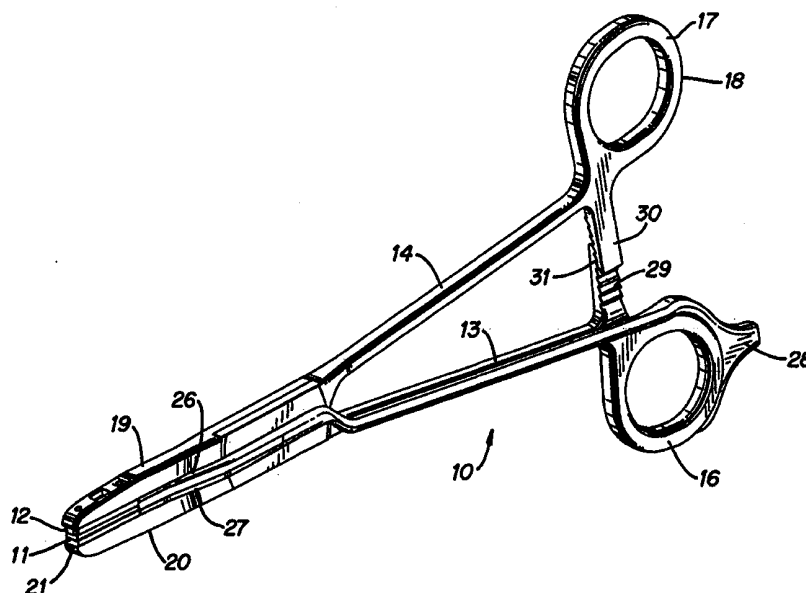


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<b>(21) International Application Number:</b> PCT/US98/23952 <b>(22) International Filing Date:</b> 11 November 1998 (11.11.98)  <b>(30) Priority Data:</b> 08/968,496 12 November 1997 (12.11.97) US  <b>(71) Applicant:</b> VALLEYLAB, INC. [US/US]; 5920 Longbow Drive, Boulder, CO 80301-3299 (US).  <b>(72) Inventors:</b> SCHMALTZ, Dale, Francis; 2319 Westview Road, Fort Collins, CO 80524 (US). LUZZI, Robert; 4670 White Rock Circle #5, Boulder, CO 80301 (US). HEARD, David, Nicholas; 3620 Silver Plume Lane, Boulder, CO 80303 (US). BUYASSE, Steven, Paul; 320 Columbine Place, Longmont, CO 80501 (US). LAWES, Kate, Ryland; 1303 Alpine Avenue 17B, Boulder, CO 80301 (US). TRIMBERGER, Daniel, Lee, II; 4147 16th Street, Greeley, CO 80634 (US). MITCHELL, Mathew, Erle; 7339 Buckingham Road, Boulder, CO 80301 (US). KENNEDY, Jenifer, Serafin; 5235 Independence Road, Boulder, CO 80301 (US).  <b>(74) Agent:</b> GERSHON, Neil, D.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06856 (US).		<b>(81) Designated States:</b> AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>

(54) Title: BIPOLAR ELECTROSURGICAL INSTRUMENT WITH REPLACEABLE ELECTRODES



## (57) Abstract

A bipolar electrosurgical instrument for vessel sealing comprises first and second members connected by a pivot. A pair of jaws have opposable seal surfaces that are designed to grasp vascular tissue and conduct bipolar electrosurgical current therethrough. Electrodes on the jaws, including the seal surfaces, are removable and disposable. The jaws of the instrument have mechanical interfaces designed to accept replacement electrodes. The instrument further comprises interlocking ratchets designed to hold a constant closure force between the seal surfaces. Wires extend from the electrodes along one of the members and are connectable to an electrosurgical generator.

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## **BIPOLAR ELECTROSURGICAL INSTRUMENT WITH REPLACEABLE ELECTRODES**

### **Field of the Invention**

This invention relates to a bipolar electrosurgical instrument, and more particularly to a bipolar electrosurgical instrument having replaceable electrodes for sealing vessels and vascular tissue.

### **Background of the Disclosure**

A hemostat is commonly used in surgical procedures to grasp, dissect and clamp tissue. It is typically a simple pliers-like tool that uses mechanical action between its jaws to constrict vessels without cutting them. It is also typical to have an interlocking ratchet between the handles so that the device can be clamped and locked in place.

Many hemostats are used in a typical open-surgical procedure. Once vascular tissue has been clamped with a hemostat, it is common for a surgeon to tie a suture around the tissue to close it off permanently prior to removing the hemostat. Several hemostats may be left in the surgical field until the surgeon has the opportunity to tie a suture around each section of clamped tissue.

Neurosurgeons have used bipolar instruments to coagulate vessels in the brain that are smaller than two millimeters in diameter. These bipolar instruments are typically tweezers-like devices with two arms that can be deflected toward each other to grasp tissue. However, it has been found that these instruments are not capable of sealing blood vessels with diameters larger than about two millimeters. There has been a long-felt need for an easy way to seal larger vessels and vascular tissue bundles without the need for sutures.

It is thought that the process of coagulating small vessels is fundamentally different than vessel sealing. Coagulation is defined as a process of desiccating tissue wherein the tissue cells are ruptured and dried. Vessel sealing is defined as the process of liquefying the collagen in the tissue so that it crosslinks and reforms into a fused mass. Thus, coagulation

of small vessels is sufficient to permanently close them. Larger vessels need to be sealed to assure permanent closure.

A number of bipolar electrosurgical forceps and clamps are known in the field. However, these instruments are not designed to apply the correct pressure to a blood vessel to achieve a lasting seal. All of these instrument also suffer from the drawback that they do not combine the simplicity and familiarity of a hemostat with a bipolar electrosurgical circuit.

An example of a bipolar electrosurgical power curve for vessel sealing is disclosed in a U.S. Patent application entitled, "Energy Delivery System for Vessel Sealing," serial number 08/530,495, filed September 19, 1995, and is hereby incorporated by reference and made a part of this disclosure.

A U.S. Patent application entitled, "Vascular Tissue Sealing Pressure Control and Method," serial number 08/530,450, filed on September 19, 1995, discloses another surgical tool for sealing vessels, and is hereby incorporated by reference and made a part of this disclosure.

U.S. Patent 371,664 discloses a pair of electric forceps with positive and negative electric poles located on the jaws.

U.S. Patent 728,883 discloses an electrothermic instrument in which electricity is used to heat one of the jaws of the instrument.

U.S. Patent 1,586,645 discloses a bipolar instrument for coagulating tissue.

U.S. Patent 2,002,594 discloses a bipolar laparoscopic instrument for treating tissue, whereby coagulation and cutting of tissue can be performed with the same instrument.

U.S. Patent 2,176,479 discloses an instrument for finding and removing metal particles. The jaws of the instrument are designed to complete an electrical circuit when conductive material is placed therebetween. An insulated pivot and an insulated ratchet are used to prevent a short circuit.

U.S. Patent 3,651,811 discloses a bipolar electrosurgical instrument for cutting and coagulating tissue.

U.S. Patent 4,005,714 discloses bipolar coagulation forceps with jaws that open and close by way of an actuating sleeve.

U.S. Patents 4,370,980 and 5,116,332 disclose an electrocautery hemostats wherein the hemostatic clamping function and the electrocautery function may be accomplished with  
5 a single instrument. Monopolar electrosurgical designs are shown and described.

U.S. Patent 4,552,143 discloses a family of removable switch electrocautery instruments, including an electrocautery hemostat. Monopolar electrosurgical designs are shown and described.

U.S. Patent 5,026,370 discloses an electrocautery forceps instrument having an  
10 enclosed electrical switching mechanism. Monopolar electrosurgical designs are shown and described.

U.S. Patent 5,443,463 discloses coagulating forceps having a plurality of electrodes.

U.S. Patent 5,484,436 discloses bipolar electrosurgical instruments for simultaneously cutting and coagulating tissue.

15 The article, "The Mechanism of Blood Vessel Closure by High Frequency Electrocoagulation" discloses experiments upon the blood vessels of dogs. The sentence starting on the last line of page 823 describes "an electrode forceps, each of the blades being insulated from the other and each connected to a terminal of the high frequency generator."

The article, "Studies on coagulation and development of an automatic computerized  
20 bipolar coagulator" discloses on page 150 that, "It was not possible to coagulate safely arteries with a diameter larger than 2 to 2.5 mm." On page 151, line 5, it is noted that "Veins can be coagulated safely up to a diameter of 3 to 4 mm."

Russian Patent 401,367, translation enclosed, discloses a bipolar instrument with a linkage that brings the working jaws together in a parallel manner.

25 Prior disclosures have not provided a design for a bipolar electrosurgical instrument with removable electrodes capable of conveniently applying a constant pressure, from a calibrated spring-loaded source held by a ratchet, that is sufficient to seal vessels and vascular tissue.

### **SUMMARY OF THE INVENTION**

It is the general object of this invention to provide a bipolar electrosurgical instrument for sealing vessels and vascular tissue. The instrument is designed to grasp and clamp vessels or vascular tissue between its jaws. The jaws have removable electrodes that  
5 are electrically connected to an electrosurgical generator. Electrosurgical current flows through the clamped tissue between the electrodes. The instrument is bipolar because electrosurgical current flows from one electrode, through the tissue, to another electrode, and both electrodes are located on the instrument. In contrast, a monopolar instrument requires a separate electrode (sometimes called a "neutral electrode") that is located  
10 remote from the instrument.

One of the advantages of the instrument is that vessels and vascular tissue can be sealed without the use of sutures, staples, or other material that is foreign to the tissue.

Another advantage of the instrument is that the removable electrodes provide safety against electrical shocks and burns. Electrically insulative materials, such as plastics, can  
15 be damaged or compromised by repeated sterilization cycles. It is also possible for electrical insulation to be cut or nicked by sharp surgical tools. Removable electrodes provide a safety advantage because they can be replaced prior to each procedure. The electrodes can also be replaced at any time if the surgeon suspects an electrical insulation failure. This advantage is particularly important for vessel sealing instruments because  
20 currents up to 4 amperes may be used.

The present invention is a bipolar electrosurgical instrument comprising first and second members having first and second jaws near a distal end, and having first and second handles near a proximal end. A pivot joint connects the first and second members to allow for arcuate motion of the first and second jaws toward each other. First and second  
25 mechanical interfaces are located respectively on the first and second jaws. The first and second mechanical interfaces are preferably shaped to removably mate with first and second electrodes. The mating portion of the electrodes are made from an insulative material to prevent electrical conduction to the members. Seal surfaces on the opposable electrodes are preferably designed to clamp vessels and vascular tissue and conduct electrosurgical current

therethrough in a bipolar circuit. First and second interlocking ratchets are located on the proximal end of the members to provide a constant closure force between the seal surfaces.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

- 5 Figure 1 is a perspective view of a bipolar electrosurgical instrument, showing the electrodes mated together in parallel opposition.
- Figure 2 is a perspective view of a bipolar electrosurgical instrument, showing one electrode removed with the socket in view, and one electrode in place.
- Figure 3 is a perspective view of a bipolar electrosurgical instrument, showing one electrode in  
10 place and one electrode removed.
- Figure 4 is a bottom view of a replaceable electrode showing the electrically insulative substrate with a portion of a wire attached.
- Figure 5 is a side view of Figure 4.
- Figure 6 is a detail view of a forked snap-fit extension.
- 15 Figure 7 is a perspective view of a replaceable electrode.
- Figure 8 is side view of an electrode showing a forked snap-fit extension.
- Figure 9 is a partial side view of a portion of a socket designed to receive the snap-fit extension.
- Figure 10 is a partial side view of an electrode seated in a socket.
- 20 Figure 11 is an enlarged view of a portion of a snap-fit extension seated in a socket.

### **DETAILED DESCRIPTION OF THE INVENTION**

Referring to Figure 1, a bipolar electrosurgical instrument 10 is shown with replaceable electrodes 11 and 12 for sealing vessels and vascular bundles. The instrument  
25 10 comprises a first member 13 and a second member 14 that are connected at a pivot joint 15. Handles 16 and 17 are located generally at the proximal end 18. Jaws 19 and 20 are located generally at the distal end 21. Sockets 22 and 23 are located on the jaws 19 and 20. The sockets 22 and 23 each preferably comprise several features, as shown in Figure 2 at the location where the electrode 11 is removed. In one embodiment, shown in Figure 1, the

jaws 19 and 20 are straight. In alternative embodiments, the jaws 19 and 20 may be curved to accept curved electrodes 11 and 12, as shown in Figure 4.

The first and second electrodes 11 and 12 are removably mounted respectively in the first and second sockets 22 and 23. While the term socket is used herein, it will be understood that either a male or female mechanical interface may be used on the jaws 19 and 20, with a mating mechanical interface on the electrodes 11 and 12. In Figure 2, one of the sockets 22 is shown with the electrode 11 removed. Figure 3 shows the socket 23 with an electrode 12 mated therein.

Each of the first and second electrodes 11 and 12 has an electrically conductive seal surface 24 and an electrically insulative substrate 25, as shown in Figures 5 and 7. Each substrate 25 is shaped to engage one of the first or second sockets 22 or 23 with mating features that fit removably within the sockets 22 or 23. In the preferred embodiment, the seal surfaces 24 are relatively flat to avoid current concentrations at sharp edges, and to avoid arcing between high points.

First and second wires 26 and 27 are connected to the first and second electrodes 11 and 12, respectively, as shown in Figures 1, 4, 5, and 7. In the preferred embodiment, the wires 26 and 27 are bundled together along one of the members 13 or 14 from the proximal end 18 to the pivot 15. Near the pivot 15, the wires 26 and 27 are separated and connected each to its respective electrode 11 or 12. This arrangement of wires 26 and 27 is designed to be convenient for the surgeon so that there is little interference with the manipulation of the instrument 10. The wires 26 and 27 are preferably terminated in a connector 28 near the proximal end 18, although in another embodiment the wires 26 and 27 may extend all the way to an electrosurgical generator. In an alternative embodiment, the wires 26 and 27 each extend along a separate handle 16 or 17.

First and second ratchets, 29 and 30, are located on the members 13 and 14 near the handles 16 and 17, as shown in Figures 1, 2, and 3. The ratchets 29 and 30 interlock in at least one position, shown in Figure 1 at 31. In the preferred embodiment, there are several interlocking positions. The ratchet position 31 holds strain energy in the first and second members 13 and 14 to force the electrodes 11 and 12 against each other in opposition.



Each member 13 and 14 is preferably designed to deflect in a shank portion, defined as the section between the pivot 15 and the location of the ratchet. The jaws 19 and 20 are preferably more rigid than the shank portions. A lateral deflection of the shank portion causes strain due to bending that behaves like a spring. The strain energy that is stored in the shank provides a constant closure force between the electrodes 11 and 12. A design without a ratchet requires the surgeon to hold the electrodes together by applying a constant squeeze to the handles. It has been found through experimentation that a constant force throughout the sealing process will yield a more predictable surgical outcome. It is difficult to hold a constant force by hand, therefore a ratchet in combination with a deflectable shank will provide a better surgical outcome.

The electrically insulative substrate 25 on each of the electrodes 11 and 12 is preferably made from an injection moldable plastic. The substrate 25 is preferably overmolded to capture the electrically conductive seal surface 24, as shown in Figure 8. Wires 26 and 27 are electrically connected to the seal surface 24 of each electrode 11 or 12. There is preferably a strain relief feature 33 on the electrodes 11 and 12, as shown in Figures 4 and 7.

The substrate 25 preferably comprises a forked snap fit extension 32 as shown in detail in Figure 6. Each jaw 19 and 20 has a socket 22 and 23 that comprises a recess 34, shown in Figure 9, shaped to capture the forked snap fit extension 32. One of the advantages of this design is that manufacturing tolerances can be accommodated by the snap fit as shown in Figure 11. The preferred embodiment also comprises a pair of alignment pins 34 and 35 that fit into the sockets 22 and 23.

In the preferred embodiment, the instrument 10 is designed so that the electrodes 11 and 12 meet in parallel opposition. Thus, opposing seal surfaces 24 meet each other in the same plane, as shown in Figure 1. In an alternative embodiment, the seal surfaces can be slightly biased to meet each other at the distal end, and further closure force at the handles will cause the seal surface 24 on each electrode 11 and 12 to deflect together in the same plane. In certain embodiments, there may be a stop to create a fixed gap, preferably about 0.3 millimeters, to prevent shorting of the electrodes. Other embodiments have an

insulative element on each jaw that opposes the conductive seal surface 24 on the opposing jaw, such that the instrument 10 does not short circuit when the jaws 19 and 20 are closed together.

It has been determined experimentally that the closure force between the seal  
5 surfaces 24 is preferably sufficient to overcome a tendency of the tissue to expand during heating. The sealed tissue thickness must be less than the initial tissue thickness, under pressure, in order to create a fused vessel wall. The amount of pressure required depends on the type of tissue, and the dimensions of the seal surfaces 24, and the size of the tissue that is grasped with the instrument 10. The pressure is expressed herein as a formula depending  
10 on the width of the seal surface and the closure force between the seal surfaces.

For an instrument designed for abdominal vessels and vascular bundles, each seal surface 24 has a width that is preferably in the range of 2 to 5 millimeters, and a length in the range of 10 to 30 millimeters. For abdominal vessels and vascular bundles, experimental results indicate that good vessel sealing performance can be achieved when  
15 the instrument 10 is calibrated to have at least one ratchet position 31 set such that the closure force (in grams) divided by the width of the seal surface (in millimeters) is in the range of 400 to 650, and most preferably 525. For example, an instrument with a seal surface width of 4 millimeters would preferably have a closure force of 2100 grams.

For an instrument designed for thick connective tissues and ligaments, particularly a  
20 hysterectomy style Heaney device, the closure force (in grams) divided by the width of the seal surface (in millimeters) is in the range of 1000 to 2000. Such an instrument would also preferably have a cross hatched or knurled seal surfaces 24 to improve grasping capability, but the height of the roughness features should be minimized to avoid arcing.

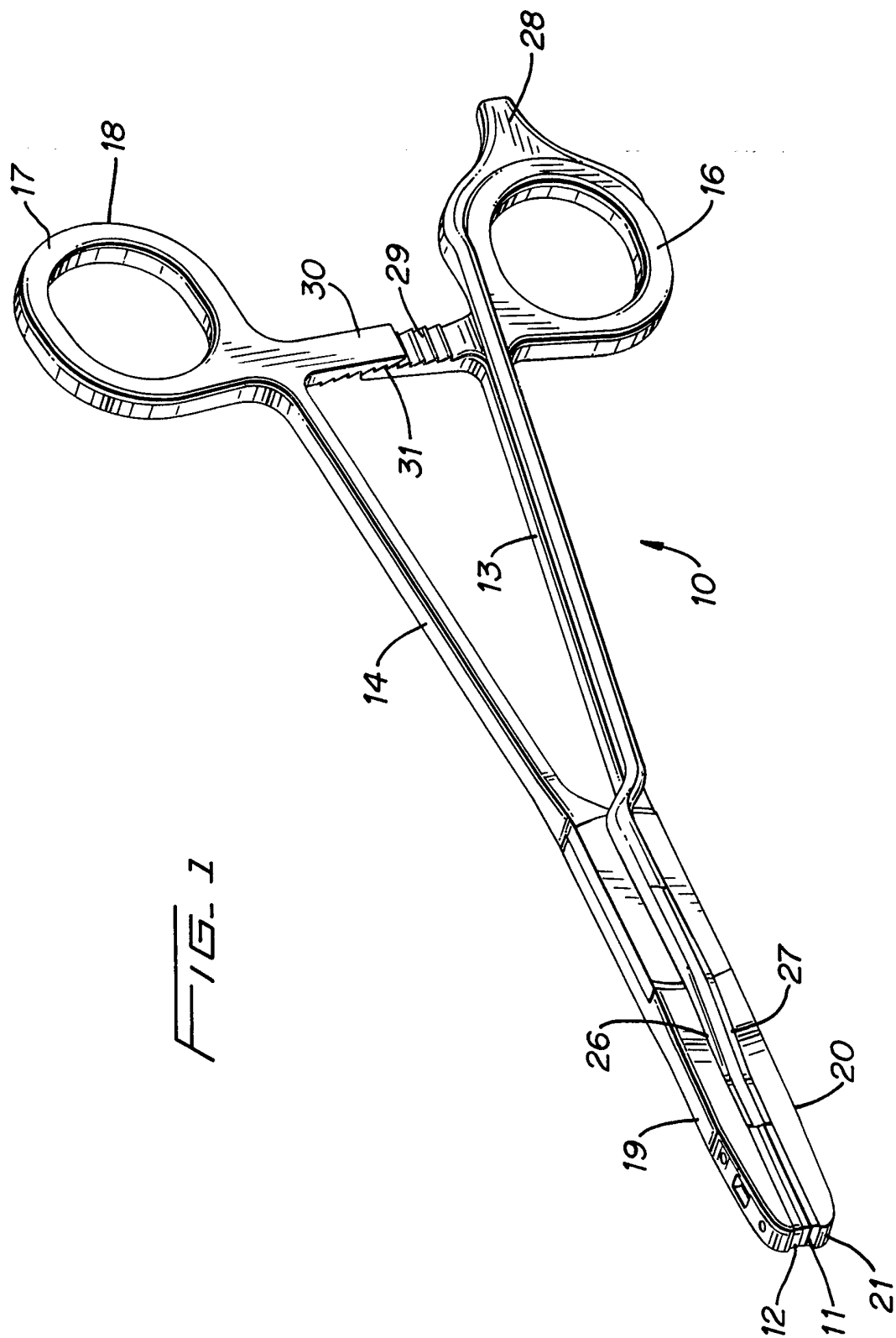
While a particular preferred embodiment has been illustrated and described, the scope  
25 of protection sought is in the claims that follow.

What is claimed is:

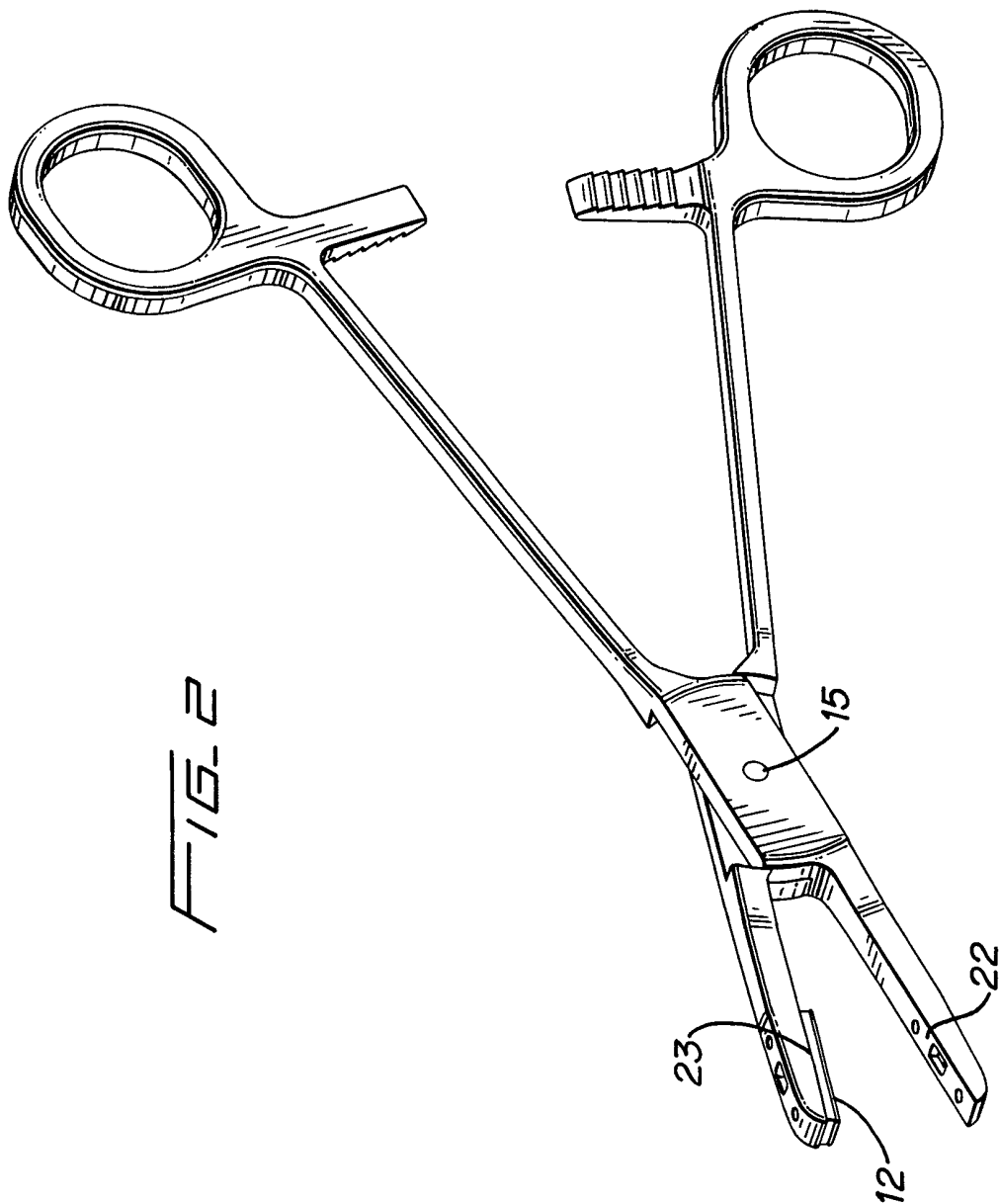
1. A bipolar electrosurgical instrument comprising:
  - a first member having a first jaw near a distal end of the instrument, and having a  
5 first handle near a proximal end of the instrument;
  - a second member having a second jaw near the distal end and having a second  
handle near the proximal end;
  - a pivot joint connecting the first and second members between the proximal and  
distal ends to allow for arcuate motion of the first and second jaws toward each other;
  - 10 a first mechanical interface on the first jaw, and a second mechanical interface on  
the second jaw;
  - first and second electrodes removably mounted in the first and second mechanical  
interfaces, respectively, wherein each of the first and second electrodes has an electrically  
conductive seal surface and an electrically insulative substrate, and wherein each substrate  
15 is shaped to engage one of the first or second mechanical interfaces;
  - first and second wires connected to the first and second electrodes, respectively;
  - a first ratchet on the first handle, and a second ratchet on the second handle,  
wherein the first and second ratchets interlock in at least one position, and wherein the  
position holds strain energy in the first and second members to force the first and second  
20 electrodes against each other in opposition defining a closure force.
2. The instrument of claim 1 wherein the insulative substrate on each of the first and  
second electrodes comprises a forked snap fit extension, and wherein each of the first and  
second mechanical interfaces has a recess shaped to capture the forked snap fit extension.
3. The instrument of claim 1 wherein the insulative substrate on each of the first and  
25 second electrodes comprises a pair of alignment pins, and wherein each of the first and  
second mechanical interfaces has a pair of recesses shaped to engage a pair of alignment  
pins.
4. The instrument of claim 1 wherein the first and second wires are removably  
attached to the first handle.

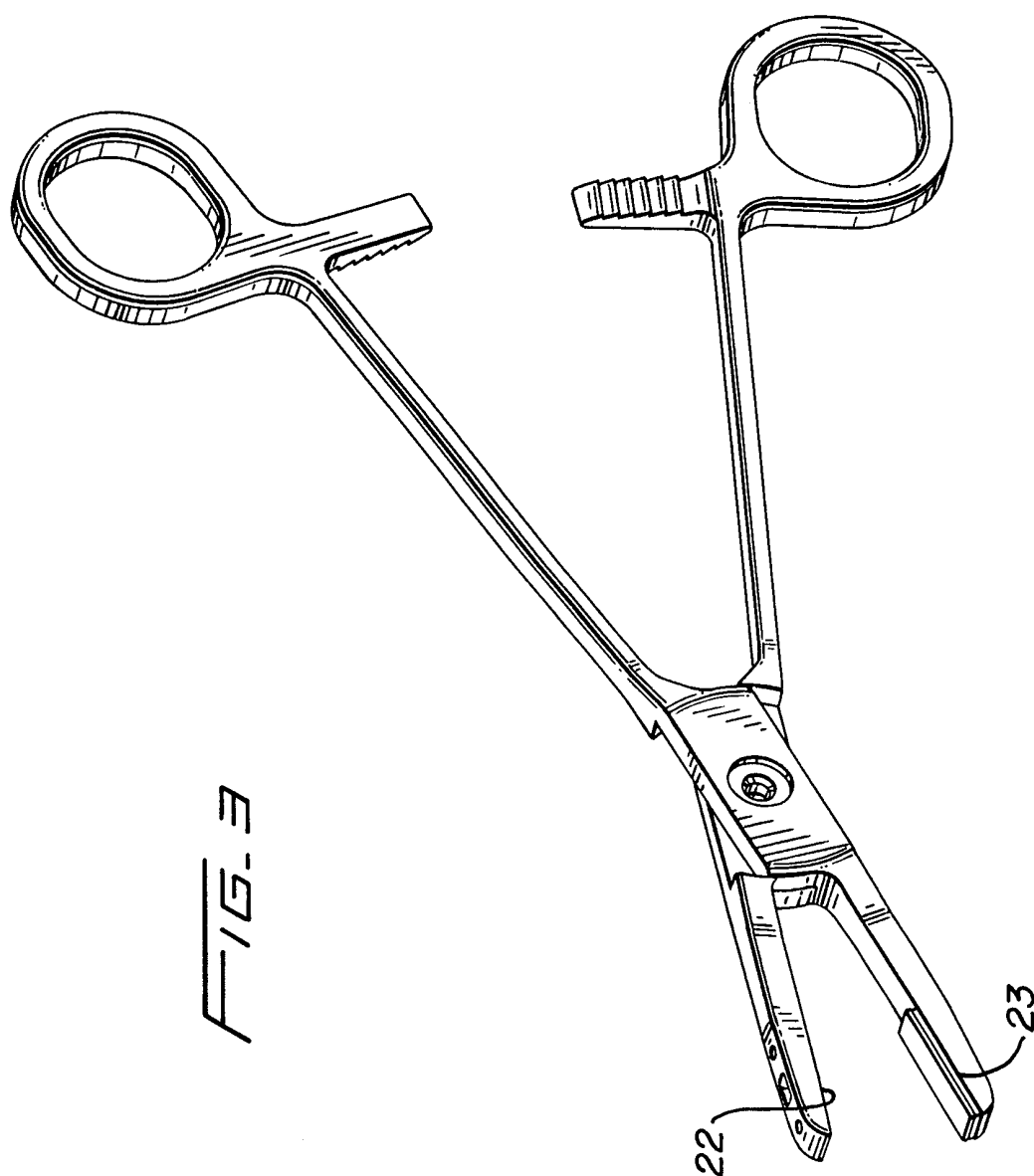
5. The instrument of claim 1 wherein the first and second wires are terminated with an electrical connector near the proximal end.
6. The instrument of claim 1 wherein the first and second electrodes are aligned to contact each other in parallel opposition.
- 5 7. The instrument of claim 1 wherein each of the first and second electrodes have planar seal surfaces.
8. The instrument of claim 1 wherein each of the first and second jaws have a curved shape.
9. The instrument of claim 1 wherein the seal surface has a width, and the closure  
10 force in grams divided by the width in millimeters is in the range of 400 to 650.
10. The instrument of claim 1 wherein the seal surface has a width, and the closure force in grams divided by the width in millimeters is in the range of 1000 to 2000.
11. A bipolar electrosurgical instrument for sealing vascular tissue, comprising:  
a first member having a first jaw near a distal end and having a first handle near a  
15 proximal end;  
a second member having a second jaw near a distal end and having a second handle near a proximal end;  
a pivot joint connecting the first and second members to allow for arcuate motion of the first and second jaws toward each other;  
20 a first mechanical interface on the first jaw, and a second mechanical interface on the second jaw;  
first and second electrodes removably mounted in the first and second mechanical interfaces, respectively, wherein each of the first and second electrodes has an electrically conductive seal surface and an electrically insulative substrate, and wherein each substrate  
25 has two pins and a forked snap fit extension that are shaped to engage one of the first or second mechanical interfaces;  
first and second wires connected to the first and second electrodes, respectively, and removably connected to the first handle and terminated with an electrical connector;

a first ratchet on the first handle, and a second ratchet on the second handle, wherein the first and second ratchets interlock in at least one position, and wherein the position holds strain energy in the first and second handles to force the first and second electrodes against each other in opposition.



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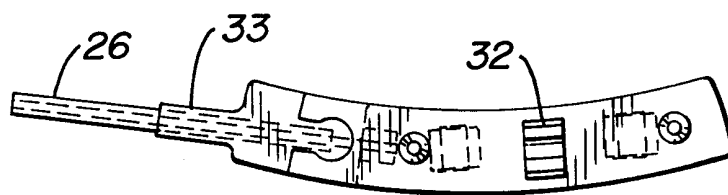


FIG. 4

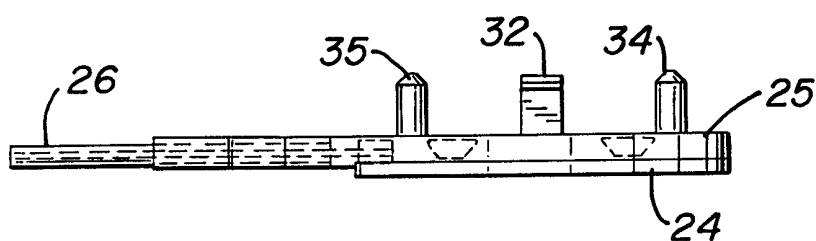


FIG. 5

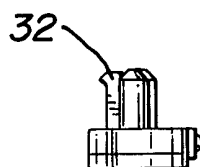


FIG. 6

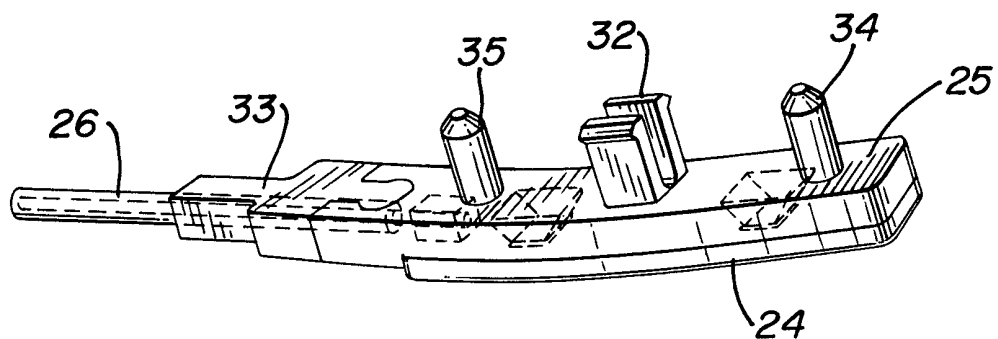


FIG. 7

FIG. 8

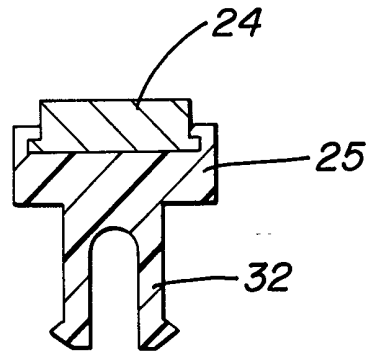


FIG. 9

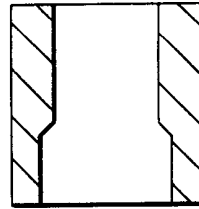


FIG. 10

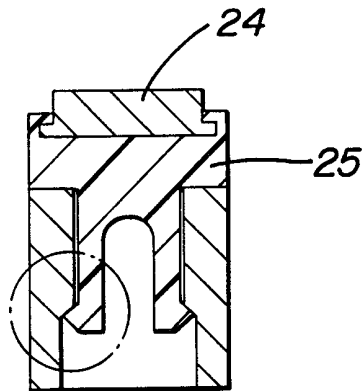


FIG. 11

