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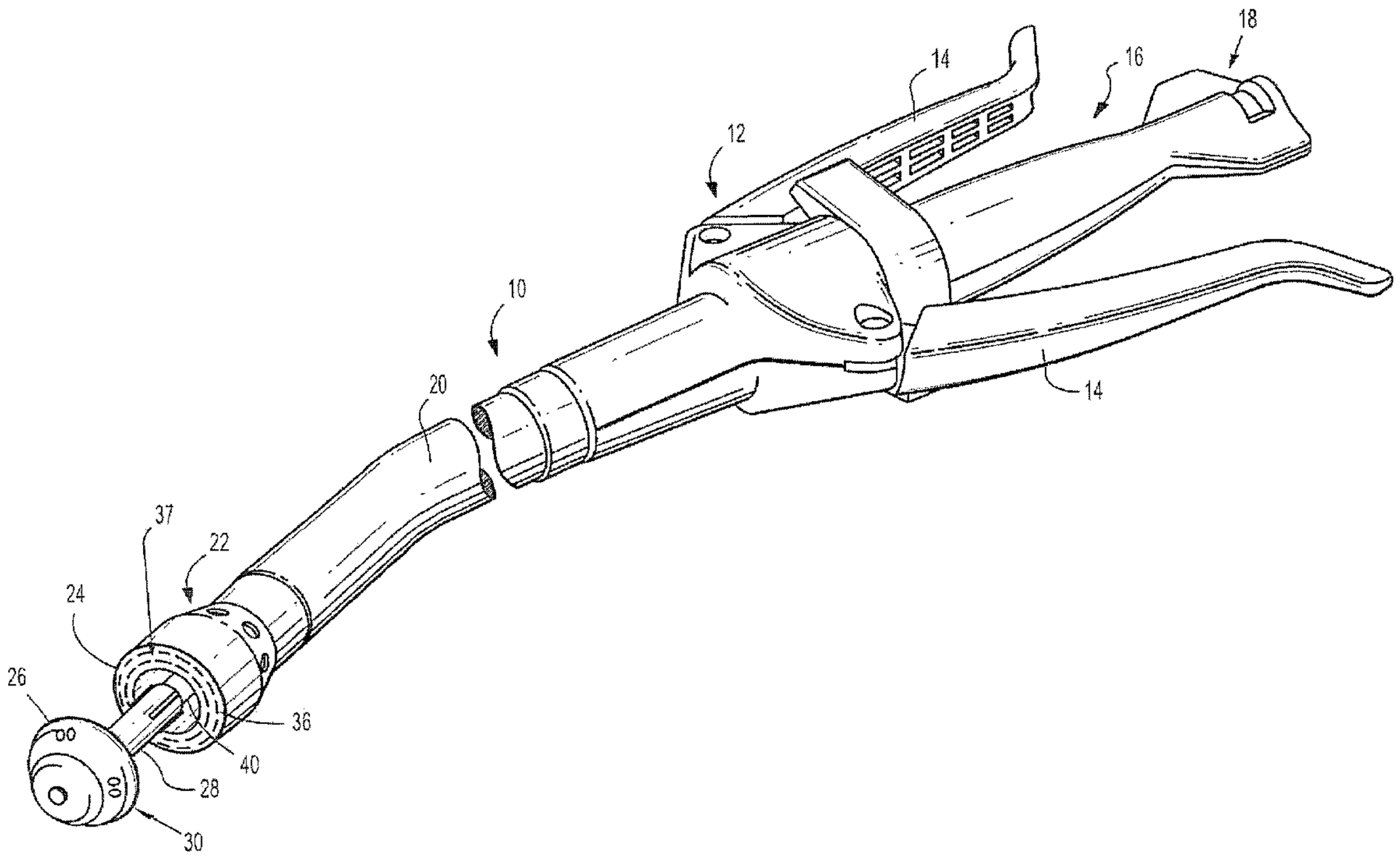
(72) **Inventeurs/Inventors:**
HODGKINSON, GERALD N., US;
CARTER, SALLY L., US

(73) **Propriétaire/Owner:**
TYCO HEALTHCARE GROUP LP, US

(74) **Agent:** OSLER, HOSKIN & HARCOURT LLP

(54) **Titre : FIXATION DE RENFORT POUR INSTRUMENT CHIRURGICAL**
(54) **Title: SURGICAL INSTRUMENT BUTTRESS ATTACHMENT**



(57) **Abrégé/Abstract:**
A surgical stapler instrument has surgical stapler jaws, at least one staple line reinforcement material, and a fastener including a hook and a loop. The hook can be disposed on one of the surgical stapler jaws and the loop can be disposed on the staple line reinforcement material. Alternatively, the hook can be disposed on the staple line reinforcement material and the look on one of the surgical stapler jaws.

Abstract

A surgical stapler instrument has surgical stapler jaws, at least one staple line reinforcement material, and a fastener including a hook and a loop. The hook can be disposed on one of the surgical stapler jaws and the loop can be disposed on the staple line reinforcement material. Alternatively, the hook can be disposed on the staple line reinforcement material and the look on one of the surgical stapler jaws.

SURGICAL INSTRUMENT BUTTRESS ATTACHMENT

Technical Field

The present disclosure relates to a buttress attachment for a surgical instrument, such as a surgical stapler. More particularly, the buttress is attached to one or more of the working surfaces of the surgical instrument utilizing a fastener.

Background

Buttresses for surgical instruments are known. Buttresses and/or staple line reinforcement materials include bioabsorbable, non-absorbable, synthetic and animal derived materials. Such buttress and/or staple line reinforcement materials are utilized to reduce the incidence of leaks and bleeding in a variety of surgical procedures. The use of staple line reinforcement material can reduce or eliminate suturing or clipping over staple lines and reduce the time for the surgical procedure.

Staple line reinforcement materials have been used with linear surgical staplers. The material can be provided in a tubular shape and slipped onto the surgical stapler jaw. In another approach, the staple line reinforcement material is attached to the working surface of the stapler utilizing pins. See U.S. Patent No. 6,045,560 to McKean et al., and U.S. Patent No. 5,503,638 et al.

Buttress and/or staple line reinforcement materials have also been used with circular staplers. The staple line reinforcement material is attached to the working surface of the circular stapler utilizing protrusions at the perimeter of the staple line reinforcement material, the protrusions having adhesive for attaching the staple line reinforcement material to the working surfaces of the circular surgical stapler. After tissue sections are stapled together, the buttress

material is attached to the tissue by the staples, with the tissue sandwiched between the staple line reinforcement material. In another approach, the staple line reinforcement material is attached to the shaft of the circular stapler. See Bauman et al., U.S. Patent No. 7,547,312, U.S. Patent No. 7,823,592, WO 03/082126, and WO 03/105698.

One drawback to some of these approaches is that the knife of a surgical stapler instrument is relied upon to cut the staple line reinforcement material so that the instrument can be removed and the staple line reinforcement material remains with the staple line.

Drawbacks to some of these approaches include excess material that must be removed when the surgical instrument is withdrawn, as well as unreliable detachment of the staple line reinforcement material from the surgical instrument.

There is a desire for improved methods of attaching staple line reinforcement material to surgical instruments so that the instrument is packaged with the staple line reinforcement already installed, with a minimum of excess material, and a staple line reinforcement material that is reliably retained on the instrument while being detached from the instrument when the instrument is removed from the surgical site.

Summary

In an aspect of the present disclosure, a surgical stapling instrument, comprising a handle assembly, a body portion, surgical stapling jaws, a staple line reinforcement material, and a fastener are disclosed. The body portion extends from the handle assembly and the surgical stapling jaws include a staple cartridge assembly and an anvil assembly disposed at the distal end of the body portion. The fastener has two parts, the two parts including a hook and a loop. At least one of the surgical stapling jaws has one of the hook and the loop, and the staple line reinforcement material has the other of the hook and the loop.

The anvil assembly has staple forming recesses and the cartridge assembly has staple receiving slots. The anvil assembly and the cartridge assembly may be arranged to form a circular staple line. Alternatively, the anvil assembly and the cartridge assembly may be arranged to form a linear staple line. The staple line reinforcement material can be a non-woven, or the staple line reinforcement material can be a mesh, or other material.

In certain embodiments, the staple line reinforcement material has a plurality of pores. At least one of the surgical stapling jaws may have a plurality of hooks that are arranged to engage the plurality of pores.

In certain embodiments, the fastener includes a sheet having a plurality of hooks on a first side and an adhesive on a second side, the adhesive being attached to at least one of the surgical stapler jaws, and the staple line reinforcement material having a plurality of loops arranged to engage the plurality of hooks.

The anvil assembly and the cartridge assembly may be arranged to form a circular staple line and the instrument can further comprise a circular knife disposed inwardly of the circular staple line. The staple line reinforcement material can be circular in shape and have a central orifice.

In certain embodiments, the hook is disposed on at least one of the surgical stapler jaws and has a glass transition temperature at or near a human body temperature. The hook can be disposed on at least one of the surgical stapler jaws and have a glass transition temperature and the instrument can further comprise at least one thermistor for heating the hook to a temperature at or near the glass transition temperature.

In certain embodiments, the hook has a first base end and a second free end, a diameter of the first base end being greater than a diameter of the second free end so that the second free end is relatively flexible.

The staple line reinforcement material may have a plurality of fibers, at least one of the surgical stapler jaws having the hook, and the hook being arranged to engage one or more of the plurality of fibers.

In another aspect of the present disclosure, a surgical stapling instrument comprises a handle assembly, a body portion extending from the handle assembly, surgical stapling jaws including a staple cartridge assembly and an anvil assembly disposed at the distal end of the body portion. The staple cartridge assembly has a first tissue contacting surface and the anvil assembly having a second tissue contacting surface. A plurality of hooks is attached to at least one of the first tissue contacting surface and the second tissue contacting surface. A staple line reinforcement material is in engagement with at least some of the plurality of hooks.

The staple line reinforcement material may define a plurality of pores, the plurality of hooks being arranged to engage the staple line reinforcement material in the plurality of pores.

The staple line reinforcement material may be non-woven. Alternatively, the staple line reinforcement material is a mesh or other material.

In certain embodiments, the fastener includes a sheet having a plurality of hooks on a first side and an adhesive on a second side.

The anvil assembly has staple forming recesses and the cartridge assembly has staple receiving slots. The anvil assembly and the cartridge assembly may be arranged to form a circular staple line. Alternatively, the anvil assembly and the cartridge assembly may be arranged to form a linear staple line.

The anvil assembly and the cartridge assembly may be arranged to form a circular staple line and the instrument can further comprise a circular knife disposed inwardly of the circular staple line. The staple line reinforcement material can be circular in shape and have a central orifice.

In certain embodiments, the hooks have has a glass transition temperature at or near a human body temperature. The hooks can be disposed on at least one of the surgical stapler jaws and have a glass transition temperature and the instrument can further comprise at least one thermistor for heating the hooks to a temperature at or near the glass transition temperature.

In certain embodiments, the hooks have a first base end and a second free end, a diameter of the first base end being greater than a diameter of the second free end so that the second free end is relatively flexible.

In a further aspect of the present disclosure, a surgical stapling instrument comprises a handle assembly, a body portion extending from the handle assembly, surgical stapling jaws including a staple cartridge assembly and an anvil assembly disposed at the distal end of the body portion. The staple cartridge assembly has a first tissue contacting surface and the anvil assembly having a second tissue contacting surface. At least one of the first tissue contacting surface and the second tissue contacting surface has a plurality of hooks. A staple line reinforcement material is in engagement with at least some of the plurality of hooks.

The staple line reinforcement material may include a plurality of fibers, the plurality of hooks being arranged to engage at least some of the plurality of fibers of the staple line reinforcement material. The staple line reinforcement material may be non-woven. Alternatively, the staple line reinforcement material is a mesh.

In certain embodiments, the instrument has a sheet having a plurality of hooks on a first side and an adhesive on a second side.

The anvil assembly has staple forming recesses and the cartridge assembly has staple receiving slots. The anvil assembly and the cartridge assembly may be arranged to form a circular staple line. Alternatively, the anvil assembly and the cartridge assembly may be arranged to form a linear staple line.

The anvil assembly and the cartridge assembly may be arranged to form a circular staple line and the instrument can further comprise a circular knife disposed inwardly of the circular staple line. The staple line reinforcement material can be circular in shape and have a central orifice.

In certain embodiments, the hooks have a glass transition temperature at or near a human body temperature. The hooks can be disposed on at least one of the surgical stapler jaws and have a glass transition temperature and the instrument can further comprise at least one thermistor for heating the hooks to a temperature at or near the glass transition temperature.

In certain embodiments, the hooks have a first base end and a second free end, a diameter of the first base end being greater than a diameter of the second free end so that the second free end is relatively flexible.

In a further aspect of the present disclosure, a surgical stapling instrument comprises a handle assembly, a body portion extending from the handle assembly, surgical stapling jaws including a staple cartridge assembly and an anvil assembly disposed at the distal end of the body portion. The staple cartridge assembly has a first tissue contacting surface and the anvil assembly having a second tissue contacting surface. The instrument includes a sheet having an adhesive at a first side of the sheet and at the second side of the sheet. At least one of the first

tissue contacting surface and the second tissue contacting surface has the first side of the sheet attached thereto so that the second side of the sheet is accessible for placement of a staple line reinforcement material thereon. In certain embodiments, the first tissue contacting surface defines rows of staple receiving slots the sheet is attached outwardly of rows of staple receiving slots. In certain embodiments, the first tissue contacting surface defines annular rows of staple receiving slots and the sheet is attached outwardly of the rows of staple receiving slots. Additionally or alternatively, the first tissue contacting surface defines annular rows of staple receiving slots and the sheet is attached inwardly of the rows of staple receiving slots. In certain embodiments, one or more sheets are attached to the second tissue contacting surface. In certain embodiments, the adhesive of the first side of the sheet is selected to so as to maintain the sheet attached to the at least one of the first tissue contacting surface and the second tissue contacting surface as the instrument is removed from a surgical site. The adhesive of the second side of the sheet is selected so as to allow the staple line reinforcement material to be released from the sheet.

Brief Description of the Drawings

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the present disclosure and, together with a general description of the disclosure given above and the detailed description of the embodiments given below, serve to explain the principles of this disclosure, wherein:

FIG. 1 is a perspective view of a surgical stapler instrument according to an embodiment of the present disclosure;

FIG. 2 is a perspective view of an anvil assembly and staple cartridge assembly according to the embodiment of FIG. 1;

FIG. 3 is a perspective view of an anvil assembly and staple cartridge assembly according to the embodiment of FIGS. 1 and 2;

FIG. 4 is a perspective view of a tissue contacting surface of a cartridge assembly according to the embodiment of FIGS. 1 through 3;

FIG. 5 is a perspective view of a tissue contacting surface of an anvil assembly according to the embodiment of FIGS. 1 through 4;

FIG. 6 is a perspective view of a plurality of hooks in accordance with further embodiments of the present disclosure;

FIG. 7 is a view in elevation of a staple line reinforcement material attached to a plurality of hooks in accordance with the embodiment of FIGS. 1 through 5;

FIG. 8 is a perspective view of a staple line reinforcement material in accordance with the embodiment of FIGS. 1 through 5 and 7;

FIG. 9 is a perspective view of a surgical stapler instrument according to another embodiment of the present disclosure;

FIG. 10 is a perspective view of the tissue contacting surface of a staple cartridge assembly in accordance with the embodiment of FIG. 9;

FIG. 11 is a perspective view of the tissue contacting surface of an anvil assembly in accordance with the embodiment of FIGS. 9 and 10;

FIG. 12 is a perspective view of a staple line reinforcement material in accordance with the embodiment of FIGS.9 through 11;

FIG. 13 is a perspective view of a sheet in accordance with the embodiment of FIGS. 9 through 12;

FIG. 14 is a perspective view of a sheet in accordance with a further embodiment of the present disclosure;

FIGS. 15a through 15e are cross-sectional views of engaging features formed on one or more tissue contacting surfaces of a surgical stapling instrument in accordance with another embodiment of the present disclosure;

FIG. 16 is a perspective view of a tissue contacting surface of a cartridge assembly according to the embodiment of FIGS. 15a through 15e;

FIG. 17 is a plan view of a tissue contacting surface of an anvil assembly according to the embodiment of FIGS. 15a through 16; and

FIG. 18 is a view in elevation of a staple line reinforcement material attached to a plurality of hooks in accordance with the embodiment of FIGS. 15a through FIG. 17.

Detailed Description

Embodiments of the presently disclosed devices and structures will now be described in detail with reference to the drawing figures wherein like reference numerals identify similar or identical elements. As used herein and as is traditional, the term "distal" refers to that portion which is furthest from the user while the term "proximal" refers to that portion which is closest to the user.

FIG. 1 illustrates a circular surgical stapling instrument which is generally designated as 10. Surgical stapling device 10 includes a handle assembly 12 having at least one pivotable actuating handle 14 and a rotatable actuator 18. A tubular body portion 20 extends from the handle assembly 12. The tubular body portion 20, which generally has a circular cross-sectional shape, may have a straight or a curved shape along its length and may be flexible or relatively rigid. Cross-sectional shapes other that circular are contemplated, so that the tubular body portion 20 can have a polygonal, elliptical, semi-circular, ovoid, or other shape. Surgical

stapling jaws including a staple cartridge assembly and an anvil assembly are disposed at a distal end of the body portion. The body portion 20 terminates in a staple cartridge assembly 22 that has a tissue contacting surface defining one or more rows 37 of staple receiving slots 36. Each staple receiving slot has a staple (not shown) disposed therein. Typically, a pair of circular rows 37 of staple receiving slots 36 is provided, although other shapes, such as annular, are contemplated. An anvil assembly 30 is positioned distally of the staple cartridge assembly 22, which includes an anvil member 26 and a shaft 28 operatively associated therewith. The anvil assembly has a tissue contacting surface that defines staple forming recesses that correspond to the circular rows of staple receiving slots, so that the stapling instrument forms circular staple lines. The tubular body portion 20 has a corresponding rod or shaft 40 centrally located with respect to the staple cartridge assembly 22. The shaft 28 is removably connectable to the shaft 40 of the tubular body portion 20.

The staple cartridge assembly 22 is connectable to the distal end of tubular body portion 20 or may be configured to concentrically fit within the distal end of tubular body portion 20. Typically, staple cartridge assembly 22 includes a staple pusher (not shown) with a distal portion defining two concentric rings of peripherally spaced fingers (not shown), each one of which is received within a respective staple receiving slot 36.

Typically, a knife (not shown) having a cutting edge is disposed within the staple cartridge assembly 22. The knife edge is circular and disposed radially inward of the rows of staples. The knife is mounted so that as the staple pusher is advanced axially in the direction of the anvil assembly, the knife is also advanced axially. The staple pusher is advanced in the distal direction to drive staples from the staple receiving slots 36 against the anvil member so that the

staple forming recesses form the staples in a closed shape. As the pusher is advanced, the knife is advanced and driven toward the anvil assembly 30 to cut tissue.

U.S. Patent No. 5,915,616 to Viola et al. discloses a circular stapling device. Although a circular stapling apparatus is shown in FIG. 1, the stapling device may be arranged to deploy staples in a semi-circular or other desired shape. Although discussed with reference to intestinal tissue, devices according to the present disclosure can be arranged to join and/or treat other tissues in other procedures.

As shown in FIGS. 2 and 3, the anvil assembly 30 is detached from the rod or shaft 40 of the tubular body portion 20 and a section of tubular body vessel, such as a section of intestine, is secured to the anvil assembly 30, typically by tying a suture "P" around the shaft 28 of the anvil assembly 30. Another section of tubular tissue is secured to the tubular body portion 20 by tying a suture around the shaft 40. See FIG. 2. The shaft 28 is then connected to the shaft 40. The actuator 18 is rotated to withdraw the shafts 28, 40 thereby approximating the anvil assembly 30 with the staple cartridge assembly 22. To fire the staples, the handles 14 are squeezed, which advances the staple pusher and the knife (not shown). The staples pass through each section of tubular tissue and are formed against the anvil so that the sections of tubular tissue are joined to one another. The knife cuts the tissue radially inward of the rows of staples, and the sutured material is removed with the circular stapling device.

Disclosed herein is a surgical stapling instrument 10, and staple line reinforcement material 50 fastened thereto. The surgical stapling instrument has surgical stapling jaws comprising the anvil assembly 30 and the staple cartridge assembly 22, each having a tissue contacting surface that engages the tissue. The tissue contacting surface 41 of the staple

cartridge assembly 22 defines the staple receiving slots 36, whereas the tissue contacting surface 42 of the anvil assembly 30 defines staple forming recesses 31.

A staple line reinforcement material ("SLRM") 50 can be attached to the surface 41, the surface 42, or both. Desirably, the SLRM 50 is attached to one or more tissue contacting surfaces before the surgical stapling instrument is packaged, so that the surgeon and/or operating room personnel are not required to install the SLRM onto the surgical stapling instrument before the surgery. However, installation of the SLRM just prior to the surgery is also contemplated.

The SLRM 50 and the surgical stapling instrument 10 define a fastener 32 having two parts. The first part is a hook, or a plurality of hooks 35, and the second part is a loop, or a plurality of loops 37. The hook or hooks 35 can be provided on the surgical stapler jaw and the loop or loops 37 can be provided on the SLRM 50. Alternatively, the hook or hooks are provided on the SLRM and the loop or loops are provided on the surgical stapler jaws. See FIG. 7.

In certain preferred embodiments, the SLRM 50 comprises a material having a plurality of pores 52 and the hooks 35 comprises fiber hooks that are applied to the surface 41 of the staple cartridge assembly 22 and to the surface 42 of the anvil assembly 30. The hooks can be formed from a polymer, metallic materials such as steel, etc. The hooks engage the SLRM in the pores. The pores can be formed as apertures in a sheet of material, or recesses, or the pores can comprise openings defined between fibers, threads wires, etc. that makeup the SLRM.

A sheet 45a having a plurality of fiber hooks 35a on a first side 46 and an adhesive material 43 on a second side 48 is applied to the working surface 41 of the staple cartridge assembly 22. The sheet 45a is circular in shape and has a central orifice 47 with a diameter D1. The diameter D1 is larger than an outer diameter D2 of the rows 37 of staple receiving slots 36.

Another sheet 45b has hooks 35 and is circular in shape and has an outer diameter that is smaller than an inner diameter D4 of the rows 37 of staple receiving slots 36. Each of the sheets 45a and 45b are adhered to the working surface 41 so that they do not overly the staple receiving slots 36. See FIGS. 4 and 7. The adhesive material is selected so that the adherence of the sheet to the instrument is strong enough so that the sheet is retained with the instrument after the staples have been fired and the tissue has been cut.

A sheet 55a having a first side with an adhesive material and a second side having a plurality of fiber hooks is attached to the working surface 42 of the anvil assembly 30 so that the sheet 55a lies outwardly of the staple forming recesses 31. Another sheet 55b with a first side having an adhesive material and a second side with a plurality of loops is attached to the working surface 42 of the anvil assembly 30 so that it lies inwardly of the staple forming recesses. See FIG. 5.

The SLRM 50 is a circular piece of porous material having a central orifice for accommodating the shaft 28 and shaft 40. See FIG. 8. The SLRM 50 is applied to the working surface 41 and the working surface 42 by pressing the SLRM 50 against the hooks 35 on the working surfaces 41 and 42. The hooks 35 engage the SLRM 50 in the pores 52 thereby retaining the SLRM 50 against the working surface 41 of the staple cartridge assembly 22 and the working surface 42 of the anvil assembly 30. The SLRM 50 is sized to overlie the working surfaces of the staple cartridge assembly 22 and the anvil assembly 30. The SLRM 50 and the sheets 45a, 45b, 55a, 55b do not interfere with the operation of the pusher or the knife, as the SLRM has a central orifice 51 that has a diameter that is larger than the diameter of the knife.

It is contemplated that the area of attachment, hook density, hook fiber strength, hook fiber length, and the pressing of the SLRM onto the hooks can be optimized to ensure retention of the SLRM and also easy release of the SLRM after the surgical stapling instrument is fired.

It is contemplated that the SLRM 50 may be fabricated from or include a surgical grade, biocompatible, non-absorbable material and may comprise a mesh. For example, the SLRM 50 may be fabricated from "TEFLON", which is a registered trademark owned by DuPont de Nemours & Co. It is further contemplated that body portion 102 may be fabricated from a biocompatible polymeric foam, felt, polytetrafluoroethylene (ePTFE), gelatin, fabric or the like, or any other biocompatible material.

Non-absorbable materials used for SLRM include, and are not limited to, those that are fabricated from such polymers as polyethylene, polypropylene, nylon, polyethylene terephthalate, polytetrafluoroethylene, polyvinylidene fluoride, and the like. Further non-absorbable materials include and are not limited to stainless steel, titanium and the like.

In one embodiment, the SLRM 50 may be fabricated from a bio-absorbable material. In other embodiments, the SLRM has at least one portion that is absorbable and at least one portion that is not absorbable. Bio-absorbable materials used for SLRM include, and are not limited to, those fabricated from homopolymers, copolymers or blends obtained from one or more monomers selected from the group consisting of glycolide, glycolic acid, lactide, lactic acid, p-dioxanone, α-caprolactone and trimethylene carbonate. Other bio-absorbable materials include and are not limited to, for example, Polyglycolic Acid (PGA) and Polylactic Acid (PLA). In one embodiment, the SLRM may be fabricated from bio-absorbable felt, gelatin or any other bio-absorbable materials.

The SLRM 50 can incorporate a wound treatment material "W", which includes and is not limited to one or a combination of adhesives, hemostats, sealants, coagulants, astringents, and medicaments. Other surgically biocompatible wound treatment materials "W" which may be employed in or applied by surgical instruments, including surgical staplers, include adhesives whose function is to attach or hold organs, tissues or structures; sealants to prevent fluid leakage; hemostats to halt or prevent bleeding; coagulants, astringents (e.g., sulfates of aluminum) and medicaments. Examples of adhesives which can be employed include protein derived, aldehyde-based adhesive materials, for example, the commercially available albumin/glutaraldehyde materials sold under the trade designation BioGlue™ by Cryolife, Inc., and cyanoacrylate-based materials sold under the trade designations Indermil™ and Derma Bond™ by Tyco Healthcare Group, LP and Ethicon Endosurgery, Inc., respectively. Examples of sealants, which can be employed, include fibrin sealants and collagen-based and synthetic polymer-based tissue sealants. Examples of commercially available sealants are synthetic polyethylene glycol-based, hydrogel materials sold under the trade designation CoSeal™ by Cohesion Technologies and Baxter International, Inc. Examples of hemostat materials, which can be employed, include fibrin-based, collagen-based, oxidized regenerated cellulose-based and gelatin-based topical hemostats. Examples of commercially available hemostat materials are fibrinogen-thrombin combination materials sold under the trade designations CoStasis™ by Tyco Healthcare Group, LP, and Tisseel™ sold by Baxter International, Inc. The W can include medicaments. Medicaments may include one or more medically and/or surgically useful substances such as drugs, enzymes, growth factors, peptides, proteins, dyes, diagnostic agents or hemostasis agents, monoclonal antibodies, or any other pharmaceutical used in the prevention of stenosis.

The SLRM may include a single layer including a homogeneous array of bio-absorbable or non-absorbable materials or a heterogeneous array of bio-absorbable and/or non-absorbable materials. The SLRM may include a layered body portion having at least two layers as indicated by first layer, film or wafer and second layer, film or wafer. In this embodiment, each layer may include a homogeneous or heterogeneous array of bio-absorbable and/or non-absorbable materials.

In certain preferred embodiments, the SLRM is a non-woven fabric. The non-woven fabric can be formed utilizing a melt blown process, including the following steps. The polymer resin is melt extruded. A melt pump meters out the molten polymer to a die head having an array of holes. By way of example, the holes have a diameter of between about 0.175 and about 0.25 millimeters. The polymer is forced through the array of holes in the die. Polymer fibers exit the die and are forced onto a conveyor belt. A stream of blowing hot air can be used to force the polymer fibers onto the conveyor. Suction through the conveyor belt surface can be used to compact the fibers against the belt and against each other, as the fibers cool. Additional compression may be applied to the fibers, such as by using a calendaring roll, which may include heating or cooling. The non-woven fabric may then be annealed. For example, isometric tension or other uniform compression can be used to drive crystallization and remove the monomer. The polymer is desirably a bioabsorbable or non-bioabsorbable polymer, such as a glycolide lactide copolymer (the material utilized in Polysorb™ sutures), a termpolymer composed of glycolide, trimethylene carbonate and dioxanone (the material utilized in Biosyn™ sutures), a polymer of glycolide, caprolactone, trimethylene carbonate, and lactide (the material utilized in Caprosyn™ sutures), and a glycolide trimethylene carbonate copolymer (the material utilized in Maxon™ sutures).

In certain embodiments, the non-woven fabric is porous. For example, the non-woven fabric can have a porousity of between about 50% and about 90%. The fiber diameter may be between about 5 and about 100 μm. The fabric thickness may be between about 150 and about 400 μm.

In other embodiments of the present disclosure, the SLRM 50 has the hooks 35 disposed on a surface thereof, and the loops 39 are attached to the tissue contacting surface 41 and/or tissue contacting surface 42.

In certain embodiments, the sheets 45a, 45b, 55a, and/or 55b, or the SLRM 50, have hooks 35 are fabricated from a polymer having a glass transition temperature at or near a human body temperature. When the surgical stapler instrument is utilized in the body, the stapler jaws will be approximated with one another to clamp on tissue. The hooks will warm and soften so that the SLRM 50 is more easily removed after the staples have been fired, but the hooks 35 are initially relatively rigid to retain the material 50 on the surgical stapler instrument 10. The surgical instrument can include thermistors for heating the hooks so that they soften when heated at some predetermined temperature which may be below or above body temperature.

In a further embodiment, the hooks 35 discussed above are formed of a shape memory polymer with shape shifting capacity at about 50 degrees Centigrade. Alternatively, the surgical stapler instrument 10 can include thermistors for heating the hooks 35 above 50 degrees Centigrade. Alternatively, the heat of a human body (about 37 Centigrade) could alter the shape of the shape memory polymer hooks to allow easier release of the SLRM 50. The heating of the hooks 35 causes a change in shape that allows the SLRM to be more easily removed from the surgical stapler instrument 10. For example, the heating can cause the hooks 35 to change from a hook configuration to a straight, or substantially straight, configuration.

In a further embodiment, any of the hooks 35 discussed above has a first base end 1 and a second free end 2. A diameter "d1" of the first base end is greater than a diameter "d2" of the second free end so that the second free end is relatively flexible. The base end is relatively stiff. See FIG. 7. The geometry of the hooks 35 is tailored so that the lifting force is reduced and the SLRM will be released more easily after the surgical stapler instrument is fired. The hooks 35 can have a variety of shapes, including polygonal, tubular, tapering, arrow-shaped, etc. See FIG. 6.

In a further embodiment, the surgical instruments discussed herein have a staple line reinforcement material has a plurality of fibers and at least one of the surgical stapler jaws has the hooks 35. The hooks are arranged to engage one or more of the plurality of fibers to releasably retain the SLRM on the stapler jaws.

FIG. 9 illustrates a linear stapling instrument 100 having stapler jaws 110, 120. The stapler jaw 110 is a staple cartridge assembly having one or more rows 137 of staple receiving slots 136. Each staple receiving slot has a staple (not shown) disposed therein. Typically, three linear rows 137 of staple receiving slots 136 are provided on either side of a channel 139. An anvil assembly 130 is positioned in opposition to the staple cartridge assembly 122 and pivotably mounted so that the anvil assembly and staple cartridge assembly can be approximated to clamp tissue therebetween. The anvil assembly includes an anvil member 126 defining a plurality of staple forming recesses 131 that correspond to the linear rows 137 so that the stapling instrument forms linear staple lines. The stapling jaws 110, 120 are disposed at a distal end of an endoscopic shaft 140. A handle assembly 101 includes a pivotable handle 103 that drives movement of a drive member through the staple cartridge assembly 122. The drive member (not shown) passes through the channel 139 and pushes a sled or camming bar through the staple

cartridge to drive staple pushers, and the staples, through the slots 136 toward the staple forming recesses of the anvil member 126. Such a surgical instrument is disclosed in U.S. Patent No. 6,241,139 to Milliman et al.

The stapling instrument has a staple line reinforcement material 150 fastened thereto. The staple cartridge assembly 122 and the anvil assembly 130 each have a tissue contacting surface that engages the tissue. The tissue contacting surface 141 of the staple cartridge assembly 122 defines the staple receiving slots 136, whereas the tissue contacting surface 142 of the anvil assembly 130 defines staple forming recesses 131.

A SLRM 150 can be attached to the surface 141, the surface 142, or both. See FIG. 12. Desirably, the SLRM 150 is attached to one or more tissue contacting surfaces before the surgical stapling instrument is packaged, so that the surgeon and/or operating room personnel are not required to install the SLRM onto the surgical stapling instrument before the surgery. However, installation of the SLRM just prior to the surgery is also contemplated.

The SLRM 150 and the surgical stapling instrument 110 define a fastener 132 having two parts. The first part is a hook, or a plurality of hooks 135, and the second part is a loop, or a plurality of loops 137. The hook or hooks 135 can be provided on the surgical stapler jaw and the loop or loops 137 can be provided on the SLRM 150. Alternatively, the hook or hooks are provided on the SLRM and the loop or loops are provided on the surgical stapler jaws.

In certain preferred embodiments, the SLRM 150 comprises a material having a plurality of pores 152 and the hooks 135 comprise fiber hooks that are applied to the surface 141 of the staple cartridge assembly 22 and/or to the surface 142 of the anvil assembly 130. The hooks can be formed from a polymer, a metallic material such as steel, etc. A sheet 145 having a plurality

of fiber hooks 135 on a first side 146 and an adhesive material 143 on a second side 148 is applied to the tissue contacting surface 141 of the staple cartridge assembly 122. The sheet 145 is generally rectangular or oblong in shape and lies outside the rows 137 of staple receiving slots. For example, at least one first sheet 145a is disposed at a distal end of the working surface 141 and at least one second sheet 145b is disposed at a proximal end of the working surface 141. The sheets 145 are adhered to the working surface 141 so that they do not overly the staple receiving slots 136. See FIG. 10.

At least one first sheet 155a having a first side with an adhesive material and a second side having a plurality of fiber hooks is attached to the tissue contacting surface 142 of the anvil assembly 130, at a distal end of the surface 142. At least one second sheet 155b is also attached at the proximal end of the surface 142. The sheets lie outwardly of the staple forming recesses 131. See FIG. 11.

The SLRM 150 is a generally rectangular piece of porous material. A SLRM 150 is applied to each of the surface 141 and the surface 142 by pressing a SLRM 150 against the hooks 135 on the tissue contacting surface 141 and pressing another SLRM against the hooks on the tissue contacting surface 142. The hooks 135 engage the SLRM 150 in the pores 152 thereby retaining the SLRM 150 against the working surface 141 of the staple cartridge assembly 122 and the working surface 142 of the anvil assembly 130. The SLRM 150 is sized to overlie the working surfaces of the staple cartridge assembly 122 and the anvil assembly 130. The SLRM 150 and the sheets 145, 155 do not interfere with the operation of the pusher or the knife. The knife, which is carried by the drive member of the stapling instrument 100, divides the SLRM, separating the SLRM into two parts.

In another embodiment, the SLRM 150 is attached to the surface 141, the surface 142, or both utilizing a sheet (145, 155) that is elongate in shape and extends alongside the rows 137 of staple receiving slots 136, the staple forming recesses 131, or both. One or more elongate sheets can be applied to the surface 141 and/or surface 142. Hooks 135 on the sheet or sheets attach the SLRM to the surface 141 and/or surface 142.

SLRM 150 comprises a material having a plurality of pores 152. Alternatively, the SLRM 150 comprises a material having a plurality of fibers, or any of the other materials discussed above. The hooks 135 that are attached to surface 141 and surface 142 engage the SLRM in the pores or the fibers of the SLRM, as discussed above.

It is contemplated that the area of attachment, hook density, hook fiber strength, hook fiber length, and the pressing of the SLRM onto the hooks can be optimized to ensure retention of the SLRM and also easy release of the SLRM after the surgical stapling instrument is fired.

In a further embodiment, the surgical stapling instrument 100 has surgical stapling jaws, a staple line reinforcement material, and an attachment sheet 245 having a first side 246 and a second side 248 with an adhesive thereon. The SLRM 50 is attached to the first side 246 by the adhesive and the second side 248 is attached to the tissue contacting surface of at least one of the circular surgical stapling jaws. The surgical stapling jaws include an anvil assembly and a cartridge assembly. In certain embodiments, the anvil assembly and the cartridge assembly are arranged to form a circular staple line. In other embodiments, the anvil assembly and the cartridge assembly are arranged to form a linear staple line.

The attachment sheet 245, as depicted in FIG. 14, has a rectangular or oblong shape and one or more attachment sheets 245 can be placed on the working surface 41 of the staple cartridge assembly 22 to attach the SLRM to the working surface 41. In certain embodiments,

the sheet or sheets 245 are placed outwardly of the rows 37 of staple receiving slots 36 defined by the surface 41 and may also be placed inwardly of the rows 37 of staple receiving slots 36. In other embodiments, the attachment sheet is circular in shape, with an orifice that is dimensioned to be larger than the staple retaining slots or staple forming recesses. Another sheet dimensioned to be smaller than the slots and/or rows can be used.

One or more attachment sheets can be placed on the tissue contacting surface 42 of the anvil assembly 30 to attach the SLRM to the surface 42. In certain embodiments, the sheet or sheets 245 are placed outwardly of the staple forming recesses 31 defined by the working surface 42 and may also be placed inwardly of the staple forming recesses 31 to attach a SLRM to the anvil assembly.

In a further embodiment, the sheet 245 having a first side 246 and a second side 248 with an adhesive thereon can be attached to the working surface 141 and/or working surface 142. The SLRM 150 is attached to the first side 246 by the adhesive and the second side 248 is attached to the working surface of at least one of the surgical stapling jaws. The adhesive on the first side 246 is selected to allow the SLRM to be released from the instrument after firing of staples and cutting of tissue so that the SLRM will remain with the stapled tissue and the instrument can be removed. Conversely, the second side has an adhesive that is selected to maintain the sheet 245 attached to the instrument as the instrument is removed. The adhesive sheet 245 can be used with instrument 10 or instrument 100 discussed above, or other surgical stapling instruments.

In another embodiment, the SLRM 150 is attached to the working surface 141, the working surface 142, or both utilizing a sheet (145, 155) that elongate in shape and extends alongside the rows 137 of staple receiving slots 136, the staple forming recesses 131, or both.

One or more elongate sheets can be attached to the working surface 142 and/or working surface 142 by adhesive and the SLRM can be attached to the sheet or sheets by adhesive.

In a further embodiment, the surgical stapling instrument 10 or the surgical stapling instrument 100, or another stapling instrument, has a handle assembly, a body portion extending from the handle assembly, surgical stapling jaws including a staple cartridge assembly and an anvil assembly disposed at a distal end of the body portion, and a staple line reinforcement material (SLRM). At least one of a tissue contacting surface of the staple cartridge assembly and a tissue contacting surface of the anvil assembly incorporates hooks or other engaging features formed in the staple cartridge assembly and/or anvil assembly so that the hooks or engaging features extend from, or recede into, the tissue contacting surface of the staple cartridge assembly and/or anvil assembly. FIGS. 15a through 15e illustrate various shapes for features that can be utilized as hooks or engaging features for engaging a SLRM and retaining the SLRM onto the stapling instrument. The hooks or engaging features are formed as a part of the anvil and/or cartridge surfaces as molded or stamped and/or machined features. Typically, the staple cartridge assembly includes a body molded from a polymeric material, whereas the anvil assembly is formed from one or more parts that are stamped and/or machined from metal. The hooks or engaging features would have geometries that could be made through these part forming methods. Other manufacturing methods can be used.

The SLRM 350 comprises a material having a plurality of pores 352 or fibers 353 that are engaged by the hooks or engaging features 335 at the tissue contacting surface 341 of the staple cartridge assembly 322 and at the tissue contacting surface 342 of the anvil assembly 330. The pores can be formed as apertures in a sheet of material, or recesses, or the pores can comprise openings defined between fibers, threads wires, etc. that makeup the SLRM.

The hooks or engaging features 335 are formed across the tissue contacting surface 341 and/or tissue contacting surface 342. Alternatively, the hooks or engaging features 335 are formed so that the hooks or engaging features 335 are disposed outwardly of linear staple lines, or outwardly and/or inwardly of circular staple lines. The SLRM 350 can be a circular piece of material having a central orifice for accommodating the shafts of a circular stapling instrument. Alternatively, the SLRM 350 is rectangular or oblong in shape for being disposed on a linear surgical stapling instrument. In certain embodiments, the SLRM 350 is applied to the tissue contacting surfaces of the staple cartridge assembly and/or the anvil assembly by pressing the SLRM 350 against the hooks or engaging features 335 on the tissue contacting surfaces. The hooks or engaging features 335 engage the SLRM 350 in the pores 352 or at fibers 353 thereby retaining the SLRM 350 against the tissue contacting surfaces. The SLRM is sized to overlie the tissue contacting surfaces of the staple cartridge assembly and the anvil assembly. The SLRM can be formed from the materials discussed above and the hooks or engaging features, and the pores or fibers of the SLRM, are sized to enable the hooks or engaging features to engage at least some of the pores or fibers in the SLRM to retain the SLRM until the instrument is fired and is removed.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the surgical stapling instrument need not apply staples but rather may apply two part fasteners as is known in the art. Further, the length of the linear row of staples or fasteners, or the length or diameter of a circular row of staples or fasteners, may be modified to meet the requirements of a particular surgical procedure. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred

embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended thereto.

The embodiments of the present invention for which an exclusive property or privilege is claimed are defined as follows:

1. A surgical stapling instrument, comprising:

a handle assembly;

a body portion extending from the handle assembly;

surgical stapling jaws including a staple cartridge assembly and an anvil assembly disposed at a distal end of the body portion;

a staple line reinforcement material; and

a fastener having two parts, the two parts including a hook and a loop, a tissue contacting surface of at least one of the surgical stapling jaws having one of the hook and the loop, and the staple line reinforcement material having the other of the hook and the loop.

2. The surgical stapling instrument according to claim 1, wherein the anvil assembly has staple forming recesses and the cartridge assembly has staple receiving slots.

3. The surgical stapling instrument according to claim 2, wherein the anvil assembly and the cartridge assembly are arranged to form a circular staple line.

4. The surgical stapling instrument according to claim 2, wherein the anvil assembly and the cartridge assembly are arranged to form a linear staple line.

5. The surgical stapling instrument according to claim 1, wherein the staple line reinforcement material is non-woven.

6. The surgical stapling instrument according to claim 1, wherein the staple line reinforcement material is a mesh.

7. The surgical stapling instrument according to claim 1, wherein the staple line reinforcement material has a plurality of pores.

8. The surgical stapling instrument according to claim 7, wherein at least one of the surgical stapling jaws has a plurality of hooks that are arranged to engage the plurality of pores.

9. The surgical stapling instrument according to claim 1, wherein the fastener includes a sheet having a plurality of hooks on a first side and an adhesive on a second side, the adhesive being attached to at least one of the surgical stapler jaws, and the staple line reinforcement material having a plurality of loops arranged to engage the plurality of hooks.

10. The surgical stapling instrument according to claim 1, wherein the anvil assembly and the cartridge assembly are arranged to form a circular staple line and further comprising a circular knife disposed inwardly of the circular staple line.

11. The surgical stapling instrument according to claim 10, wherein the staple line reinforcement material is circular in shape and has a central orifice.

12. The surgical stapling instrument according to claim 1, wherein the hook is disposed on at least one of the surgical stapler jaws and has a glass transition temperature at or near a human body temperature.

13. The surgical stapling instrument according to claim 1, wherein the hook is disposed on at least one of the surgical stapler jaws and has a glass transition temperature and further comprising at least one thermistor for heating the hook to a temperature at or near the glass transition temperature.

14. The surgical stapling instrument according to claim 1, wherein the hook has a first base end and a second free end, a diameter of the first base end being greater than a diameter of the second free end so that the second free end is relatively flexible.

15. The surgical stapling instrument according to claim 1, wherein the staple line reinforcement material has a plurality of fibers, at least one of the surgical stapler jaws having the hook, the hook being arranged to engage one or more of the plurality of fibers.

16. A surgical stapling instrument, comprising

a handle assembly;

a body portion extending from the handle assembly;

surgical stapling jaws including a staple cartridge assembly and an anvil assembly disposed at a distal end of the body portion, the staple cartridge assembly having a first tissue contacting surface and the anvil assembly having a second tissue contacting surface;

a fastener including a sheet having a plurality of hooks on a first side and an adhesive on a second side, the adhesive being attached to at least one of the surgical stapling jaws; and

a staple line reinforcement material having a plurality of loops in engagement with at least some of the plurality of hooks.

17. The surgical stapling instrument according to claim 16, further comprising a staple line reinforcement material defining a plurality of pores, the plurality of hooks being arranged to engage the staple line reinforcement material in the plurality of pores.

18. The surgical stapling instrument according to claim 16, wherein the staple line reinforcement material is non-woven.

19. The surgical stapling instrument according to claim 16, wherein the staple line reinforcement material is a mesh.

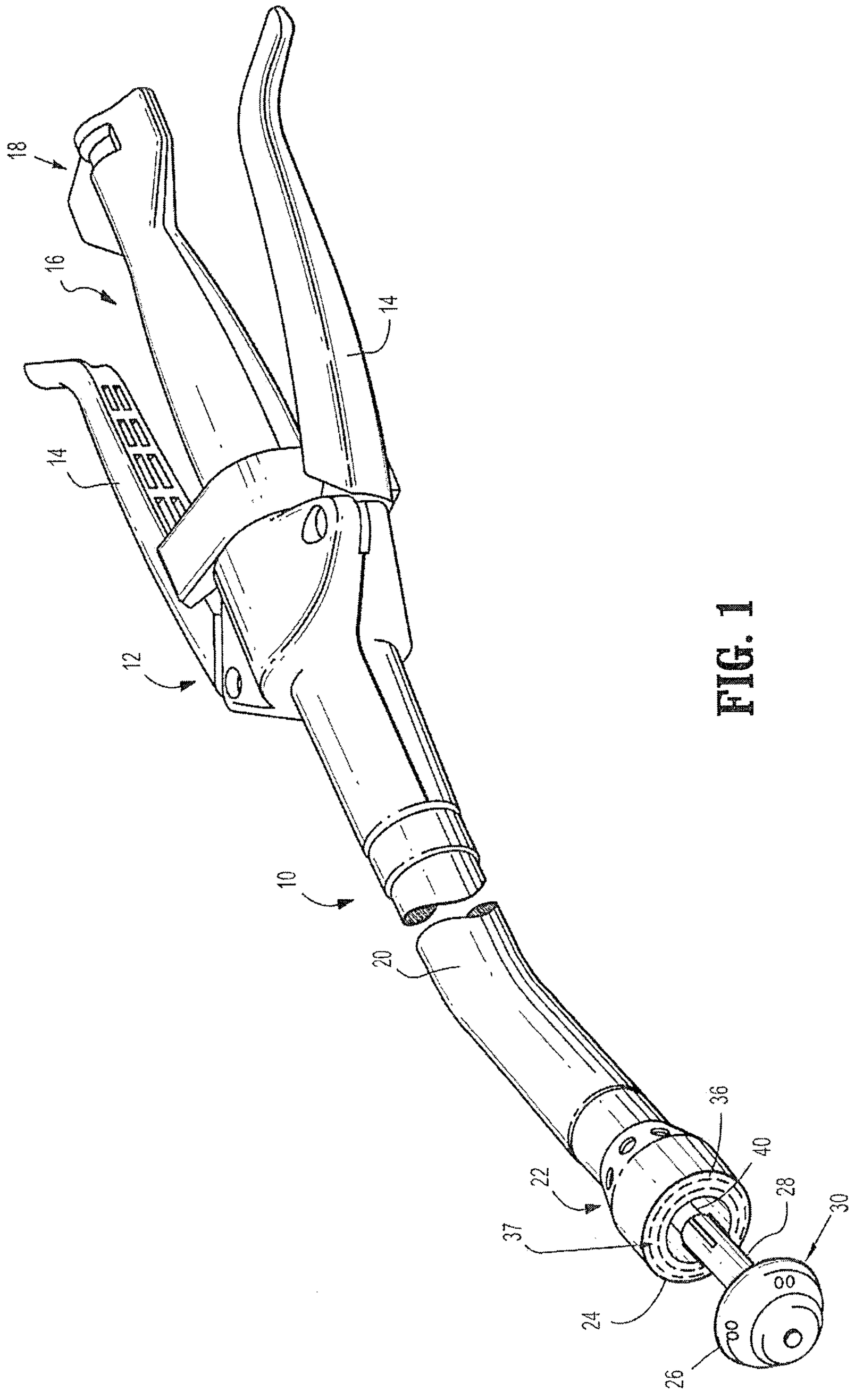


FIG. 1

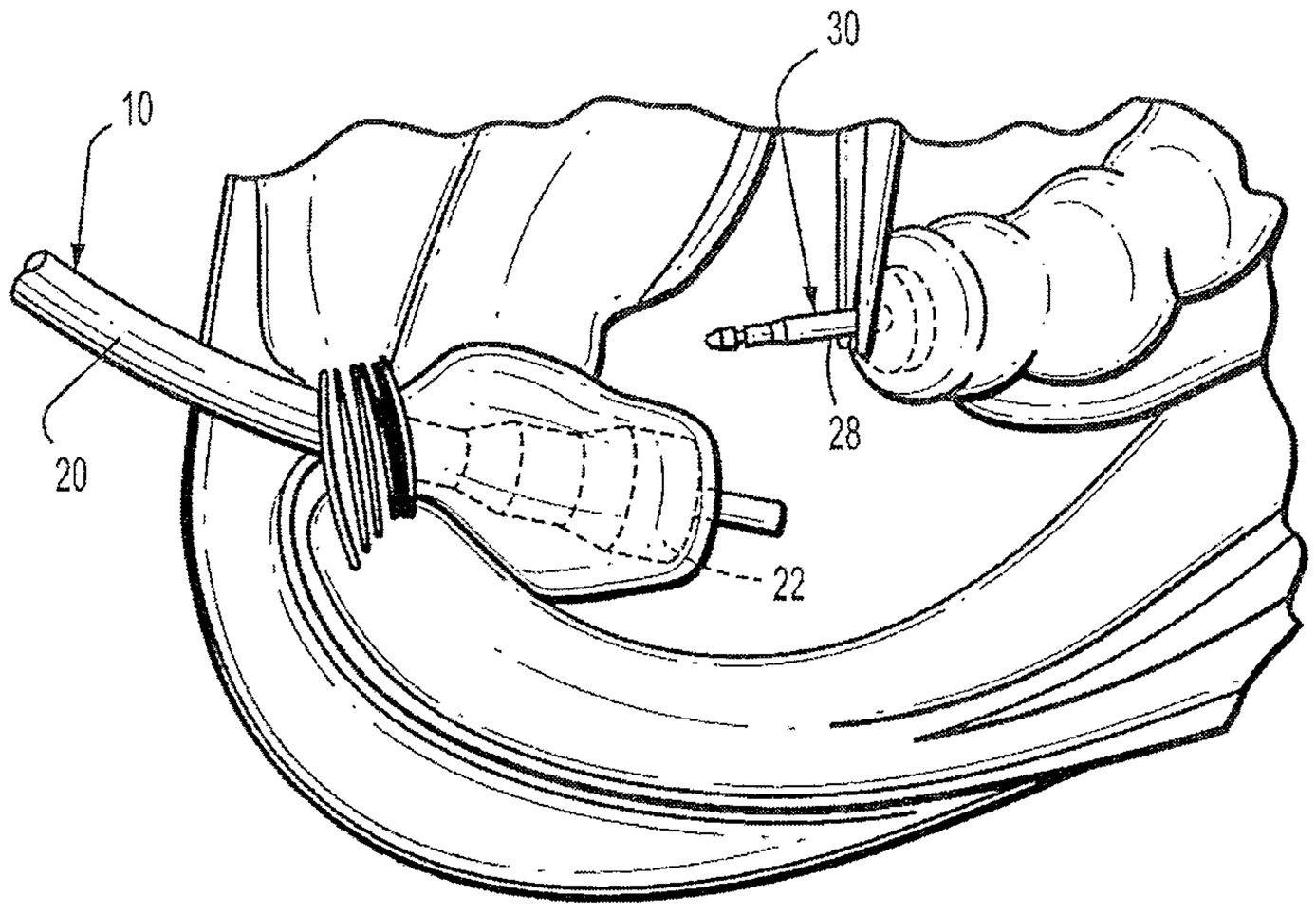


FIG. 2

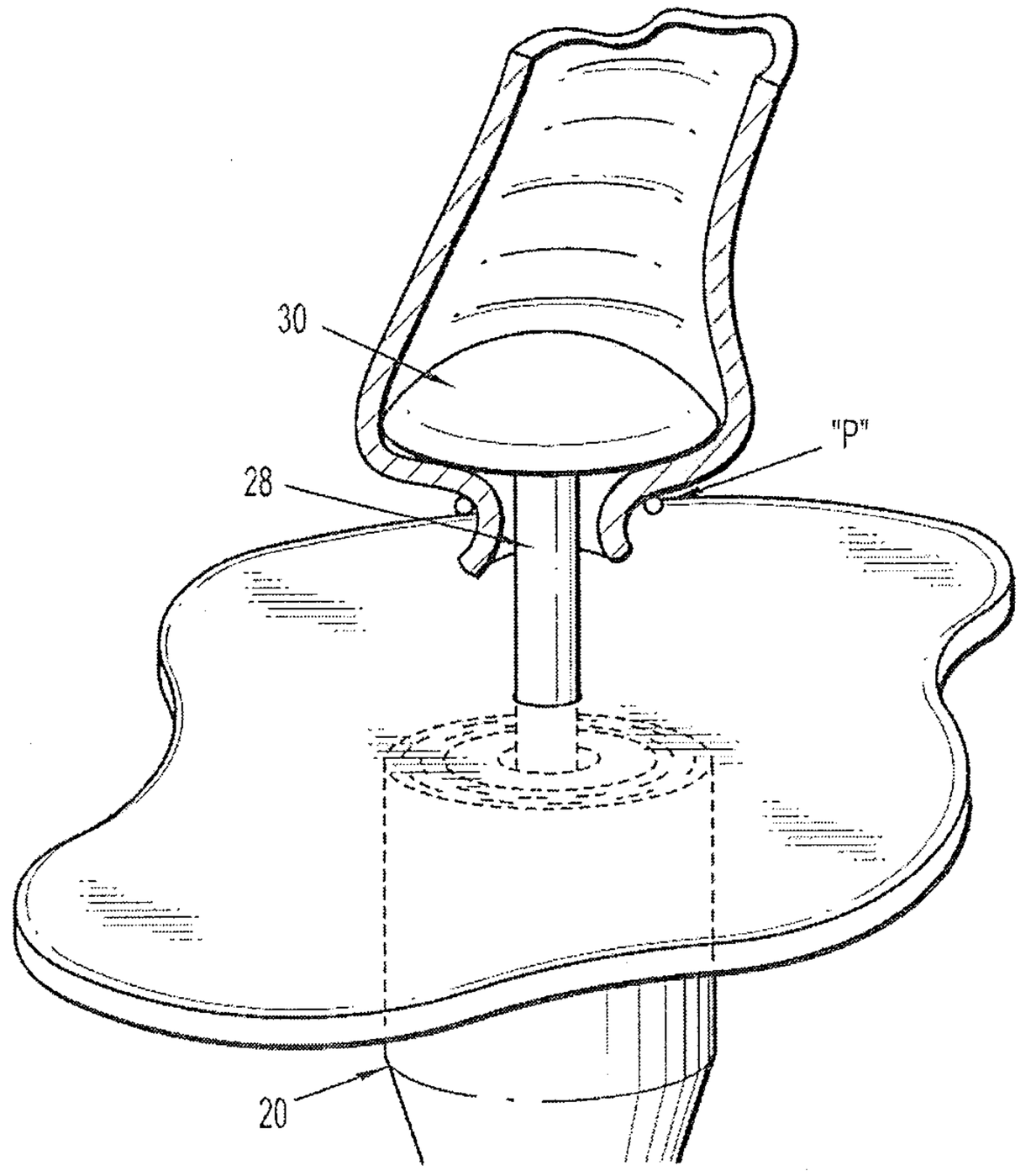


FIG. 3

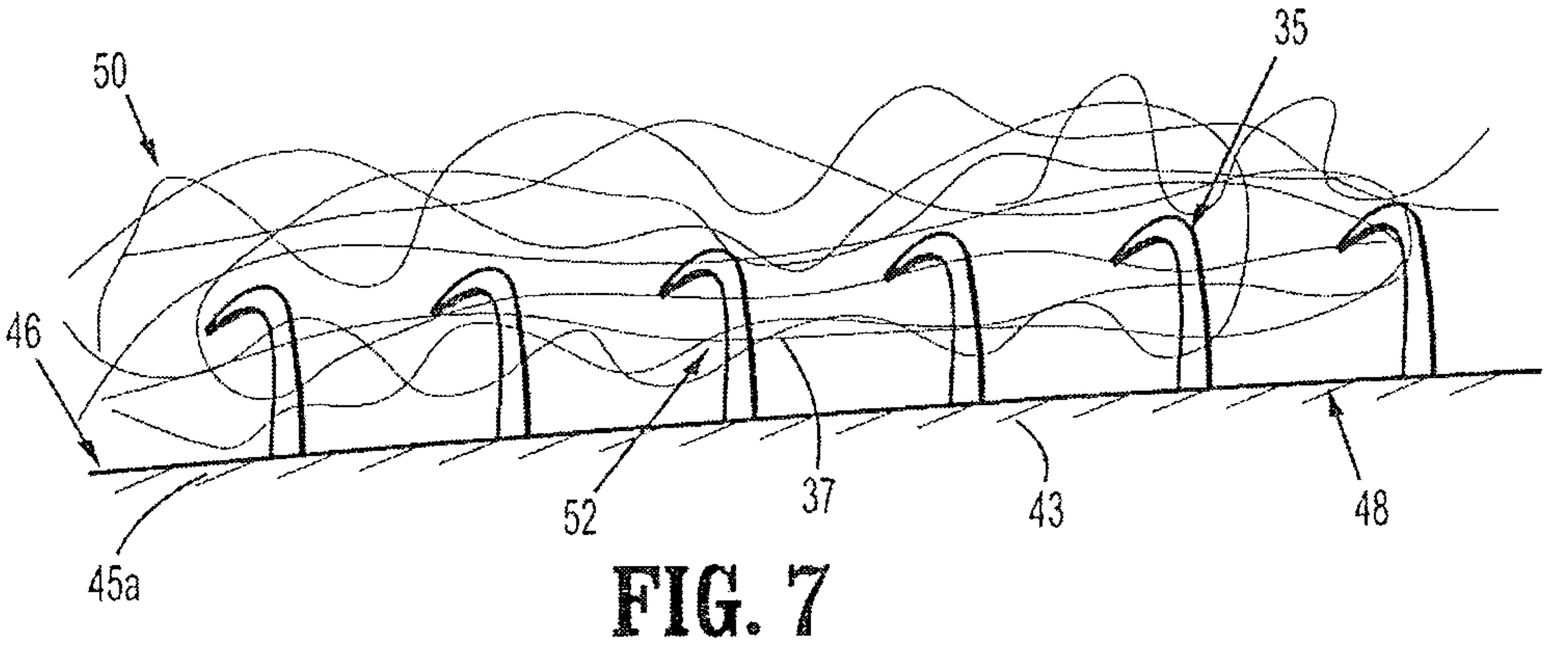


FIG. 7

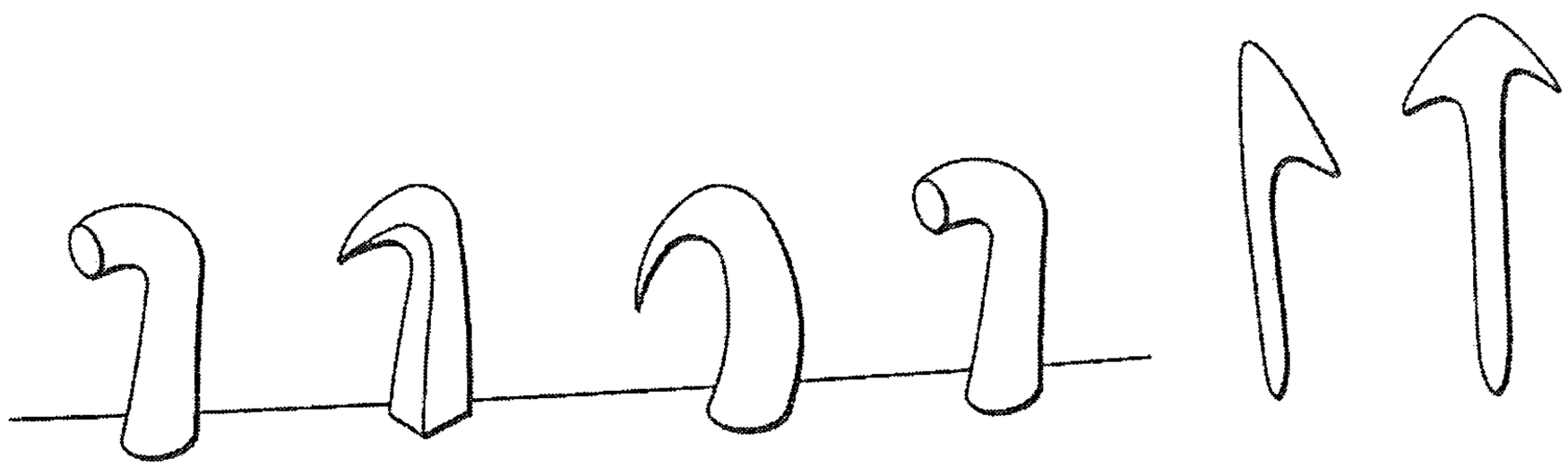


FIG. 6

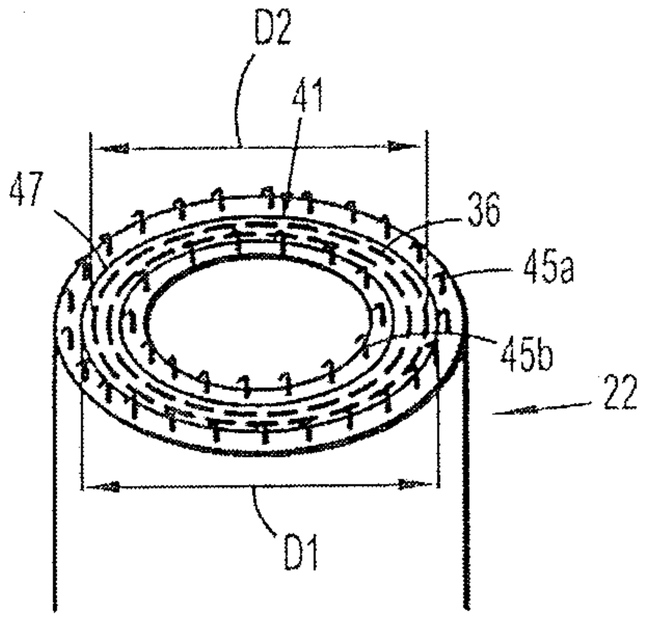


FIG. 4

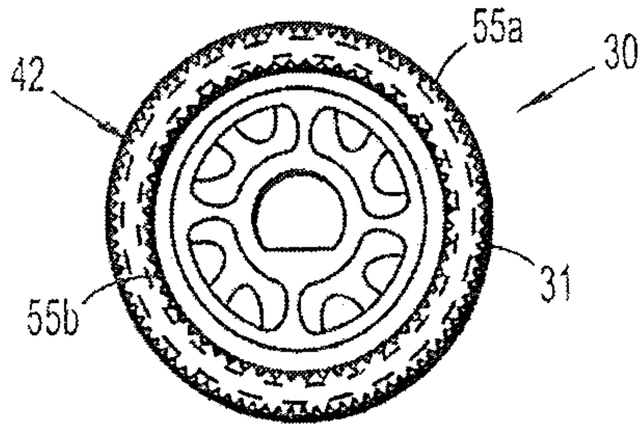


FIG. 5

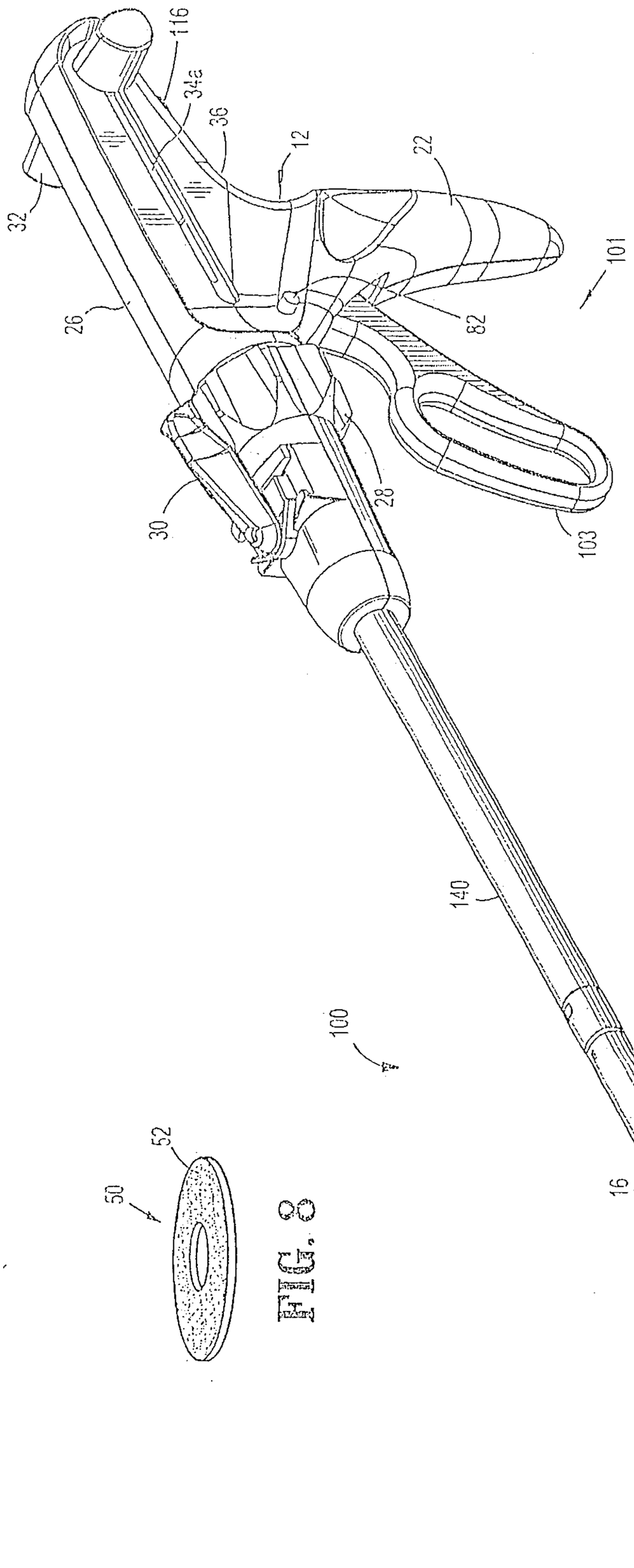


FIG. 5

FIG. 8

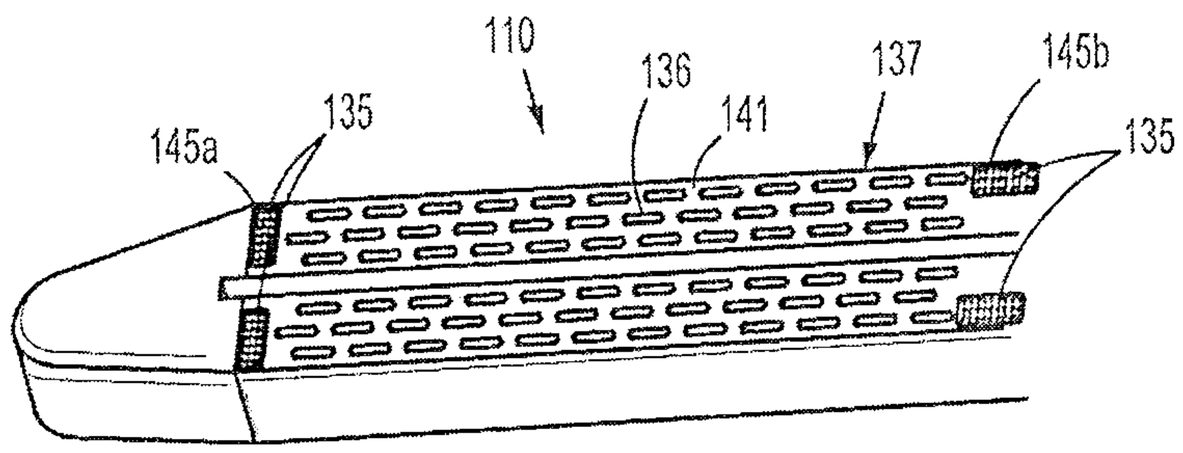


FIG. 10

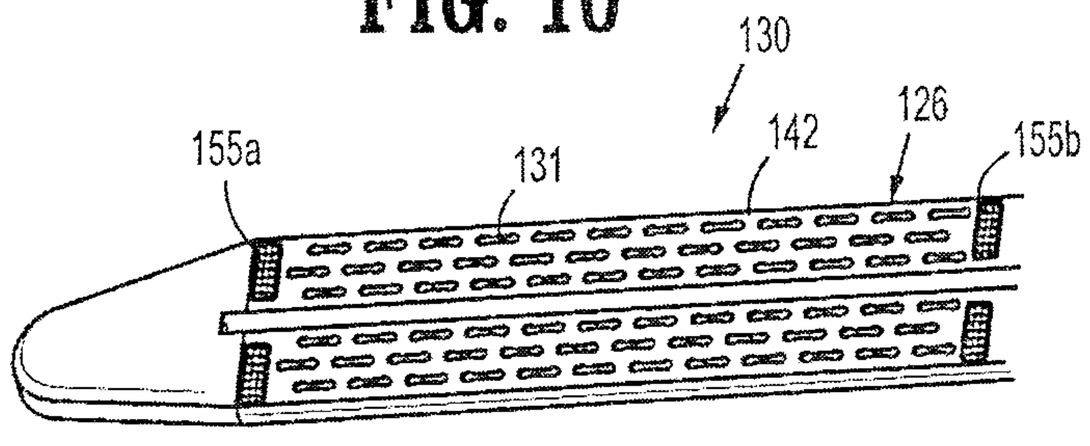


FIG. 11

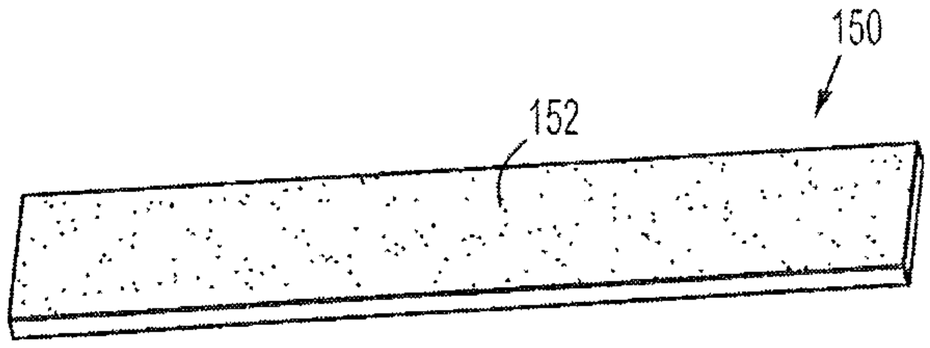


FIG. 12

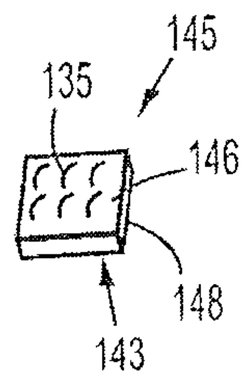


FIG. 13

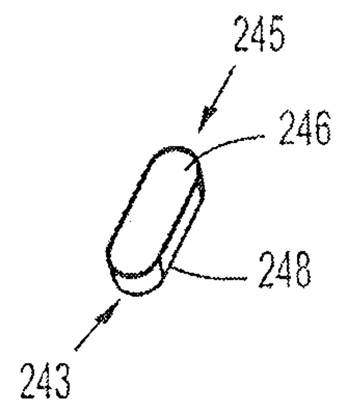


FIG. 14

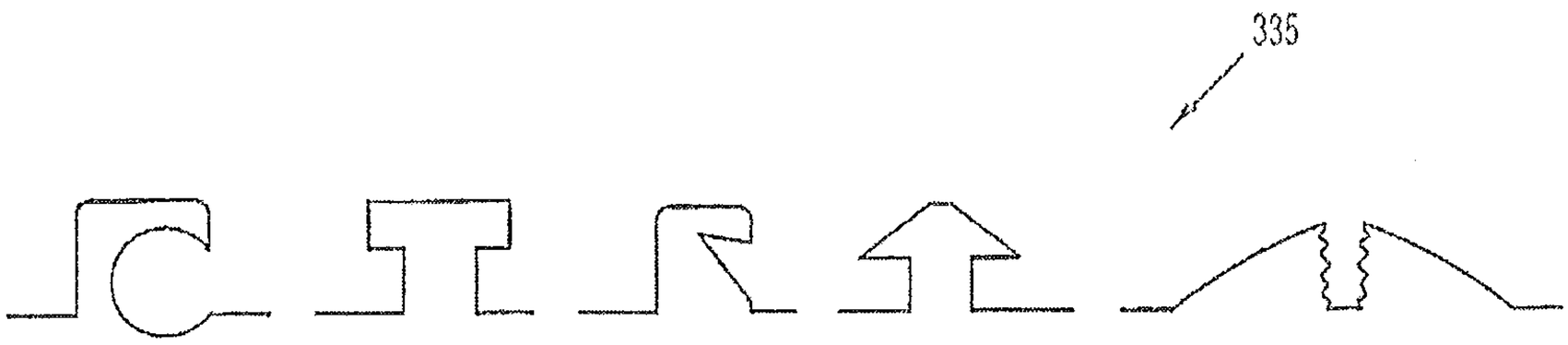
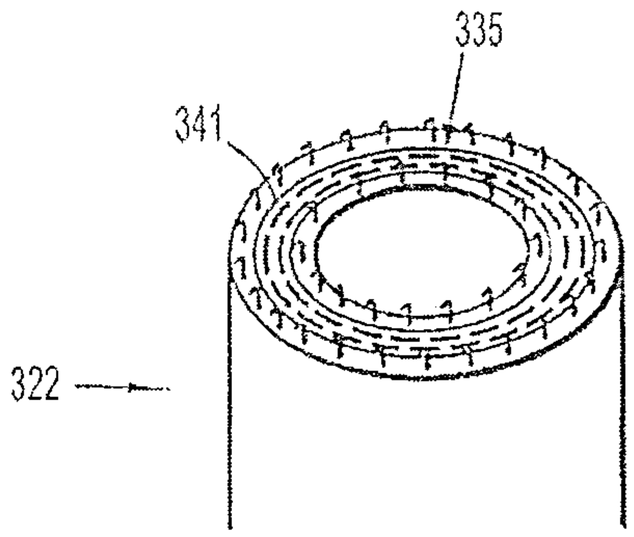


FIG. 15A FIG. 15B FIG. 15C FIG. 15D FIG. 15E



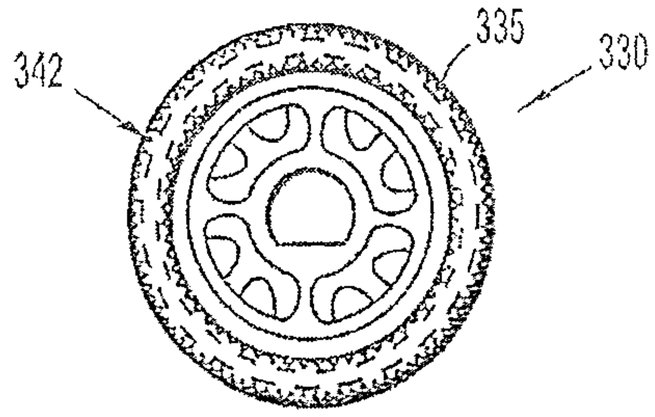


FIG. 16 FIG. 17

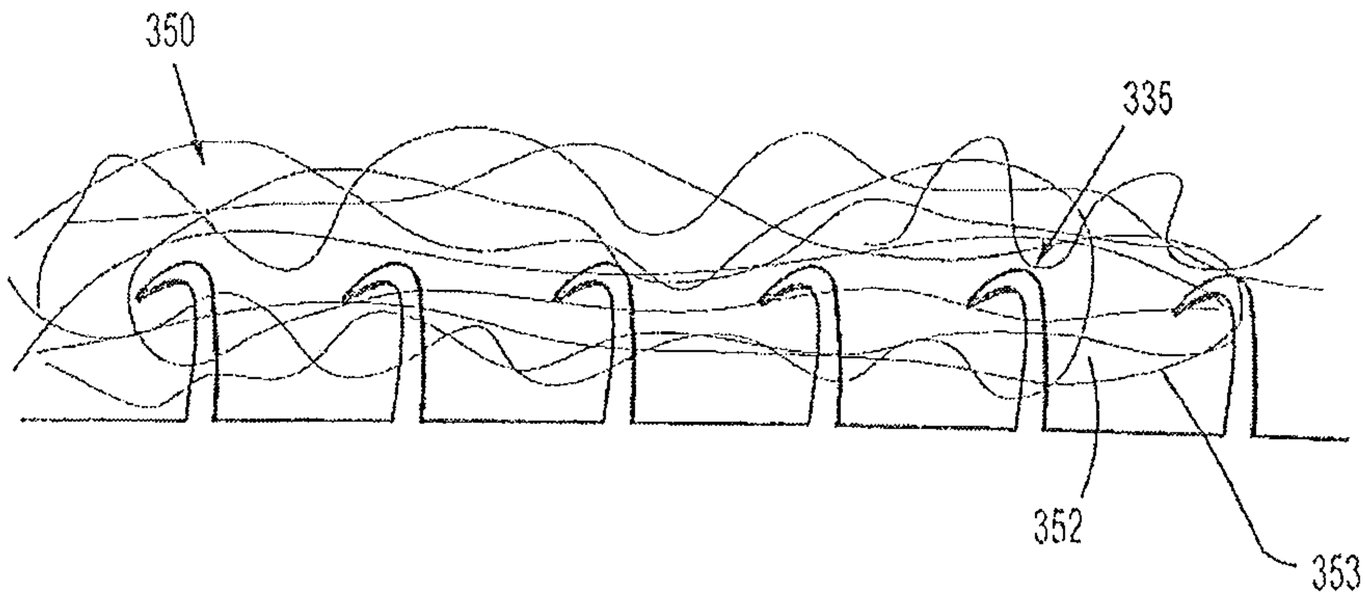
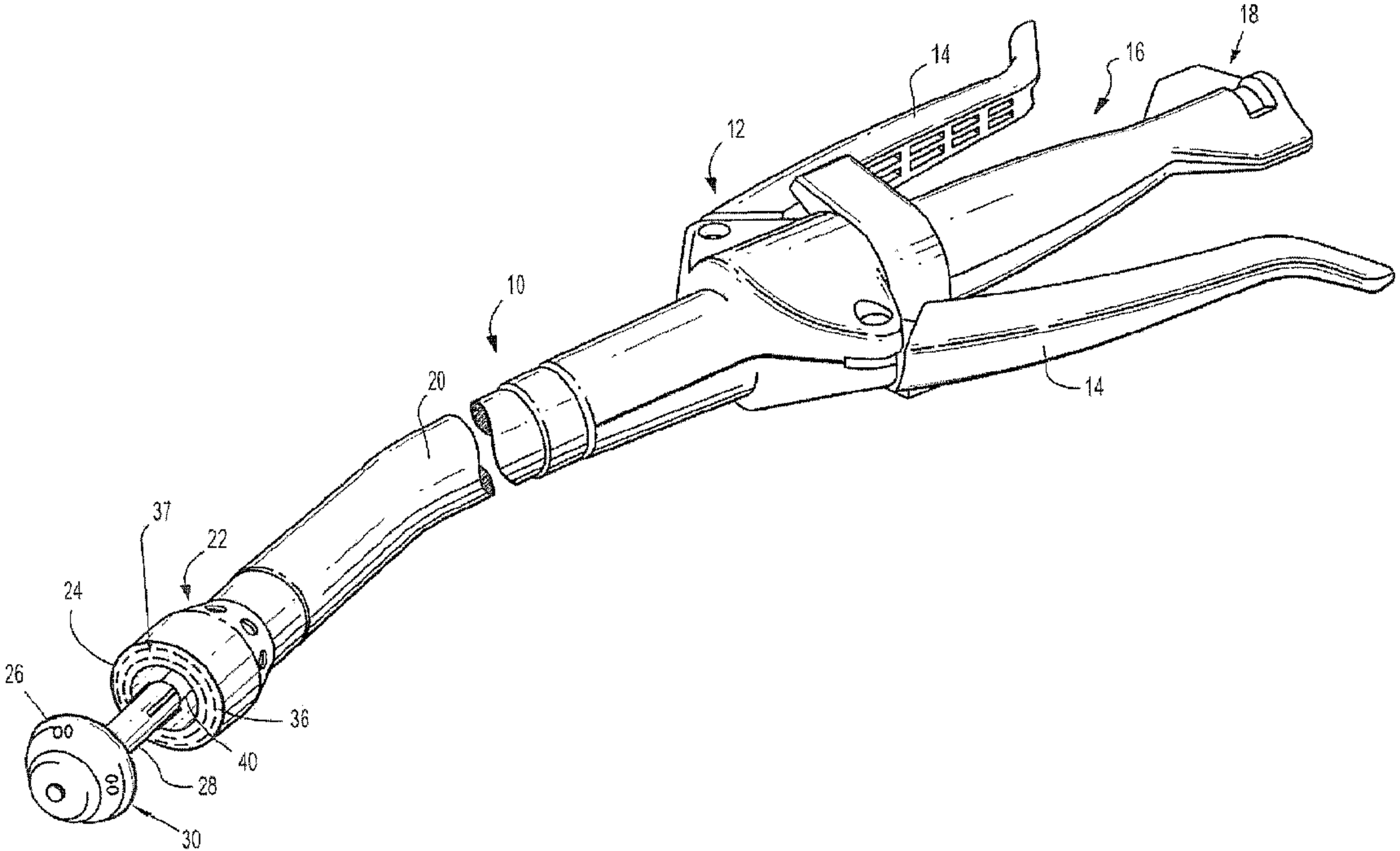


FIG. 18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