Surgical instrument and method of using the same

A surgical instrument comprises a non-rotating position tube having at least one lumen. A blade shaft (which may be a hollow tube) passes through the lumen and one or more blades are attached to the distal end of the blade shaft. The blades have a non-cutting position in which they are retracted so that their diameter is roughly equivalent to the diameter of the lumen and a cutting position in which the blades extend radially outwards beyond the lumen diameter. The blades are moved between the non-cutting position and the cutting position by sliding the blade shaft relative to the sheath. During a cutting procedure, the blade shaft and the attached blades are rotated while the tube remains fixed. The instrument may also be modular in construction with a main module and additional modules that are interchangeable. These additional modules can include an excision module for removing tissue and a treatment module for applying various therapeutic materials to the surgical site.
SURGICAL INSTRUMENT AND METHOD OF USING THE SAME

FIELD OF THE INVENTION
This invention relates to medical instruments, and more specifically to such
instruments used in surgery and minimally invasive therapeutics.

BACKGROUND OF THE INVENTION
As men age, their prostate glands often enlarge due to growth of intraprostatic
periurethral gland tissue (prostate adenoma). This condition, known as benign
prostatic hypertrophy (BPH), leads to obstruction of urine flow in the urethra resulting
in complete, or partial, inability to urinate. The incidence of BPH for men in their fifties
is approximately 50%, rising to 90% by age 85. About 25% of men in the United
States are treated for BPH by the age of 80.

Various surgical interventions for the treatment of BPH are known in which
prostate tissue is excised. These include Transurethral Resection of the Prostate
(TURP), Transurethral Incision of the Prostate (TUIP) and Suprapubic or Retropubic
(Open) Prostatectomy (SPP/RPP). Of these, the gold standard of therapy is
endoscopic resection of the prostate from within or Transurethral Resection of the
Prostate (TURP).

TURP provides the best means of reducing urinary obstruction though it carries
the burden of predominantly being an inpatient procedure. Further, TURP often has
post-procedure pain, bleeding and requires the use of post-procedure drainage
catheters for an extended period of time. Other limitations include retrograde
ejaculation and impotence. While highly effective in reducing an obstruction, the
dominant mechanism behind TURP is progressive coring-out of the prostate beginning
at the level of the urethra, progressing radially to the prostatic capsule. As such, while
the obstructing adenoma is removed, many non-diseased elements of the prostate are
also removed or destroyed. The uncontrolled destruction of prostatic structures such
as the urethra and the periurethral tissue column are largely responsible for negative
side effects of TURP. The inability to control tissue destruction due to use of primitive
surgical tools without geographic control of cutting and tissue destruction further
underlies the limitations of TURP.
In an attempt to limit hospital stay and patient discomfort, several alternative "less invasive" means of reducing prostatic obstruction have emerged. Many of these methods utilize alternative energy means for removing or destroying prostatic tissue. These include Transurethral Vaporization of the Prostate (TURVP), Visual and Contact Laser Ablation of the Prostate (V-LAP and C-LAP) and TransUrethral Needle Ablation (TUNA). In TUNA, for example, radio-frequency (RF) energy is used to thermally denature or cauterize prostate tissue. In this procedure, one or two RF electrodes are transurethrally inserted into prostatic tissue. Heat generated by the electrodes cauterizes the adjacent prostatic tissues. While somewhat less invasive than TURP with less bleeding, all of these alternative methods as well lead to significant destruction of normal prostatic tissue structures. Despite the advance in urology provided by these new methods, none is as effective as TURP. As such the advance of the present invention is the description of a surgical device allowing significant selective tissue removal equal, or superior, to TURP, with simultaneous preservation of the prostatic urethra and periurethral tissues.

Various surgical devices have been used to remove tissue and can be used in the above procedures. Surgical devices known in the art having blades that alternate between a non-cutting position and a cutting position are disclosed in U.S. Patent Nos. 5,030,201, 5,556,408; 5,154,724; 5,158,564; 5,318,576 and 5,395,311.

U.S. Patent No. 749,689 discloses a pivoting monopolar RF tip for performing TUIP. Similarly, U.S. Patent No. 5,192,280 to Parins, discloses an RF instrument that contains a pair of bipolar RF electrodes formed in a ceramic head at the end of the instrument. The electrodes lie in the axis of the instrument when being inserted through the urethra into the prostate. The ceramic head is then pivoted to bring the electrodes perpendicular to the axis. Radial incisions are made by applying RF energy across the electrodes from an external power source and drawing the electrodes across prostate gland tissue to cauterize the tissue.

U.S. Patent No. 5,415,656 discloses an RF cutter in which the cutter is an electrically conducting loop positioned in a tube. During insertion, the loop is in a non-cutting position within the tube, and is brought into a cutting position by being pushed out of the tube. A disadvantage of this cutter is that a loop-shaped cutter is not ideal for making an incision.
U.S. Patent No. 5,941,876 discloses a rotating cutting device that uses RF to enhance the cutting capabilities of the mechanical cutter. The rotating blades or rotating drill serve as active energy delivery electrodes so that cutting is easier and the cutter stays sharp for a longer time period.

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**SUMMARY OF THE INVENTION**

In accordance with the principles of the invention, the surgical instrument comprises a slender long sheath designed to be used in transurethral surgery. The sheath accommodates an optics system that allows the surgeon to visualize the surgical site. The sheath will also comprise at least one lumen for use by the cutting mechanism. A non-rotating positioning tube runs through this lumen and can be slidably extended or retracted beyond the distal end of the sheath by the surgeon. The positioning tube may be rigid or flexible, or have a preformed “gooseneck” that causes the distal end to swing orthogonal, or at an angle, to the device axis when the positioning tube is extended beyond the distal end of the sheath thereby providing radial extension and curvature to allow deeper lateral tissue access.

A blade shaft (which may be a hollow tube) passes through the positioning tube and one or more blades are attached to the distal end of the blade shaft. The blades have a non-cutting position in which they are retracted so that their diameter is roughly equivalent to the diameter of the lumen and a cutting position in which the blades extend radially outwards beyond the lumen diameter. The blades are moved between the non-cutting position and the cutting position by sliding the blade shaft relative to the positioning tube.

Alternatively, in some embodiments, the blade shaft does not slide relative to the positioning tube. Instead, an additional control link, which runs through the hollow blade shaft, slides relative to the blade shaft thereby moving the blade to the cutting position. The control link rotates with the blade shaft. During a cutting procedure, the blade shaft and the attached blades are rotated while the positioning tube remains fixed.

In one embodiment, a superelastic wire is coaxially attached to the end of the blade shaft and the tip of the wire functions as a cutting blade. The wire is bent at a right angle to the shaft axis and has a shape “memory.” In the non-cutting position,
the wire blade is retracted into a positioning tube so that the blade is constrained to a straight shape. The wire blade is brought into the cutting position by extending it beyond the distal tip of the positioning tube, whereupon the wire spontaneously assumes a bent position due to its shape memory.

In another embodiment of the invention, one or more blades are fabricated from a resiliently flexible or superelastic material. Each blade is a strip of material and can have a round or generally rectangular cross-section. A first end of the blade is affixed to the distal end of the blade shaft, while a second end is affixed to a second shaft (the control link described above) passing through the blade shaft. In the non-cutting position, the second shaft extends past the distal end of the blade shaft and the blade lies parallel to the blade shaft. The blade is brought into the cutting position by sliding the second shaft into the blade shaft causing the second end of the blade to move towards the first end. This motion, in turn, causes the center of the blade to bulge outwardly from the shaft. During cutting, both the blade shaft and the second shaft rotate together.

In still another embodiment, one or more blades, such as outlined in the above embodiments, or other single or multiple blade configurations will incorporate at least one blade that has an intrinsic true cutting edge. As such, this edge can be formed of a hardened material which tapers to infinite thinness to act as a true surgical tissue slicing, cutting or plane-separating mechanism, with minimal tissue friction and shearing. Blade edges may be constructed of stainless steel, carbide steel, Nitinol, diamond or other contiguous or bonded hardened materials. The longitudinal cutting edge of the blade may be straight, curvilinear, scalloped, serrated or any other complex cutting configuration.

An instrument constructed in accordance with still another embodiment may have an injection needle that runs through the hollow second shaft for the transfer of fluids, gases and other flowable media between the body exterior and the prostate. The fluids may, for example, be irrigants, hemostatic agents, drugs, monomers, prepolymers, and polymers, colloids and other biologically active compositions. The needle is configured to pierce the urethral wall and to act as a guide for the cutting instrument. Since the needle does not rotate during the cutting process, external accessories, such as a syringe, may be easily connected to the proximal end of the
needle during cutting. Alternatively, since the needle is hollow, a guidewire may be inserted and transported through the needle for guidance purposes.

In yet another embodiment, a rigid blade is attached at one end to a pivot point located at the distal end of the blade shaft. The blade is controlled to rotate about the pivot point by means of an actuating wire (the control link described above) that extends though the blade shaft. In the non-cutting position, the blade lies substantially parallel to the blade shaft. In the cutting position, the blade is rotated into a position substantially perpendicular to the blade shaft.

In another embodiment, the longitudinal axis of the blade shaft is offset from the longitudinal axis of the instrument and the blade is mounted perpendicular to the shaft so that the blade only extends beyond the instrument circumference for a part of its rotational cycle. Thus, the blade can be positioned in a non-protruding position when the instrument is inserted into the patient. Another advantage of the off-center rotational axis is that the blade is wiped clean of debris as it rotates and periodically comes in contact with the edge of the instrument shaft.

In yet another embodiment, the distal end of the instrument shaft is made of a transparent material so the surgeon can see all the prostate tissue even when the cutter is rotating.

One or more of the cutting blades may optionally also function as a monopolar electrode in order to perform a coagulation or cauterization procedure. During this procedure, the blade is locked to prevent rotation and an electrical generator, such as a radio frequency (RF) generator, is applied across a blade and the tissue and electrical energy is applied to the tissue. The blade shaft may be insulated electrically from the positioning tube. The electrode may be used for making incisions in the prostate or for coagulation.

In yet another embodiment, the blade may be directly heated via electrical resistance means, conductance means or convective means. Alternatively, the blades may serve as antennae allowing for local microwave-based heating.

In the treatment of BPH, the distal end of the instrument is inserted into the urethra and through the urethral wall into the prostate. During insertion, the blades are in the non-cutting position. After insertion, the blades are brought into the cutting position and the blade shaft and blades are then rotated around the longitudinal axis.
of the shaft to cut adjacent tissue. High-speed rotation of the shaft and the blades ensures rapid excision of material that is morsellated or liquified. Morsellated material may be left in place, irrigated, allowed to egress or evacuated. The blades are then moved to the non-cutting position. Via the irrigation channel, the created tissue cavity may be flushed, washed, or otherwise prepared post-tissue excision with hemostatic agents, medicaments, polymeric materials or adhesives. The instrument is then withdrawn.

In still another embodiment of the invention, the surgical instrument comprises a slender long sheath designed to be used in transurethral surgery; however, in contrast to the previous embodiments, the device is partially, or fully, modular. The sheath contains a permanent, or removable, optical, ultrasound or other imaging system that allows the surgeon to visualize the surgical site. The sheath will also comprise at least one lumen that accommodates several removable modules, each of which is specialized for one part of the surgical procedure. For example, one module may be an excision module specialized for use by a cutting mechanism that may be advanced through the sheath body, either directly or over a guidewire, for use and then removed via sliding or telescoping. This cutting mechanism can be the same or similar to the embodiments discussed above. At the completion of cutting portion of the procedure, the entire excision "module" is removed and replaced with one or more secondary treatment modules. The incorporated illumination and visualization optics of the main external sheath are used to visually, ultrasonically, or otherwise monitor both the excision procedure and the operation of the secondary treatment modules.

Such secondary treatment modules include modules specialized for the application of drugs, polymers or other flowable therapeutic fluids or materials. These modules may be fabricated as insertable hollow tubular members that slide readily, either directly or over a guidewire, into the lumen in the main instrument sheath. Such tubular members may contain one or multiple lumens. Lumens may be included for fluid ingress, egress, mixing, application of two interacting fluids, and means for "physical" fluid activation. Fluid ingress lumens may exit at the end of the device as blunt, angulated or lateral ports. Ports may be single or multiple. Fluid egress lumens may be similar to ingress lumens though most commonly with more inlet ports located proximally in the treatment zone.
A mixing lumen allows for instillation of carrier fluids or gases that serve to mix, stir or otherwise disturb the initially instilled fluid. Alternatively, a physical tubular member such as a shaft with a propeller or screw-like end may be advanced through the treatment module and into the treatment zone, beyond the device, to allow for fluid mixing. Further, mixing may be achieved through tip nozzles that induce vortices or create “venturi” effects.

The treatment module can have two separate lumens for application of two interacting fluids. The use of separate lumens allows mixing of the interacting fluids directly in the treatment site while preventing mixing of the fluids within the module. For example, a monomeric first fluid can be instilled at the treatment site and then a secondary catalyst fluid can be introduced, via a second lumen, to polymerize the first fluid. The use of two separate lumens prevents initiation of polymerization before both fluids are present in the treatment zone, the desired location for polymerization.

A lumen for physical activation of a fluid allows conduction of electrical, thermal, ultrasonic, optical, electromagnetic energy, or other energy forms, in order to activate, polymerize, change the state of, or otherwise modify, an instilled fluid.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The above and further advantages of the invention may be better understood by referring to the following description in conjunction with the accompanying drawings in which:

Figure 1A is perspective view of the proximal end of a surgical instrument constructed in accordance with one embodiment of the invention showing the handles by which a surgeon manipulates the instrument.

Figure 1B is another view of the proximal end of the instrument showing the motor shaft and gears that rotate the blade shaft.

Figure 2A is a cross-sectional diagram of a portion of the distal end of a surgical instrument constructed in accordance with a first embodiment of the invention showing the blade in a non-cutting position.

Figure 2B is a cross-sectional diagram of a portion of the distal end of a surgical instrument constructed in accordance with a first embodiment of the invention showing the blade in a cutting position.
Figure 2C is a cross-sectional diagram of a portion of the distal end of a surgical instrument constructed in accordance with a first embodiment of the invention showing an alternative viewing system.

Figure 2D is a cross-sectional diagram of a portion of the distal end of a surgical instrument constructed in accordance with a first embodiment of the invention showing still another alternative viewing system.

Figure 2E is a cross-sectional diagram of a portion of the distal end of a surgical instrument constructed in accordance with a first embodiment of the invention showing yet another alternative viewing system.

Figure 3A is a diagram of a portion of the distal end of surgical instrument constructed in accordance with a second embodiment of the invention showing the blade in a non-cutting position.

Figure 3B is a diagram of a portion of the distal end of surgical instrument constructed in accordance with a second embodiment of the invention showing the blade in a cutting position.

Figure 4A is a diagram of a portion of the distal end of surgical instrument constructed in accordance with a third embodiment of the invention showing the blade in a non-cutting position.

Figure 4B is a diagram of a portion of the distal end of surgical instrument constructed in accordance with a third embodiment of the invention showing the blade in a cutting position.

Figure 4C is a diagram of a portion of the distal end of surgical instrument constructed in accordance with a third embodiment of the invention showing an alternative arrangement for attaching the pivoting blade to an actuating wire.

Figure 5 is a locking mechanism used in some embodiments to lock the radial position of the wire and prevent rotation during the application RF power.

Figure 6A illustrates another embodiment of a locking mechanism used in some embodiments to lock the radial position of the wire and prevent rotation during application of RF power.

Figure 6B illustrates a first cam used in the locking mechanism shown in Figure 6A.
Figure 6C illustrates a second cam used in the locking mechanism shown in Figure 6A.

Figure 6D illustrates the interaction of the first and second cam during rotation in one direction.

Figure 6E illustrates the interaction of the first and second cam during rotation in the direction opposite to that shown in Figure 6D.

Figures 7A-7D illustrate cross-sections of various blades including embodiments in which the blades are formed into knife-edges or have knife edges bonded to them.

Figures 7E-7G are plan views of different knife-edges illustrating scalloped and serrated edges.

Figure 8A is an illustration of the proximal end of a modular device in which the excision module is detachable.

Figure 8B is an illustration of the proximal end of a modular device in which the excision module has been detached, removed, and replaced with a treatment module.

Figures 9A-9C are cross-sectional diagrams of alternative embodiments of the treatment module showing embodiments with one or more lumens.

Figures 10A-10F are schematic diagrams that illustrate the steps in a transurethral surgical procedure utilizing the modular device shown in Figures 8 and 9.

Figures 11A-11F are schematic diagrams that illustrate the steps in an alternative transurethral surgical procedure utilizing the modular device shown in Figures 8 and 9.

Figure 12 is a perspective view that illustrates another embodiment of the present invention showing a surgical instrument in which the axis of the blade shaft is offset from the axis of the instrument.

Figure 13A is a side view of the embodiment shown in Figure 12 in which the cutting blade has been extended to allow for RF coagulation at remote tissue locations.

Figure 13B is a side view of the embodiment shown in Figure 12 in which the cutting blade has been retracted to allow for a cutting operation.
Figure 14A is a view of the distal end of the embodiment illustrated in Figure 12 illustrating how the cutting blade extends beyond the periphery of the instrument during one portion of its rotation.

Figure 14B is a view of the distal end of the embodiment illustrated in Figure 12 illustrating how the cutting blade can be positioned so that no portion of the blade extends beyond the periphery of the instrument to allow insertion of the instrument into a patient.

**DETAILED DESCRIPTION**

The present invention relates to a surgical instrument for cutting tissue. As used herein, the term “cutting” refers to any type of surgical intervention of a tissue, such as excising, morsellating and liquefying. While the instrument will be described primarily with reference to prostate surgery, it should be understood that the instrument might also be used in other forms of surgery minimally invasive or percutaneous therapeutics. Figures 1A and 1B show a surgical instrument 102 constructed in accordance with the principles of the invention and particularly illustrate details of the proximal end that is held and manipulated by the surgeon. The instrument 102 has distal and proximal ends, 110 and 112, respectively, and comprises a body 153 and a slender sheath 155. The sheath 155 has an integral shield 152 and is attached to the body 153 by means of a coupling 154 that allows the sheath to be removed for sterilization purposes.

Body 153 has an integral handle 160 with an opening 165 into which a surgeon can insert his fingers. A frame 125 is slidably mounted on the body 153. By placing his thumb in opening 170, a surgeon can slide the frame longitudinally along the body 153. Control lever 171 is rotationally mounted on the frame 125. An opening 172 in the control lever is designed to receive the tip of the thumb after it passes through opening 170. The instrument also comprises an endoscopic viewing system to allow the surgeon to view or visualize the mechanical or RF cutting site. The viewing system includes an eyepiece 145 (or a connection for a viewing camera) at the proximal end 112 of the instrument 102 and may comprise an optical system, an ultrasound system or a thermal imaging system. Alternatively, two viewing systems, such as an optical and an ultrasound system, can be used in parallel to better
visualize the surgical site. The sheath 155 may also contain a lumen (shown in Figures 2A-2D) for transporting fluids or tissue fragments into or out of the surgical site. The lumen terminates at the proximal end 112 in an aspiration port 191 and 192. Both the lumen and optical system are contained in a coaxial tube 158 that extends out of sheath 155.

As will be hereinafter described, the cutting blades are rotated by a motor 140 that is connected to the blade shaft by a gear mechanism illustrated in Figure 1B. The motor 140 is preferably operated by means of a foot pedal (not shown) that can control the direction and speed of the rotation. The motor also supports an electrical plug 175 that allows an RF generator (not shown) and a DC power supply (not shown) to be attached. The plug 175 has a DC socket 180 and an RF socket 185.

In general, the structural portions of the instrument, including sheath 155, positioning tube 100, and the various shafts can be constructed out of suitable materials, such as stainless steel, other conventional alloys, hard rubber, plastics, polymeric materials, ceramics or composite materials, such as graphite composites. Flexible polymeric materials can also be used. The structural materials can be suitably fully or partly coated with polymeric materials and other plastics, such as Teflon or other known materials, to provide for lubrication to aid in insertion and to provide electrical, mechanical and fluid isolation. The remainder of the instrument can also be constructed of stainless steel or polymeric materials.

Figure 1B is a partially cut-away drawing illustrating the connection of the motor 140 to the blade shaft 105. Motor 140 has a shaft 174 that passes through a bearing 71 in frame 125 and terminates in a bevel gear 182. Gear 182 meshes with a corresponding bevel gear 183 that is affixed to the blade shaft 105 to cause the shaft 105 to rotate. Shaft 105 passes though the gear 183 and bearing 186. The bearing 186, in turn, is affixed to the sliding frame 125. The proximal end 101 of positioning tube 100 is fixed on the sliding frame 125. When the frame is slid forward, the positioning tube, the bearing and the blade shaft also slide forward relative to the sheath 155. The positioning tube and the blade shaft slide forward together but only the blade shaft is free to rotate. The sliding motion of frame 125 moves the blade shaft to the desired location where the surgeon wishes to remove tissue. Subsequently, the surgeon must manipulate control lever 171 to move the blade from
a non-cutting to a cutting position. Control level 171 pushes and pulls bearing 184. Bearing 184 can move slidably relative to frame 125. A linkage exists between bearing 184 and the blade so that when bearing 184 slides relative to bearing 186 the blade moves from cutting to non-cutting positions or the reverse.

In one embodiment, the blade shaft is directly pushed and pulled by bearing 184 and the blade shaft slides through the bearing 186 and the gear 183 in order to control the cutting blade as described below. In other embodiments, the blade shaft is fixed in gear 183 and a control link passes through the hollow blade shaft that connects the blade to bearing 184 in order to control the cutting blade as described below.

The motor shaft 174 is made of an electrically conductive material and has an electrically conductive slip ring 72 affixed thereto. The RF socket 180 is electrically connected to a sliding contact 175 to allow RF power to be provided to the blade as discussed in detail below.

A longitudinal cross-section of the distal end 110 of the instrument constructed in accordance with a first embodiment of the invention is shown in Figures 2A-2D. A positioning tube 100 extends along the length of the sheath 155, and a blade shaft 105 extends along the lumen of the tube 100. In this embodiment, the blade shaft may be solid. The position of the shaft 105 in the tube 100 is adjusted by means of the control lever 171 located on the sliding frame 125 as discussed above. Moving sliding frame 125 relative to body 153 extends the positioning tube 100 beyond the distal end of sheath 155. The positioning tube with the blade shaft is slid longitudinally along the sheath 155 to position the blade within the surgical site. As previously mentioned, the instrument also comprises a viewing system. In the embodiment shown in Figures 2A and 2B, this viewing system is an optical system that includes an optical fiber bundle 148 extending along the length of the instrument and an objective lens system 160 at the distal end 110 of the instrument. Another optical fiber may also be provided to conduct from a light source to the lens system in order to illuminate the surgical site. This latter optical cable can be connected to the instrument via a connection 190. The sheath 155 may also contain a lumen 157 for transporting fluids or tissue fragments into or out of the tissue.
The shaft 105 has a short piece of wire 106 attached to its distal end 115. Wire 106 may be made from any superelastic material that has a shape, or mechanical, memory. A mechanical memory is a phenomenon whereby a deformed and constrained part "remembers" and recovers its pre-deformed shape when the constraint is removed. A suitable material is a nickel titanium alloy sold under the name "Nitinol." Using known techniques, the wire 106 is formed into a right angle curve as shown in Figure 2B. The wire tip 107 forms the cutting blade.

Figure 2A shows the blade in the non-cutting position. In this position, the blade shaft 105 is moved towards the proximal end of the instrument so that the wire 106 is withdrawn entirely within the positioning tube 100. In this position, the wire is constrained by the tube 100 into a substantially linear form. This position allows the blade 107 and the positioning tube 100 to be guided in the correct area in the surgical site.

Figure 2B shows the instrument 102 with the blade in the cutting position. In this position, the distal end 115 of the shaft 105 extends beyond the distal tip 116 of the tube 100 allowing the wire 106 to extend fully out of tube 100. When the wire 106 extends beyond the distal end 116 of tube 100, the constraint forcing into a linear shape is removed and it spontaneously resumes its curved shape due to the mechanical memory characteristic of the material used to fabricate it. The distal end 107 of the wire 106 thus forms a blade that can be rotated.

In use, the distal end 110 of the instrument 102 is inserted into the body with the blade 107 in its non-cutting position using the handle 160, and is brought to the surgical site where tissue is to be removed. The frame 125 is then slid towards the distal end 110 of the instrument causing the positioning tube 100, the shaft 105 and the wire 106 to extend distally from sheath 155. The positioning tube is extended until it contacts the tissue to be cut. Manipulating lever 171 causes shaft 105 and wire 106 to extend beyond the positioning tube so that the wire tip 107 is in the cutting position as shown in Figure 2B. The motor 140 is then used to rotate the blade 107 in its cutting position causing the blade 107 to cut tissue in its vicinity.

When mechanical excision of the tissue has been completed, the wire 106 may be used as a monopolar RF electrode to make RF incisions or to coagulate by applying a voltage across the wire 106 and the tissue, as is known in the art. In order
to use the wire 106 as an RF electrode, the wire 106 is locked in a desired radial position using a locking mechanism (not shown in Figures 2A and 2B) which is explained in detail below. The wire 106 is electrically connected to one terminal of a voltage source (not shown) by means of the contact 73 and slip ring 72 illustrated in Figure 1B. The other terminal of the voltage source is electrically connected to the patient's body so that a voltage is applied across the blade and the tissue. An electrically insulating material (not shown) may be placed between the positioning tube and the blade shaft. For removal of the instrument from the body, the shaft 105 and wire 106 are brought back into the non-cutting position as shown in Figure 2A by sliding the shaft 105 proximally relative to the positioning tube 100 using the lever 171. The positioning tube 100 is then retracted into the sheath 155 by sliding frame 125. The instrument is then removed from the surgical site.

Figures 2C, 2D and 2E illustrate the embodiment of Figure 2A with alternative embodiments of the viewing system. Such a system may comprise, for example, an ultrasonic or thermal imaging system. In Figure 2C, an ultrasonic transducer 190 is positioned at the distal end of the instrument and connected by a shaft 194 to the proximal end of the instrument. The shaft 194 may contain electrical connections to the transducer 190 and can be used to rotate the transducer 190 about the longitudinal axis of the shaft 194. If the shaft 194 rotates, a bearing 192 is used to support the shaft at the distal end. In this embodiment, the viewing area is forward of the instrument.

In an alternative embodiment of the viewing system shown in Figure 2D., an ultrasonic transducer 190 is positioned at the distal end of the instrument and connected by a shaft 194 to the proximal end of the instrument. In this embodiment, the transducer 190 is mounted at an angle to the shaft. The shaft 194 may contain electrical connections to the transducer 190 and rotates the transducer 190 about the longitudinal axis of the shaft 194. A bearing 192 is used to support the shaft at the distal end. In this embodiment, the viewing area is to the side of the instrument distal tip.

In still another embodiment shown in Figure 2E, a reflecting mirror 190 is positioned at the distal end of the instrument and connected by a shaft 194 to the proximal end of the instrument. In this embodiment, the mirror 190 is mounted at an
angle to the shaft. The shaft 194 rotates the transducer 190 about the longitudinal axis of the shaft 194. A bearing 192 is used to support the shaft at the distal end. Ultrasonic signals are generated by fixed transducer 196 which is connected by electrical connections 198 to the instrument proximal end. Ultrasonic signals generated by transducer 196 propagate towards rotating mirror 190, and are reflected from the mirror to the tissue. The signals returning from the tissue are again reflected from mirror 190 to transducer 196 where they are converted to electrical signals and forwarded via connections 198 to the proximal instrument end. In this embodiment, the viewing area is to the side of the instrument distal tip.

Figures 3A and 3B show an illustration of the distal end 110 of the instrument 102 utilizing another embodiment of the invention with a different cutting blade arrangement. The sheath 155, optical fiber bundle 148, objective lens system 160 and lumen 157 have been omitted in these figures for clarity. In this embodiment, the blade shaft 105 is a hollow tube and a hollow control link 200 passes through the lumen of the blade shaft 105.

One or more blades 210 are attached to the shaft 105 at their proximal ends 226. The blades 210 are attached at their distal ends 224 to the hollow control link 200 at the distal tip 220 of the shaft. The blades 210 may be fabricated from any resilient material or a superelastic material such as the aforementioned “Nitinol” alloy. The blades may have a generally circular or rectangular cross-section. The control link 200 has a plurality of holes 240 that pass through the link wall into an interior lumen (not shown.) The interior lumen in the control link 200 may be used for transporting fluids or tissue fragments into or out of the tissue. Optionally, a needle 250 can be slid through the hollow control link 200 and may be used to transport fluids. Control link 200 and shaft 105 rotate together but needle 250 does not. Since needle 250 does not rotate, it permits attachment of other devices to the instrument even during blade rotation.

In Figure 3A, the blades 210 lie parallel to the control link 200 and are in their non-cutting position. The blades 210 are brought into a cutting position by sliding the shaft 105 distally relative to the control link 200 using the control lever 171. Alternatively, the control link 200 may be slid proximally relative to the shaft 105. In either case, the relative movement of shaft 105 and control link 200 causes the distal
end 226 of the shaft 105 to exert a compressive force on the blades 210. This compressive force causes the blades 210 to form radial bulges 215 as shown in Figure 3B. The bulging is facilitated if the blades are constructed from a material with mechanical memory and the blades are preformed with the shape shown in Figure 3B.

In use, the distal end 110 of the instrument 102 is inserted into the body with the blades 210 in their non-cutting position and with positioning tube 100 retracted into sheath 155. Using the handle 160, the instrument is brought to the surgical site where the tissue is to be removed. The frame 125 is then slid towards the distal end 110 of the instrument causing positioning tube 100, the blade shaft 105 and control link 200 to extend distally from sheath 155. The positioning tube is extended until the blades 210 contact the tissue to be cut. Manipulating lever 171 causes control link 200 to slide relative to shaft 105 bringing the blades to their cutting position as shown in Figure 3B. The motor 140 is then operated to rotate the shaft 105 causing the blades 210 to excise tissue. When mechanical excision has been completed, one or more of the blades 210 may be used as a monopolar RF electrode to make RF incisions or to coagulate by applying a voltage across a blade 210 and the tissue, as explained with reference to the first embodiment. For removal of the instrument from the body, the blades 210 are brought back into the non-cutting position as shown in Figure 3A by sliding the shaft 105 relative to the control link 200 using lever 171 and then both shafts are retracted into the sheath by sliding frame 125.

Figures 4A, 4B and 4C show an illustration of the distal end 110 of the instrument 102 utilizing another embodiment of the invention with still another cutting blade arrangement. In this embodiment, the shaft 105 is hollow and a solid control link 300 passes through the lumen of the shaft 105. A blade 310, located at the distal end 110 of the instrument contains a pivot point 315 near one end 325. There is another hole 320 in the blade between the pivot point 315 and the end 325. The blade fits into a slot (not shown) cut into the end of shaft 105. A short axle (not shown) passes through this pivot point 315 and is affixed at both ends to the distal end 116 of shaft 105. The distal end of control link 300 is attached to hole 320 of the blade 310. Therefore, movement of the control link 300 longitudinally within the shaft 105 moves the blade. A section 335 is cut out of the end of shaft 105 to allow clearance for the control link to move.
Figure 4A shows the blade in its non-cutting position in which it lies parallel to the longitudinal axis of the sheath 155. The blade 310 is brought into a cutting position as shown in Figure 4B by sliding the control link 300 in a distal direction relative to shaft 105 using lever 171. In a further embodiment shown in Figure 4C, the control link 300 may be attached to blade 310 by an additional link 360 in order to reduce the size of the cutout 335 and to reduce friction.

In use, the distal end 110 of the instrument is inserted into the body and brought to the site where tissue is to be excised. Sliding frame 125 is used to extend shaft 105 and blade 310 beyond the distal end of sheath 155 to the site. Lever 171 is used to slide control link 300 distally to bring the blade 310 into the cutting position as shown in Figures 4B and 4C. The motor 140 rotates the shaft 105 causing the blade 310 to excise tissue. When tissue removal is complete, the blade 310 may also be used as a monopolar RF electrode to make RF incisions or to coagulate by applying a voltage across a blade 310 and the tissue, as explained with reference to the first embodiment. An insulating tube, made from a material such as Teflon, (not shown) may be used to insulate the blade shaft from the positioning tube. When excision of the tissue has been completed, the blade 310 is brought back into the non-cutting position as shown in Figure 3A by sliding the control link 300 proximally relative to shaft 105 and the instrument is withdrawn.

Figure 5 shows a locking mechanism 180 used to lock the radial position of the cutting blade 115, 210 or 310 during the application of RF power. A cam 400 has a locking shoulder 408 and is affixed to the shaft 105, to motor shaft 174 or to any appropriate place on the drive train from the motor to the blade. The cam 400 is rotated together with the rotation of motor 140. An elongated locking arm 410 is pivoted at one end to the frame 125 by pivot 415. Spring 420 keeps the other end of the locking arm 410 bearing against the cam 400. During the mechanical cutting procedure, the cam 400, together with the shaft 105 are rotated in a counterclockwise direction by the motor 140 as indicated by the direction of the arrow 430. Thus, the locking arm 410 does not interfere with the rotation since the cam 400 raises it out of locking step 408.

In order to lock the blade, the rotation is reversed and the cam 400, together with the shaft 105, is rotated clockwise until the end of the locking arm 410 engages
the locking shoulder 408. The motor rotation is maintained in the reverse direction
during the RF procedure in order to maintain the blades in the locked position. In this
mode, the motor can be held by a reverse current applied with a pulse-width-
modulated signal that provides high torque with low power.

Figure 6A shows another embodiment of the locking mechanism. The locking
mechanism consists of two cams 630 and 640 that are placed between gear 182 and
motor 140. In this embodiment, the motor 140 is attached to gear 182 by a split shaft
comprising motor shaft 674 and gear shaft 675, which shafts are coaxial, but are not
directly connected. Cam 630 is affixed to motor shaft 674 and cam 640 is affixed to
gear shaft 675. Pin 620 is in contact the perimeters of both cams 630 and 640 at all
times. Spring 610 maintains this contact.

Figure 6B shows the gear-side cam 640. Cam 640 rotates around axis 645 and
has a primarily circular circumference 643. There is a notch 641 cut out of the
circumference and a drive pin 642 extends perpendicularly from the lower surface of
the cam 640. Drive pin 642 is used to transfer motor torque between the two cams
630 and 640 as discussed below.

Figure 6C shows the motor-side cam 630. The cam 630 rotates about axis 635
and has a substantially spiral shaped outer periphery 635 that forms a lifting surface
for pin 620. Cam 630 also has a semicircular slot 631 that is centered at the cam axis.
When the faces of the two cams 630 and 640 are brought together, the slot 631 is
located to receive drive pin 642 so that, as cams rotate relative to each other, the drive
pin 642 can slide from slot end 633 to slot end 634. The slot 631 allows for some
relative motion between the cams before the drive pin engages one slot end.

Figure 6D shows the two cams with their faces placed together, as viewed from
the underside (motor side). When the cams 630 and 640 are placed together, drive
pin 642 protrudes through slot 631. When the motor rotates in a clockwise direction
as indicated by arrow 650 it drives cam 630 in a clockwise direction so that slot 631
slides around drive pin 642. When drive pin 642 engages the end 633 of slot 631, the
torque applied to cam 630 by the motor is transferred to cam 640 by pin 642. When
pin 642 engages end 633 of slot 631, the lifting surface 635 of cam 630 is positioned
so that the notch 641 of cam 640 is exposed. The two cams continue to rotate
together until pin 620 falls into notch 641, thereby effectively locking the two cams in
radial position. After the pin 620 is in the notch 641, the motor can be stopped and the gear-cam 640 remains locked.

Figure 6E shows the release of the two cams from locking pin 620. When the motor rotates in the counter-clockwise direction as shown by arrow 651 in Figure 6E then cam 630 rotates relative to cam 640 and drive pin 642 slides in slot 631. Cam 640 is held by pin 620 at this point, but the lifting surface 635 of cam 630 forces pin 620 back as the cam turns. Pin 642 eventually encounters end 634 of slot 631. At this position, the lifting surface 635 of cam 630 has lifted pin 620 out of notch 641 on cam 640. Consequently, the two cams are free to continue rotating in the counter-clockwise direction without interference from pin 620. Reversing the rotation direction again brings the cam back to the relative position shown in Figure 6D and allows pin 620 to enter notch 641.

In the embodiments shown in Figures 2, 3 and 4, one or more of the blades has a true cutting or knife-edge. This knife-edge can be formed of a hardened material which tapers to infinite thinness to act as a true surgical tissue slicing, cutting or plane-separating mechanism, with minimal tissue friction and shearing. Blade edges may be constructed of stainless steel, carbide steel, Nitinol, diamond or other contiguous or bonded hardened materials. The blade itself may be constructed of a material that can be ground to a knife-edge and then hardened or a hardened knife-edge can be bonded onto the blade. Alternative arrangements are illustrated in Figures 7A-7D. In particular, Figure 7A illustrates the cross section of a blade 700 that has itself been ground to a knife-edge 702. Figure 7B illustrates a blade 704 which has a knife-edge 706 bonded to it. Knife-edges may be ground or bonded on the both the leading 708 and trailing edges 710 of the blade 712 as illustrated in Figure 7C. Figure 7D illustrates a knife edge 716 positioned at one side of the blade 714. In accordance with the invention a knife edge could be positioned at any position on the blade.

Figures 7E-7G show plan views of the knives. As illustrated, the longitudinal cutting edge of the blade may be straight as shown in Figure 7E, curvilinear or scalloped as shown in Figure 7F or serrated as shown in Figure 7G. Alternatively, the blade edge may be a complex cutting configuration of the configurations shown.

An additional embodiment is illustrated in Figures 12, 13A, 13B and 14A, 14B. Figure 12 illustrates the components of this embodiment of the instrument 102.
Components with functions similar to those shown in Figure 1 have been given similar numeral designations. As with previous embodiments, a longitudinal tubular sheath 155 connects the distal end of the instrument 110 to the proximal end (not shown.) Also, as with previous embodiments, an optical system indicated at its distal end by numeral designation 148 passes through the sheath 155 and terminates in an objective lens system 160. Also passing through sheath 155 is the blade shaft 105. The blade 105 is attached at its proximal end to a coupling (not shown) which links it rotationally to a motor (not shown.) A tubular element 1200 is also attached to the distal end of the sheath 155. This tubular element continues all lumens from sheath 155. Tubular element 1200 is made of a substantially transparent material and the distal edge of tubular element 1200 is indicated by 110.

In this embodiment, the rotational axis of shaft 105 is offset from the axis of the instrument 102. Shaft 105 is capable of high speed rotation about its longitudinal axis. At the distal end of the shaft is fixed blade 1203. Blade 1203 is designed to rotate in a plane that is primarily normal to the longitudinal axis of the blade shaft 105, although the blade 1203 is not necessarily limited to this plane. In a preferred embodiment, the blade is flexible so that it can pass over the objective lens system 160 which extends slightly beyond the distal end 100 of tubular element 1200.

The offset rotational axis of the blade shaft 105 yields several advantages.

First, as shown in Figures 14A, the blade 1203 only extends beyond the circumference of the tubular element 1200 for a part of its rotational cycle. Thus, the blade 1203 will only cut tissue when it extends beyond the circumference of the instrument during a portion of its rotational cycle. During the remainder of its rotational cycle, the blade 1203 will be shielded from the tissue by the tubular element 1200.

For the purpose of inserting the instrument into a patient, the blade 1203 can be parked in a non-protruding position as illustrated in Figure 14B. In addition, for optimum visibility, the blade 1203 can be parked so that it does not cover the objective lens 160 as illustrated in Figure 14B.

Another advantage of the off-center rotational axis of the blade 1203 is that the blade 1203 slides over the edge 1206 of the tubular element 1200 as the blade 1203 rotates. The contact between the blade 1203 and the tubular element edge 1206 gradually wipes off any tissue that has accumulated on the blade 1203.
The tubular element 1200 affixed to the distal end 110 of the instrument 102 is made of a transparent material so that the surgeon can see the surgical site even when the cutting blade 1203 is rotating. Three factors insure excellent visibility at all times: the blade 1203 rotates at high speed, does not block the optics 160 for a large part of its cycle and is generally clean.

As shown in Figures 13A, the blade 1203 can be moved distally away from the distal end 110 of the transparent tubular element 1200 so that the blade tip can perform an RF operation, such as coagulation, at remote tissue locations. When the blade 1203 is in contact with distal end 110, RF power is electrically disconnected during cutting for safety reasons. Similarly, when the blade 1203 is not in contact with distal end 110, the motor (not shown) that rotates the blade shaft 105 is electrically disabled so that rotation does not inadvertently start during RF operations.

Figures 8A and 8B show a modular surgical instrument 102 constructed in accordance with the principles of the invention and particularly illustrate details of the proximal end that is held and manipulated by the surgeon. This embodiment is similar in construction to that shown in Figures 1A and 1B with the exception that the housing 153 is comprised of two sections. The upper housing section 153a is an integral structure that includes the handle 160, the viewing or imaging system 145, 158 and 190, and the sheath coupling mechanism 154. This housing section is the main module that is fitted with the sheath 155 and maneuvered into position at the surgical site and is held in place during the entire surgical procedure. The lower section 153b is an excision module that includes the motor and gear assembly 140, 174, 182, 183, the sliding frame 125, the bearing 184, the blade shaft 105 and the positioning tube 100. The upper section 153a and lower section are slidably locked together by means of a conventional mechanical arrangement such as a spline and groove arrangement shown in Figure 8A. The upper and lower section may also be provided with a conventional mechanism (not shown) that prevents the two sections from sliding relative to each other when in use. Electrical contact can be made between the sections, if necessary, by means of flush face-to-face contacts which are urged together by backing springs as appropriate. Similarly, any mechanical, hydraulic or vacuum contacts could also be of the quick release type.
The spline and groove attachment allows the lower excision module 153b to be removed after the excision operation is complete. In particular, any locking mechanism present is released and the entire module 153b is slid towards the rear of the device. This rearward movement simultaneously withdraws the positioning tube 100, blade shaft 105 and attached blades through the sheath lumen. In this manner, the entire excision mechanism can be removed leaving the sheath lumen clear to the surgical site.

Next, a treatment module is inserted through the open sheath lumen. This treatment module is schematically shown in Figure 8B. The treatment module may also have a housing section 153c with channels that slide over the splines on the main section 153a in order to lock the treatment module to the main module. The treatment module may have multiple lumens for removing or adding treatment material to the surgical site. The treatment material can include fluids, electrolyte solutions, monomers, macromers, pre-polymers, catalysts, polymers, cells, genes, viral vectors, anti-sense agents and other biological or pharmaceutical materials. These lumens terminate at their proximal ends in tubes 800, 802, 804 and 806 connected to conventional couplers 808, 810, 812 and 814, respectively. One of more of the tubes 800-806 may be mounted on a sliding frame (not shown) similar to sliding frame 125 which can be manipulated by means of handle 820. The tubes so mounted extend through the treatment module to the sheath distal end. The sliding frame allows some of the tubes to be projected out beyond the end of the sheath to a position closer to the surgical site. Any of the tubes 800-806 can be connected to a reservoir, such as reservoir 822.

Figures 9A-9C shown the distal end of the modular surgical instrument with the treatment module in place showing several illustrative lumen arrangements. Since the treatment module is removable and interchangeable with other treatment modules, the lumen configuration can be tailored to a particular surgical procedure or step. In addition, one treatment module can be used during one step of a surgical procedure with a lumen configuration that is advantageous for that step. Subsequently, during another step of the same surgical procedure, the treatment module can be removed and replaced allowing a new lumen configuration that is particularly advantageous for the subsequent step.
Figure 9A illustrates the sheath 155 with the lens 160 and irrigation lumen 157. The treatment module 900 has now been inserted into the lumen 902 formerly occupied by the excision module (not shown.) In the particular embodiment shown in Figure 9A, the treatment module 900 has egress lumen 904 and an ingress tube 906. As previously mentioned the ingress tube 906 may be mounted on a sliding frame that allows it to be extended beyond the end of the sheath 155 by manipulation at the proximal end.

Figure 9B shows an alternative lumen arrangement in which coaxial lumens are used. In particular, lumen 908 is separated from lumen 910 by a flexible wall 912. Such a lumen configuration might be useful for introducing fluids that react and form a polymer at the surgical site. Further, a series of concentric, parallel or a mixture of concentric and parallel lumens may be utilized.

Still another lumen arrangement is illustrated in Figure 9C. In this arrangement, a rod 914 located in one lumen 916 can be mounted on the aforementioned sliding frame so that the rod 914 can be extended into the surgical site to mix fluids introduced into the site via lumen 918.

Figures 10A-10F illustrate steps in the treatment of a prostatic site by means of the illustrative modular surgical instrument shown in Figures 7-9. In Figure 10A, the surgical instrument 1000 including the sheath 155 has been inserted through the urethra 1002 into the vicinity of the prostate tissue mass to be treated schematically illustrated by 1004 and 1006.

In the next step, illustrated in Figure 10B, the sheath 155 of the instrument 1000 is maneuvered to position the distal end 1012 of the instrument sheath 155 near the surgical site and the cutting blade 1010 and positioning tube are extended or exposed beyond the distal end 1012 of the sheath 155 in the manner described above in connection with Figures 2-4. With the cutting blade in the non-cutting position, the cutting blade and positioning tube will pierce the wall of the urethra. Figure 10C shows the cutting blade pivoted or moved so that it can start cutting. The cutting blade is then rotated to create a tissue void 1014 as shown in Figure 10D filled with morsellated tissue 1016. As this point, a guidewire 1015 can be optionally inserted into a lumen in the instrument for guidance and stabilization. The excision module is
then retracted as described above and the treatment module is inserted, either directly
or over the guidewire 1015.

As shown in Figure 10E, an ingress tube 1018, as shown in Figure 9A, is
extended by means of the sliding frame as previously described. This tube 1018 may
have several openings 1020 along its sides to spray the treatment area with treatment
fluid. Morsellated tissue may be left in place, allowed to egress, actively irrigated,
expelled or vacuumed out. Other treatment agents may be introduced via other
lumens (not shown.)

Finally, as illustrated in step 10F, the surgical instrument is removed after filling,
sealing, change or replacement of the tissue void 1022.

Figures 11A-11F illustrate steps in an alternative treatment of a prostatic site by
means of the illustrative modular surgical instrument shown in Figures 7-9. In Figure
11A, the surgical instrument 1100 including the sheath 155 has been inserted through
the urethra 1102 into the vicinity of the prostate tissue mass to be treated
schematically illustrated by 1104 and 1106.

In the next step, illustrated in Figure 11B, the sheath 155 of the instrument
1100 is maneuvered to pierce the urethral wall and position the distal end 1112 of the
instrument sheath 155 near the surgical site. In Figure 11C, the cutting blade 1110 is
extended or exposed beyond the distal end 1112 of the sheath 155 in the manner
described above in connection with Figures 2-4.

The cutting blade is then rotated to create a tissue void 1114 as shown in
Figure 11D filled with morsellated tissue 1116. As this point, a guidewire 1115 can be
optionally inserted into a lumen in the instrument for guidance and stabilization. The
excision module is then retracted as described above and the treatment module is
inserted, either directly or over the guidewire 1115.

As shown in Figure 11E, an ingress tube 1118, as shown in Figure 9A, is
extended by means of the sliding frame as previously described. This tube 1118 may
have several openings 1120 along its sides to spray the treatment area with treatment
fluid. Morsellated tissue may be left in place, allowed to egress, actively irrigated,
expelled or vacuumed out. Other treatment agents may be introduced via other
lumens (not shown.)
Finally, as illustrated in step 11F, the surgical instrument is removed after filling, sealing, change or replacement of the tissue void 1122.

Although several exemplary embodiments of the invention have been disclosed, it will be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the spirit and scope of the invention. For example, it will be obvious to those reasonably skilled in the art that other equivalent blade configurations can be used with the same effect. Other aspects, such as the specific mechanical configuration of the instrument, as well as other modifications to the inventive concept are intended to be covered by the appended claims.

What is claimed is:
CLAIMS

1. A surgical instrument for cutting a tissue, comprising:
   a positioning tube having a longitudinal axis and a diameter;
   a shaft positioned in the tube, the shaft having a proximal end, and a
distal end;
   at least one two-position blade affixed to the shaft distal end, the blade
having a non-cutting position in which the blade does not extend outside the
tube diameter and a cutting position in which the blade extends outside of the
tube diameter;
   a mechanism operable from the shaft proximal end that moves the blade
between the non-cutting position and the cutting position; and
   a mechanism operable from the shaft proximal end that rotates the blade
in the cutting position about the longitudinal axis so that the tissue is cut.

2. The instrument according to claim 1 wherein at least one blade comprises a
wire affixed to the shaft distal end and extending along the longitudinal axis, the
wire being composed of a material with a mechanical memory and preformed
into a right angle curve so that, in the non-cutting position, the wire is withdrawn
into the tube and constrained in a linear shape and, in the cutting position, the
wire is extended beyond the tube distal end and assumes the preformed right
angle shape.

3. The instrument according to claim 1 wherein the shaft is hollow with a second
lumen extending there through and a control link with a distal end is located in
the second lumen and wherein the at least one blade comprises a flexible strip
of material with a first end connected to the shaft distal end and a second end
connected to the control link distal end, so that, in a non-cutting position, the
blade is parallel to the longitudinal axis and, in a cutting position, the first shaft
and control link are moved relative to one another to cause the blade to extend
beyond the tube diameter.
4. The instrument according to claim 1 wherein the shaft is hollow with a second lumen extending there through and wherein at least one blade comprises a rigid blade with an end and a pivot point near the end, the blade pivoting about an axle affixed to the shaft distal end and a control link extending through the second lumen and attached to the blade end so that, in a non-cutting position the blade lies along the longitudinal axis, and, in a cutting position, the blade is rotated about the pivot point by sliding the control link in the second lumen to a position substantially perpendicular to the longitudinal axis.

5. The instrument according to claim 4 wherein the control link is connected to the blade end by an additional link.

6. The instrument according to claim 4 further comprising a guidewire extending through the second lumen for guidance and stabilization.

7. The instrument according to any of claims 1-6 further comprising a mechanism that locks the angular orientation of the blade when the blade is in the cutting position.

8. The instrument according to claim 7 wherein the locking mechanism is actuated when the blade rotates in one direction and is released when the blade rotates in the opposite direction.

9. The instrument according to any of claims 1-6 further comprising an electrical generator that applies electrical energy across the blade and the tissue to allow the blade to cauterize tissue or to cut tissue.

10. The instrument according to claim 9 wherein the locking mechanism comprises a cam affixed to the shaft, the cam having a periphery and a locking shoulder and a locking arm having a free end which bears against the cam periphery so that when the blade rotates in one direction the locking arm lodges against the shoulder in order to lock the blade and when the blade rotates in the opposite
direction, the cam periphery lifts the locking arm clear of the shoulder to allow
the blade to rotate.

11. The instrument according to claim 9 wherein the rotating mechanism comprises
a motor attached to the shaft to rotate the shaft.

12. The instrument according to claim 11 wherein the locking mechanism
comprises a first cam affixed to the shaft, the first cam having a periphery with
a locking notch therein and a drive pin, a second cam affixed to the motor, the
second cam having a slot for accommodating the drive pin, and a lifting surface
periphery, and a locking pin which bears against the first cam periphery and the
second cam periphery.

13. The instrument according to claim 12 wherein the drive pin engages the slot in
order to transfer torque generated by the motor through the first and second
cam to the shaft and wherein the locking pin engages the locking notch when
the motor rotates in a first direction in order to lock the blade.

14. The instrument according to claim 13 wherein the second cam rotates relative
to the first cam when the motor direction is reversed from the first direction so
that the lifting surface lifts the locking pin out of the locking notch to allow the
first and second cam and the shaft to rotate.

15. The instrument according to claim 14 further comprising an electrical generator
that applies electrical energy across the locked blade and the tissue to allow
the blade to cauterize tissue or to cut tissue.

16. The instrument according to any of claims 1-6 wherein the positioning tube has
a distal end and the instrument further comprises an electrical resistive element
attached to the positioning tube distal end and an electrical source that supplies
electrical energy to the resistive element to heat, cut and coagulate tissue.
17. The instrument according to any of claims 1-6 wherein the positioning tube has a distal end and the instrument further comprises a tip containing a fluid circuit therein attached to the distal end of the positioning tube and means for conducting a heated fluid to the tip to allow the tip to heat, cut and coagulate tissue.

18. The instrument according to any of claims 1-6 further comprising an antenna attached to the blade and a microwave energy source that supplies microwave energy to the antenna to heat, cut and coagulate tissue.

19. The instrument according to any of claims 1-6 wherein the blade has a knife-edge formed thereon.

20. The instrument according to any of claims 1-6 wherein the blade has a knife-edge bonded thereto.

21. The instrument according to any of claims 1-6 further comprising an ultrasonic imaging system for viewing the surgical site.

22. The instrument according to any of claims 1-6 further comprising a thermal imaging system for viewing the surgical site.

23. The instrument according to any of claims 1-6 wherein the shaft is fabricated of a rigid material.

24. The instrument according to any of claims 1-6 wherein the shaft is fabricated of a flexible material.

25. The instrument according to claim 24 wherein the shaft has a longitudinal axis and is preformed with a distal tip that extends at an angle to the axis.
26. The instrument according to any of claims 1-6 wherein the positioning tube is fabricated of a rigid material.

27. The instrument according to any of claims 1-6 wherein the positioning tube is fabricated of a flexible material.

28. The instrument according to claim 27 wherein the positioning tube is preformed with a distal tip that extends at an angle to the axis.

29. A method for performing a surgical procedure involving the cutting of tissue at a surgical site using a surgical instrument having a positioning tube with a longitudinal axis and a diameter, a shaft positioned in the tube, the shaft having a proximal end, and a distal end, at least one two-position blade affixed to the shaft distal end, the blade having a non-cutting position in which the blade does not extend outside the tube diameter and a cutting position in which the blade extends outside of the tube diameter, the method comprising:

(a) positioning the instrument at the surgical site with the blade in the non-cutting position;

(b) moving the blade from the non-cutting position to the cutting position with the shaft;

(c) rotating the blade in the cutting position about the longitudinal axis to cut the tissue;

(d) moving the blade from the cutting to the non-cutting position with the shaft; and

(e) removing the instrument from the surgical site.

30. The method according to claim 29 wherein step (a) comprises maneuvering the positioning tube with the blade contained therein to the surgical site and extending the blade beyond the positioning tube to a location adjacent to the tissue to be cut.
31. The method according to claim 29 wherein step (c) comprises locking the angular orientation of the blade when the blade is in the cutting position after cutting the tissue.

32. The method according to claim 31 wherein the locking step comprises locking the angular orientation of the blade when the blade rotates in one direction and releasing the rotation of the blade when the blade rotates in the opposite direction.

33. The method according to any of claims 29-32 further comprising:
   (f) applying electrical energy across the blade and the tissue to allow the blade to cauterize tissue or to cut tissue.

34. The method according to any of claims 29-32 further comprising:
   (g) applying thermal energy to the tissue to cauterize tissue or to coagulate tissue.

35. The method according to claim 29 wherein step (c) comprises using a motor attached to the shaft to rotate the shaft.

36. A modular surgical instrument for treating a tissue mass at a surgical site, comprising:
   (a) a main module having a sheath with a diameter;
   (b) an excision module adapted to be removably attached to the main module and having,
       a shaft positioned in the sheath, the shaft having a proximal end, and a distal end;
       at least one two-position blade affixed to the shaft distal end, the blade having a non-cutting position in which the blade does not extend outside the sheath diameter and a cutting position in which the blade extends outside of the sheath diameter;
a mechanism operable from the shaft proximal end that moves
the blade between the non-cutting position and the cutting position;
a mechanism operable from the shaft proximal end that rotates
the blade in the cutting position about the longitudinal axis so that the
tissue is cut; and
(c) a treatment module adapted to be removably attached to the main
module, the treatment module having at least one lumen for delivering a
therapeutic material to the surgical site.

37. A modular surgical instrument according to claim 36 wherein the main module
further comprises an optical system for viewing the surgical site.

38. A modular surgical instrument according to claim 36 wherein the main module
further comprises an ultrasonic imaging system viewing the surgical site.

39. A modular surgical instrument according to claim 36 wherein the main module
further comprises a thermal imaging system viewing the surgical site.

40. A modular surgical instrument according to claim 36 wherein the treatment
module is adapted to replace the excision module.

41. A modular surgical instrument according to claim 36 wherein the excision
module further comprises:
a positioning tube having a proximal end and located inside the sheath
and wherein the shaft is positioned inside the positioning tube; and
a sliding mechanism located at the positioning tube proximal end for
moving the positioning tube and the shaft into the surgical site.

42. The instrument according to claim 41 wherein the positioning tube is fabricated
of a rigid material.
43. The instrument according to claim 41 wherein the positioning tube is fabricated of a flexible material.

44. The instrument according to claim 43 wherein the positioning tube has a longitudinal axis and is preformed with a distal tip that extends at an angle to the axis.

45. A modular surgical instrument according to claim 36 wherein the treatment module further comprises:
   a fluid delivery tube having a proximal end and located in the one lumen; and
   a sliding mechanism located at the delivery tube proximal end for moving the delivery tube into the surgical site.

46. The instrument according to claim 45 wherein the fluid delivery tube is fabricated of a rigid material.

47. The instrument according to claim 45 wherein the fluid delivery tube is fabricated of a flexible material.

48. The instrument according to claim 47 wherein the fluid delivery tube has a longitudinal axis and is preformed with a distal tip that extends at an angle to the axis.

49. A modular surgical instrument according to claim 36 wherein the treatment module comprises a plurality of lumens arranged to facilitate a predetermined surgical procedure.

50. A modular surgical instrument according to claim 49 wherein at least some of the lumens are coaxial.
51. A modular surgical instrument according to claim 49 wherein a rod passes through at least one of the lumens.

52. A modular surgical instrument according to claim 49 wherein at least some of the lumens are fluidly connected to reservoirs of treatment material.

53. A modular surgical instrument according to claim 49 wherein at least some of the lumens are fluidly connected to reservoirs of two treatment materials that react in order to activate, polymerize and change that state of the materials at the local surgical site.

54. The instrument according to claim 36 wherein the shaft is fabricated of a rigid material.

55. The instrument according to claim 36 wherein the shaft is fabricated of a flexible material.

56. The instrument according to claim 55 wherein the shaft has a longitudinal axis and is preformed with a distal tip that extends at an angle to the axis.

57. The instrument according to claim 36 wherein the sheath contains a lumen and the instrument further comprises a guidewire positioned in the lumen for guidance and stabilization.

58. The instrument according to claim 36 wherein the instrument further comprises a guidewire positioned in the treatment module lumen for guidance and stabilization.
59. A surgical instrument for cutting a tissue, comprising:
    a sheath having a longitudinal axis and a diameter;
    a shaft positioned in the sheath, the shaft having a proximal end, a distal
    end and a longitudinal axis that is radially offset from the sheath longitudinal
    axis;
    at least one cutting blade affixed substantially perpendicular to the shaft
    distal end, the blade having a non-cutting position in which the blade does not
    extend outside the sheath diameter and a cutting position in which the blade
    extends outside of the sheath diameter; and
    a mechanism operable from the shaft proximal end that rotates the blade
    about the shaft longitudinal axis so that the tissue is periodically cut as the
    blade rotates between the cutting and non-cutting position.

60. The instrument according to claim 59 wherein the sheath has a proximal end
    and a distal end and the sheath distal end is fabricated of a substantially
    transparent material.

61. The instrument according to claim 60 further comprising an optical system that
    extends from the sheath proximal end to the sheath distal end, passing through
    the transparent material.

62. The instrument according to claim 59 wherein the sheath has a proximal end
    and a distal end and the cutting blade comes into contact with the sheath distal
    end during at least a part of its rotation so that tissue accumulated on the
    cutting blade is wiped away.

63. The instrument according to claim 59 further comprising a mechanism located
    at the sheath proximal end for moving the shaft in a longitudinal direction to
    position the cutting blade away from the sheath distal end.
64. The instrument according to claim 63 further comprising an RF generator for applying RF power to the shaft and cutting blade when the cutting blade is positioned away from the sheath distal end.

65. The instrument according to claim 59 wherein the cutting blade is substantially "L" shaped.
Figure 12

Figure 13A

Figure 13B

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