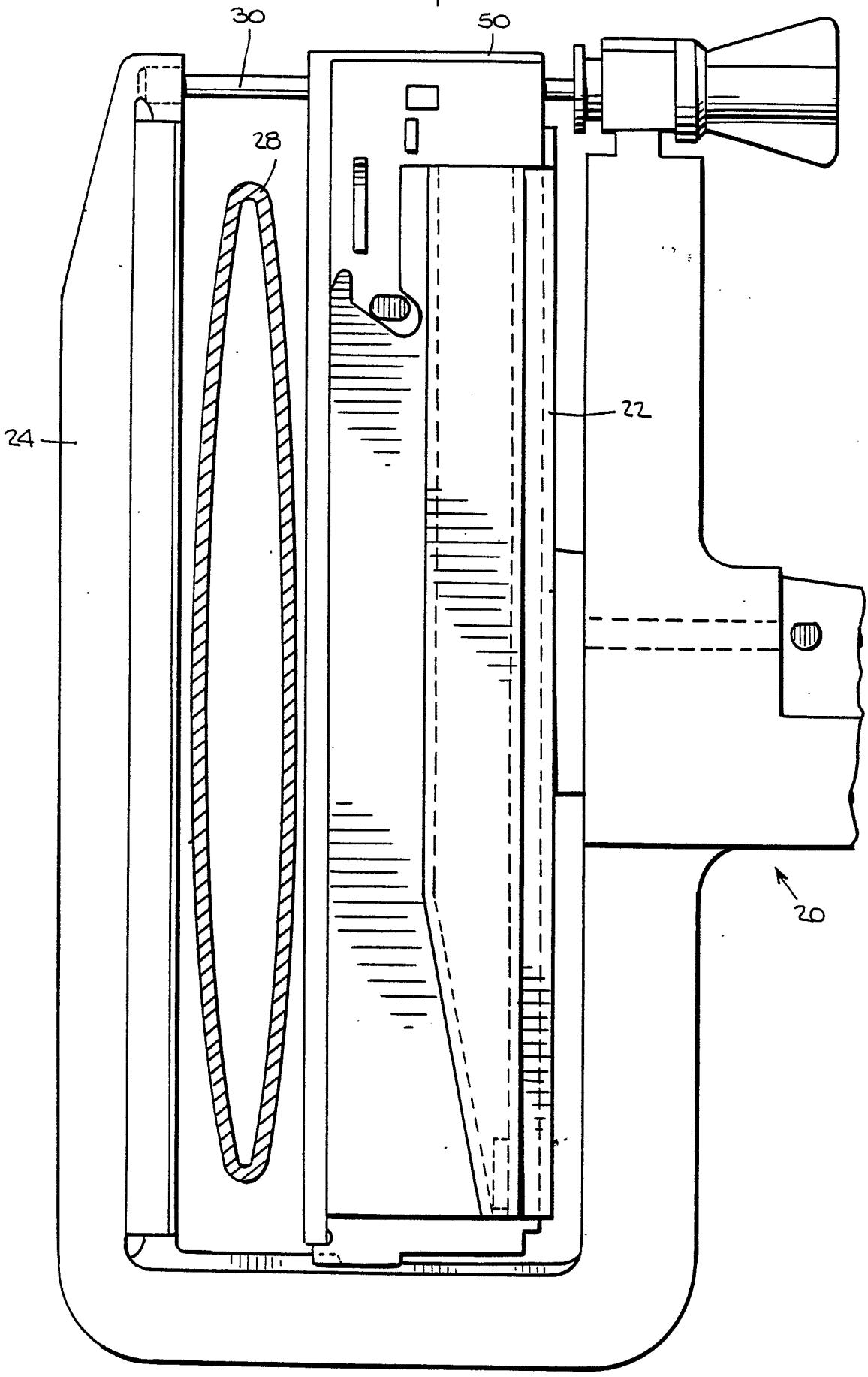

Fig. 5.

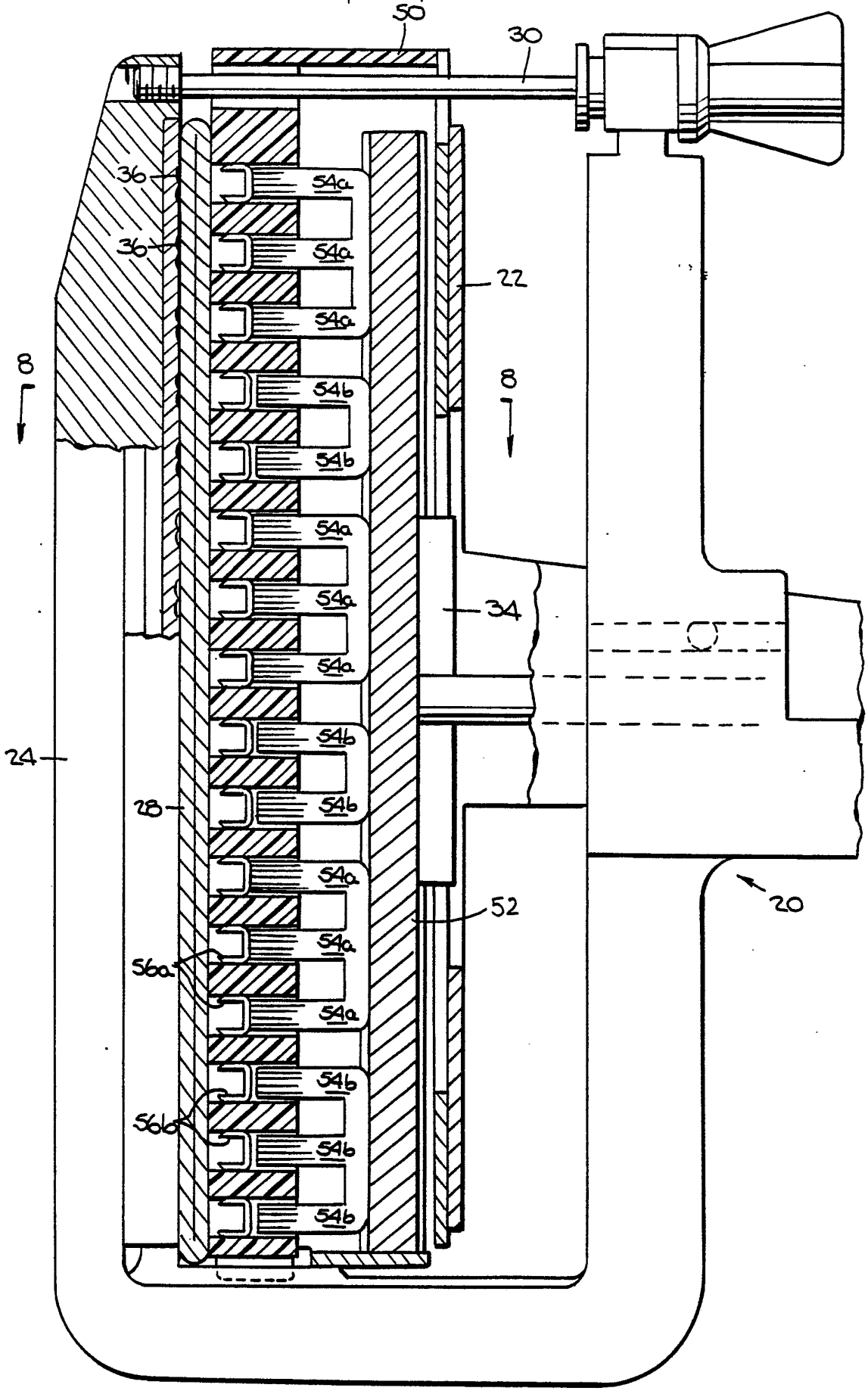
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Fig. 8.

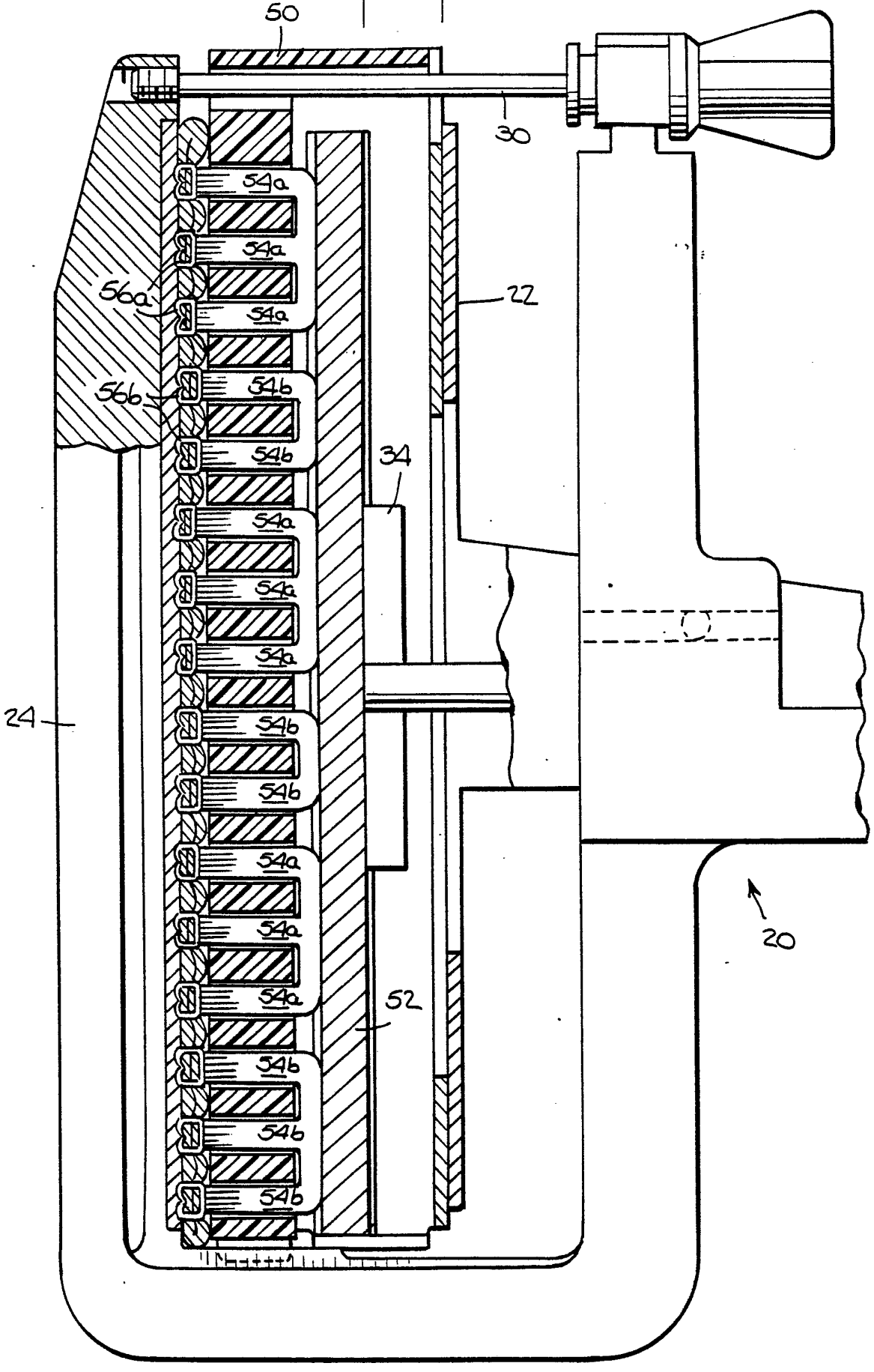
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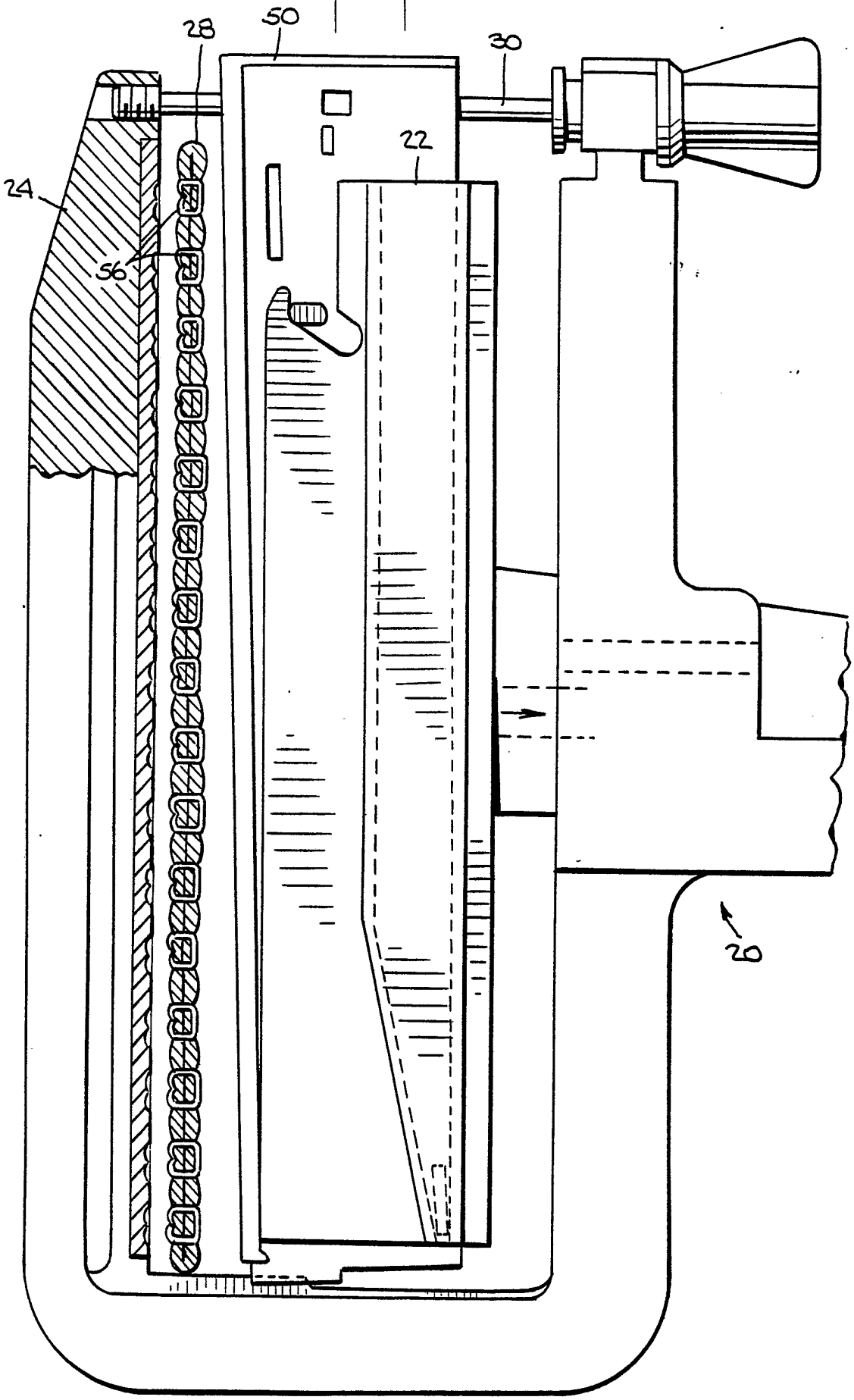
Fig. 7.



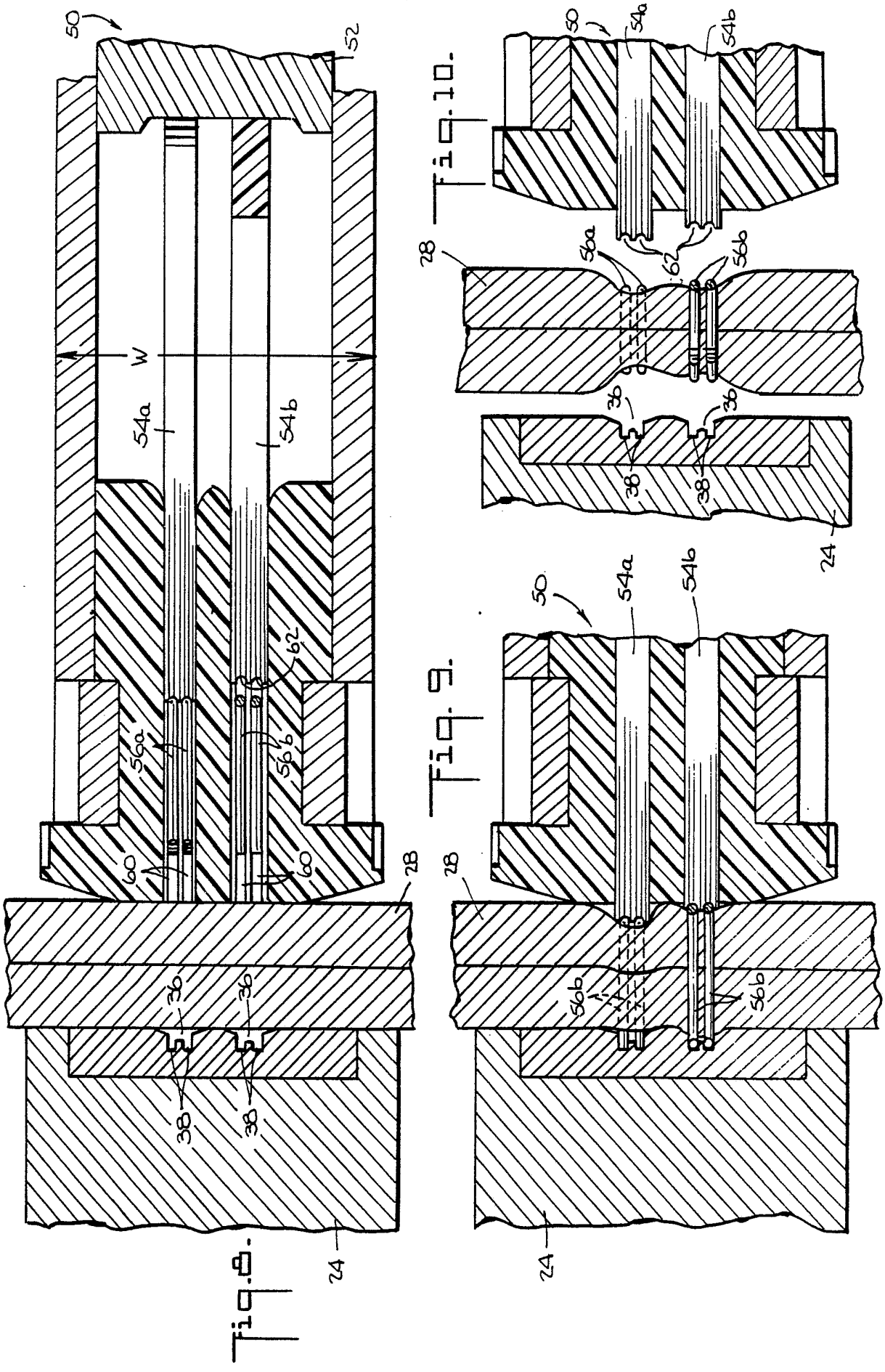
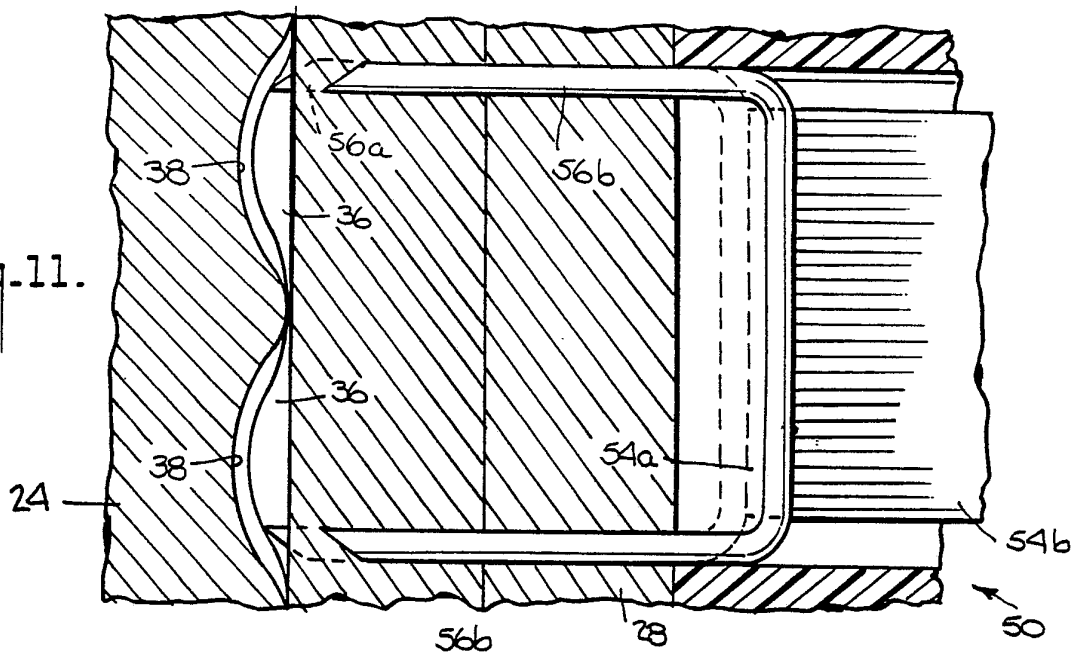


Fig. 8.

Fig. 9.

Fig. 10.

Fig.11.



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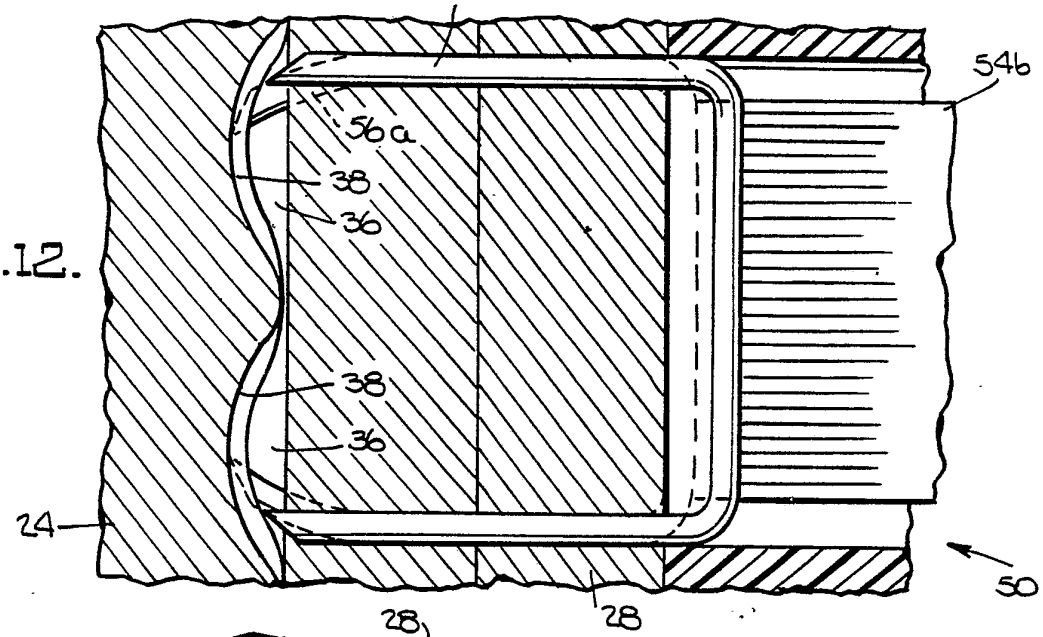

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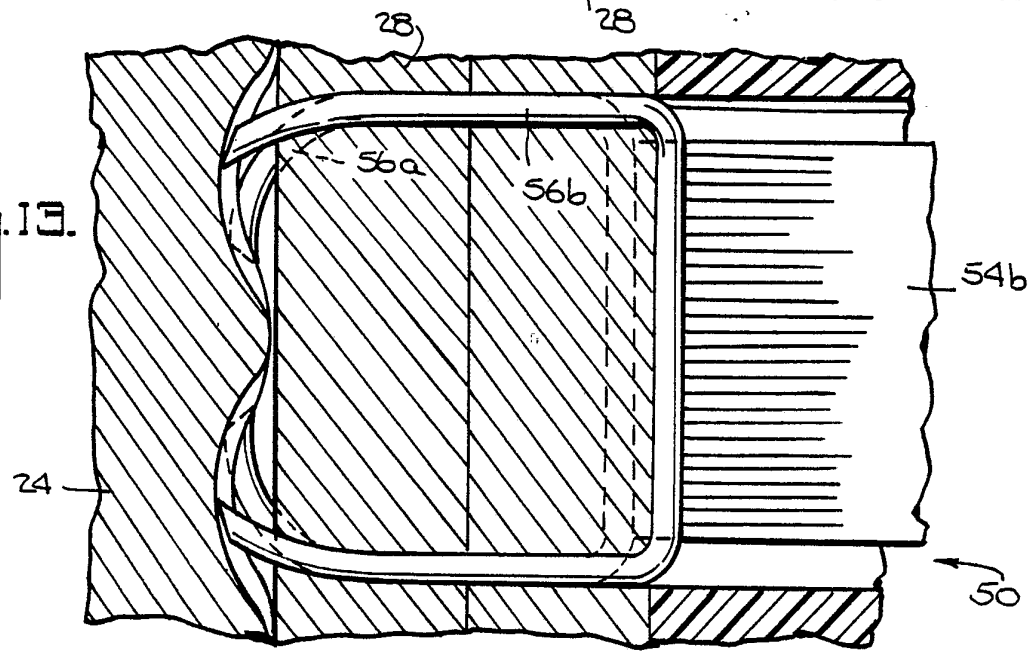

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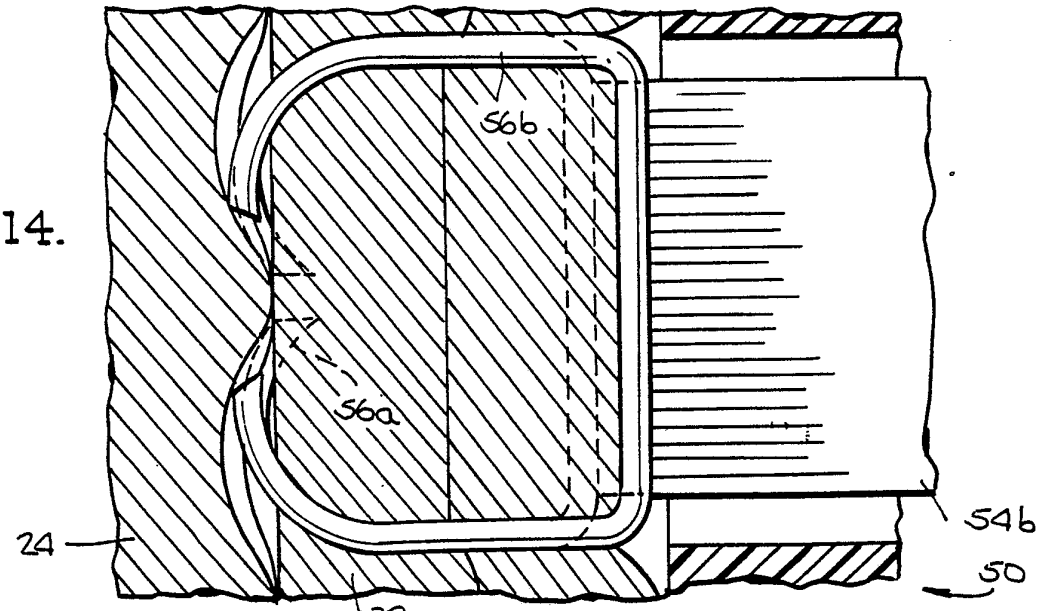
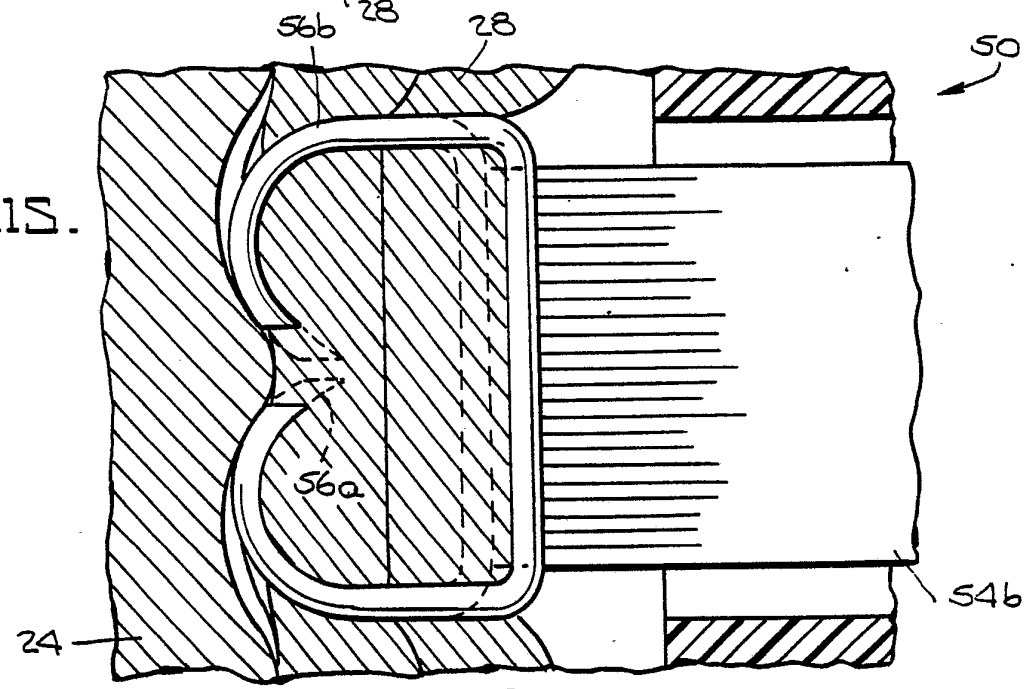


Fig.15.



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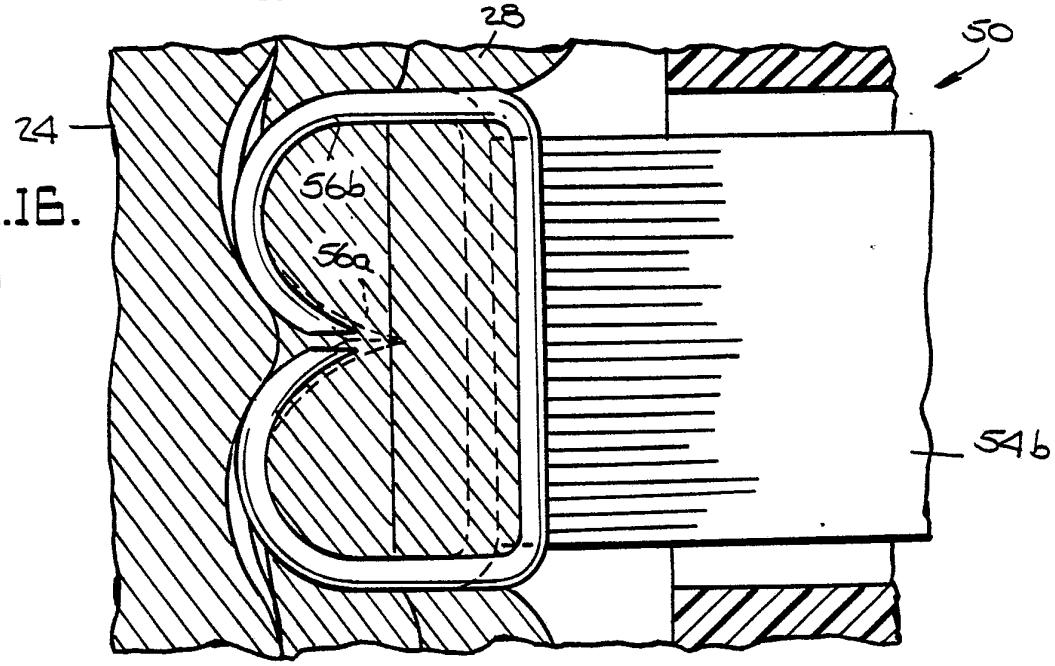
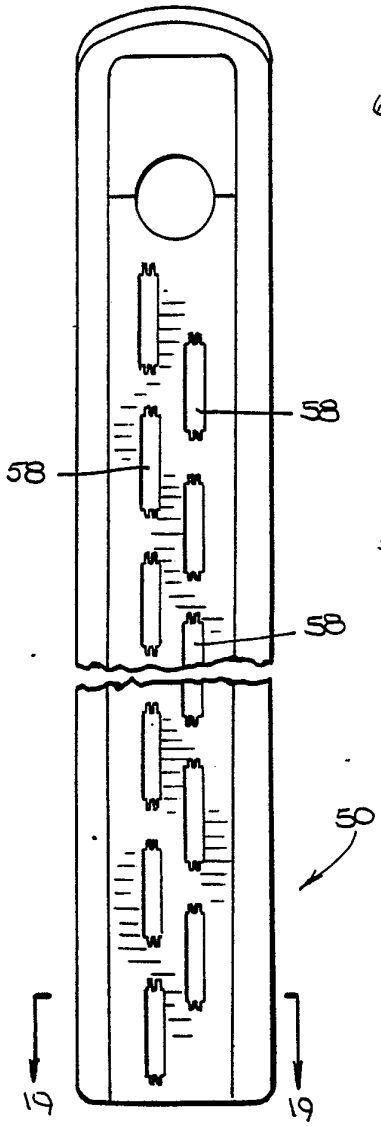


Fig.17.



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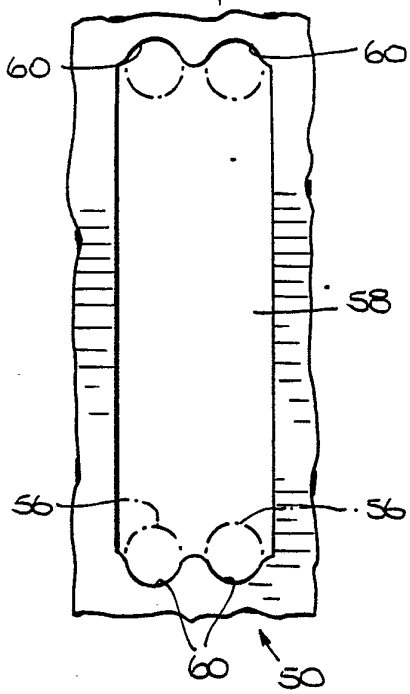

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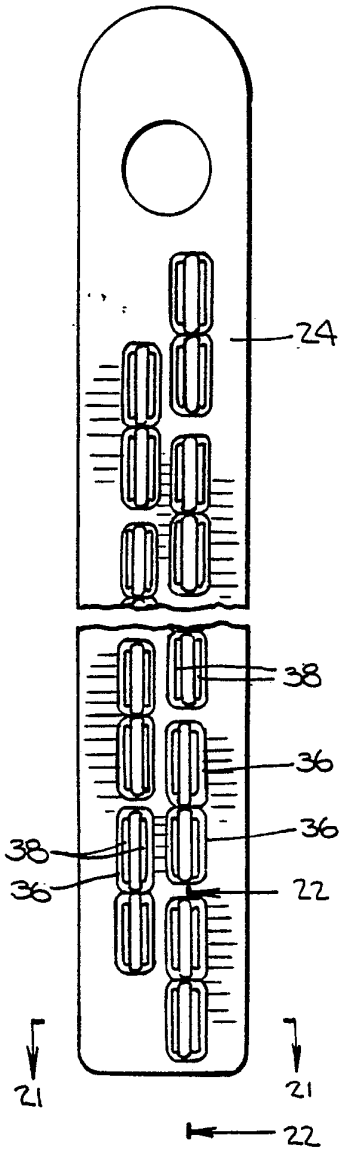

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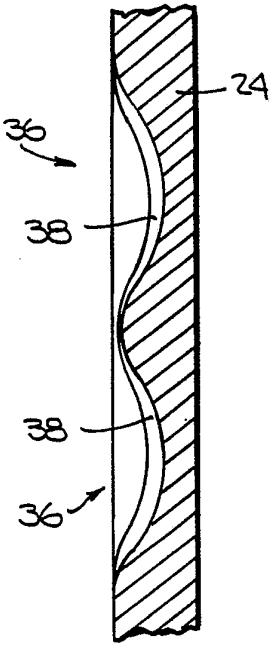

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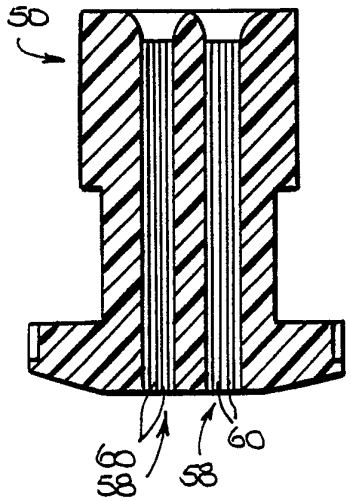

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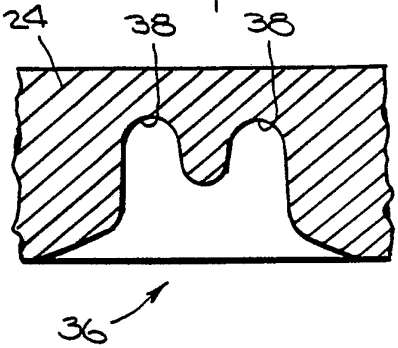
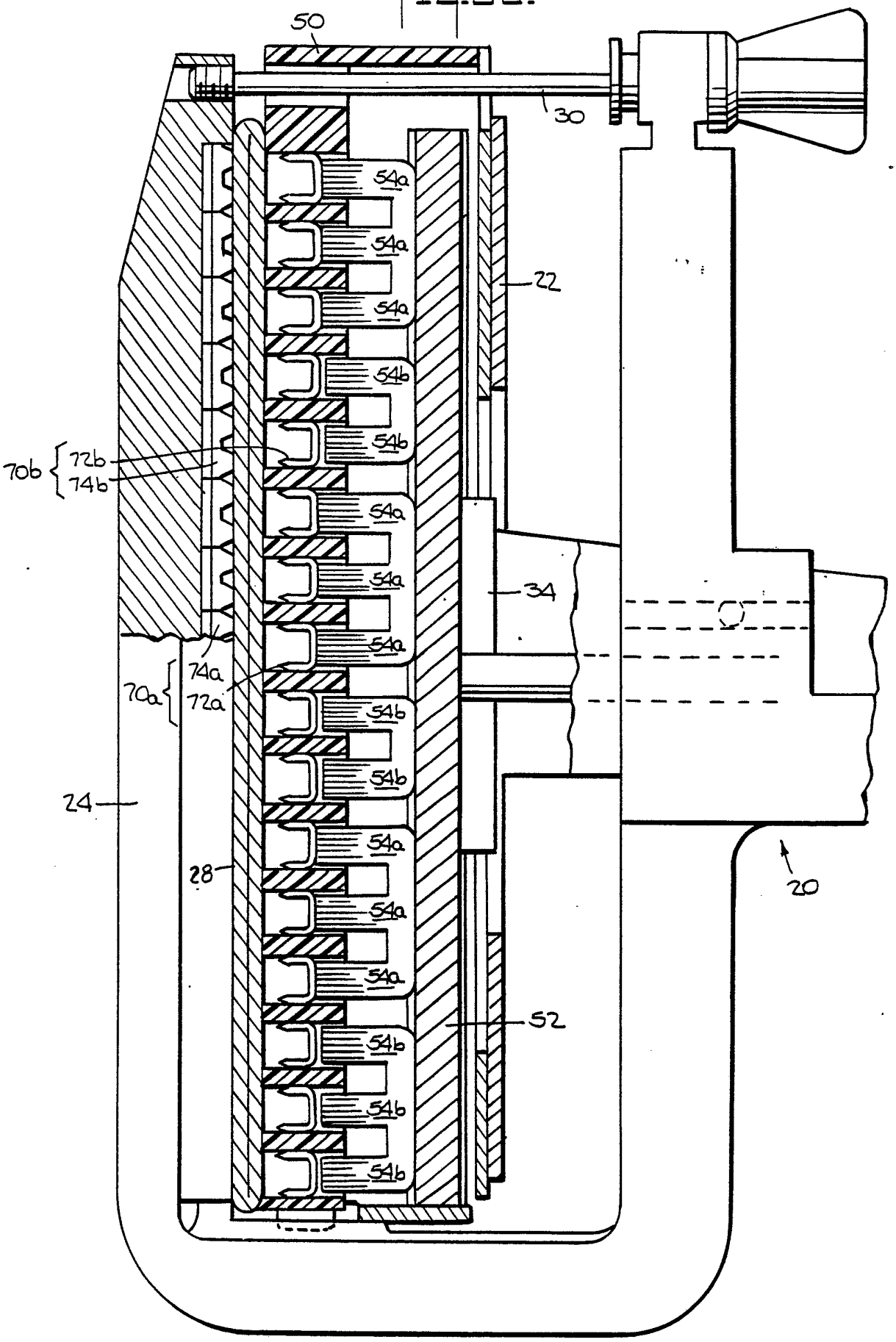


Fig.2B.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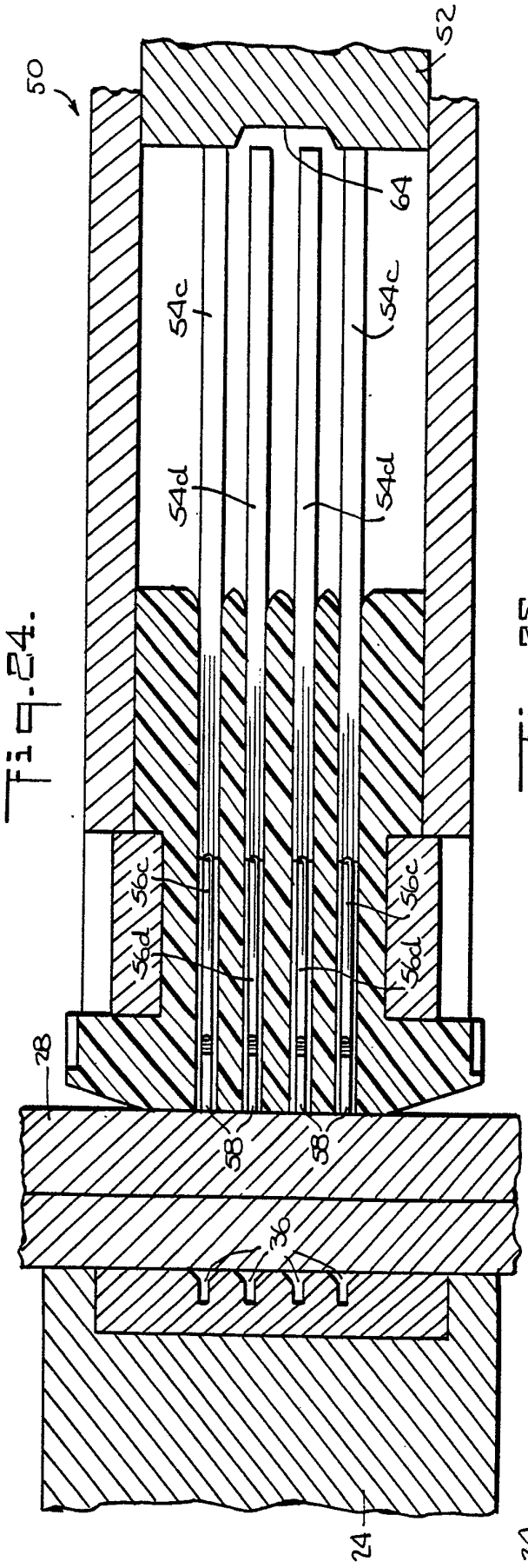
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Fig. 24.

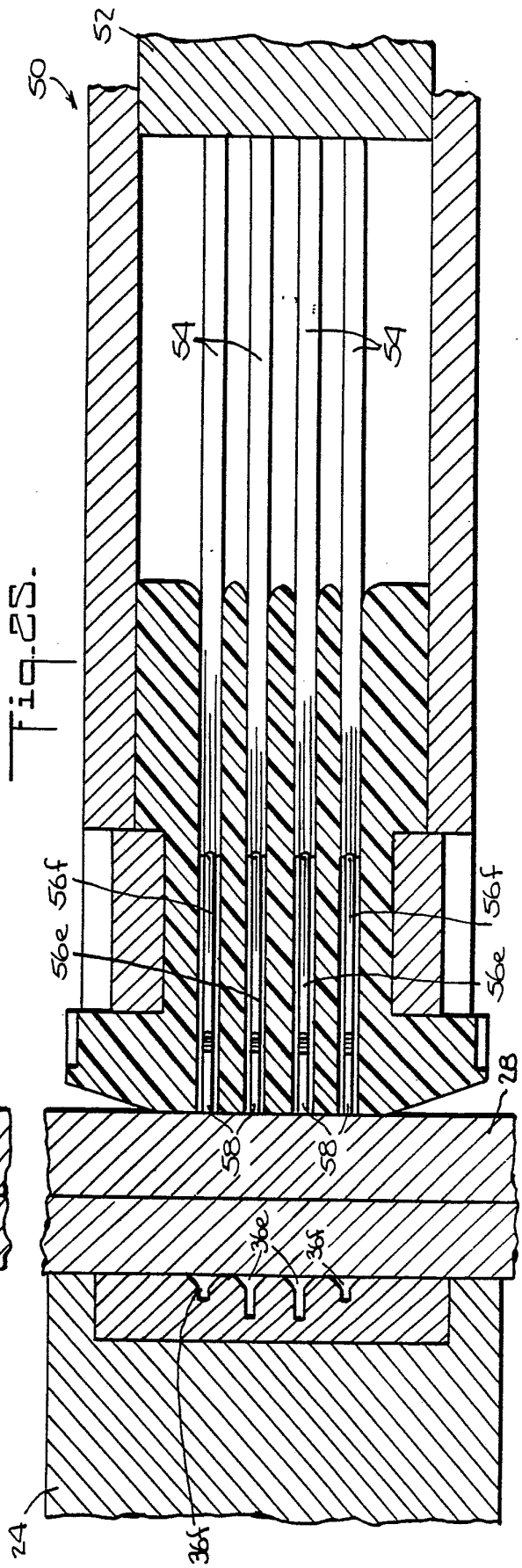
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Fig. 25.

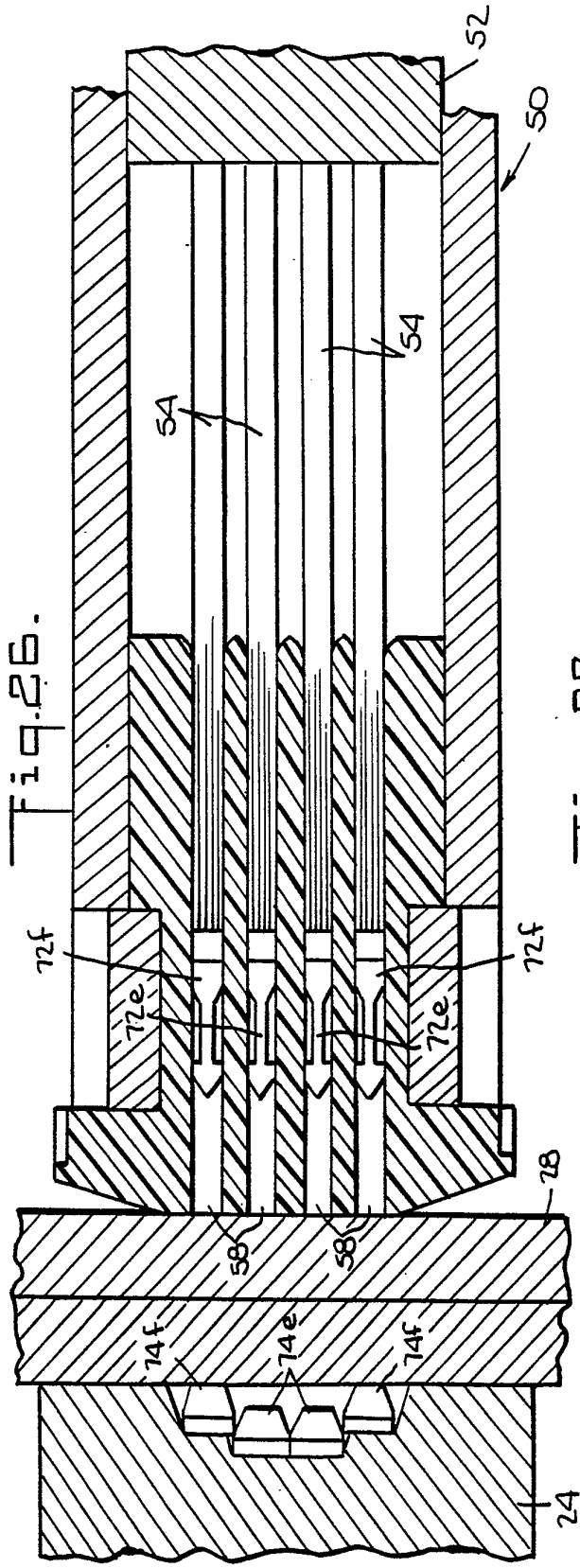
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Fig.26.

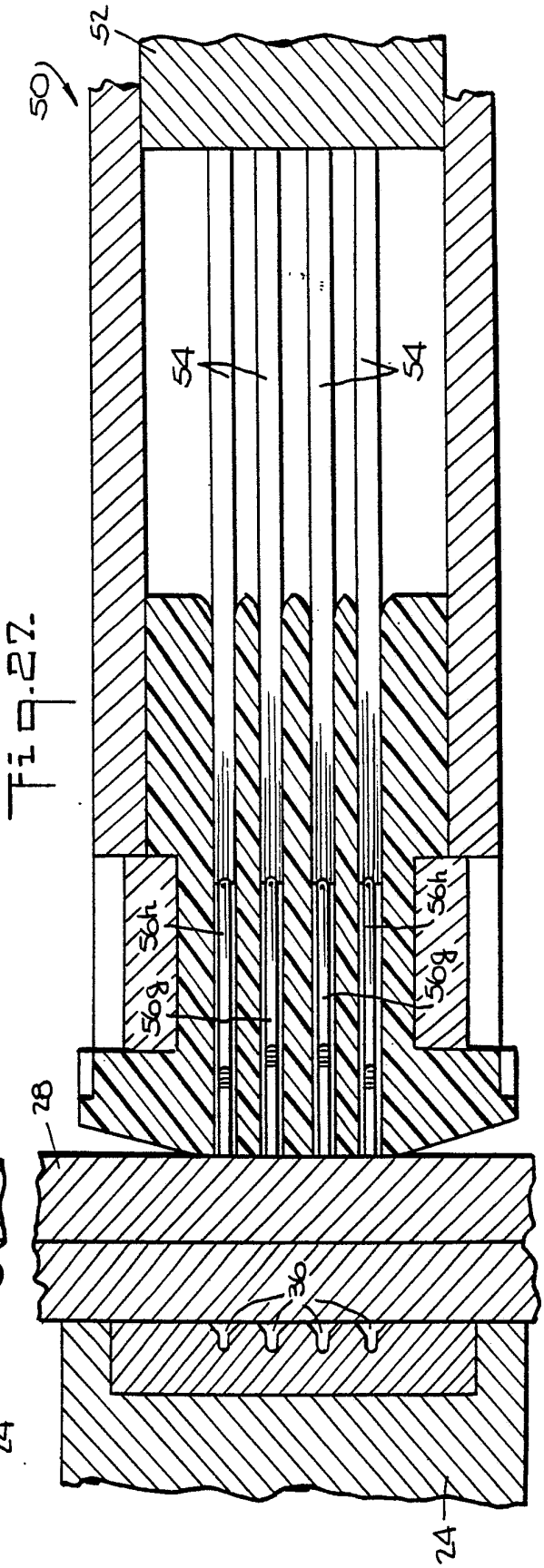
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Fig.27.

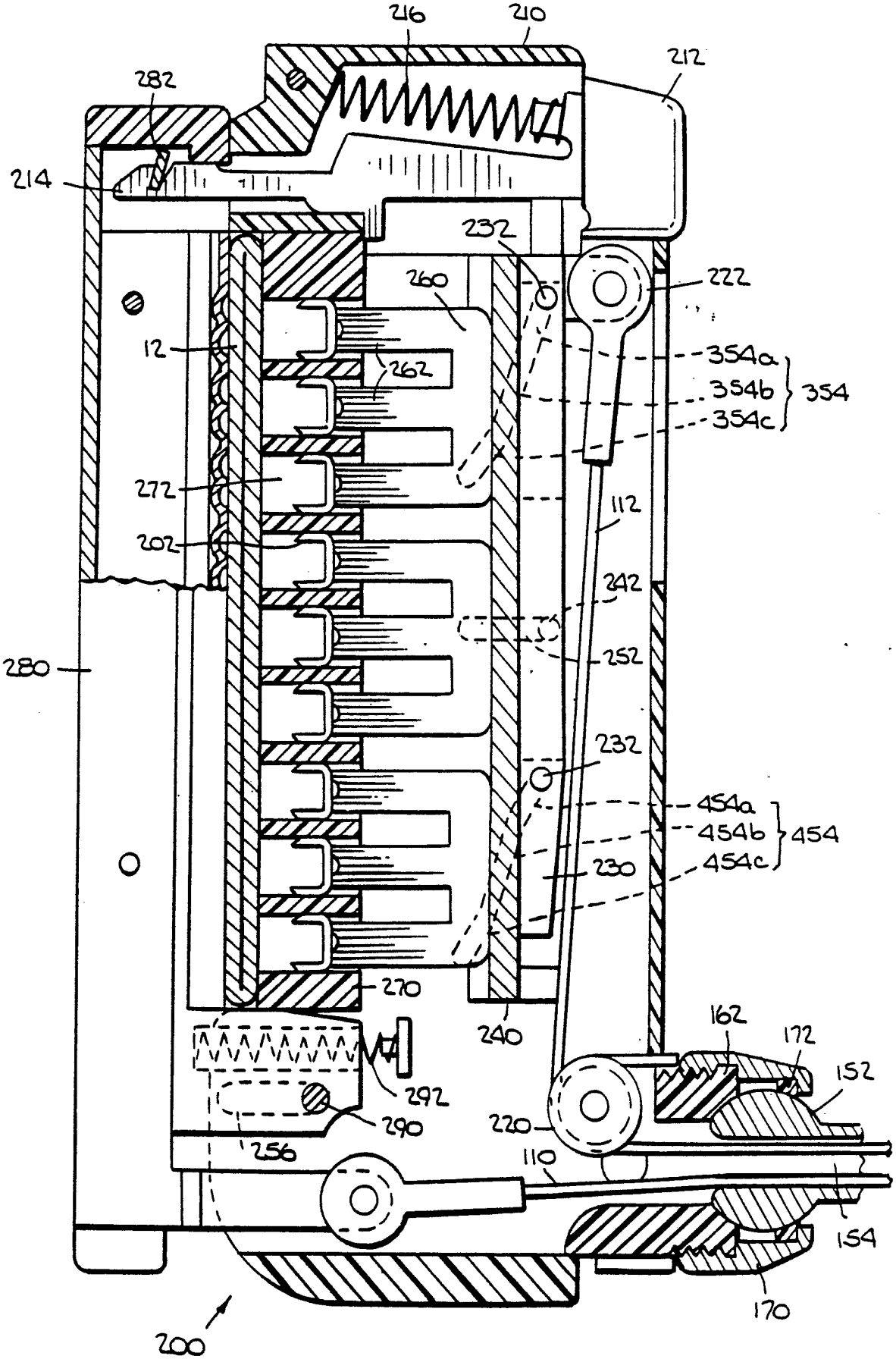
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Fig. 2B.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US85/01982

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.[4] A 61 B 17/00
US CL. 227/19

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	227/ 19/ 83 / Dig 1 128/ 334R

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	U.S. A 4,289,133 Published 15 September 1981 Rothfuss	1 , 2
X	U.S. A 3,458,099 Published 29 July 1969 Schick	8 - 10
X	U.S. A 3,822,818 Published 09 July 1974 Strekopytov et al.	6
A	U.S. A 4,241,861 Published 30 December 1980 Fleischer	1 - 7
A	U.S. A 4,475,679 Published 09 October 1984 Floury, Jr.	1 - 7
A, P	U.S. A 4,530,453 Published 23 July 1985 Green	1 - 7

* Special categories of cited documents: [15]

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular 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

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
23 December 1985	03 JAN 1986
International Searching Authority [1]	Signature of Authorized Officer [20]
ISA/US	PAUL A. BELL PRIMARY EXAMINER