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US 4657018 A

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(54) Electrosurgical interstitial resector

(57) An electrosurgical apparatus for resecting tissue within a body has an elongated hollow shaft 16 with a sharp point at the distal end, an opening in the shaft to allow passage of resected tissue, an electrically conducting deflectable member located within the shaft and connected to a supply of RF current 33, and a deflection control connected to the deflectable member at the proximal end for deflecting the member outwardly through the opening, eg by know increments using a ratchet 29. Tissue is cut and coagulated by the deflectable member as the apparatus is rotated by a rotation control through a rack and pinion 31,32. The sharp tip allows the apparatus to be inserted percutaneously. A source of irrigation fluid 26 and a source of suction 25 may be connected selectively by a rocker switch 28.

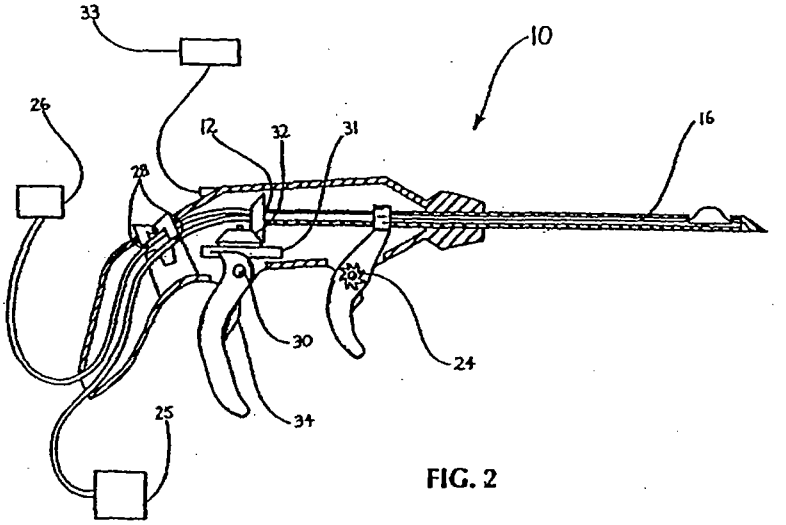

FIG. 2

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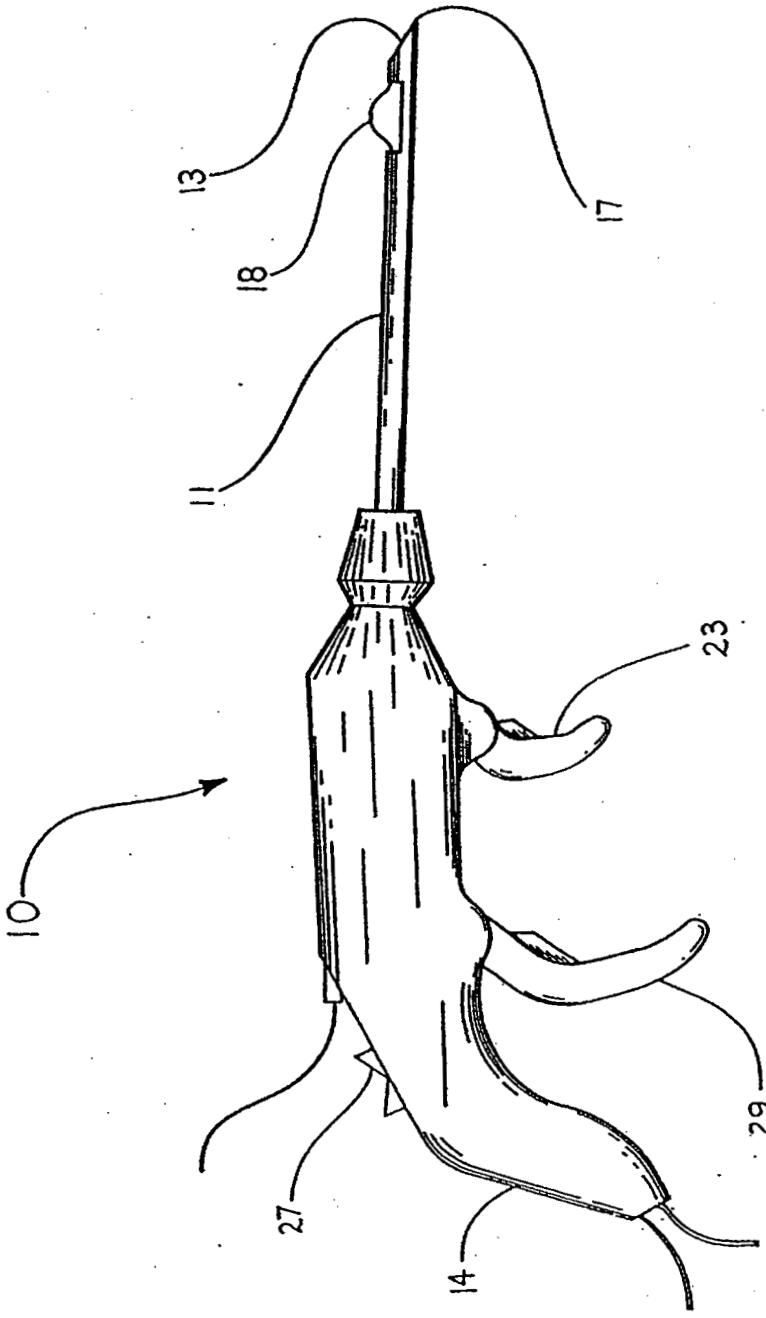

FIG. 1

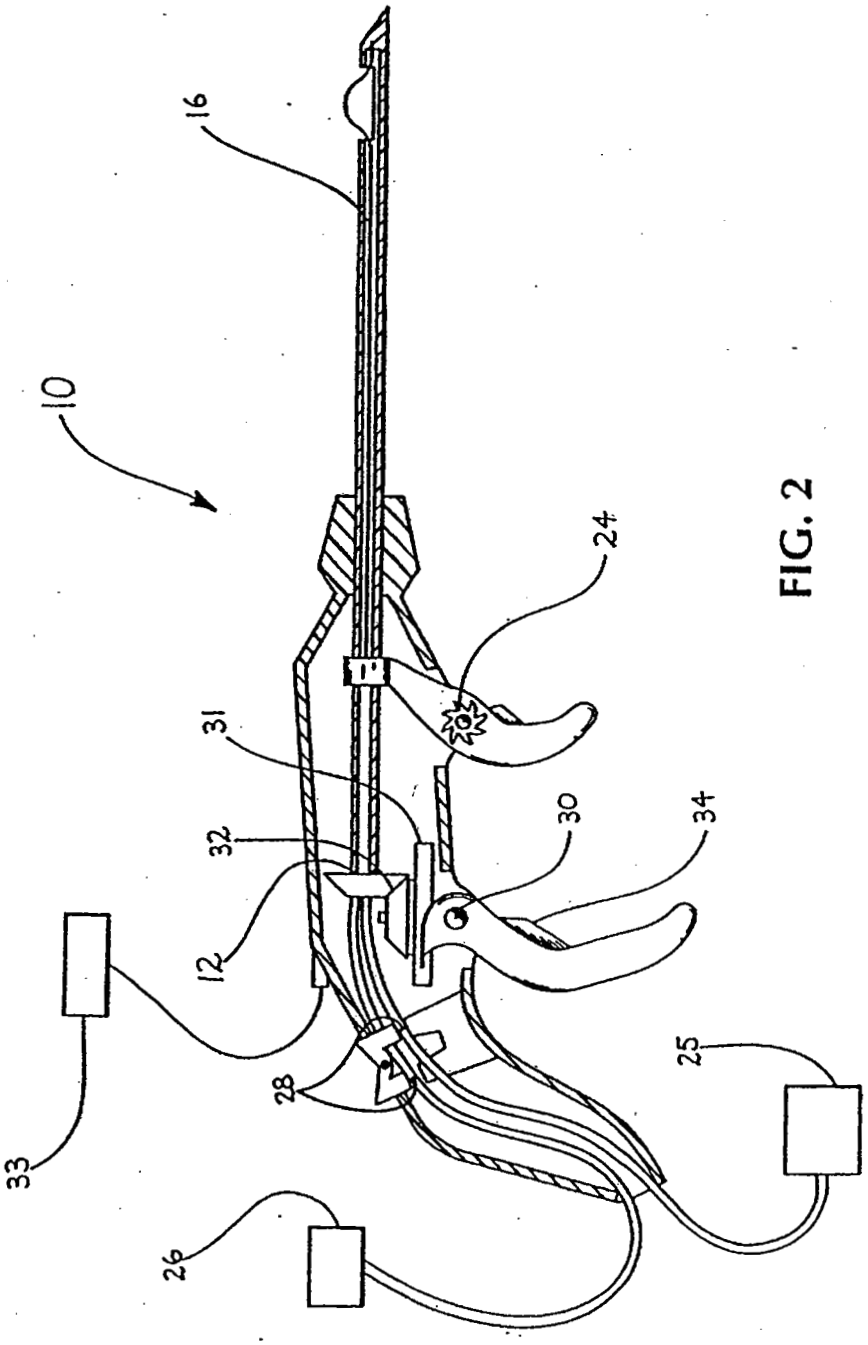

FIG. 2

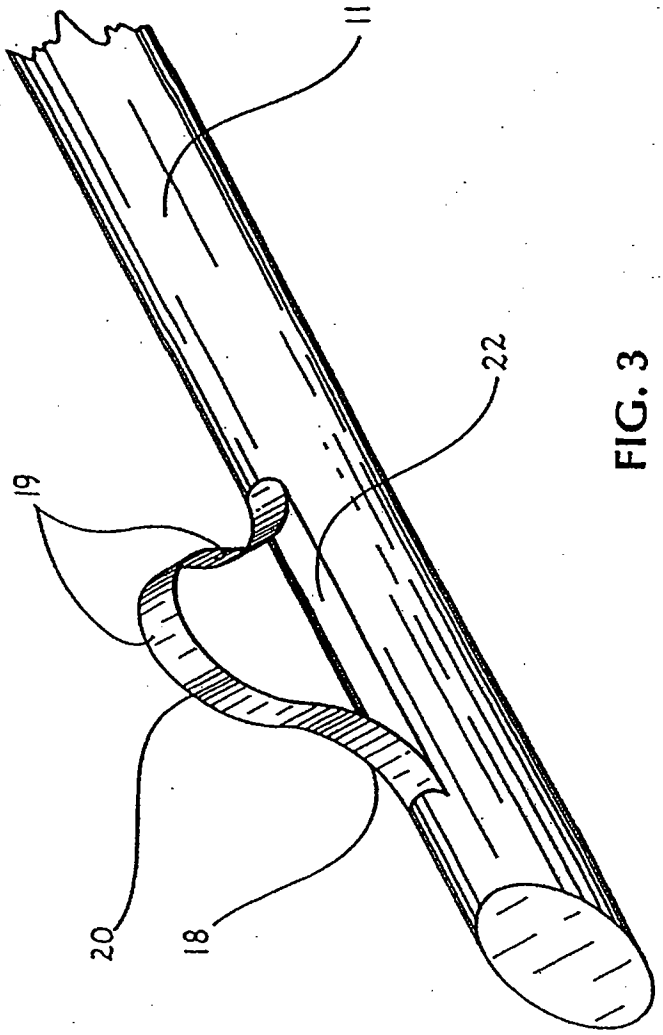

FIG. 3

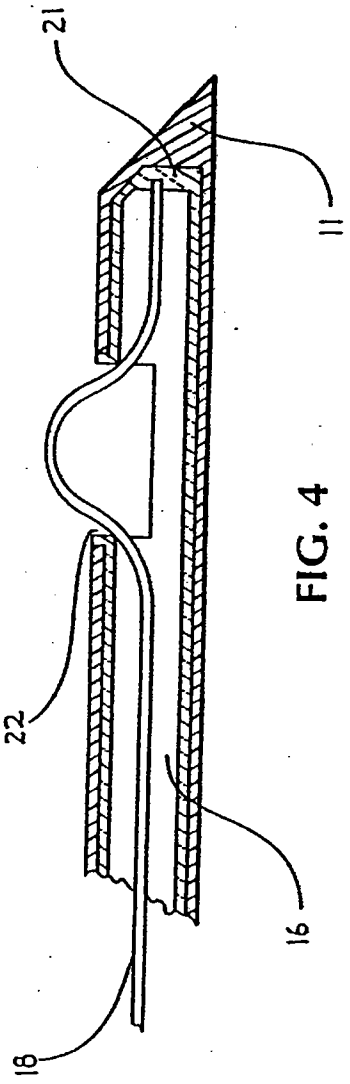

FIG. 4

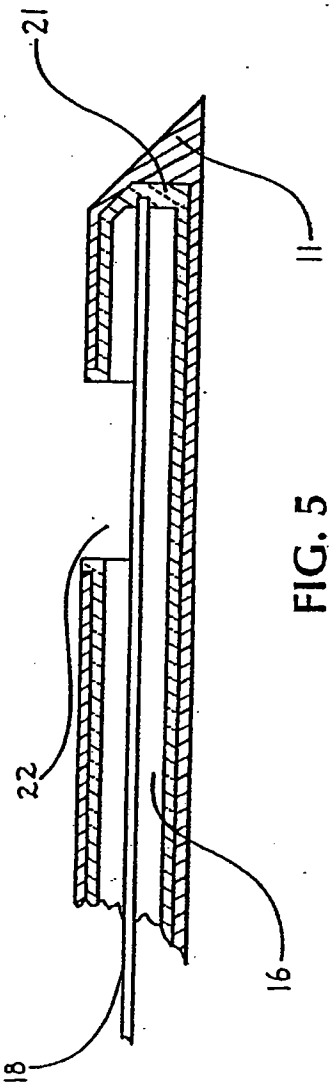

FIG. 5

ELECTROSURGICAL INTERSTITIAL RESECTOR

Field of Invention This invention relates to an electrosurgical apparatus. More particularly, the invention relates to an electrosurgical tool for percutaneously debulking and removing the prostate or other tissue, and to a method for performing debulking and removal of tissue using RF electrical energy.

Background of the Invention Benign prostatic hyperplasia (BPH) is a benign enlargement of the prostate gland resulting in a reduction in urine flow through the urethra. BPH typically affects men over the age of 45 and increases in frequency with age. BPH can result in both obstructive and irritative symptoms which can range in severity from mild reduction in flow to acute retention.

A common surgical procedure for BPH is the transurethral resection of the prostate (TURP) which removes portions of the prostate through the urethra using a transurethral resectoscope and electrocautery. TURPs are not without their problems and can result in extended hospital stays, blood loss sometimes requiring transfusion, impotence and incontinence. An additional concern is the absorption of the irrigating fluid (TUR syndrome) creating huge increases in cardiac load.

Various instruments for performing surgical cutting operations in body lumens, for example TURPs, are known in the art. U.S. Patent No. 5,415,656 discloses an electrosurgical apparatus for incision of a stricture within or adjacent to a body lumen. The apparatus comprises an electrically conducting, deflectable wire that is connected to a source of RF electrical current. The disclosure does not include any apparatus that would permit or suggest the insertion of the instrument through the skin, i.e. percutaneously.

reference and made a part of this disclosure.

U.S. Patent No. 3,910,279 discloses an electrosurgical instrument for resecting bodily tissue. The instrument is designed for insertion through an existing body lumen and into a body cavity. The apparatus is not designed for percutaneous insertion into tissue. The disclosure also does not address the need for a suction or irrigation capability.

There have been many attempts to develop new therapies which provide an alternative to TURPs for BPH. These therapies have been generally directed toward less-invasive modalities such as transurethral ablation, although some interstitial methods may be known. These therapies include the use of lasers, stents, cryotherapy, ultrasound, microwaves, RF electrical current, balloons, and transurethral incisions, and drugs. Not all of these have proven to be very effective and the ideal therapy for one type of patient may not necessarily be the same for another.

Interstitial therapies offer advantages over TURPs by minimizing blood loss, eliminating concerns about TUR syndrome, and reducing the occurrence of retrograde ejaculation by completely sparing the bladder neck and urethra. Another advantage with these procedures is that patients can typically resume normal activities more quickly than patients who undergo TURP.

Interstitial therapies offer advantages over other transurethral ablation technologies because there is no sloughing of tissue through the urethra after the procedure. Further, interstitial therapies offer benefits over standard hyperthermia technologies because it has been shown that over time, a demonstrable lesion can be created in the prostate.

The downfalls with current interstitial ablation methods, as well as with all the non-invasive modalities, is that no tissue samples can be obtained for pathology during the procedure. Even more critical, in all of the known less-invasive therapies, obstruction relief is not immediate and a catheter must often be placed post-surgically. There is yet no known device which can create immediate post-operative relief from BPH obstruction and provide tissue for pathological analysis, without the need for a post-operative catheter.

Summary of the Invention

An interstitial resector, described herein, may be used for surgery on the prostate. The interstitial resector uses a wire loop to cut and cauterize tissue that is subsequently sucked out through an aspiration port. This device is intended to provide the benefits of minimizing bleeding and reducing the likelihood of TUR syndrome, while obtaining the same rapid obstruction relief and pathological samples as from a TURP.

The present invention is based on the idea of destroying and immediately removing tissue from within the prostate while causing minimal damage to the

prostatic urethra. An advantage of this product is that it combines the benefits of TURPs (immediate obstruction relief, tissue sampling) and interstitial ablation (minimized bleeding, no damage to the urethra or bladder neck, and quick recovery) into one product.

The interstitial resector may be disposable and may consist of a rigid plastic handle connected to a semi-flexible shaft having a sharp tip. At the distal portion of the shaft, one or more cutting elements could be variably exposed. These elements can be energized with electrosurgical current or electrocautery. A suction/irrigation channel may be within the shaft to inject fluid or to remove tissue from the operative site. The importance of removing tissue is that it provides the surgeon with samples for pathology testing.

The procedure for use of the interstitial resector may require transrectal ultrasound or transurethral visualization. Once the interstitial resector was inserted within the tissue, the active element may be moved slightly outward at the distal end of the shaft. Upon the activation of energy, the resector would be rotated, thus cutting off wedge sections of tissue which could then be removed through the aspiration channel using suction. The active element could be incrementally extended to remove greater and greater lumps of tissue as the procedure progresses. The utilization of electrosurgical energy would cause coagulation of the remaining tissue. Any post-operative bleeding should be self-limited since the surgical wound is encapsulated.

Brief Description of the Drawings

Figure 1 is a side view of an electrosurgical interstitial resector.

Figure 2 is a schematic cross-sectional view of an electrosurgical interstitial resector.

Figure 3 is a view of the distal end of the shaft.

Figure 4 is a cross-sectional view of the distal end of the shaft showing a member in its deflected position.

Figure 5 is a cross-sectional view of the distal end of the shaft showing a member in its nondeflected position.

Detailed Description of the Invention

The present invention is an electrosurgical apparatus 10, as shown in Figure 1 for resecting tissue within a body. The apparatus 10 is designed for percutaneous insertion into the body and may be used for operations on the prostate gland. The apparatus is particularly suited for treatment of benign prostatic hyperplasia (BPH).

The apparatus 10 comprises an elongated hollow shaft 11 having a proximal end 12 and a distal end 13. The proximal end 12 of the shaft 11 is connected to a handle 14 with controls for the surgeon. The distal end 13 of the shaft 11 is designed for contact with the tissue of the patient. The shaft 11 has a hollow interior 16 with a diameter sized to allow passage of resected tissue from the distal end 13 to the proximal end 12. In one embodiment, the shaft 11 is a needle in the range of 18 to 14 gauge.

There is a sharp point 17 on the distal end 13 of the shaft 11. The sharp point 17 is used for introducing the apparatus 10 percutaneously. The sharp point 17 offers the surgeon the ability to push the distal end 13 into the prostate without maneuvering through a body lumen. This feature, in part, distinguishes the present invention 10 from wire resectors with blunt tips.

An electrically conducting, deflectable member 18 is located within the hollow interior 16 of the shaft 11, as shown in Figures 4 and 5. In one embodiment, the member 18 is a wire. In another embodiment, the member 18 has two flat surfaces 19 and at least one sharp edge 20. The sharp edge 20 allows the member 18 to cut mechanically while cauterizing with electrosurgical current. The flat surfaces 19 are designed so that the member 18 will bow in a predictable manner. In another embodiment, the member 18 has a preset and permanent bend, so that tension or compression on the member 18 will result in a repeatable and predictable deflection. In one embodiment, the member 18 is made from a superelastic alloy. In another embodiment, the member 18 is made from an alloy of nickel and titanium.

An electrically insulative material 21 is disposed between the member 18 and the shaft 11, as shown in Figures 4 and 5. In one embodiment, the insulative material 21 is on the member 18 such that electrical current will not flow between the member 18 and the shaft 11. In another embodiment, the insulative material 21 is on the shaft 11. In yet another embodiment, both the member 18 and the shaft 11 have electrically insulative coverings.

There is an opening 22 near the distal end 13 of the shaft 11. In one embodiment the opening 22 is rectangular in shape. In another embodiment the opening 22 is oval in shape. The opening 22 is large enough so that resected portions of tissue can be drawn through the opening 22 and into the hollow interior 16 of the shaft 11, as shown in Figure 3.

A deflection control 23 is located on the handle 14. The surgeon can use the deflection control 23 for deflecting a portion of the member 18 outwardly relative to

the opening 22. In a preferred embodiment, the deflection control 23 has a ratcheting mechanism 24 that positions the member 18 in known increments of deflection from the opening 22.

A source of suction 25 is connected to the proximal end 12, as shown in Figure 2. The suction is used for drawing fluids and tissue inward from the opening 22. The suction must be strong enough to draw the resected tissue through the opening 22, along the shaft 11, and out beyond the proximal end 12 of the apparatus 10. The tissue and fluids are then collected in a standard trap for later pathological analysis.

A source of irrigation fluid 26 is connected to the proximal end. The irrigation fluid can be directed through the shaft 11 and out of the opening 22. In the preferred embodiment, a suction/irrigation switch 27 mounted on the apparatus 10 near the proximal end 12 is used for selecting either suction or irrigation in the shaft 11. The switch 27 is connected to simple trumpet valves 28 to open and close the ports to the sources of suction 25 or irrigation 26, as shown in Figure 2.

In the preferred embodiment, the suction/irrigation switch 27 is a three position rocker switch. The rocker switch 27 is biased such that no suction or irrigation fluid is applied at the opening. When the switch 27 is depressed in a first direction, the source of irrigation fluid 25 is connected to the interior passageway 16, thus providing irrigating fluid through the opening 22. When the switch 27 is depressed in a second direction, the source of suction 25 is connected to the interior passageway 16, thus providing suction at the opening 22.

A rotation control 29 is connected near the proximal end 12 of the shaft 11 to provide the surgeon with a mechanism for rotating the shaft 11 relative to the tissue. When the member 18 is extended from the opening 22, rotation of the shaft 11 causes the member 18 to resect the tissue. In one embodiment, the rotation control 29 may be a knob which is rigidly mounted to the shaft 11. In the preferred embodiment, the rotation control 29 is a lever which has a pivot 30 that allows motion back and forth along the direction of the shaft 11. A rack 31 and pinion gear 32 train connects the lever to the shaft 11 such that the pivotal motion of the lever produces a rotational motion of the shaft 11, as shown in Figure 2.

A source of RF electrical current 33 is connected to the member 18. The source of RF electrical current 33 may be any of the commercially available electrosurgical generators, for example the Force FX Electrosurgical Generator manufactured by Valleylab, Inc. in Boulder, CO. An electrical switch 34 connects the

source of RF electrical current 33 to the member 18. Standard medical grade switch technology can be used.

A method for using the electrosurgical interstitial resector 10 is also herein described. The method comprises the following steps: introducing the apparatus 10 into tissue by forcing the sharp point 17 through the tissue; deflecting the member 18 such that the member 18 protrudes through the opening 22; applying electrosurgical current through the member 18; rotating the shaft 11 such that the protruding portion of the member 18 resects tissue from the body; drawing the resected tissue through the shaft 11 with suction, and irrigating the tissue by forcing irrigating fluid through the shaft 11 and out of the opening 22.

CLAIMS

1. An electrosurgical apparatus for resecting tissue within a body, the apparatus comprising:

an elongated hollow shaft having a proximal end, a distal end, an interior passageway, and an exterior surface;

an opening in the shaft between the interior passageway and the exterior surface near the distal end, and of sufficient size to allow passage of resected tissue;

an electrically conducting, deflectable member located within the interior passageway and set to deflect through the opening;

a deflection control connected to the deflectable member at the proximal end for deflecting a portion of the deflectable member outwardly through the opening;

a source of RF electrical current connected to the deflectable member; and

a sharp point on the distal end.

2. An apparatus according to Claim 1, in which the deflectable member further includes surfaces which are bounded by at least one sharp edge.

3. An apparatus according to Claim 1 or Claim 2, in which the deflectable member is made from a superelastic alloy.

4. An apparatus according to any preceding Claim, further comprising an electrical switch connected between the source of RF electrical current and the deflectable member.

5. An apparatus according to any preceding Claim, further comprising a rocker switch located at the proximal end, wherein a first position of the switch connects a source of irrigation fluid with the interior passageway, a second position of the switch connects a source of suction with the interior passageway, and a third position of the switch closes the interior passageway to both suction and irrigation fluid.

6. An apparatus according to any preceding Claim, further comprising a ratcheting mechanism connected to the deflection control, wherein each successive position of the ratchet advances deflection of the deflectable member.

7. An apparatus according to any preceding Claim, further comprising a rotation control located near the distal end and mechanically coupled to the shaft.

8. An apparatus according to any preceding Claim, further comprising a source of suction connected to the interior passageway for drawing fluids and resected tissue into the interior passageway through the opening.

9. An apparatus according to any preceding Claim, further comprising a source of irrigation fluid connected to the interior passageway for sending irrigation fluid outwardly through the opening.

10. An electrosurgical apparatus for resecting tissue within a body, the apparatus comprising:

an elongated hollow shaft having a proximal end, a distal end, an interior passageway, and an exterior surface;

an opening in the shaft between the interior passageway and the exterior surface near the distal end, and of sufficient size to allow passage of resected tissue;

an electrically conducting, deflectable member located within the interior passageway and set to deflect through the opening;

a deflection control connected to the deflectable member at the proximal end for deflecting a portion of the deflectable member outwardly through the opening;

a racheting mechanism connected to the deflection control, wherein each successive position of the ratchet advances the deflection of the deflectable member;

a rotation control located near the distal end and mechanically coupled to the shaft;

a source of suction connected to the interior passageway for drawing fluids and resected tissue into the interior passageway through the opening;

a source of irrigation fluid connected to the interior passageway for sending irrigation fluid outwardly through the opening;

a source of RF electrical current connected to the deflectable member; and

a sharp point on the distal end.

11. An electrosurgical apparatus substantially as described herein, with reference to Figures 1 to 5 of the Drawings.

The Patent Office

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Application No: GB 9703792.3 **Examiner:** Bob Clark
Claims searched: All **Date of search:** 14 May 1997

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RHCC, RHCE)

Int Cl (Ed.6): A61B 17/36, 17/38, 17/39

Other: Online database: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB2156222 A	(OLYMPUS WINTER) Whole document	1, 4
X	GB0618528 A	(AMERICAN CYTOSCOPE) Whole document	1,4, 7-9
X	WO93/24062 A1	(LAPAROMED) Line 15 on page 11 to line 18 on page 12	1, 4
X	US4657018	(HAKKY) Line 17 column 5 to line 5 column 6.	1,4,8.9

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.