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(54) **ULTRASONIC SURGICAL BLADES**

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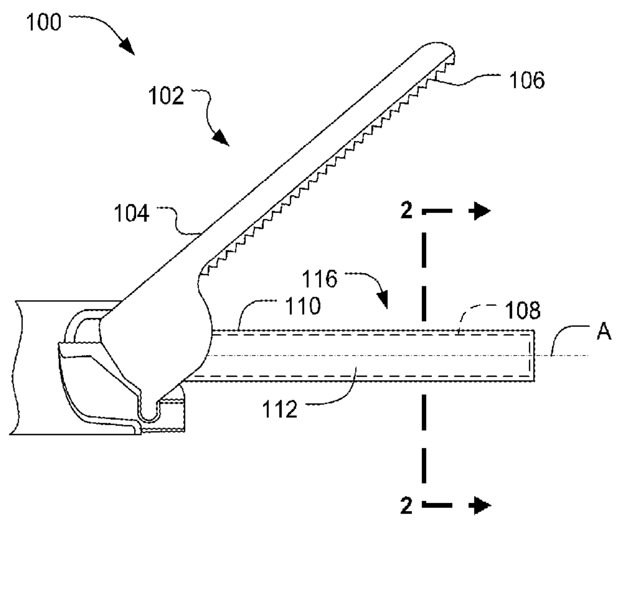
(57) **ABSTRACT**

An ultrasonic surgical blade includes a body having a proximal end, a distal end, and an outer surface. The distal end is movable relative to a longitudinal axis in accordance with ultrasonic vibrations applied to the proximal end. At least a portion of the outer surface of the body comprises a lubricious coating adhered thereto. The lubricious coating has a coefficient of friction that is less than the coefficient of friction of the outer surface of the body.

17 Claims, 10 Drawing Sheets



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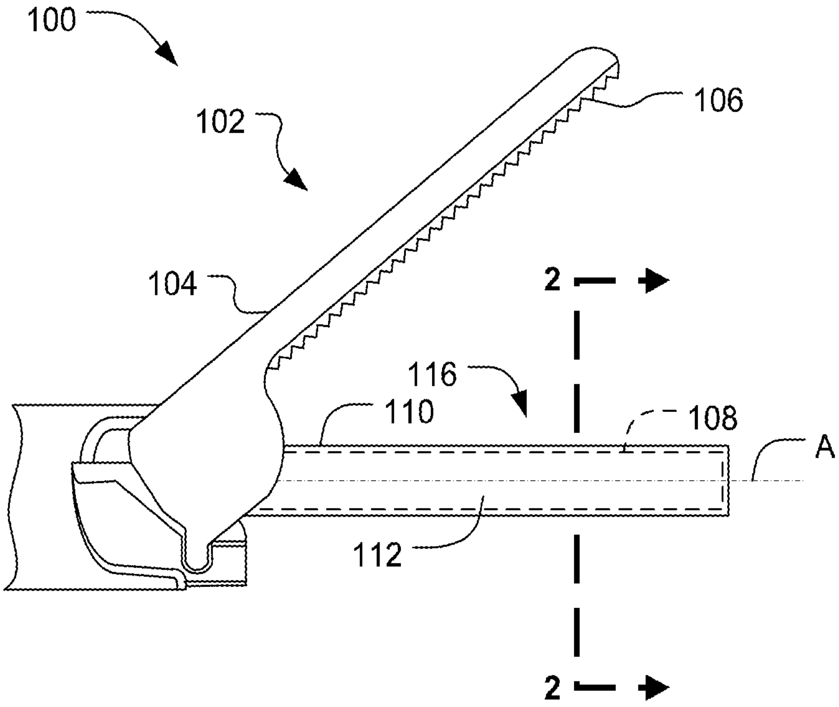

FIG. 1

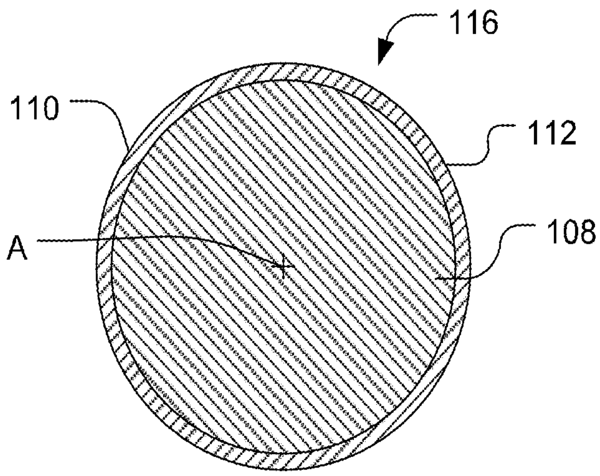

FIG. 2

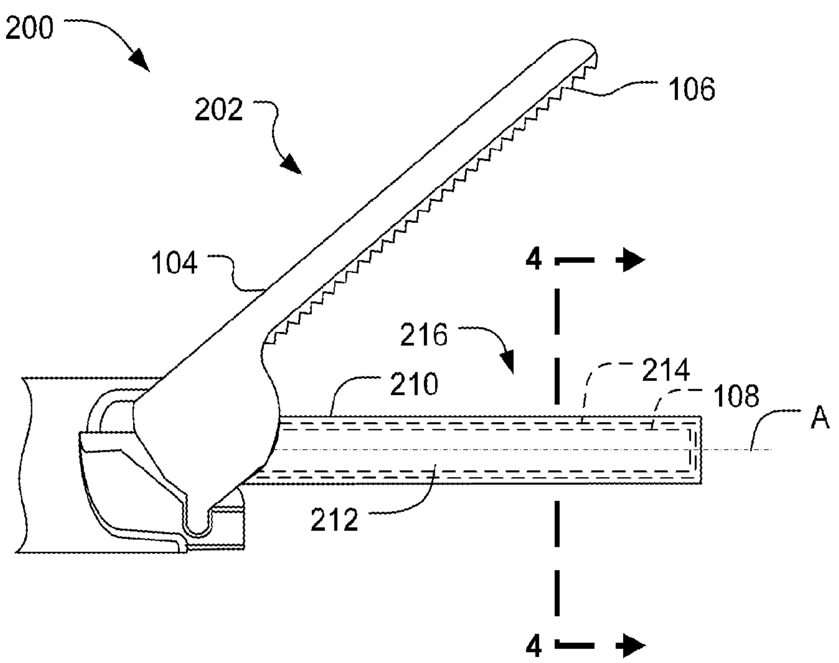

FIG. 3

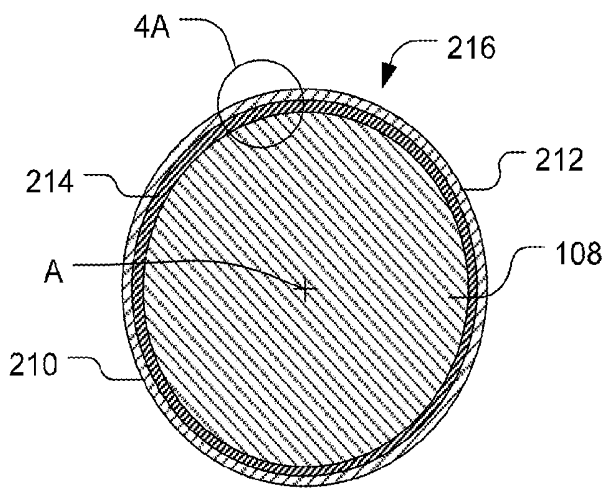

FIG. 4

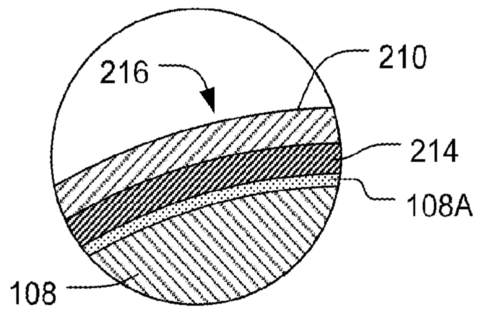

FIG. 4A

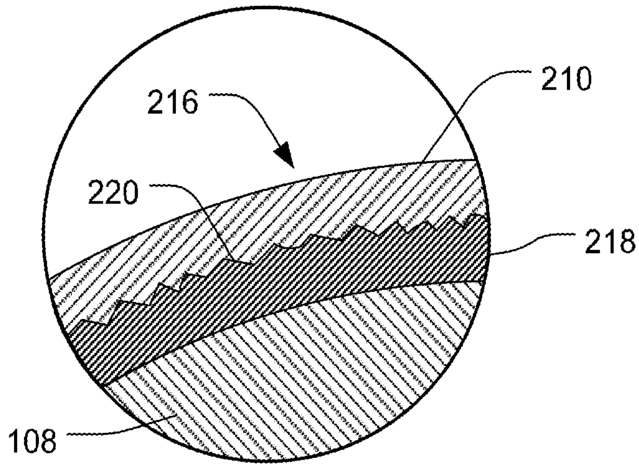

FIG. 4B

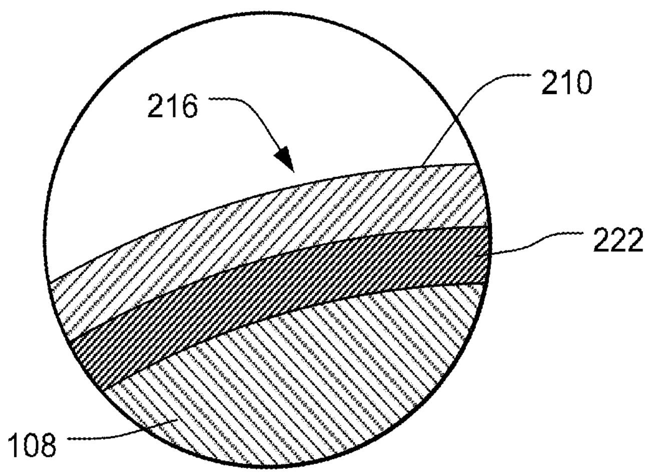

FIG. 4C

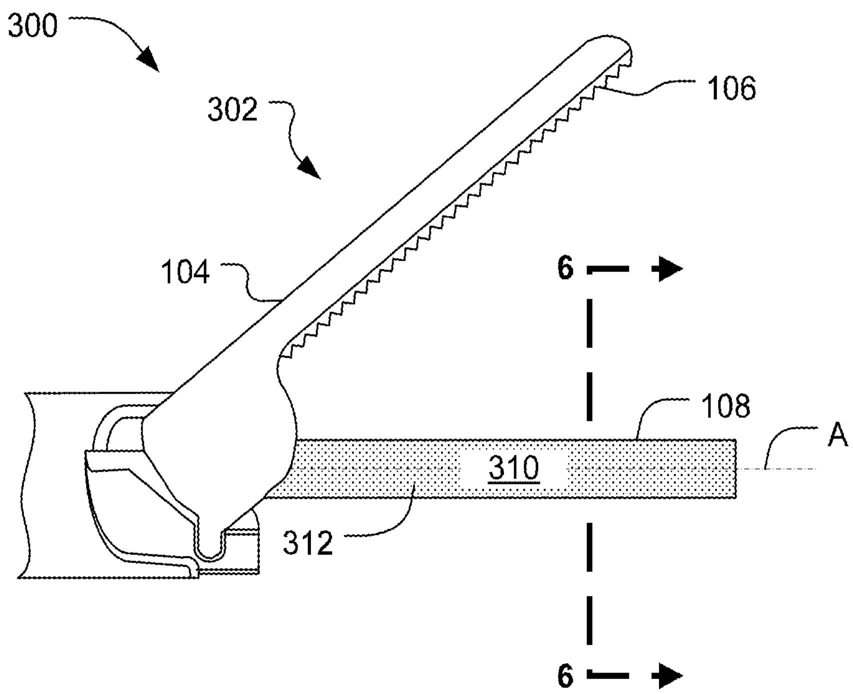

FIG. 5

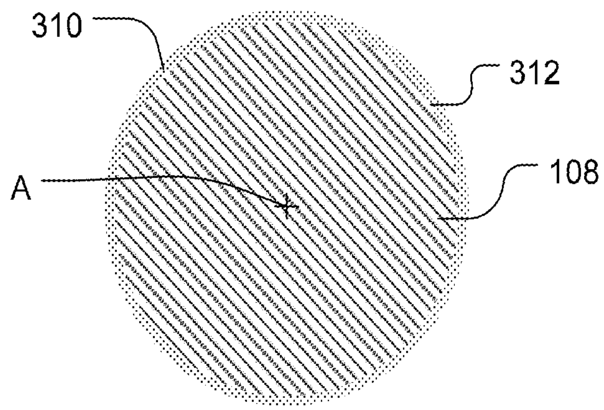

FIG. 6

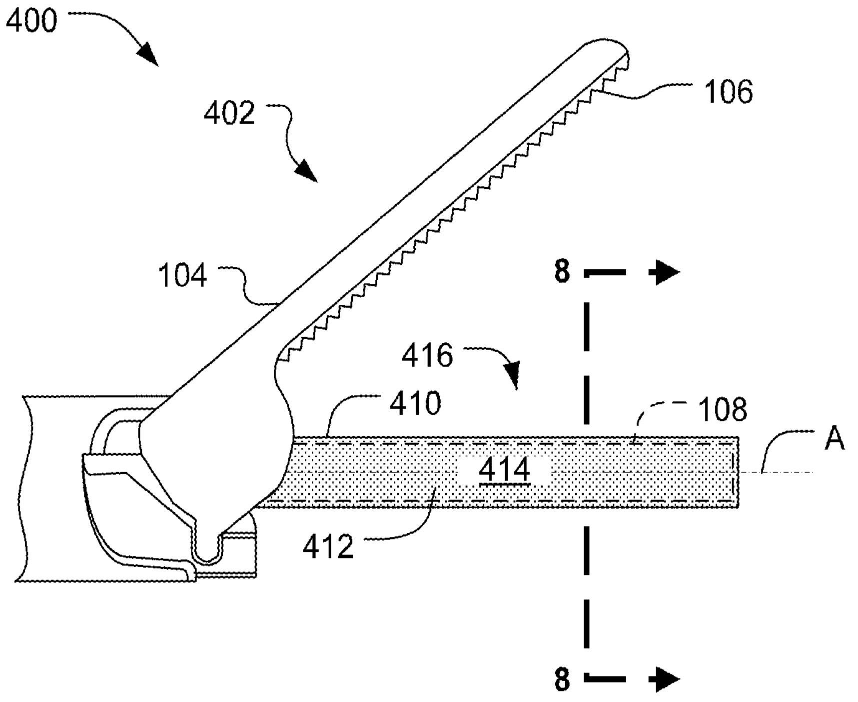

FIG. 7

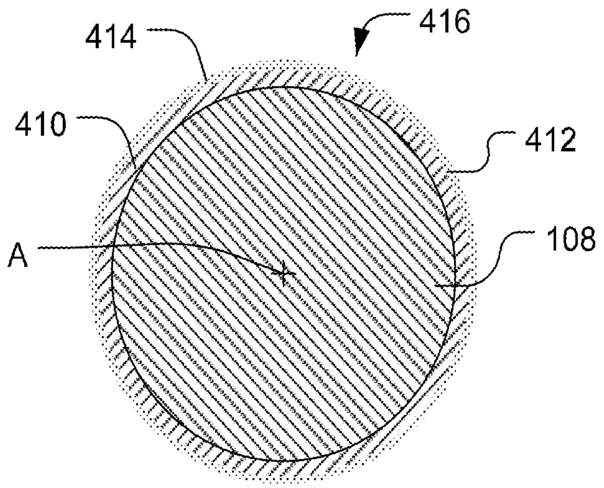

FIG. 8

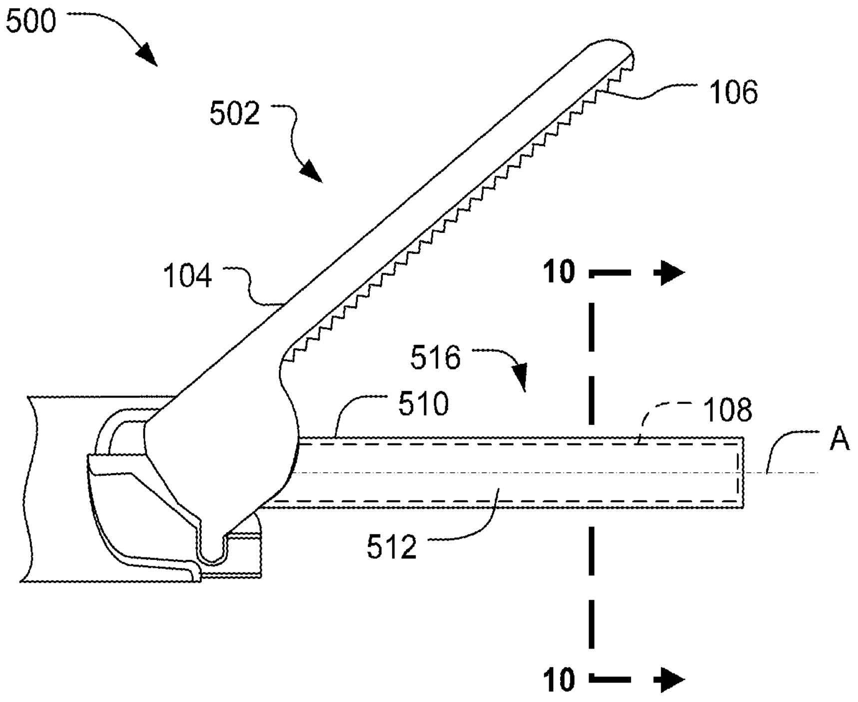
500
502
106
104
10
516
510
108
A
512
10

FIG. 9

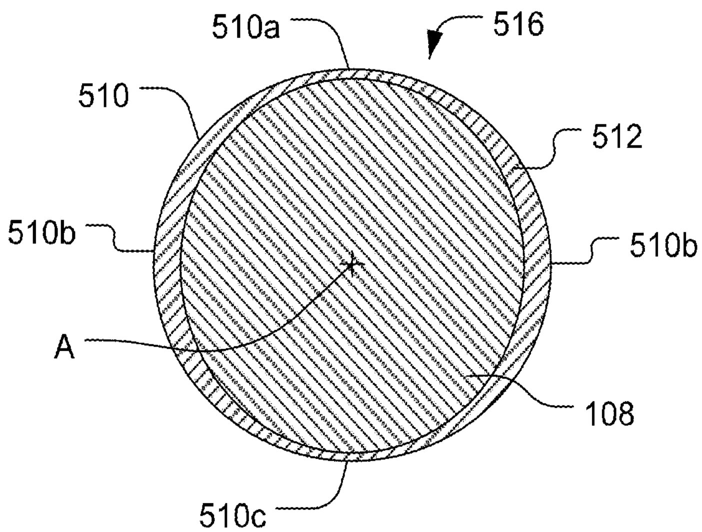
510a
516
510
512
510b
510b
A
108
510c

FIG. 10

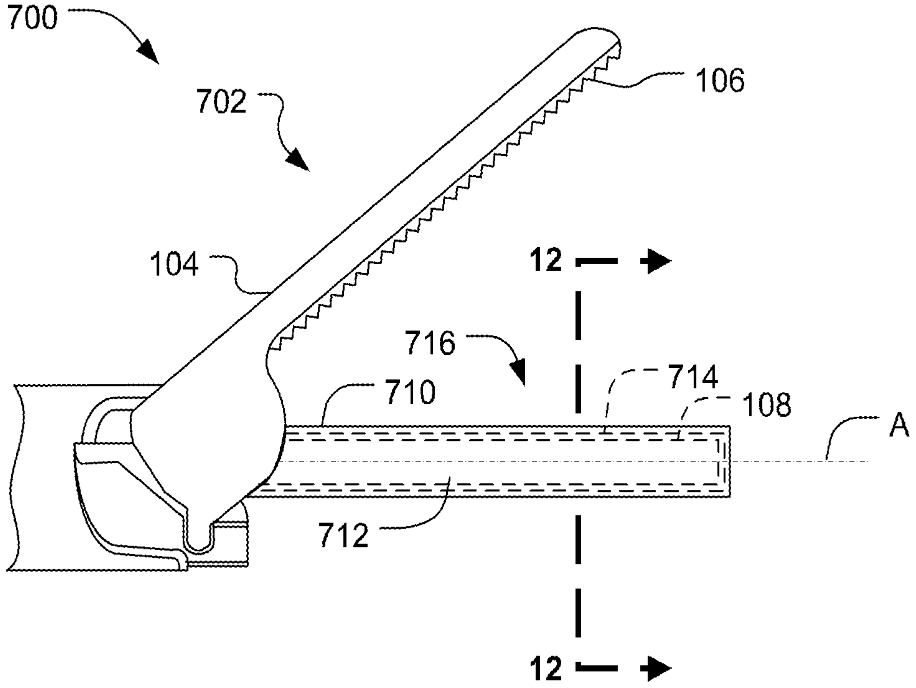

FIG. 11

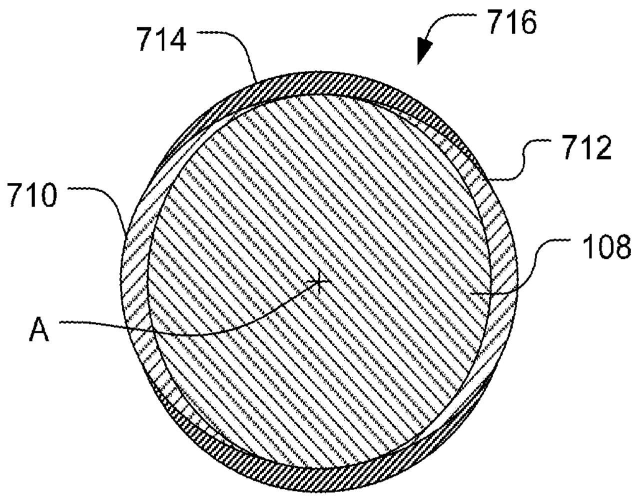

FIG. 12

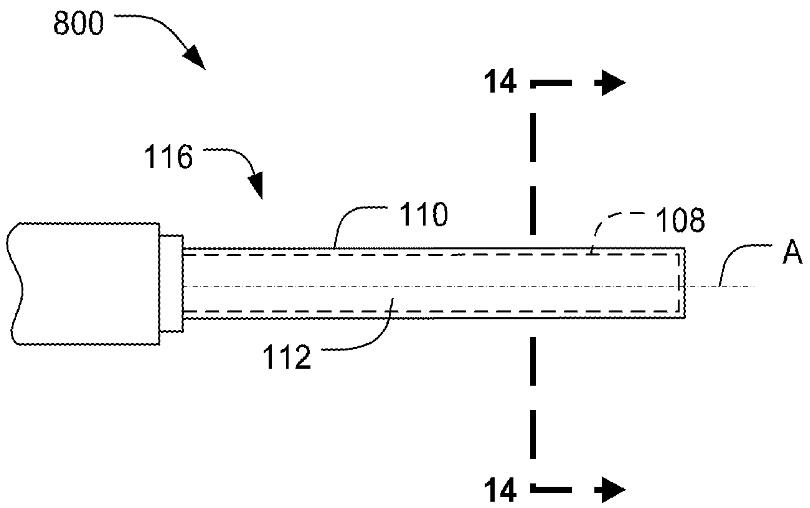

FIG. 13

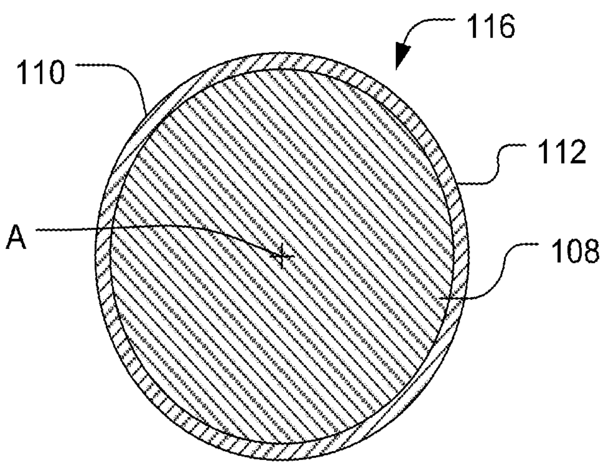

FIG. 14

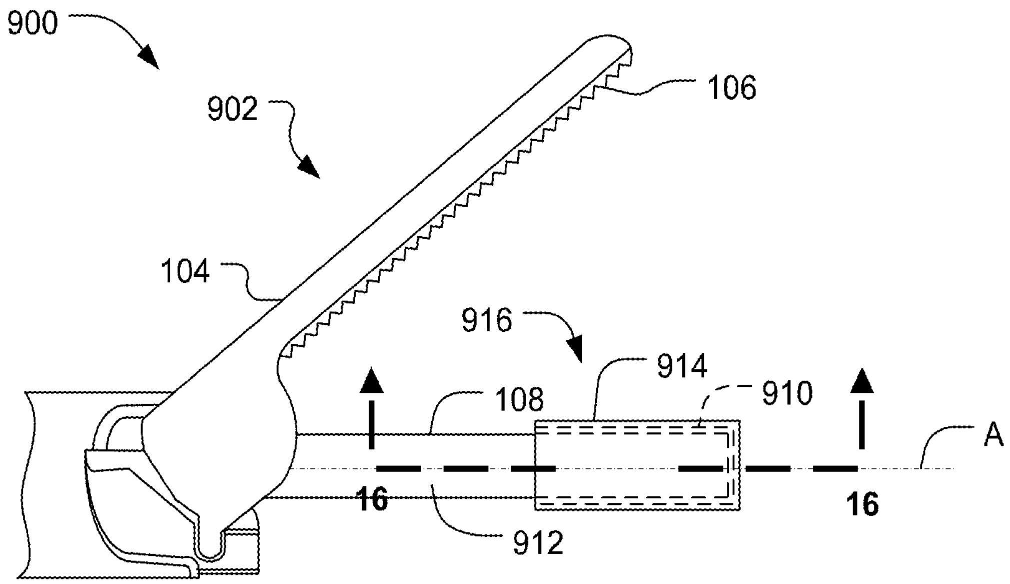

FIG. 15

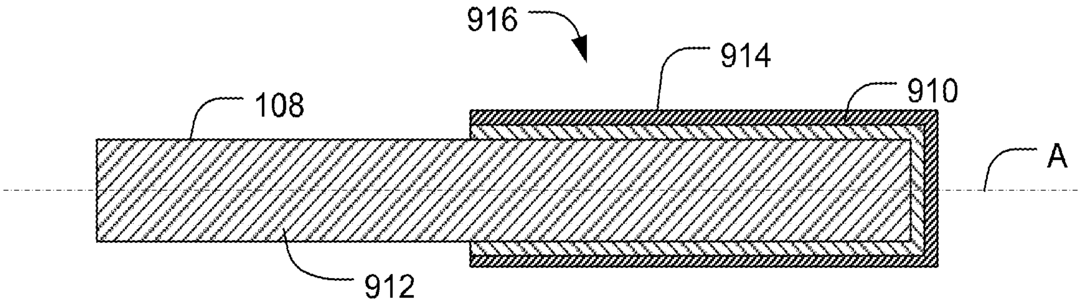

FIG. 16

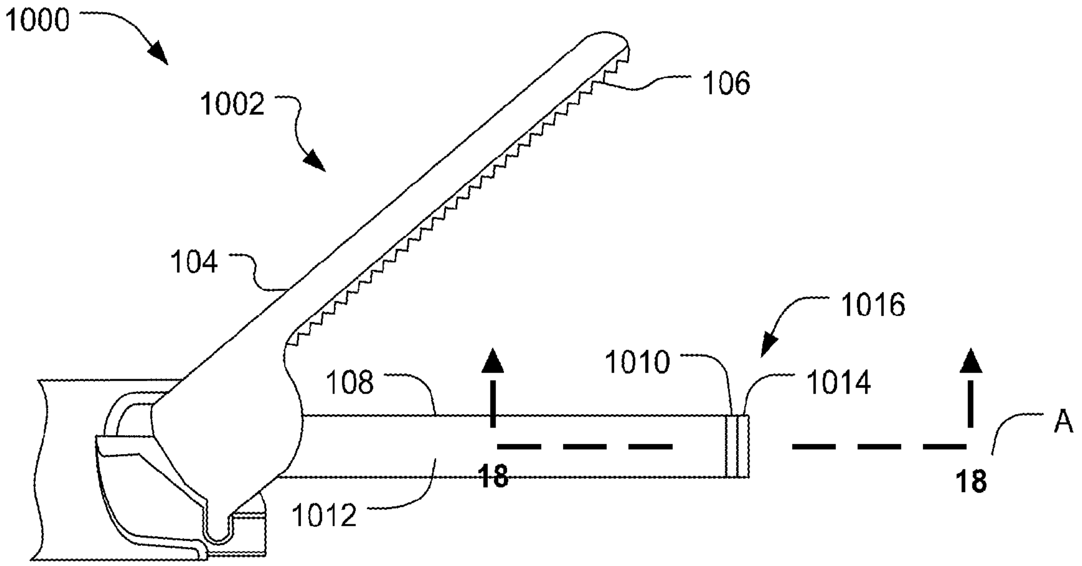
1000
1002
106
104
1016
1010
1014
108
A
18
1012
18

FIG. 17

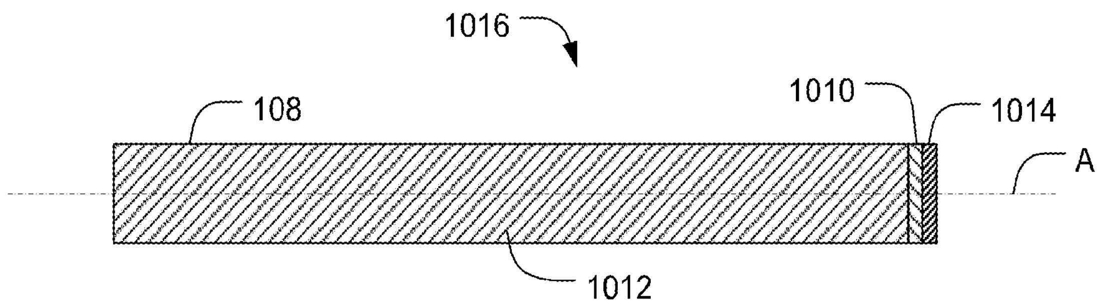
1016
108
1010
1014
A
1012

FIG. 18

ULTRASONIC SURGICAL BLADES

CROSS REFERENCE TO RELATED APPLICATION

This application claims the benefit under Title 35, United States Code § 119(e), of U.S. Provisional Patent Application Ser. No. 61/004,961, filed Nov. 30, 2007 and entitled "Ultrasonic Surgical Blades," which is hereby incorporated by reference in its entirety.

BACKGROUND

The present disclosure is generally directed to ultrasonic surgical blades employed in ultrasonic instruments. At present, ultrasonic instruments are used in open as well as minimally invasive surgical procedures, including endoscopic and laparoscopic surgical procedures where an end-effector portion of the ultrasonic instrument is passed through a trocar to reach the surgical site. Due, in part, to the rising popularity of minimally invasive surgical procedures, ultrasonic instruments are increasingly being used for the safe and effective treatment of many medical conditions. The operation of instruments employing an ultrasonic transducer in this context is well known in the art and it will not be repeated herein for the sake of conciseness and brevity. Stated briefly, an ultrasonic transducer excited by an electrical generator produces mechanical vibrations at ultrasonic frequencies, which are transmitted longitudinally through a transmission component or waveguide to an end-effector. The mechanical vibrations induce longitudinal, transverse, or torsional vibratory movement to the end-effector relative to the transmission component. The vibratory movement of the end-effector generates localized heat within adjacent tissue, facilitating both cutting and coagulating of tissue at the same time. Accordingly, the ultrasonic vibrations, when transmitted to organic tissue at suitable energy levels using a suitable end-effector, may be used to cut, dissect, separate, lift, transect, elevate, coagulate or cauterize tissue, or to separate or scrape muscle tissue away from bone with or without the assistance of a clamping assembly.

It is generally accepted that ultrasonic instruments, and particularly ultrasonic instruments comprising contact ultrasonic elements, provide certain advantages over other surgical instruments. Among these advantages is that the ultrasonic mechanical vibrations can cut and coagulate tissue at the same time using relatively lower temperatures than conventional cutting and cauterizing surgical instruments. The nature of ultrasonic instruments lend themselves to multiple applications and a variety of end-effectors may be designed to perform numerous functions.

Ultrasonic instruments may be classified into single-element end-effector devices and multiple-element end-effector devices. Single-element end-effector devices include instruments such as blades, scalpels, hooks, and/or ball coagulators. Although generally, these types of end-effectors are formed of solid materials suitable for propagating ultrasonic waves, there also exist end-effectors with a hollow core to deliver a fluid stream or provide a suction channel. Multiple-element end-effectors include the single-element end-effector—blade—operatively coupled to a clamping mechanism for pressing or clamping tissue between the blade and the clamping mechanism. Multiple-element end-effectors include clamping scalpels, clamping coagulators or any combination of a clamping mechanism and a single-element end-effector. Clamping end-effectors are particularly useful when a substantial amount of pressure

is necessary to effectively couple ultrasonic energy from the blade to the tissue. Clamping end-effectors apply a compressive or biasing force to the tissue to promote faster cutting and coagulation of tissue, particularly loose and unsupported tissue.

With this general background in mind, it should be noted that surgical environments where ultrasonic instruments are employed can be particularly harsh due to the mechanical vibratory forces applied to the end-effector, the resulting thermal effects, and the general caustic conditions present at the surgical site. For example, in use, the end-effector comes into contact with surgical matter, which includes coagulants, proteins, blood, tissue particles, and other constituent fluids. Over time, the surgical matter tends to desiccate and adhere to the outer (e.g., external) surface of the end-effector. This buildup of surgical matter tends to reduce the performance of the end-effector by reducing the ability of the end-effector to cut and/or coagulate tissue and increasing the impedance at the end-effector/tissue interface. To compensate for the increase in interface impedance, the generator supplies increasing amounts of power to the end-effector to continue transecting tissue until the power delivered by the generator exceeds a predetermined threshold at which time the generator shuts down or goes into "lockout." Lockout is a condition where the impedance of the end-effector is so high that the generator is unable to provide meaningful amounts of power to the tissue. Generator lockout is an undesirable result that occurs when the generator is unable to supply adequate power to the end-effector to complete a transection under the increased interface impedance condition. The completion of a transection is indicated to the user by the visual separation of the tissue from the device end-effector. When the generator goes into lockout, the surgical procedure is interrupted. Therefore, generator lockout results in increased cutting and transection times, or worse, down time during the surgical procedure.

Accordingly, there is a need for an end-effector with a suitable coating or suitable combination of a coating and a surface treatment to protect the end-effector from harsh surgical environments. In this regard, the suitable coating or suitable combination of a coating and a surface treatment prevents or minimizes buildup of surgical matter on the outer surface of the end-effector, minimizes generator lockout, minimizes power draw, improves pad wear in clamping type end-effectors, and improves the thermal characteristics of the end-effector. There is also needed a process of applying one or more suitable coatings to an outer surface of an end-effector to enable the adhesion of the one or more coatings to the outer surface of the end-effector.

SUMMARY

In one general aspect, the various embodiments are directed to an ultrasonic surgical blade. The ultrasonic surgical blade comprises a body having a proximal end, a distal end, and an outer surface. The distal end is movable relative to a longitudinal axis in accordance with ultrasonic vibrations applied to the proximal end. At least a portion of the outer surface of the body comprises a lubricious coating adhered thereto. The lubricious coating has a coefficient of friction that is less than the coefficient of friction of the outer surface of the body.

FIGURES

The novel features of the various embodiments are set forth with particularity in the appended claims. The various embodiments, however, both as to organization and methods of operation, may be best understood by reference to the following description, taken in conjunction with the accompanying drawings as follows.

FIG. **1** illustrates one embodiment of a multi-element end-effector.

FIG. **2** illustrates a cross-sectional view of an ultrasonic blade portion of the multi-element end-effector shown in FIG. **1** taken along line **2-2**.

FIG. **3** illustrates one embodiment of a multi-element end-effector.

FIG. **4** illustrates a cross-sectional view of the ultrasonic blade portion of the multi-element end-effector shown in FIG. **3** taken along line **1-4**.

FIG. **4**A is an enlarged view of a portion of the cross-sectional portion of one embodiment of the ultrasonic blade portion of the multi-element end-effector shown in FIG. **3**.

FIG. **4**B is an enlarged view of a portion of the cross-sectional portion of one embodiment of the ultrasonic blade portion of the multi-element end-effector shown in FIG. **3**.

FIG. **4**C is an enlarged view of a portion of the cross-sectional portion of one embodiment of the ultrasonic blade portion of the multi-element end-effector shown in FIG. **3**.

FIG. **5** illustrates one embodiment of a multi-element end-effector.

FIG. **6** illustrates a cross-sectional view of the ultrasonic blade portion of the multi-element end-effector shown in FIG. **5** taken along line **6-6**.

FIG. **7** illustrates one embodiment of a multi-element end-effector.

FIG. **8** illustrates a cross-sectional view of the ultrasonic blade portion of the multi-element end-effector shown in FIG. **7** taken along line **8-8**.

FIG. **9** illustrates one embodiment of a multi-element end-effector.

FIG. **10** illustrates a cross-sectional view of the ultrasonic blade portion of the multi-element end-effector shown in FIG. **9** taken along line **10-10**.

FIG. **11** illustrates one embodiment of a multi-element end-effector.

FIG. **12** illustrates a cross-sectional view of the ultrasonic blade portion of the multi-element end-effector shown in FIG. **11** taken along line **12-12**.

FIG. **13** illustrates one embodiment of a single element end-effector.

FIG. **14** illustrates a cross-sectional view of an ultrasonic blade portion of the single element end-effector shown in FIG. **13** taken along line **14-14**.

FIG. **15** illustrates one embodiment of a multi-element end-effector.

FIG. **16** illustrates a cross-sectional view of an ultrasonic blade portion of the multi-element end-effector shown in FIG. **15** taken along line **16-16**.

FIG. **17** illustrates one embodiment of a multi-element end-effector.

FIG. **18** illustrates a cross-sectional view of an ultrasonic blade portion of the multi-element end-effector shown in FIG. **17** taken along line **18-18**.

DESCRIPTION

Before explaining the various embodiments in detail, it should be noted that the embodiments are not limited in application or use to the details of construction and arrangement of parts illustrated in the accompanying drawings and description. The surgical instruments and end-effector configurations disclosed herein are illustrative only and not meant to limit the scope of the appended claims or application thereof. The illustrative embodiments may be implemented or incorporated in other embodiments, variations and modifications, and may be practiced or carried out in various ways. Furthermore, unless otherwise indicated, the terms and expressions employed herein have been chosen for the purpose of describing the illustrative embodiments for the convenience of the reader and are not to limit the scope thereof.

The various embodiments relate, in general, to end-effectors for use in ultrasonic surgical instruments. An ultrasonic surgical instrument generally comprises an ultrasonic transducer, an ultrasonically activated end-effector, and a substantially solid, or hollow, ultrasonic waveguide that connects the ultrasonic transducer to the end-effector. The ultrasonic transducer is contained in a transducing handpiece. The end-effector may be formed of a base material (e.g., body) that is suitable for efficiently transmitting or propagating acoustic waves at ultrasonic frequencies. Thus, the end-effector is an ultrasound-propagating element, which may be coupled to the ultrasonic transducer either directly or by way of the ultrasonic transmission waveguide. Examples of ultrasonic surgical instruments are disclosed in U.S. Pat. Nos. 5,322,055 and 5,954,736 and combinations of ultrasonic end-effectors (e.g., blades) and surgical instruments are disclosed in U.S. Pat. Nos. 6,309,400 B2, 6,278,218 B1, 6,283,981 B1, and 6,325,811 B1, which are incorporated herein by reference in their entirety. These references provide a suitable general description of ultrasonic instruments and end-effectors. Accordingly, the particular operation of such ultrasonic instruments and end-effectors will not be discussed in detail herein.

More particularly, the embodiments are directed to ultrasonic end-effectors comprising one or more coatings formed as layers of materials, surface treatments, and/or any combination thereof. A suitable coating formed on an outer surface of an ultrasonic end-effector provides a lubricating effect and, therefore, is useful in minimizing adhesion of surgical matter to the outer surface of the end-effector. The lubricating coating also reduces friction between the end-effector and the tissue and thus minimizes the interface impedance between the end-effector and the tissue and reduced the heat buildup in the end-effector. This results in less power being drawn from the ultrasonic generator and an end-effector with a cooler thermal profile that minimizes generator lockout and improves the overall operational stability of the surgical instrument. One skilled in the art would expect that a decrease in average power draw (due, again, to reduced interface impedance) would result in a corresponding increase in the time required to perform surgical procedures such as the cutting and coagulation of a tissue bundle. However, this tradeoff in transection time has not been seen in testing and, in fact, an unexpected decrease in transection times has been consistently obtained. Further investigation has revealed two causes for the unexpected results that heretofore have not been described in the art: (1) the lower coefficient of friction coatings (most coatings presented herein have low friction constituents such as polytetrafluoroethylene generally known as TEFLON® and referred to hereinbelow as PTFE) do not adhere to tissue and thus the tissue releases from the blade (the indication of a completed transection) more uniformly and more quickly than a comparable uncoated blade and (2) the lower coefficient of friction and, therefore, interface impedance, results in a lower average power draw and therefore far fewer incidents of generator lockout. In some embodiments, the transection time has been reduced by about 34% by virtue of the first listed cause. In some embodiments, lengths of thick, tough tissue (uterine broad ligament, for example) have been transected in successive applications with a coated end-effector blade while a comparable uncoated instrument was unable (in any reasonable length of time) to accomplish the same task; this due to the second listed cause. In use, various embodiments of the end-effector blades comprising one or more coatings as described herein, may improve tissue effects such as hemostasis by providing more uniform transection and/or coagulation of tissue.

As described herein, a coating may comprise one or more layers of materials formed on an outer surface of a body portion of an ultrasonic end-effector. The outer surface of the end-effector may be partially or completely coated with one or more than one layer of material. Each layer may comprise one or more materials. In other embodiments, one or more surface treatments may be applied either to the entire end-effector body or to a portion thereof. Still in other embodiments, the end-effector body may comprise a combination of coatings and applications of surface treatments. This combination may be applied to the entire end-effector or to a portion thereof.

In some embodiments, materials, surface treatments, and/or combinations thereof, may be suitably applied to an outer surface of the end-effector, or portion thereof, to produce an end-effector having a coefficient of friction that is lower than that of the end-effector base material alone. End-effectors with a lower coefficient of friction operate at lower temperatures and minimize generator lockout promoting faster cutting of tissue. In other embodiments, surface treatments may be suitably applied to an outer surface of the end-effector, or portion thereof, to produce an end-effector having a coefficient of friction that is greater than that of the end-effector base material alone. End effectors with a higher coefficient of friction improve the tissue sealing effects of the end-effector. Therefore, in some embodiments, it may be desirable to provide an end-effector with a lower coefficient of friction in the cutting region and a higher coefficient of friction in the tissue sealing region by applying various combinations of coatings and surface treatments to different portions of the end-effector.

Certain embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting embodiments and the scope of the various embodiments is defined solely by the claims. The features illustrated or described in connection with one embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the appended claims.

It will be appreciated that the terms "proximal" and "distal" are used herein with reference to a clinician gripping a hand piece assembly of an ultrasonic surgical instrument. Thus, the end-effector is distal with respect to the more proximal hand piece assembly. It will be further appreciated that, for convenience and clarity, spatial terms such as "top" and "bottom" also are used herein with respect to the clinician gripping the hand piece assembly. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and absolute.

FIG. **1** illustrates one embodiment of a multi-element end-effector **100**. In the illustrated embodiment, the multi-element end-effector **100** comprises a clamp arm assembly **102**, shown in an open position, operatively coupled to an ultrasonic surgical blade **112** (blade). The multiple-element end-effector **100** may be employed in a conventional clamping coagulating type ultrasonic instrument, for example. The clamp arm assembly **102** comprises a clamp arm **104** and a tissue pad **106** attached to the clamp arm **104**. The blade **112** is an ultrasound-propagating element suitable for coupling to conventional ultrasonic surgical instruments. The blade **112** comprises a body **108** having a proximal end and a distal end and defining an elongated treatment region therebetween. The body **108** defines a longitudinal axis A extending between the proximal end and the distal end. The proximal end is adapted and configured to couple to an ultrasonic transducer either directly or through an ultrasonic transmission waveguide in a known manner. Mechanical vibrations produced by the ultrasonic transducer propagate along the transmission waveguide and are coupled to the proximal end of the body **108**. The distal end of the body **108** is selected such that it is movable relative to the longitudinal axis A by the mechanical vibrations produced by the ultrasonic transducer. The distal end and the elongated treatment region is used to effect tissue (e.g., dissect, transect, cut, coagulate). These tissue effects may be enhanced by clamping the tissue between the camp arm **104** and the blade **112**.

In one embodiment, a coating **116** may be formed or applied on at least a portion of an outer (e.g., external) surface of the body **108** that at least corresponds with the elongated treatment region. The coating **116** may comprise one or more than one layer **110** formed on the outer surface of the body **108**. Each of the one or more than one layer **110** may consist of one or more than one material. Accordingly, in one embodiment, the layer **110** may in effect comprise several sub-layers. In one embodiment, the coating **116** may consist of a base layer (e.g., primer layer, first layer) as well as an overcoat layer (e.g., top layer, second layer) and one or more than one layer **110** therebetween. The surface area of the body **108** may include a surface treatment applied thereto to enhance the adhesion of the layer **110** of material to the body **108**. The coated blade **112** enhances tissue effects during dissecting, transecting, cutting, and coagulating and improves the operational stability of the ultrasonic surgical instrument by minimizing or eliminating generator lockout.

FIG. **2** illustrates a cross-sectional view of the ultrasonic surgical blade **112** portion of the multi-element end-effector **100** taken along line **2-2** in FIG. **1**. As shown in the cross-sectional view of FIG. **2** of the illustrated embodiment, the body **108** has a substantially circular cross sectional shape. In other embodiments, the body **108** may have any suitable cross sectional shape and may be symmetric or asymmetric in nature. For example, the body **108** may have a cross-sectional shape that defines a triangle, square, rectangle, pentagon, hexagon, any suitable polygon, or irregular shape, whether symmetric or asymmetric. The body **108** may be fabricated from a base material suitable for transmission of ultrasonic energy in the form of acoustic waves. The base material of the body **108** may comprise titanium (e.g., Ti6Al-4V ELI), aluminum, stainless steel, or any material or composition that is suitable for propagating acoustic waves efficiently, for example.

In one embodiment, the coating **116** may be formed as one layer **110** over at least a portion of the outer surface of the blade body **108**. The layer **110** may consist of at least one material and in other embodiments may include multiple layers consisting of a base material (e.g., primer layer, first layer) and an overcoat material (e.g., top layer, second layer) as described in more detail herein with reference to FIGS. **3** and **4**. The thickness of the layer **110** may be anywhere from about 0.0001 to about 0.010 inches (0.1 mils to 10 mils). The coating **116** may partially or completely cover the outer surface of the body **108**. The layer **110** may be formed over the entire body **108** or may be formed over portions of the body **108**. The coating **116** material may be selected to have a lower coefficient of friction than the body **108** material.

The layer **110** may comprise a variety of materials including polymeric and polymer containing materials. The term "polymeric materials" and the word polymer, as used herein, include, but are not limited to, homopolymers, copolymers, terpolymers, and the like. Non-limiting examples of polymeric and polymer-containing materials include tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) copolymers (FEP), liquid FEP, FEP/ceramic composites, liquid FEP ceramic epoxy composites, polytetrafluoroethylene (PTFE or TEFLON®), and PTFE/ceramic composites. In other non-limiting embodiments, the layer **110** may comprise a dry film lubricant, such as, but not limited to, tungsten disulfide, molybdenum disulfide, graphite, and fluorinated polymers. Still in other non-limiting embodiments, the layer **110** may comprise ceramics, such as, but not limited to, metal oxydes, metal nitrides, and metal carbides. Examples of ceramics, include, but are not limited to, chromium carbide, tungsten carbide, titanium nitride, alumina, and chromium nitride. Yet in other non-limiting embodiments, the layer **110** may comprise metals. Metals include, but are not limited to, aluminum, stainless steel, and molybdenum. In other non-limiting embodiments, the layer **110** may comprise a metallized ceramic, such as, but not limited to, stainless steel embedded in ceramic.

In various embodiments, the coating **116** may be formed in multiple layers including any of the materials previously discussed with respect to the layer **110**. Examples of multilayer coatings or composites include, but are not limited to, molybdenum/alumina/tungsten carbide, aluminum oxide/stainless steel, aluminum oxide/stainless steel 15/15%, chromium carbide/tungsten oxide, molybdenum/aluminum oxide/tungsten carbide, cobalt/molybdenum, graphite/tungsten oxide, aluminum oxide/stainless steel 25/30%, molybdenum/aluminum oxide/tungsten carbide/stainless steel, or chromium carbide/tungsten oxide, among other suitable materials.

In use, the blade **112** may be exposed to particularly harsh environments including ultrasonic vibrations, heat, and caustic solutions of blood and proteins referenced to herein as surgical matter. Consequently, the harsh operating environment tends to delaminate, erode, or wear the coating **116**. Accordingly, the layer **110** should be applied to the body **108** using any suitable application technique that promotes good adhesion between the base material of the body **108** and the layer **110** to prevent or minimize delamination, erosion, or wear of the layer **110** from the body **108**. The layer **110** may be applied to the body using suitable material application techniques: coating, dipping, spraying, brushing, drying, melting, laser curing, anodizing, electroplating, electroless chemical deposition, sintering, fused curing, physical vapor deposition (PVC), chemical vapor deposition (CVD), thermal spray, thick film high velocity oxygen fuel (HVOF) plasma, and any other suitable material application techniques. Other well known material deposition techniques are described in U.S. Pat. No. 7,041,088 and U.S. Pat. No. 6,663,941, which are incorporated herein by reference. One suitable material application technique is a process developed by Integrated Surgical Sciences, Corp. (ISSC) of Sedalia, Colo., USA. Alternatively, the materials for forming the coating **116**, or any constituent material forming the various layers thereof, may be purchased from ISSC and applied in accordance with any suitable material application techniques.

In various embodiments, a surface treatment or a plurality of surface treatments may be applied to the body **108** using a variety of techniques: peening, sand blasting, micro blasting, bead blasting, knurling, engraving, chemical treatment such as acid or base etching, laser etching, plasma etching, corona discharge etching, heat etching, carving, scoring, vibratory deburring, abrasive flow machining, and other techniques. The surface treatment can advantageously improve the adhesion of the layer **110** to the surface of the body **108**. However, care should be taken when applying surface treatments to prevent damage to the body **108** during application, which later may lead to failure of the blade **112** during use. For example, surface bead blasting may increase the stress concentrations in the end-effector body **108** and may lead to the failure of the end-effector during use. FIG. **4**A illustrates one example of a surface treatment **108**A that may be applied to the surface of the body **108** to enhance the adhesion of the layer **110** to the surface of the body **108**.

In use, the blade **112** comprising the coating **116** formed over the body **108** provides several advantages such as improved cutting and coagulating functions over an uncoated blade. In one embodiment, the coating **116** has a coefficient of friction that is lower than the coefficient of friction of the surface of the base material of the body **108** alone. Thus, the coating **116** forms a lubricious layer over at least a portion of the body **108**. The blade **112** comprising the lubricious coating **116** provides several benefits and/or advantages over conventional uncoated bare end-effector blades. For example, the coated blade **112** provides improved tissue cutting (e.g., transecting) along the longitudinal length of the blade **112** resulting in more uniform transection of tissue, improved vessel sealing and homogeneity of the tissue layer, and improved thermal and structural properties of the blade **112**, which facilitates more uniform transection of the tissue. The coated blade **112** may further facilitate uniform serosa-to-serosa adhesion along the cut length of the tissue, thus minimizing or eliminating discontinuities of adhesion along the tissue cut length, which commonly occur with conventional uncoated blades. The lubricious property of the coating **116** also minimizes the adhesion of surgical matter to the surface of the blade **112** during surgical procedures. As previously discussed, "surgical matter" includes coagulants, proteins, blood, tissue, and/or other constituent fluids, which may be present during a surgical procedure and tend to desiccate and adhere to the surface of uncoated blades raising the interface impedance of the blade. As previously discussed, to compensate for the increased impedance, the ultrasonic generator supplies increasing amounts of power to the blade to continue transecting tissue until the power delivered by the generator exceeds a predetermined threshold at which time the generator shuts down or goes into "lockout." As previously discussed, lockout is a condition where the impedance of the end-effector is so high that the generator is unable to provide meaningful amounts of the power to the tissue. Therefore, by minimizing the deposition, buildup, or adhesion of surgical matter, the coated blade **112** reduces the electrical power required to operate the blade **112** when transecting tissue. As a result, the coated blade **112** minimizes the power supplied by the generator and minimizes or prevents lockouts of the generator.

Those skilled in the art will appreciate that ultrasonic end-effector blades are relatively efficient and that the electrical power required for driving the end-effector blade correlates well with the power delivered to tissue loads. Essentially, the lubricious coating **116** reduces the friction between the blade **112** and the tissue, thus reducing the thermal profile of the blade **112**. Because the tissue does not adhere to the coating **116**, it releases from the blade **112** more easily and uniformly than an uncoated blade requiring less average power draw (less total energy applied) and less time (even less total energy applied) than an uncoated blade giving a truly unexpected and synergistic effect. In certain instances, the time required to transect tissue, for example, may be reduced by as much as 34%. Additionally, because the coated blade **112** reduces or minimizes the number of generator lockouts that may occur over a surgical procedure, the coated blade **112** even more substantially reduces the overall time required to complete the surgical procedure.

It is generally well known that tissue pads tend to degrade and wear over time due to frictional engagement with a blade when no tissue is present therebetween. The lubricious coating **116**, however, also lowers the coefficient of friction between the coated blade **112** and the tissue pad **106** and as a result can extend the life of the tissue pad **106**. Accordingly, the coated blade **112** can reduce or minimize the degradation and deterioration of the tissue pad **106** caused by abrasion and frictional engagement with the blade **112**. Consequently, the coated blade **112** can substantially extend the operational life of the tissue pad **106** when compared to conventional uncoated blades.

FIG. **3** illustrates one embodiment of a multi-element end-effector **200**. In the illustrated embodiment, the multi-element end-effector **200** comprises a clamp arm assembly **202**, shown in an open position, operatively coupled to an ultrasonic surgical blade **212** (blade). The multiple-element end-effector **200** may be employed in clamping coagulating type ultrasonic instruments, for example. The clamp arm assembly **202** comprises a clamp arm **104** and a tissue pad **106** attached thereto. The blade **212** is an ultrasound-propagating element suitable for use in ultrasonic surgical instruments. The body **108**, previously discussed with reference to FIGS. **1** and **2**, forms a portion of the blade **212**. As previously discussed, the body **108** comprises a proximal end and a distal end and defines an elongated treatment region therebetween. The proximal end is adapted and configured to couple to an ultrasonic transducer either directly or through an ultrasonic transmission waveguide. The distal end and the treatment region is used to effect tissue (e.g., dissect, transect, cut, coagulate). In one embodiment, a coating **216** is formed on at least a portion of the outer surface of the body **108** that at least corresponds with the elongated treatment region. The coating **216** may comprise at least two layers **210**, **214** of materials. In the illustrated embodiment, a primer layer **214** (e.g., base layer, first layer) may be formed on the outer surface of the body **108**. An overcoat layer **210** (e.g., top layer, second layer) may be formed over the primer layer **214**. In one embodiment, the overcoat layer **210** may be formed over a portion of the primer layer **214**. The primer layer **214** forms a suitable adhesive bond with the outer surface of the body **108** and is formulated to enhance the adhesion of the overcoat layer **210** to the body **108**. The primer layer **214** and/or the overcoat layer **210** each may comprise multiple layers of materials. The layers **210**, **214** may be formed on the body **108** using any suitable material application technique including techniques discussed herein with respect to FIGS. **1** and **2** (e.g., the coating application process developed by ISSC).

FIG. **4** illustrates a cross-sectional view of the ultrasonic surgical blade **212** portion of the multi-element end-effector **200** taken along line **4-4** in FIG. **3**. As shown in the cross-sectional view of FIG. **4**, in the illustrated embodiment, the coating **216** comprises multiple layers **214**, **210** of materials. The primer layer **214** is the first layer applied to the body **108**. In various embodiments, the primer layer **214** may comprise a polymer or polymeric materials and/or ceramic. In various embodiments, the primer layer **214** may comprise FEP or liquid FEP. In one embodiment, the primer layer **214** may comprise aluminum oxide or any suitable material composition containing aluminum oxide. In another embodiment the primer layer **214** may comprise titanium nitride or any suitable material composition containing titanium nitride. The overcoat layer **210** is then applied over the primer layer **214** material to form the top layer of the coating **216**, which has lubricious properties similar to the coating **116** previously discussed with reference to FIGS. **1** and **2**. The overcoat layer **210** may be applied to a portion of the primer layer **214** or may be applied over the entire primer layer **214**. The overcoat layer **210** may comprise a variety of materials including polymeric and polymer containing materials. As previously discussed, the term "polymeric materials" and the word polymer, as used herein, include, but are not limited to, homopolymers, copolymers, terpolymers, and the like. As previously discussed, non-limiting examples of polymeric and polymer-containing materials include FEP, liquid FEP, FEP/ceramic composites, liquid FEP ceramic epoxy composites, PTFE, and PTFE/ceramic composites. In other non-limiting embodiments, the overcoat layer **210** may comprise a dry film lubricant, such as, but not limited to, tungsten disulfide, molybdenum disulfide, graphite, and fluorinated polymers. Still in other non-limiting embodiments, the overcoat layer **210** may comprise ceramics, such as, but not limited to, metal oxydes, metal nitrides, and metal carbides. Examples of ceramics, include, but are not limited to, chromium carbide, tungsten carbide, titanium nitride, alumina, and chromium nitride. Yet in other non-limiting embodiments, the overcoat layer **210** may comprise metals. Metals include, but are not limited to, aluminum, stainless steel, and molybdenum. In other non-limiting embodiments, the overcoat layer **210** may comprise a metallized ceramic, such as, but not limited to, stainless steel embedded in ceramic. In one embodiment, the overcoat layer **210** may be applied using conventional powder coating techniques.

FIG. **4**A is an enlarged view of the cross-sectional portion of one embodiment of the blade **216** shown in FIG. **4**. As shown in FIG. **4**A, in one embodiment, the surface of the body **108** may be prepared with a suitable surface treatment **108**A prior to the application of the primer layer **214** to further enhance or promote the adhesion of the primer layer **214** material to the outer surface of the body **108**. In another embodiment, a surface treatment may be applied to the surface of the primer layer **214** prior to the application of the overcoat layer **210** to enhance the adhesion of the overcoat layer **210** to the primer layer **214**. The surface treatment **108**A may be applied the surface of the body **108** using any of the techniques previously described with reference to FIGS. **1** and **2** (e.g., peening, micro blasting, sand blasting, bead blasting, knurling, engraving, chemical treatment such as acid or base etching, laser etching, plasma etching, corona discharge etching, heat etching, carving, scoring, and other techniques) to produce a predetermined surface roughness

R_A of about 16 microinches (μ in) to about 256 μ in. In one embodiment, a surface treatment may be applied to an outer surface of the body **108** to produce a predetermined surface roughness R_A of about 16 μ in to about 63 μ in, for example. However, other surface roughnesses also may be produced. After coating the body **108** with the primer layer **214**, the preferred surface roughness R_A range of the finished product is about 16 μ in to about 32 μ in.

FIG. **4**B is an enlarged view of the cross-sectional portion of one embodiment of the blade **216** shown in FIG. **4**. As shown in FIG. **4**B, in one embodiment, a primer layer **218** may be formed directly on the outer surface of the body **108**. In one embodiment, the primer layer **218** has a surface **220** having a predetermined surface roughness that enhances or promotes adhesion of the topcoat layer **210** to the primer layer **218**. In one embodiment, the surface **220** may be achieved using a rough titanium nitride coating as the primer layer **218**. The rough surface **220** of the primer layer **218** provides a good bonding surface for a topcoat layer **210** having a low coefficient of friction. The primer layer **218** comprising titanium nitride provides a good bond to the outer surface of the body **108** without the need for a surface treatment. In another embodiment, the surface **220** may be achieved using a rough aluminum oxide coating as the primer layer **218** to provide a good bonding surface for a topcoat layer **210** having a low coefficient of friction. The aluminum oxide coating also may provide a good bond to the outer surface of the body **108** without the need for a surface treatment.

FIG. **4**C is an enlarged view of the cross-sectional portion of one embodiment of the blade **216** shown in FIG. **4**. As shown in FIG. **4**C, in one embodiment, a primer layer **222** may be formed directly on the outer surface of the body **108**. In one embodiment, the primer layer **222** has a surface that enhances or promotes adhesion of the topcoat layer **210** to the primer layer **222**.

In various embodiments, any of the primer layers **214**, **218**, **222** may comprise aluminum oxide, titanium nitride, FEP, or liquid FEP, which passivates the surface of the body **108** for better adhesion of the overcoat layer **210**. In various embodiments, any of the primer layers **214**, **218**, **222** may consist essentially of aluminum oxide, titanium nitride, FEP or liquid FEP. In other embodiments, any of the primer layers **214**, **218**, **222** may comprise any of the base materials previously discussed with reference to FIGS. **2-4**.

FIG. **5** illustrates one embodiment of a multi-element end-effector **300**. In the illustrated embodiment, the multi-element end-effector **300** comprises a clamp arm assembly **302**, shown in an open position, operatively coupled to an ultrasonic surgical blade **312** (blade). The multiple-element end-effector **300** may be employed in clamping coagulating type ultrasonic instruments, for example. The clamp arm assembly **302** comprises a clamp arm **104** and a tissue pad **106** attached thereto. The blade **312** is an ultrasound-propagating element suitable for use in ultrasonic surgical instruments. The body **108**, previously discussed with reference to FIGS. **1-4**, forms a portion of the blade **312**. As previously discussed, the body **108** comprises a proximal end and a distal end and defines an elongated treatment region therebetween. The proximal end is adapted and configured to couple to an ultrasonic transducer either directly or through an ultrasonic transmission waveguide. The distal end and the elongated treatment region is used to effect tissue (e.g., dissect, transect, cut, coagulate). A surface treatment **310** may be applied to an outer surface of the body **108** that at least corresponds with the elongated treatment region. Those skilled in the art will appreciate, that the surface treatment **310** having a particular surface roughness R_A may be produced using the well known techniques previously described with reference to FIG. **2**, for example, provided that the underlying structure of the body **108** is not compromised.

FIG. **6** illustrates a cross-sectional view of the ultrasonic blade **312** portion of the multi-element end-effector **300** taken along line **6-6** in FIG. **5**. With reference to FIGS. **5** and **6**, in one embodiment, the surface treatment **310** (e.g., roughness) may be formed or applied to the outer surface of the body **108** or may be formed on the outer surface of a coating layer applied to the body **108** as described later herein with reference to FIGS. **7** and **8**. A suitable surface treatment **310** has a coefficient of friction that is greater than the coefficient of friction of the untreated outer surface area of the body **108**. A rough "frictional" surface treatment **310** has a predetermined surface roughness R_A of about 16 μ in to about 256 μ in. In one embodiment, the rough "frictional" surface treatment **310** has a predetermined surface roughness R_A of about 32 μ in. The surface treatment **310** may be formed on the outer surface of the body **108** to assist the blade **312** to frictionally engage (grip) and stabilize the walls of blood vessels and as a result provide improved and more reliable vessel sealing. Because of the rougher surface treatment **310**, the blade **312** remains engaged with the tissue long enough to prevent the vessel walls from pulling away from the seal line. Consequently, this promotes the communication of tissue collagen from one side of the seal line to the other to create a very reliable seal, as will be appreciated by those skilled in the art.

FIG. **7** illustrates one embodiment of a multi-element end-effector **400**. In the illustrated embodiment, the multi-element end-effector **400** comprises a clamp arm assembly **402**, shown in an open position, operatively coupled to an ultrasonic surgical blade **412** (blade). The multiple-element end-effector **400** may be employed in a clamping coagulating ultrasonic instrument, for example. The clamp arm assembly **402** comprises a clamp arm **104** and a tissue pad **106** attached thereto. The blade **412** is an ultrasound-propagating element suitable for use in ultrasonic surgical instruments. The body **108**, as previously discussed with reference to FIGS. **1-6**, forms a portion of the blade **412**. As previously discussed, the body **108** comprises a proximal end and a distal end and defines an elongated treatment region therebetween. The proximal end is adapted and configured to couple to an ultrasonic transducer either directly or through an ultrasonic transmission waveguide. The distal end and the treatment region are used to effect tissue (e.g., dissect, transect, cut, coagulate). In one embodiment, a coating **416** comprising a first layer **410** of material may be formed on an outer surface of the body **108** using any of the material application techniques previously described (e.g., the coating application process developed by ISSC). The first layer **410** may comprise any of the polymeric materials, dry film lubricants, ceramics, metals, and metallized ceramics previously described with reference to FIG. **2**.

FIG. **8** illustrates a cross-sectional view of the ultrasonic blade **412** portion of the multi-element end-effector **400** taken along line **8-8** in FIG. **7**. A surface treatment **414** having a predetermined roughness R_A of about 16 μ in to about 256 μ in may be produced over the layer **410** using any of the techniques previously discussed with reference to FIG. **2**. The body **108** defines a longitudinal axis A extending between the proximal end and the distal end. The distal end of the body **108** is movable relative to the longitudinal axis A by the vibrations produced by the transducer propagating along the longitudinal axis A. With reference to FIGS. **7** and **8**, in one embodiment, the surface treatment **414** having a predetermined surface roughness R_A of about 16 μ in to about 256 μ in may be formed over the first layer **410**, or portions thereof. However, other suitable values surface roughness R_A may be successfully produced. For example, a surface treatment of a predetermined surface roughness R_A having a coefficient of friction that is greater than the coefficient of friction of the first layer **410** may be produced over the first layer **410** to assist the blade **412** in gripping and stabilizing the walls of blood vessels and producing better, more reliable, vessel seals. The surface treatment **414**, having a coefficient of friction slightly greater than the first layer **410**, enables the blade **412** to remain engaged with the tissue long enough to prevent the joined vessels walls from pulling away or shrinking away from the seal line prior to completing the sealing operation. It will be appreciated, that the surface treatment **414** may be formed over a portion of the body **108** in order to take advantage of the lubricious properties of the coating **410** for cutting operations while also taking advantage of the rougher surface treatment **414** portion for sealing operations.

FIG. **9** illustrates one embodiment of a multi-element end-effector **500**. In the illustrated embodiment, the multi-element end-effector **500** comprises a clamp arm assembly **502**, shown in an open position, operatively coupled to an ultrasonic surgical blade **512** (blade). The multiple-element end-effector **500** may be employed in clamping coagulating type ultrasonic instruments, for example. The clamp arm assembly **502** comprises a clamp arm **104** and a tissue pad **106** attached thereto. The blade **512** is an ultrasound-propagating element suitable for use in ultrasonic surgical instruments. The body **108**, as previously discussed with reference to FIGS. **1-8** forms a portion of the blade **512**. As previously discussed, the body **108** comprises a proximal end and a distal end and defines an elongated treatment region therebetween. The proximal end is adapted and configured to couple to an ultrasonic transducer either directly or through an ultrasonic transmission waveguide. The distal end and the treatment region are used to effect tissue (e.g., dissect, transect, cut, coagulate).

FIG. **10** illustrates a cross-sectional view of the ultrasonic blade **512** portion of the multi-element end-effector **500** taken along line **10-10** in FIG. **9**. A coating **516** comprising a layer **510** of material may be formed on at least a portion of an outer surface of the blade body **108**. One or more than one layer **510** of material may be formed on the body **108** using any suitable application technique discussed herein (e.g., the coating application process developed by ISSC).

With reference to FIGS. **9** and **10**, in one embodiment, the one or more than one layer **510** of material may be formed on the blade **512** non-uniformly such that the layer **510** has variable thickness about the outer surface of the body **108**. In the illustrated embodiment, the layer **510** is formed thicker to assist thermal bonding. In one embodiment, a thinner layer **510***a* may be formed on a top surface portion of the body **108** where the blade **516** comes in contact with the tissue pad **106** and thicker layers **510***b* of the material may be formed on lateral surface portions of the body **108**. A layer **510***c* of any suitable thickness may be formed on the bottom surface portion of the body **108** opposite of the top surface portion. In the illustrated embodiment, the layer **510***c* on the bottom surface portion of the body **108** is formed with the same thickness as the thinner layer **510***a*. In other embodiments, the layer **510***c* at the bottom surface portion of the body **108** may be formed with the same thickness as the thicker layers **510***b*, thicker than the layers **510***b*, or other suitable thicknesses. In other embodiments, multiple layers may be formed of varying thicknesses on the lateral portions of the body **108** to prevent excessive thermal damage to these areas of the seal. The one or more than one layer **510** of material may comprise any of the polymeric materials, dry film lubricants, ceramics, metals, and metallized ceramics previously discussed with reference to FIG. **2**. In other embodiments, a primer layer and/or a surface treatment may be applied to the outer surface of the body **108** prior to the application of the one or more than one layer **510** of material. To the extent that one embodiment of the blade **512** comprises a primer layer, the primer layer may comprise any of the base materials previously discussed with reference to FIGS. **2** and **4**. To the extent that one embodiment of the blade **512** comprises a surface treatment, the surface treatment may be applied in accordance with the techniques previously discussed with reference to FIGS. **2** and **4**A.

FIG. **11** illustrates one embodiment of a multi-element end-effector **700**. In the illustrated embodiment, the multi-element end-effector **700** comprises a clamp arm assembly **702**, shown in an open position, operatively coupled to an ultrasonic surgical blade **712** (blade). The multiple-element end-effector **700** may be employed in clamping coagulating type ultrasonic instruments, for example. The clamp arm assembly **702** comprises a clamp arm **104** and a tissue pad **106** attached thereto. The blade **712** is an ultrasound-propagating element suitable for use in ultrasonic surgical instruments. The body **108**, as previously discussed with reference to FIGS. **1-10**, forms a portion of the blade **712**. As previously discussed, the body **108** comprises a proximal end and a distal end defining an elongated treatment region. The proximal end is adapted and configured to couple to an ultrasonic transducer either directly or through an ultrasonic transmission waveguide. The distal end and the treatment region are used to effect tissue (e.g., dissect, transect, cut, coagulate).

FIG. **12** illustrates a cross-sectional view of the ultrasonic blade **712** portion of the multi-element end-effector **700** taken along line **12-12** in FIG. **11**. In various embodiments, a coating **716** may be formed on the outer surface of the blade body **108**. The coating **716** may comprise one or more layers of materials, surface treatments, and/or combinations thereof. In the illustrated embodiment, a first layer **710** and a second layer **714** are formed on the outer surface of the body **108**. In one embodiment, the second layer **714** may be formed over a portion of the first layer **710**. The one or more material layers **710**, **714** may be formed on the body **108** using any suitable material application technique including techniques discussed herein (e.g., the coating application process developed by ISSC). As shown in FIG. **12**, the blade **712** may comprise multiple layers of materials, each of varying thicknesses. The first layer **710** may be formed thicker on the lateral surface portions of the body **108** and may be formed thinner on the top surface portions of the body **108**, for example, where the blade **712** contacts the tissue pad **106**. A second layer **714** may be formed on the first layer **710**. The second layer **714** may be formed thicker on the top surface portion of the body **108** where the blade **712** contacts the tissue pad **106** is relatively thinner on the lateral surface portions of the body **108**. In one material application technique, the first layer **710** is applied to the body **108** and the second layer **714** is subsequently applied over on the first layer **710** or, as shown in FIG. **12**, over portions of the first layer **710**. The first and second layers **710**, **714** may comprise any of the polymeric materials, dry film lubricants, ceramics, metals, and metallized ceramics previously discussed with reference to FIGS. **2** and **4**. In other embodiments, a primer layer and/or a surface treatment may be applied to the outer surface of the body **108** prior to the application of the first and second layers **710**, **714**. To the extent that one embodiment of the blade **712** comprises a primer layer, the primer layer may comprise any of the base materials discussed with reference to FIGS. **2** and **4**. To the extent that one embodiment of the blade **712** comprises a surface treatment, the surface treatment may be applied in accordance with the techniques previously discussed with reference to FIGS. **2** and **4A**.

FIG. **13** illustrates one embodiment of a single element end-effector **800**. In one embodiment, the single element end-effector **800** comprises the ultrasonic surgical blade **112** (blade), shown and described with reference to FIGS. **1** and **2**. The single-element end-effector **800** may be a scalpel, hook, or ball coagulator, for example. As previously discussed, the coating **116** may be formed on at least a portion of an outer surface of the body **108**. The coating **116** also may comprise one or more layers **110** formed on the outer surface of the body **108**.

FIG. **14** illustrates a cross-sectional view of the ultrasonic blade **112** portion of the single element end-effector **800** taken along line **14-14** in FIG. **13**. As shown in the cross-sectional view of FIG. **14**, in the illustrated embodiment, the blade **112** and the body **108** may have a substantially circular cross sectional shape. In other embodiments, the shape of the blade **112** may be selected according to the type of end-effector used, such as any of the shapes described with reference to FIG. **2**.

FIG. **15** illustrates one embodiment of a multi-element end-effector **900**. In the illustrated embodiment, the multi-element end-effector **900** comprises a clamp arm assembly **902**, shown in an open position, operatively coupled to an ultrasonic surgical blade **912** (blade). The multiple-element end-effector **900** may be employed in clamping coagulating type ultrasonic instruments, for example. The clamp arm assembly **902** comprises a clamp arm **104** and a tissue pad **106** attached thereto. The blade **912** is an ultrasound-propagating element suitable for use in ultrasonic surgical instruments. The body **108**, as previously discussed with reference to FIGS. **1-14**, forms a portion of the blade **912**. As previously discussed, the body **108** comprises a proximal end and a distal end defining an elongated treatment region. The proximal end is adapted and configured to couple to an ultrasonic transducer either directly or through an ultrasonic transmission waveguide. The distal end and the treatment region are used to effect tissue (e.g., dissect, transect, cut, coagulate). A coating **916** may be formed on at least a portion of an outer surface of the body **108**. The coating **916** also may comprise one or more layers **910**, **914** formed on the outer surface of the body **108**.

FIG. **16** illustrates a cross-sectional view of the ultrasonic blade **912** portion of the multi-element end-effector **900** taken along line **16-16** in FIG. **15**. In various embodiments, the coating **916** may be formed on a portion of the outer surface of the blade body **108**. In one embodiment, the coating **916** may comprise a first layer **910** (e.g., primer layer, first layer) and a second layer **914** (e.g., topcoat layer, second layer). In one embodiment, the second layer **914** may be formed over a portion of the first layer **910**. The first and second layers **910**, **914** may comprise any of the polymeric materials, dry film lubricants, ceramics, metals, and metallized ceramics previously discussed with reference to FIGS. **2** and **4**. In other embodiments, a surface treatment may be applied to the outer surface of the body **108** prior to the application of the first and second layers **910**, **914**. To the extent that one embodiment of the blade **912** comprises a surface treatment, the surface treatment may be applied in accordance with the techniques previously discussed with reference to FIGS. **2** and **4A**.

FIG. **17** illustrates one embodiment of a multi-element end-effector **1000**. In the illustrated embodiment, the multi-element end-effector **1000** comprises a clamp arm assembly **1002**, shown in an open position, operatively coupled to an ultrasonic surgical blade **1012** (blade). The multiple-element end-effector **1000** may be employed in clamping coagulating type ultrasonic instruments, for example. The clamp arm assembly **1002** comprises a clamp arm **104** and a tissue pad **106** attached thereto. The blade **1012** is an ultrasound-propagating element suitable for use in ultrasonic surgical instruments. The body **108**, as previously discussed with reference to FIGS. **1-16**, forms a portion of the blade **1012**. As previously discussed, the body **108** comprises a proximal end and a distal end defining an elongated treatment region. The proximal end is adapted and configured to couple to an ultrasonic transducer either directly or through an ultrasonic transmission waveguide. The distal end and the treatment region are used to effect tissue (e.g., dissect, transect, cut, coagulate). A coating **1016** may be formed on at least a portion of an outer surface of the body **108**. The coating **1016** also may comprise one or more layers **1010**, **1014** formed on the outer surface of the body **108**.

FIG. **18** illustrates a cross-sectional view of the ultrasonic blade **1012** portion of the multi-element end-effector **1000** taken along line **18-18** in FIG. **17**. In various embodiments, a coating **1016** may be formed on a distal end of the outer surface of the blade body **108**. The coating **1016** may comprise a first layer **1010** (e.g., a primer layer, first layer) and a second layer **1014** (e.g., a topcoat layer, second layer) of material, surface treatment, and/or combination thereof. The first and second layers **1010**, **1014** may comprise any of the polymeric materials, dry film lubricants, ceramics, metals, and metallized ceramics previously discussed with reference to FIGS. **2** and **4**. In other embodiments, a surface treatment may be applied to the outer surface of the body **108** prior to the application of the first and second layers **1010**, **1014**. To the extent that one embodiment of the blade **1012** comprises a surface treatment, the surface treatment may be applied in accordance with the techniques previously discussed with reference to FIGS. **2** and **4A**.

With reference now to FIGS. **1-18**, in various embodiments, the blade **112** (**212**, **312**, **412**, **512**, **612**, **712**, **912**, **1012**) in addition to the shown circular cross sectional shape may have various cross sectional forms or shapes, which may be symmetrical or asymmetrical in nature. For example, the blade may comprise a square, rectangular, triangular, or other polygonal cross-sectional shapes. As previously discussed, in various embodiments, the body **108** also may comprise a variety of symmetrical or asymmetrical shapes. For example, the body **108** may be curved in one or more directions. More details regarding curved or asymmetric blades are described in U.S. Pat. No. 6,283,981, which is incorporated herein by reference.

In still other embodiments, the body **108** may be configured with a neck or transition portion that protrudes from the proximal end of the treatment region. The neck portion may be configured to attach to an ultrasonic transmission waveguide by a stud, weld, glue, quick connect, or other suitable attachment methods, for example. In various other embodiments, the body **108** and the ultrasonic transmission waveguide may be formed as a single unitary body. In either configuration, the ultrasonic transmission waveguide may have gain steps to amplify the mechanical vibrations transmitted to the body **108** as is well known in the art.

With reference to FIGS. **1-18**, in one embodiment, any of the end-effectors described herein (e.g., blades **112**, **212**, **312**, **412**, **512**, **612**, **712**, **912**, **1012**) may comprise coatings formed of soft or deflectable layers of material to establish frictional engagement (e.g., gripping) with the tissue for improved tissue sealing. Examples of deflectable materials include materials having a durometer hardness of Shore D from about 25 to about 70 Shore units. In other embodiments, the end-effector may include coatings formed of layers of material combined with other technologies such as augmentation via clips and other fasteners. In other embodiments, the end-effector may include a lumen formed through the longitudinal axis A to facilitate suction and removal of expressed fluids from the sealing site to prevent excessive thermal damage to a non-value-added portion of the seal. In other embodiments, the end-effector may include a coating formed of one or more layers of materials that are suitable for use on difficult/hard tissues such as cartilage and bone. In other embodiments, the end-effector may include a surface treatment that has a roughness R_A that is suitable for use on difficult/hard tissues such as cartilage and bone.

The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present disclosure.

Any of the end-effectors described herein (e.g., blades **112**, **212**, **312**, **412**, **512**, **612**, **712**, **912**, **1012**) may be reconditioned for reuse after at least one use. In one embodiment, reconditioning can include obtaining an ultrasonic surgical blade and applying at least one layer of a first material on at least a portion of the body **108** to form a lubricious coating on the outer surface of the body **108**. The lubricious coating may be applied in accordance with any suitable material application techniques, including material application techniques described herein. Then, sterilizing the ultrasonic surgical blade and storing the ultrasonic surgical blade in a sterile container. In another embodiment, reconditioning can include obtaining an ultrasonic surgical blade and forming at least one surface treatment on at least a portion of the body **108** to produce a frictional coating on the outer surface of the body **108**. The surface treatment may be applied in accordance with any suitable surface treatment techniques, including the surface treatment techniques described herein. Then, sterilizing the ultrasonic surgical blade and storing the ultrasonic surgical blade in a sterile container.

Preferably, the various embodiments described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK® bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

It is preferred that the device is sterilized. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam. Accordingly, in one embodiment, an ultrasonic surgical blade comprising a body having a proximal end, a distal end, and an outer surface, the distal end is movable relative to a longitudinal axis in accordance with ultrasonic vibrations applied to the proximal end, and a lubricious coating being formed on at least a portion of the outer surface of the body, is obtained. The ultrasonic surgical blade is then sterilized and stored in a sterile container. In another embodiment, an ultrasonic surgical blade comprising a body having a proximal end, a distal end, and an outer surface, the distal end is movable relative to a longitudinal axis by ultrasonic vibrations applied to the proximal end and a predetermined surface treatment having a predetermined surface roughness being formed on at least a portion of the body, is obtained. The ultrasonic surgical blade is then sterilized and stored in a sterile container.

Although various embodiments have been described herein, many modifications and variations to those embodiments may be implemented. For example, different types of end-effectors may be employed. In addition, combinations of the described embodiments may be used. For example, blade coatings may be formed of any combination of layer materials and surface treatments described herein. Also, where materials are disclosed for certain components, other materials may be used. The foregoing description and following claims are intended to cover all such modification and variations.

Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

What is claimed is:

1. An apparatus, comprising:

an ultrasonic surgical blade for at least one of cutting and coagulating tissue, wherein the ultrasonic surgical blade comprises:

a body having a proximal end, a distal end, and an outer surface comprising a treatment region configured to directly contact the tissue to be treated, wherein the distal end is movable relative to a longitudinal axis in accordance with ultrasonic vibrations applied to the proximal end; and

a lubricious coating for contacting tissue, wherein the lubricious coating comprises a coefficient of friction that is less than the coefficient of friction of the outer surface of the body, wherein the lubricious coating is adhered to at least a portion of the treatment region of the outer surface of the body, and wherein the lubricious coating comprises a polymeric material.

2. The apparatus of claim **1**, wherein the polymeric material is selected from the group consisting of tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) copolymers (FEP), liquid FEP, FEP/ceramic composites, liquid FEP ceramic epoxy composites, polytetrafluoroethylene (PTFE), and PTFE/ceramic composites.

3. The apparatus of claim **1**, wherein the lubricious coating comprises a dry film lubricant.

4. The apparatus of claim **3**, wherein the dry film lubricant is selected from the group consisting of tungsten disulfide, molybdenum disulfide, graphite, and fluorinated polymers.

5. The apparatus of claim **1**, comprising a surface treatment formed on the at least a portion of the treatment region of the outer surface of the body to enhance adhesion of a material to the at least a portion of the treatment region of the outer surface of the body.

6. The apparatus of claim **1**, wherein the lubricious coating has a thickness of about 0.0001 to about 0.010 inches.

7. The apparatus of claim **1**, wherein the longitudinal axis extends between the proximal end and the distal end of the body, and wherein the longitudinal axis defines at least one curve.

8. An apparatus, comprising:

an ultrasonic surgical blade for at least one of cutting and coagulating tissue, wherein the ultrasonic surgical blade comprises:

a curved body having a proximal end, a distal end, an outer surface, and a longitudinal axis defined between the proximal end and the distal end of the curved body, wherein the longitudinal axis defines at least one curve, and wherein the distal end is movable relative to the longitudinal axis in accordance with ultrasonic vibrations applied to the proximal end, and wherein the outer surface comprises a treatment region configured to directly contact the tissue to be treated; and

a lubricious coating having a coefficient of friction that is less than the coefficient of friction of the outer surface of the curved body, wherein the lubricious coating is adhered to at least a portion of the treatment region of the outer surface of the curved body, and wherein the lubricious coating comprises a polymeric material.

9. The apparatus of claim **8**, wherein the polymeric material is selected from the group consisting of tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) copolymers (FEP), liquid FEP, FEP/ceramic composites, liquid FEP ceramic epoxy composites, polytetrafluoroethylene (PTFE), and PTFE/ceramic composites.

10. The apparatus of claim **8**, wherein the lubricious coating comprises a dry film lubricant.

11. The apparatus of claim **1**, wherein the lubricious coating has a thickness of about 0.0001 to about 0.010 inches.

12. An apparatus, comprising:

an ultrasonic blade structured to coagulate and cut tissue, the ultrasonic blade comprising:

a proximal end;

a distal end movable relative to a longitudinal axis in accordance with ultrasonic vibrations applied to the proximal end;

an outer surface comprising a tissue treatment region configured to directly contact the tissue to be treated;

a surface treatment applied to at least a portion of the tissue treatment region; and

a lubricious coating applied over at least a portion of the surface treatment, wherein the lubricious coating comprises a coefficient of friction that is less than the coefficient of friction of the outer surface, wherein the surface treatment is configured to enhance adhesion of the lubricious coating to the outer surface, and wherein the lubricious coating comprises a polymeric material.

13. The apparatus of claim **12**, wherein the polymeric material is selected from the group consisting of tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) copolymers (FEP), liquid FEP, FEP/ceramic composites, liquid FEP ceramic epoxy composites, polytetrafluoroethylene (PTFE), and PTFE/ceramic composites.

14. The apparatus of claim **12**, wherein the lubricious coating comprises a dry film lubricant.

15. The apparatus of claim **14**, wherein the dry film lubricant is selected from the group consisting of tungsten disulfide, molybdenum disulfide, graphite, and fluorinated polymers.

16. The apparatus of claim **12**, wherein the lubricious coating has a thickness of about 0.0001 to about 0.010 inches.

17. The apparatus of claim **12**, wherein the ultrasonic blade comprises a curved body.

* * * * *

patsnap

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摘要(译)

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