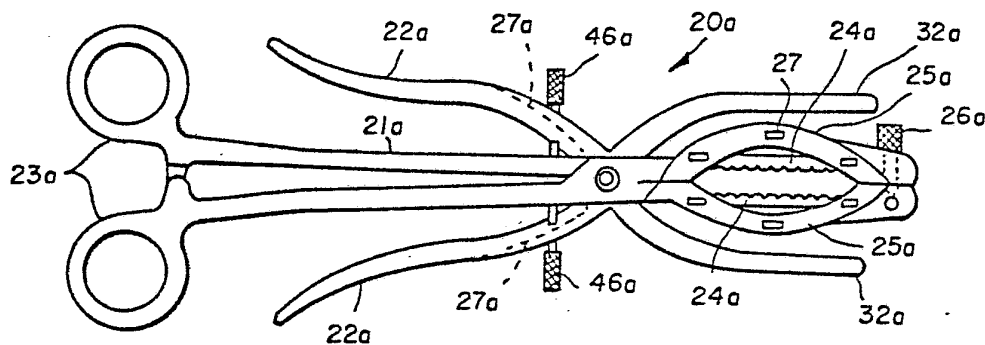


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(54) Title: SURGICAL CUTTER STAPLER



(57) Abstract

A surgical stapler accomplishes end-to-end anastomoses of tubular tissue by clamping and everting the tissue ends respectively in a pair of clamp actuators (20a) and (20b) that are interconnected to bring the everted tissue ends into juxtaposed registry. A four part disposable staple cartridge (30) formed as two mating pairs of elements includes staples (35) and staple folding pads (36) formed in curves that fit around the everted ends of the tissue. Each part of clamp actuators (20) has double jaws (24 and 25) that respectively clamp the tissue and hold the staple cartridge elements (30). Pins (40) on the cartridge elements hold the everted ends of the tissue, and curved knives (34) arranged between the pins and the staple array trim away excess tissue. Actuator wedges (37) disposed in the staple holding elements are moved by actuator pliers (22) to drive the staples and knives to secure the staple array in place and trim off the tissue around the staple array.

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SURGICAL CUTTER STAPLER

BACKGROUND OF THE INVENTION

My invention improves on surgical staplers for end-to-end anastomoses of tubular tissue such as bowel, bile duct, and vascular arteries and veins. It accomplishes an end-to-end, rather than a side-to-side, anastomosis; 5 and it uses several features that shorten the time and reduce the trauma of tubular tissue anastomosis while improving the accuracy and reliability of the tissue stapling. My stapler can accommodate different sized tissue, can operate in cramped quarters, and generally 10 simplifies and reduces the cost of stapling anastomoses.

SUMMARY OF THE INVENTION

My surgical stapler is for end-to-end anastomoses of tubular tissue; and it includes a two part clamp actuator that grips the tissue, holds its ends in everted 15 orientation, and brings the everted ends into juxtaposed registry as the clamp actuator parts are interconnected. My stapler uses a four part disposable staple cartridge formed as two mating pairs of elements that include staple holders and staple folding pads formed in curves that 20 fit around the everted ends of the tissue. Each part of the clamp actuator has one pair of jaws for clamping the tissue and another pair of jaws for holding mating pairs of elements of the staple cartridge. Each part of the staple cartridge has pins for holding the everted 25 tissue, and a pair of curved knives are arranged in staple holding elements of the staple cartridge to be positioned radially inward from the tissue holding pins and radially outward from the array of staples and are shaped to encircle the staple array. Actuator wedges are movably disposed 30 in the staple holding elements of the staple cartridge, and actuator pliers on the part of the clamp actuator

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that holds the staple holding elements are arranged to engage and operate the wedges to drive the staples and knives to secure the staple array in place and trim off the tissue around the staple array.

5 DRAWINGS

Figures 1-9 show one preferred embodiment of my stapler including a two part clamp actuator with actuator pliers on each part for driving staples through from both sides of the intended anastomosis;

10 Figure 1 is a side elevational view of one part of a clamp actuator;

Figure 2 is a plan view of the clamp actuator part of FIG. 1;

15 Figure 3 is a side elevational view of the clamp actuator of FIG. 1 loaded with disposable staple cartridge elements;

Figure 4 is a side elevational view of the other part of a clamp actuator loaded with the other mating pairs of elements of a disposable staple cartridge;

20 Figure 5 is a plan view of both clamp actuators interconnected to accomplish an anastomosis;

Figure 6 is a side elevational view of a preferred embodiment of an element of a staple cartridge used in the embodiment of FIGS. 1-9;

25 Figure 7 is a rear elevational view of the cartridge element of FIG. 6;

Figure 8 is a partially cross sectioned end elevational view of the cartridge element of FIG. 6;

30 Figure 9 is a partially cross sectioned end elevational view of both clamp actuators loaded with cartridge elements and interconnected for operation;

Figures 10 and 11 are respective plan and side elevational views of an alternative plierless clamp actuator for use with a mating clamp actuator having actuator pliers such as shown in FIG. 4;

35 Figures 12-15 show an alternative embodiment of clamp actuators having an angle between handles and



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working jaws, with FIGS. 12 and 13 showing plan views of interconnectable parts of the clamp actuator and FIGS. 14 and 15 showing respective fragmentary elevational views of the jaws of the actuators of FIGS. 12 and 13 loaded with cartridge elements; and

Figure 16 is a partially schematic, elevational cross-sectional view of an end-to-end anastomosis made with my surgical stapler.

DETAILED DESCRIPTION

My tool uses two interconnectable parts that clamp end regions of tubular tissue, hold the tissue ends in everted orientation, and interconnect to position the everted ends in juxtaposed registry. Actuator pliers then drive staples through the everted tissue ends and operate curved knives that trim off tissue around the staple array.

The form of end-to-end anastomosis made with my stapler is shown in FIG. 16. Two lengths of tubular tissue 10 and 11 have their respective ends 12 and 13 everted and fastened by a double row of staples 15. The anastomosis is completed along a seam line 14 where the tissue scars together to join elements 10 and 11 in the position maintained by staples 15. The stapled tissue is shaped like a flange extending around tubes 10 and 11, and excess tissue radially outward from the outer row of staples 15 is neatly trimmed away.

My stapler uses a pair of clamp actuators that hold four parts of a disposable staple cartridge and fasten to the tissue to be anastomosed. The clamp actuators clamp to and hold the tissue ends in everted orientation and interconnect to position the everted ends for stapling. Actuator pliers then drive the staples through the tissue and against staple folding pads and simultaneously operate the trimming knives to cut away excess tissue. The embodiment of FIGS. 1-9 includes actuator pliers on each part of the clamp actuator and drives staples through the tissue



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from both sides of the anastomosis, and the alternative embodiments of FIGS. 10 and 11 and FIGS. 12-15 drive staples through tissue in one direction only with a single set of actuator pliers.

5 In the double actuator embodiment of FIGS. 1-9, clamp actuators 20a and 20b are respectively shown separately in FIGS. 1 and 4 and interconnected for operation in FIGS. 5 and 9. Each clamp actuator 20 includes both a double jawed tissue clamp and staple cartridge holder
10 21a and 21b and also actuator pliers 22a and 22b. The clamps 21 hold the tissue and the staple cartridge elements in proper positions for stapling, and the pliers 22 drive the staples through the tissue and against staple folding pads and also operate the trimming knives.

15 Clamps 21 have conventional handles 23, a pair of tissue clamping jaws 24, and a pair of cartridge element holder jaws 25. An optional nose pin 26 accurately registers the noses of holder jaws 25 by extending through one jaw 25 and into a recess in the mating jaw 25.

20 Tissue clamping jaws 24a and 24b are disposed to clamp tubular tissue a short distance from the ends to be joined and also close off or occlude the lumen of the tissue. Holder jaws 25a and 25b have projections
25 27 positioned for fitting recesses 28 in staple cartridge elements that are mounted for operation on jaws 25. Closing clamps 21 both clamp the tissue to be joined with jaws 24 and also brings cartridge elements into a mating relationship surrounding the tissue end regions.

 Staple cartridge 30 is disposable after a single
30 use and has four parts formed as two mating pairs of elements 30a, a' and 30b, b' respectively held on jaws 25a and 25b for closing around tissue to be joined. Cartridge elements 30 are formed partly of molded plastic and partly of stainless steel and can be made in several
35 sizes that fit a single clamp actuator tool 20.

 In the embodiment of FIGS. 1-9, each staple cartridge element 30 includes a curved array of staples



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35 and a corresponding curved array of staple folding pads 36 so that staples can be driven through tissue from both sides. Cartridge elements 30a and a' have staples 35a on an inner curve and staple folding pads 36a on an outer curve, and cartridge elements 30b and b' have folding pads 36b on an inner curve for folding staples 35a from cartridge elements 30a and a' and also have a curved array of staples 35b on an outer curve to be folded by the pads 36a of cartridge elements 30a and a'.

Curved trimming knives 34b and b' are arranged in cartridge elements 30b and b' to extend around the curved array of staples 35b. Knives 34b push against knife pads 34a and a' in a corresponding curve around the outer ring of staple folding pads 36a of cartridge elements 30a and a'. As knives 34b and b' press against pads 34a and a', they trim off the tissue cleanly and neatly around the staple array.

Staples 35a and 35b and knives 34b are driven by wedges 37 that are movably trapped in each staple cartridge 30. A staple and knife pusher element 38 as best shown in FIG. 8 is movable laterally within each cartridge element 30 and engages staples and knives. A ramp 39 guides wedge 37 to move laterally against pusher 38 as wedge 37 is pressed radially inward toward the clamped tissue. Wedge 37 thus drives pusher 38 to press staples 35 into position and push knives 34 to trim away excess tissue.

Each staple element 30 has radial pins 40 spaced around the staple array for holding the everted ends of the clamped tissue. The surgeon pulls the tissue ends radially outward and hooks them over pins 40 to evert the tissue ends for stapling.

When clamp actuators 20 are secured to the tissue and the tissue ends are everted and held on pins 40, the clamp actuators 20 are interconnected as shown in FIG. 5 to bring the everted ends of the tissue into juxtaposed

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registry with staple cartridge elements 30 properly positioned for stapling. This is done by fitting pins 41 and 42 on clamp actuator 20a into holes 43 and 44 through clamp actuator 20b and securing the clamp actuators 5 20a and 20b together with wing nuts 45 threaded on the ends of pins 41 and 42. Locator pin 26b can be screwed against pin 42 to help accomplish the interconnection of clamp actuators 20 as shown in FIG. 5.

Wedges 37 that operate staple cartridge 30 are 10 in turn operated by actuator pliers 22, which have jaws 32 disposed to engage wedges 37. With clamp actuators 20 interconnected as shown in FIG. 5 to hold tissue in proper position, the surgeon squeezes pliers 22a and 22b to close jaws 32a and 32b and drive wedges 37 radially 15 inward. This forces pushers 38 laterally to drive staples 35 and knives 34 as previously explained. The result is a double row of staples passing through the anastomosis from both sides and folded securely in position, with the excess tissue neatly trimmed around the outer staple 20 row. The excess tissue that is trimmed away remains on pins 40; and when the surgeon loosens and removes clamp actuators 20, the anastomosis is complete.

Clamp actuators 20 are preferably formed of stainless steel and are relatively simple and partially 25 conventional so they can be cleaned conveniently. Cartridge elements 30 are discarded after a single use to achieve several advantages. Cartridge elements 30 have tiny openings and would be difficult to clean; they are also relatively small and can be made at low cost from 30 molded plastic. Staple folding pads 36 operate only once and do not become worn, and knives 34 need not be resharpened.

Cartridge elements 30 can be made in several sizes to fit a single set of clamp actuators 20. This 35 is done conveniently by changing the curvature of the staple array and knives from circular to oval along the



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axis of jaws 25. This maintains a constant relationship between wedges 37 and plier jaws 32 for uniform actuation, with a circular shaped cartridge 30 fitting a small sized tissue tube and increasingly elongated oval shapes fitting successively larger tissue tubes. Different sized cartridges 30 can all have appropriate recesses 28 to mate with projections 27 on jaws 25.

Safety locks 46a and 46b immobilize the handles of actuator pliers 22a and 22b to prevent any premature movement of staples or knives as the tools are manipulated before stapling. Locks 46 rotate clear of plier handles to allow stapling. Springs 47 trapped within the plier handles hold pliers 22 in the open position and return the pliers to this position after stapling.

The embodiment of FIGS. 10 and 11 differs from the embodiment of FIGS. 1-9 in driving all the staples through from one side of the anastomosis against staple folding pads located on the opposite side and using only a single pair of actuator pliers 22. This allows a double jawed clamp 50 such as shown in FIGS. 10 and 11 to cooperate with a clamp actuator such as shown in FIG. 4 provided with different staple cartridge elements that dispose all the staples on one part of the tool for operation by a single pair of pliers 22 to drive the staples through the tissue and against staple folding pads 36 formed on the cartridge elements 30 held on clamp 50. Otherwise, the embodiment of FIGS. 10 and 11 operates as previously described.

The embodiment of FIGS. 12-15 is similar to the embodiment of FIGS. 10 and 11 in using only a single pair of actuator pliers 22 and driving all the staples from cartridge elements 30a and a' through the tissue from the same side and against staple folding pads 36 on cartridge elements 30b and b'. The difference in the embodiment of FIGS. 12-15 is the angle between the jaws and the handles allowing the stapler to reach into confined places such as required for resection of the low interior

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of the rectum. Staplers with jaws that are angled relative to their handles may also be more convenient for other uses.



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I claim:

1. A surgical stapler for end-to-end anastomosis of tubular tissue, said stapler including a clamp actuator having two interconnectable parts for clamping end regions of said tissue in everted orientation, bringing said everted ends of said tissue into juxtaposed registry as said clamp actuator parts are interconnected, and means for securing an array of staples through said everted ends, said stapler comprising:
 - a. a four part disposable staple cartridge formed as two mating pairs of elements that include staple holders and staple folding pads formed in curves that fit around said everted ends of said tissue;
 - b. each part of said clamp actuator having double jaws;
 - c. one of said jaws being a clamp for said tubular tissue;
 - d. another of said jaws being a holder for one of said mating pairs of elements;
 - e. each part of said staple cartridge having pins for holding said everted tissue;
 - f. a pair of curved knives arranged in said staple holding elements of said staple cartridge;
 - g. said knives being positioned radially inward from said tissue holding pins and radially outward from said array of staples and being shaped to encircle said staple array;
 - h. actuator wedges disposed in said staple holding elements of said staple cartridge;
 - i. actuator pliers on the part of said clamp actuator that holds said staple holding elements; and
 - j. said pliers being arranged to engage and operate said actuator wedges to drive said staples and said knives to secure said staple array in place and trim off said tissue around said staple array.

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2. The stapler of claim 1 wherein said actuator pliers and said double jawed clamp are arranged on a common pivot.

3. The stapler of claim 1 wherein said actuator
5 pliers are arranged on each part of said clamp actuator, and said staple holding elements are held on each part of said clamp actuator for driving said staples through said everted tissue from each direction.

4. The stapler of claim 1 including a nose pin and
10 recess for registering a nose region of said jaws as said clamp actuator closes.

5. The stapler of claim 1 including pins and recesses for holding said parts of said staple cartridge in said holder jaws.

6. The stapler of claim 1 including safety lock means for preventing unintentional operation of said actuator pliers.

7. The stapler of claim 1 including means for trapping said actuator wedges movably within said staple
20 holding elements of said staple cartridges.

8. The stapler of claim 1 wherein said staple holding elements of said staple cartridge include staple and knife pushers operated by said actuator wedges.

9. The stapler of claim 8 including means for trapping
25 said actuator wedges movably within said staple holding elements of said staple cartridges.

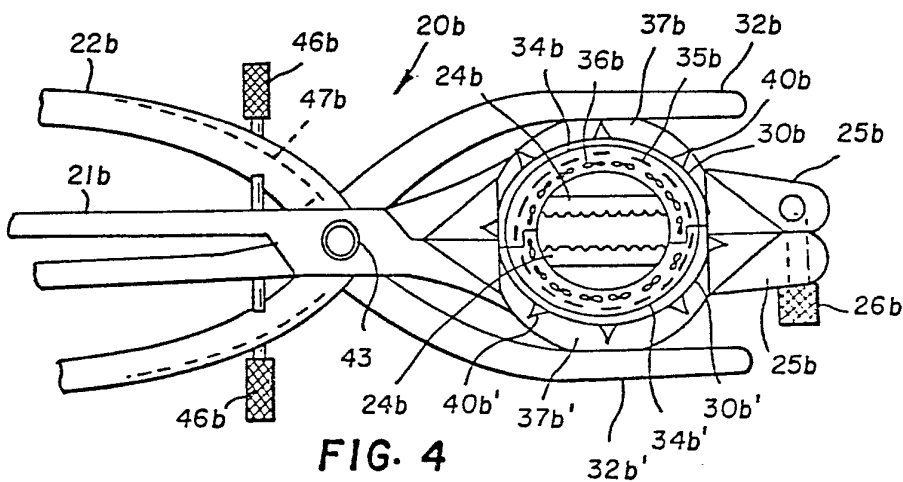
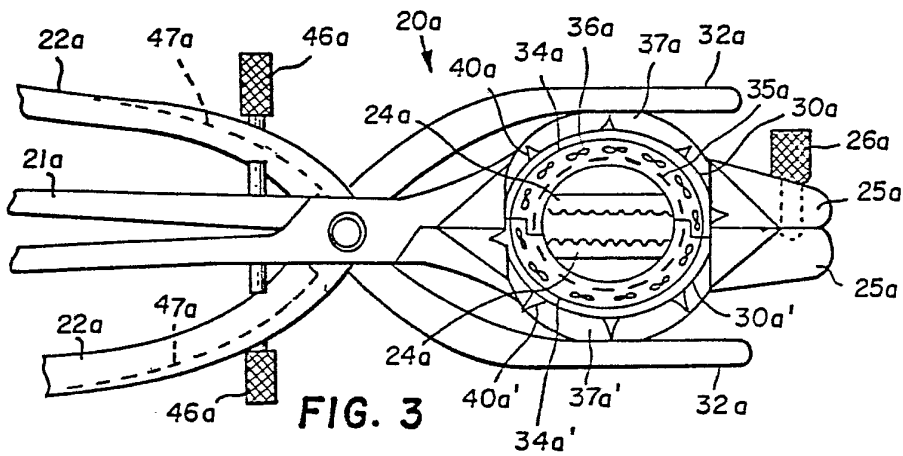
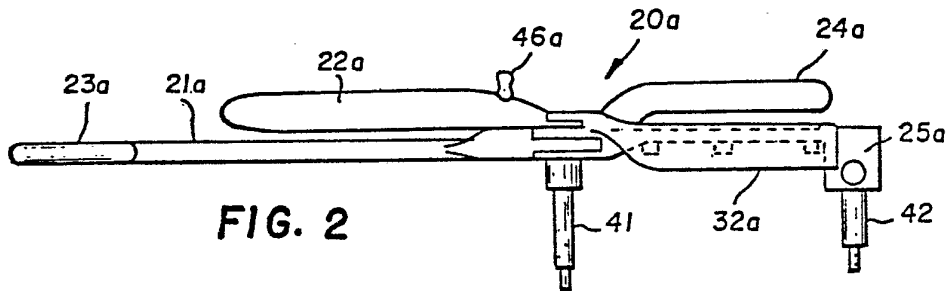
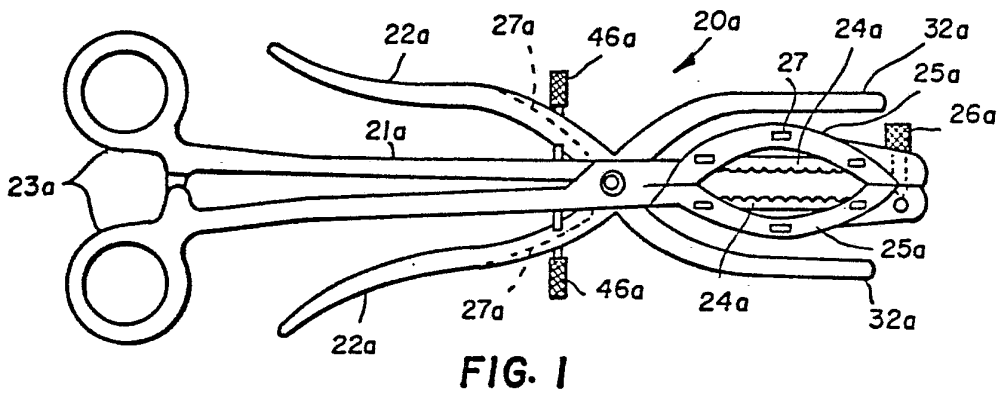
10. A four part disposable staple cartridge for a surgical stapler for end-to-end anastomosis of tubular tissue, said staple cartridge comprising:

- 30
- a. two pairs of elements that mate to form closed curves;
 - b. each of said elements having pins for holding everted tissue surrounded by said mated elements;
 - c. at least two of said elements holding staples
35 arranged in a closed curve array;
 - d. a pair of curved knives arranged in said staple holding elements;

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- e. said knives being positioned radially outward of said staple array and radially inward from said tissue holding pins; and
- f. actuator wedges disposed movably in each of said staple holding elements to drive said staples and said knives to secure said staple array in place and trim off said tissue around said staple array.
11. The staple cartridge of claim 10 wherein said staple holding elements of said staple cartridge include staple and knife pushers operated by said actuator wedges.
12. The staple cartridge of claim 11 including means for trapping said actuator wedges movably within said staple holding elements of said staple cartridges.
13. The staple cartridge of claim 10 wherein said elements have location recesses for positioning said elements correctly in an actuator tool.





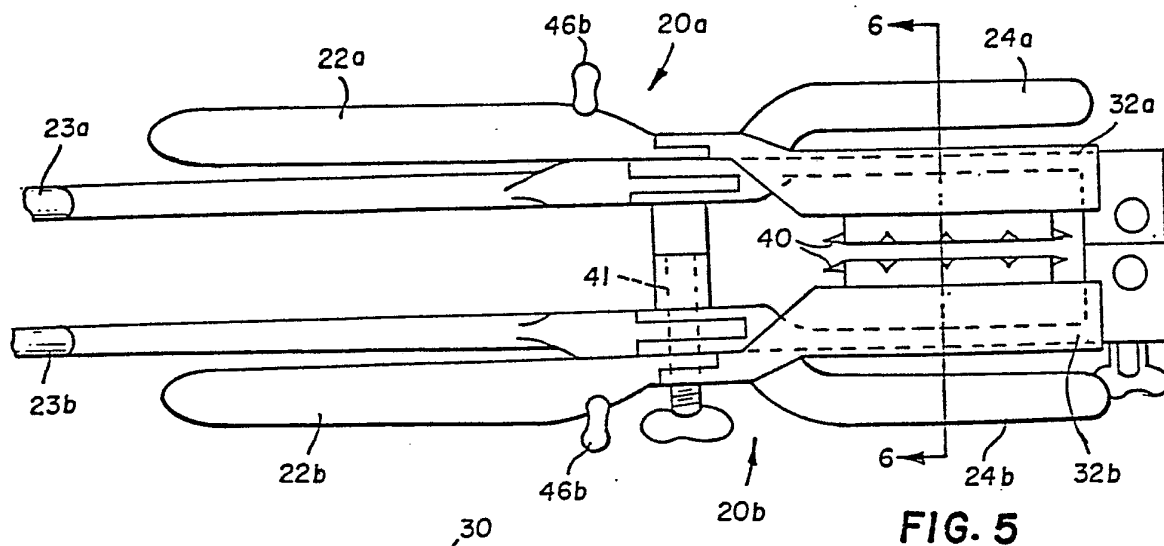


FIG. 5

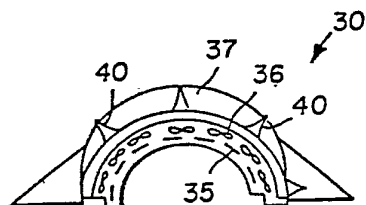


FIG. 6

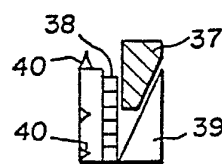


FIG. 8

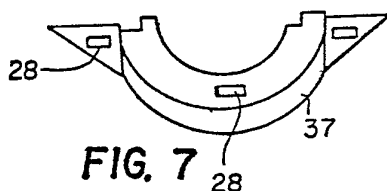


FIG. 7

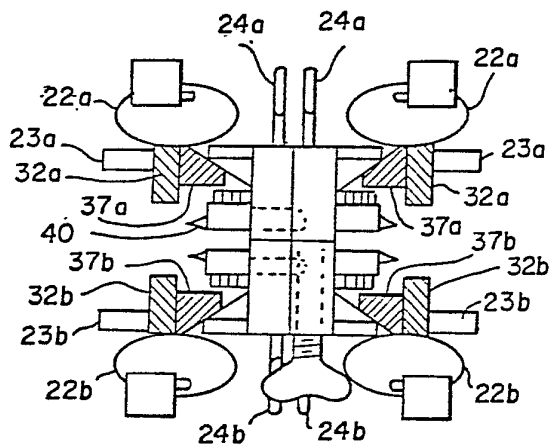


FIG. 9

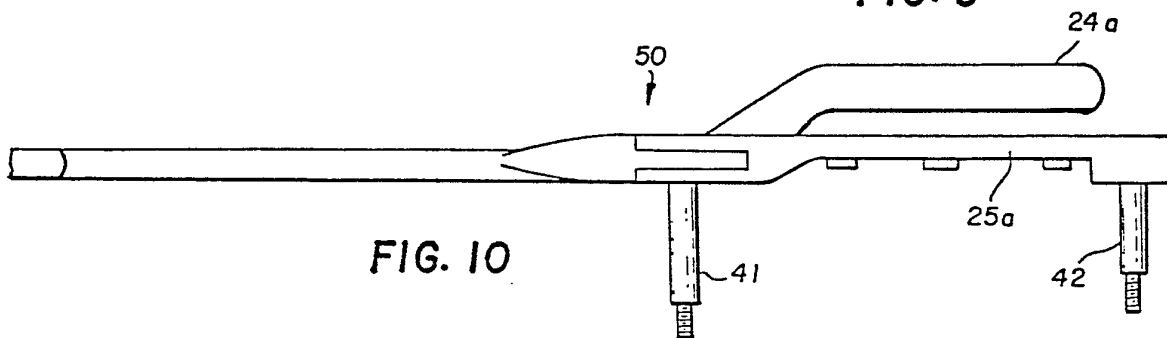


FIG. 10

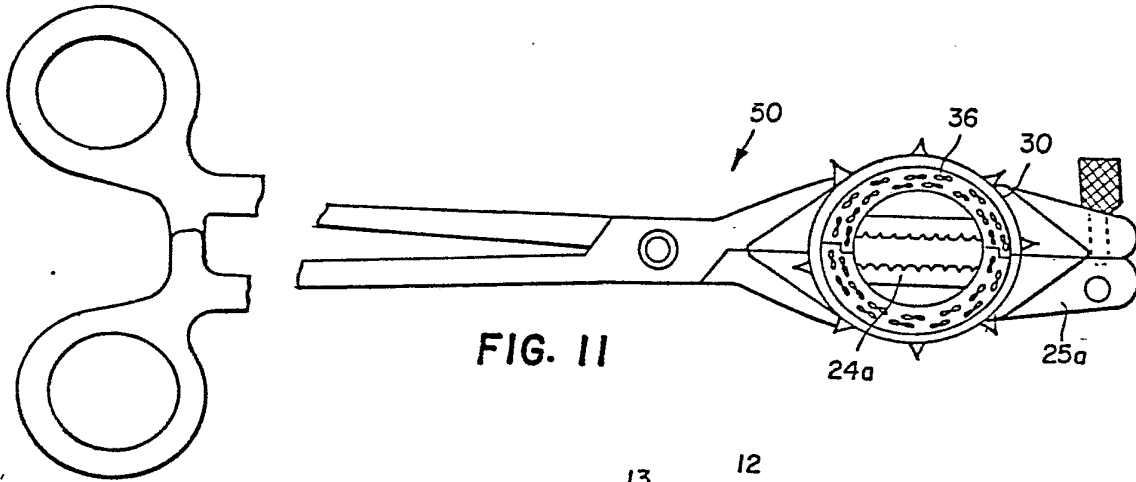


FIG. 11

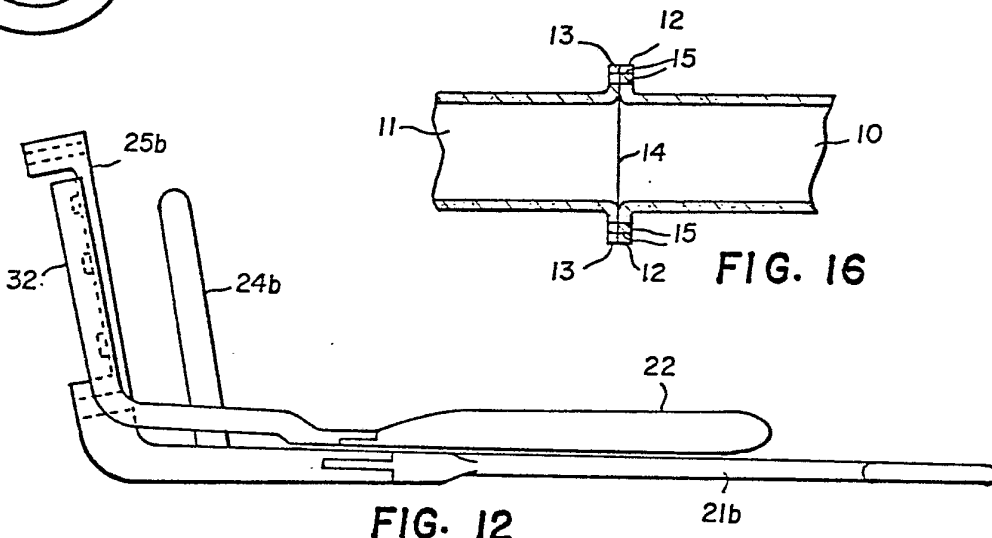


FIG. 12

FIG. 16

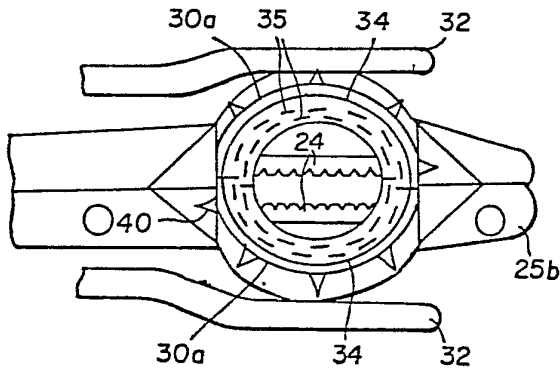


FIG. 14

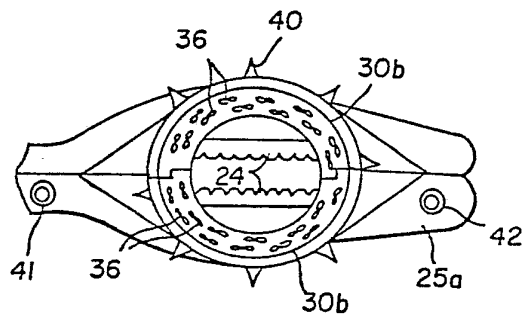


FIG. 15

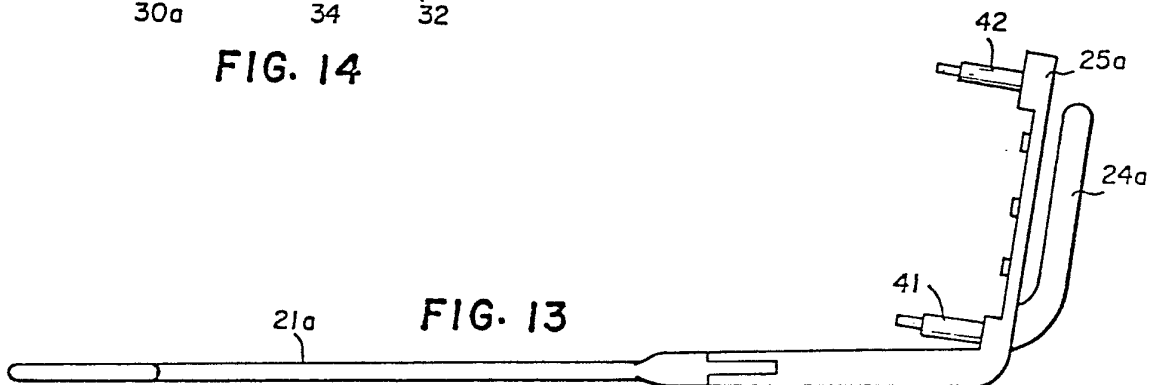


FIG. 13



INTERNATIONAL SEARCH REPORT

International Application No PCT/US81/00054

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
INT. CL. ³ A61F 17/32		
U.S. CL. 128/305		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
US	128/305, 325, 334R; 227/Dig.1, 19, 135, 144 ; 29/816	
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
P	US, A, 3,144,654 Published 18 August 1964, Mallina et al.	1-13
	US, A, 3,176,896, Published 06 April 1965, Mallina	1-13
	US, A, 3,388,847, Published 18 June 1968, Kasulin et al.	1-13
	US, A, 3,638,652, Published 01 February 1972, Kelley	1-13
	US, A, 4,242,902, Published 06 January 1981, Green	1-13
	US, A, 3,552,626, Published 05 January 1971, Astafier	1-13
	US, A, 2,965,900, Published 27 December 1960, Inokovchi	1-13
	US, A, 2,940,451, Published 14 June 1960, Vogelfanger et al.	1-13
	US, A, 3,606,888, Published 21 September 1971, Wilkinson	1-13
	US, A, 3,973,709, Published 10 August 1976, Akopov et al.	3
<p>* Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document cited for special reason other than those referred to in the other categories</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 on or after the priority date claimed</p> <p>"T" later document published on or 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</p>		
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