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(54) Title: ROTATING THERAPY DEVICE

(57) Abstract: The invention provides a therapy device that includes an insertion instrument with a therapy structure coupled to the distal end that permits rotation of the therapy structure about the insertion device. There is also provided a method for using the therapy device that includes advancing the insertion instrument into an alimentary tract, rotating the therapy structure about the insertion instrument and delivering therapy to the tissue adjacent to the therapy device. In another aspect, the therapy structure is an ablation device and the insertion instrument is an endoscope. The ablation structure may be moved around the longitudinal axis of the endoscope to face a target tissue, and then deliver a dose of ablation energy to the target tissue.
ROTATING THERAPY DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

[001] This application claims the benefit of priority of United States Provisional Patent Application Serial Number 61/167,041 filed April 6, 2009, entitled "Ablational Device with Ability to Rotate Around the Longitudinal Axis of an Endoscope," the entirety of which is incorporated herein by reference.

FIELD OF THE INVENTION

[002] The present invention devices and methods for ablating target tissues within a luminal organ; more particularly, precision ablating of focal sites within a luminal organ, such as the colon or the stomach.

BACKGROUND OF THE INVENTION

[003] Treatment of tissues in a luminal organ such as the stomach may be approached through the use of treatment devices placed using an insertion instrument. However, given the limits of a non-invasive or minimally invasive therapy approach, the therapy element on such a treatment device is often small compared to the total surface area of the organ or tissue to be treated. This is an effective and appropriate approach to therapy when particular focal areas are the treatment target. An example of such a target is provided by the vascular lesions in the stomach that occur in cases of gastric antral vascular ectasia (GAVE). Therapy devices are typically supported on the distal end of an endoscope through which a physician can visualize the targeted treatment site, and provide therapy.

[004] However, the ability to place the therapy element with precision against the target area is a technical challenge even though an endoscope, itself, provides a considerable level of control in terms of its ability to be directed to a target site. In some treatment procedures, precise control of rotational manipulation is particularly desirable. However, relying only on rotational movement of the endoscope can be problematic for the patient. As such, therapy devices and methods that improve the ease with which a treatment element may be rotated or manipulated in a particular therapeutic situation is desirable.
SUMMARY OF THE INVENTION

[005] In one aspect, there is provided a therapy device having an insertion instrument; a guide on the exterior of the insertion instrument; a therapy structure coupled to the guide, the therapy structure comprising a connector and an therapy element; an elongate element that extends along the insertion instrument and is connected to the therapy structure, the elongate element having a curved portion proximal to the connection between the therapy structure and the elongate element; and a handle connected to the elongate element, wherein rotation of the handle moves the therapy structure along the guide.

[006] In one alternative aspect, the insertion instrument is any one of: a catheter, a cannula, an endoscope or a colonscope.

[007] In other alternative aspects, the guide extends partially around the circumference of the insertion instrument or completely around the circumference of the insertion instrument. In one embodiment, the elongate element is connected to the therapy structure using the connector. The connector couples the therapy structure to the guide. The elongate element is connected to the ablation structure at the connector. The connector comprises a shaped end. The shaped end is a knob or a rail. In one aspect, the shaped end has a length and curvature configured to conform to a partial circumference or a complete circumference of the insertion instrument. The connector has an exterior surface that complements a shape of the guide. In one alternative, when the exterior surface is engaged with the guide, the connector exterior surface is at least partially within the guide. In another alternative, when the connector is engaged with the guide, the therapy structure is spaced apart from the insertion instrument.

[008] In another alternative aspect, the therapy structure further comprising an expansion structure.

[009] In another alternative aspect, the guide also includes a recessed portion. In one version, the recessed portion is shaped to accept a portion of the connector and in another the guide is formed in a wall of the insertion instrument. In an additional aspect, the elongate element connects to the therapy structure at more than one position. In one aspect, the elongate element connects to the therapy structure above a midline of the therapy structure, at or near the midline of the therapy structure or below the midline of the therapy structure. In another aspect, the connector is coupled to the insertion instrument the guide is positioned adjacent a portion of the therapy element above a midline of the therapy structure, at or near the midline of the therapy structure or below the midline of the therapy structure.
In another aspect, the guide is proximal to the distal end of the insertion instrument. In another aspect, the guide is at or near the distal end of the insertion instrument. In another aspect, the elongate instrument extends along the insertion instrument by passing though a working channel of the insertion instrument. In another aspect, there is also a housing shaped to fit onto or pass over the distal end the insertion instrument, wherein the guide is provided by the housing.

In still another aspect, there is also a treatment source that provides electromagnetic energy, photonic energy or cryogenic liquid or gas. In addition, the therapy element is configured to provide electromagnetic energy, photonic energy or cryogenic liquid or gas depending upon the type of treatment source. In addition, there may also be a radio frequency generator, wherein the therapy element is an electrode array connected to the radio frequency generator. In still other aspects, when the connector is engaged with the guide therapy structure is positioned to allow the therapy structure to pivot relative to the insertion instrument.

In an additional aspect, there is provided a method of providing therapy to tissue within a body, including coupling an therapy structure to an insertion instrument; advancing an elongate element along the insertion instrument to couple the distal end of the elongate element to the therapy structure; and rotating the elongate element to move the therapy structure relative to the insertion instrument. There may also be the added step of connecting the therapy structure to a treatment source at the proximal end of the insertion instrument. In addition, there may also be using the therapy structure to provide a treatment from the treatment source to a portion of tissue in proximity to the therapy structure. The treatment source provides one of: electromagnetic energy, photonic energy or cryogenic liquid or gas. In addition or alternatively, inserting the insertion instrument into the body until the therapy device is adjacent to a tissue selected for treatment. In addition or alternatively, there may also be the step of deflecting the therapy structure relative to the insertion instrument. In addition or alternatively, there may also be the step of expanding a structure associated with the therapy structure before, during or after providing the therapy using the therapy device. In addition of alternatively, there may also be the step of rotating the therapy structure relative to the insertion instrument before, during or after using the therapy structure to provide a treatment.

An aspect of the invention provides an endoscope with a rotatable operative element at the distal end of the endoscope, such rotation being independent of the rotation of the endoscope itself, as well as methods by which to operate such instrument. One embodiment of the invention provides an ablation device that includes an endoscope having a central longitudinal axis, a housing supported on a distal end of the endoscope, an ablational surface supported by the
housing, and a first coupling mechanism that couples the housing to the endoscope and is configured to allow rotational movement of the housing around the longitudinal axis of the endoscope. The first coupling mechanism is configured to be able to drive rotational movement of the housing around the longitudinal axis of the endoscope, and may include a rotational actuator at the proximal end of the endoscope, the actuator coupled to the first coupling mechanism. A physician operating the endoscope, for example, can drive rotation the ablational surface by way of the first coupling mechanism with manual operation of the actuator from the proximal end of the endoscope.

[0014] In some embodiments of the device, the first coupling mechanism includes a stylet rotatably disposed within a host channel of the endoscope and which projects distally from the channel; the stylet includes a distal angled portion that is configured to extend laterally beyond the diameter of the endoscope, and a distal end adapted to support the housing that supports the ablational surface. In some embodiments, the host channel is eccentrically disposed within the diameter of the endoscope such that the radial distance between the channel and the lateral surface of the endoscope varies around the circumference of the endoscope, and, accordingly, the angled portion of the stylet is sufficiently flexible that it can conform to that variable radial distance and maintain an inwardly-directed bias.

[0015] In some embodiments of the device, the first coupling mechanism is configured to allow complete rotational movement of the ablational surface around the endoscope; in other embodiments, the first coupling mechanism is configured to allow rotational movement through an arc of less than 360 degrees.

[0016] Some embodiments of the device include a second coupling mechanism that couples the housing to the endoscope and is configured to allow rotational movement of the housing around the longitudinal axis of the endoscope. In some of these embodiments, the second mechanism is configured to support the housing at a site on the housing proximal to a site of engagement for the first coupling mechanism.

[0017] Some embodiments of the device further include an open-front guide cap that fits over the distal end of the endoscope. These embodiments may include a second coupling mechanism that includes a first coupling feature disposed annularly around an external circumference of the endoscopic cap. In some of these embodiments, the second coupling mechanism further includes a second coupling feature disposed on a surface of the ablational surface housing, the first coupling feature and the second coupling feature being mutually complementary. In some of these embodiments, the surface on which the second coupling feature of the second coupling mechanism is disposed is the endoscope-facing surface of the housing, the ablational surface
supported by the housing being disposed on the housing surface that faces away from the endoscope.

[0018] In some embodiments of the device, the first coupling feature of the second coupling mechanism comprises a groove sized and configured to be complementary to the second coupling feature disposed on a surface of the ablation housing. In some embodiments, the second coupling feature of the second coupling mechanism includes a projecting feature complementary to the first coupling feature; such projecting feature may be a knob or a rail.

[0019] In some embodiments of the device, the open-front cap guide includes a compliant material, such as silicone. In some embodiments, the open-front cap guide includes an annular groove around an external surface, and wherein at least the groove portion of the open-front cap guide comprises a lubricious composition.

[0020] Some embodiments of the device further include a feature adapted to provide visual reference as to where the housing is positioned within its circumferential range. Such a feature may include, for example, an endoscopic camera with a sufficiently wide viewing angle that the distally-extending portion of the stylet is within the field of view.

[0021] Embodiments of the invention also provide a method of ablating a target tissue in an alimentary tract the makes use of a device as summarized above: Such method includes providing an endoscope having a central longitudinal axis, a housing having a longitudinal axis, an ablation structure supported by the housing, and a coupling mechanism that attaches the housing to the endoscope while allowing allow rotational movement of the housing around the longitudinal axis of the endoscope, advancing the endoscope into the alimentary tract, rotating the housing around the longitudinal axis of the endoscope to face a target tissue, and delivering ablational energy to the target tissue. In some embodiments of the method, the rotating step is completed before initiating the delivering energy step; in other embodiments the delivering energy step occurs at least partially during the rotating step.

[0022] In some embodiments of the method, the rotating step includes rotating a stylet disposed within a channel of the endoscope, the stylet comprising a distal angled portion configured to extend laterally beyond the diameter of the endoscope, such portion supporting an ablation structure housing on its distal end. In some embodiments of the method, the rotating step includes controlling the rotation with a rotational control positioned at the proximal end of the endoscope. In some embodiments of the method, the rotating and the delivering energy steps are repeated, such that after delivering energy, the method further includes another rotating step and another delivering energy step. In various embodiments of the method, the method further...
includes pivoting between the longitudinal axis of the housing and the longitudinal axis of the endoscope in response to deflection of the ablation structure against a surface.

[0023] From a more general perspective, aspects of the invention provide an endoscopic treatment device that includes an endoscope having a central longitudinal axis, an operative element supported at a distal end of the endoscope, and a first coupling mechanism that couples the operative element to the endoscope and is configured to allow rotational movement of the operative element around the longitudinal axis of the endoscope. The operative element of the device may provide any form therapeutic delivery, surgical intervention, or diagnostic evaluation capability.

[0024] Such devices may include embodiments with an open-front guide cap that fits over the distal end of the endoscope. In such embodiments, the device may include a second coupling mechanism, the second coupling comprising a first coupling feature disposed annularly around an external circumference of the cap. In such embodiments, the second coupling mechanism may further include a second coupling feature disposed on the operative element, the first coupling feature and the second coupling feature being mutually complementary.

[0025] In a related aspect of the invention, there is a method of treating or diagnosing a target tissue in a body lumen with an endoscope having a central longitudinal axis, an operative element supported by the endoscope, and a coupling mechanism that attaches the operative element to a distal end of the endoscope while allowing allow rotational movement of the operative element around the longitudinal axis of the endoscope. The method includes advancing the endoscope into the body lumen, rotating the operative element around the longitudinal axis of the endoscope so as to be operatively directed to the target tissue; and treating or diagnosing the target tissue with the operative element.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0026] FIG. 1 is a perspective view of a therapy device;

[0027] FIG. 2 is a therapy structure coupled to the distal end of an insertion instrument;

[0028] FIG. 3 is a perspective view of an elongate element having a knob, curved distal end and a connection;

[0029] FIGs. 4A and 4B are perspective views showing the change of curvature in the curved portion of an elongate element as it rotates about an insertion instrument;

[0030] FIGs. 5A, 5B and 5C illustrate various connection configurations between an elongate element and a therapy structure.
FIGs. 6A-8B illustrate alternative elongate elements having 2, 3 and 4 connection points, respectively, to a therapy structure;

FIG. 9 is a cross section view of a housing having an end stop positioned on an insertion instrument;

FIG. 10 is a cross section view of a housing position on the distal end of an insertion instrument where the guide is beyond the distal end of the insertion instrument;

FIGs. 11A and 11B are perspective and section views, respectively, of a two part housing structure;

FIG. 12 is a section view of an embodiment of a mechanical joint that may be used in a two part housing structure;

FIG. 13 is a perspective view of a therapy structure;

FIG. 14 is a section view of a therapy structure coupled to a housing;

FIG. 15 is a section view of a housing having a guide with a rounded rectangular cross section;

FIG. 16 is a section view of a housing having an offset adjacent the guide to provide a spacing between the therapy structure and the housing to allow pivoting relative to the insertion instrument;

FIGs. 17 and 18 are perspective views of connectors having rail (FIG. 17) and semicircular (FIG. 18) cross section shapes;

FIG. 19 is a top down view of an therapy structure with a connector that includes a loop;

FIG. 20 is a top down view of a therapy structure with a connector that includes a clamp;

FIG. 21 is a perspective view of a raised guide provided at the distal end of an insertion instrument and a complementary shaped connector on the therapy structure;

FIG. 22 is a perspective view of a guide formed in a sidewall of an insertion instrument;

FIG. 23 is a perspective view of a therapy device coupled to an insertion instrument using a connector having a hinge or pivot;
FIG. 24 is a perspective view of a therapy structure coupled to an insertion instrument where the therapy structure includes an expansion element on a connector such as in FIGs. 19 or 20.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the invention provide a device and method for treating target sites in the body using a minimally invasive approach. In one aspect, the therapy is performed in the gastrointestinal tract using an endoscopic approach. Aspects of the invention are particularly advantageous for ablation of focal sites in relatively large luminal organs, such as the colon and stomach, including sphincters of the gastrointestinal tract, for example, the lower esophageal sphincter, the pylorus and the anus. Focal target sites in large luminal organs are generally treated by a therapy structure sized to treat a relatively small fraction of the organ, lumen or structure in the body, thus controlled rotation of the therapy structure is a useful therapeutic approach. Conventional rotational control is provided by rotational manipulation of the insertion instrument itself; however, embodiments of the present invention provide additional rotational control of the therapy structure around the insertion instrument. There are limitations and disadvantages associated with rotation of an insertion instrument during procedures, and thus providing rotational capabilities of a therapy structure without rotation of the insertion instrument is beneficial. Often, in fact, ability of a physician to rotate an insertion instrument is limited by physical constraint of the insertion instrument once it is in place to such an extent that in order to effect a rotation, the physician needs to withdraw the insertion instrument and reinsert it in a desired rotation orientation. In such cases, the process of withdrawal and insertion, itself, can be irritating or injurious to the patient, as well as consuming of procedural time. As such, the addition of specific rotational control of a therapy device carried by an insertion instrument in addition to rotation of the instrument itself (where available) contributes to the overall level and resolution of rotational control.

FIG. 1 is a perspective view of an embodiment of a therapy device. An insertion instrument 10 is connected to a handle 6 at the proximal end and a therapy structure 50 coupled to a guide 43 at or near the distal end. The guide 43 is on the exterior of the insertion instrument either in a housing 41, as shown, or formed in the instrument (as shown in FIG. 22). The therapy structure 50 includes a therapy element 21. An elongate element 31 extends along the insertion instrument 10 and is connected to the therapy structure 50. The elongate element 31 has a curved portion 33 proximal to the connection point between the therapy structure 50 and elongate element 31. A control knob 18 is provided on the handle 6 is connected to the elongate element 31. Rotation of the control knob 18 rotates the elongate element 31 that in turn produces
movement of the therapy structure 50 along the guide 43. Continued rotation of the knob 18 produces movement along the circumference of the insertion instrument. The direction of movement of the therapy structure relative to the insertion instrument may be changed by changing the direction of rotation of the knob 18. An indicator or markings (not shown) may be provided on the knob 18 or handle 6 to indicate to a user the position, amount of rotation, orientation or other indicia of therapy structure movement.

[0049] Depending upon the type of therapy element employed by the therapy structure, an appropriate energy source 159 and coupling 165 will be provided either through the handle 6 (as shown) to connection line 62 or connected directly to the therapy structure 50 (see connection line 62 in FIG. 23). The energy source 159, coupling 165 and connection line 62 are selected in a manner appropriate to the type of therapy delivered. In the case of therapy using radiofrequency energy, for example, the therapy element 21 would be an electrode or electrode array connected to an energy source 159 configured as a radiofrequency generator. The RP generator is connected using a coupling 165 and connection line 62 suited to the transmission of radiofrequency energy to the electrode array. In the case of therapy using microwave energy, for example, the therapy element 21 would be an appropriate antenna or array connected to an energy source 159 configured as a source of microwave energy. The microwave source is connected using a coupling 165 and connection line 62 suited to the transmission of microwave energy to the antenna or array. In the case of cryogenic therapy, for example, the therapy element 21 would be an appropriate applicator for the cryogenic gas or liquid such as a nozzle, array of nozzles in the case of a spray delivery or a receptacle for a cryogenic fluid in the case where the therapy is applied via contact with a low temperature receptacle. The cryogenic applicator is connected to the cryogenic source 159 using a coupling 165 and connection line 62 suited to the controlled delivery of the cryogenic gas or liquid. In the case of photo-therapy, for example, the therapy element 21 would provide the appropriate fixed or moving lens or lens array suited as appropriate for the light source being used. The photonic delivery element 21 is connected to the light source 159 using a coupling 165 and connection line 62 suited to the controlled delivery of the light or phototherapy energy generated by the phototherapy source 159.

[0050] For each of the various different therapy types, appropriate connections and routing points (not shown) suited to the therapy energy being delivered are provided to permit rotating connection between the therapy element and the energy source. Connections and routing points would include rotating couplings, curved connectors and the like were needed between the
energy source 159 and the insertion instrument 10, along the insertion instrument 10 and between the insertion instrument 10 and the therapy element 21.

[0051] Also shown in FIG. 1 is a monitor or display 160 provided for use with an insertion instrument having a camera or optical system, such as the case when the insertion instrument 10 is an endoscope, a colonoscope or other surgical access tool that provides a view to the user of the operating environment. The insertion instrument is may be any device suited to delivery of the therapy structure to the region of the body designated to receive treatment. The insertion instrument may be a catheter, a cannula, an endoscope or a colonoscope.

[0052] FIG. 2 is an end view of a therapy device having a therapy structure 50 coupled to a guide 43 on the exterior of an insertion instrument 10. The therapy structure 50 includes a therapy element 21 supported by a housing 22. A connector 23a is attached to the housing 22 and forms a cooperative engagement with the groove 43. While the groove 43 may be formed directly in the insertion instrument (i.e., see FIG. 22), a housing 41 may also be used to provide the guide 43. In the illustrated embodiment, the connector 23a includes a shaped head with an exterior surface shape that conforms to the shape of the guide 43. The elongate element 31 extends along the insertion instrument 10 and is coupled to the therapy structure 50.

[0053] In the embodiment illustrated in FIG. 2, the elongate element 31 extends along the insertion instrument 10 within a working channel 16. The elongate element 31 is connected to the therapy structure 30 at a connection 36 on the side of the therapy support 22 opposite to the therapy element 21. Because of the relative position of connection 36 to the connector 23a and the therapy structure 50, the therapy structure 50 may move along the guide 43 (as indicated by the arrow near guide 43) but also in a tilting or pivoting aspect relative to the distal end of the insertion instrument (as indicated by the arrow at the distal end of the support 22). As will be described in greater detail below, variations in the number and position of connections between the elongate element and the ablation structure as well as the connection between the ablation structure and the insertion instrument permit user to delivery therapy in a wide array of configurations.

[0054] FIGs. 3, 4A and 4B will now be used to describe the operation of the elongate element 31. FIG. 3 illustrates the elongate element 31 separated from the insertion instrument 10. The knob 18 is connected to the proximal end and the distal end includes a connection 37. A curved portion 33 is provided proximal to the connection 37. The curved portion 33 ensures a sufficient length of the elongate element 31 is provided as the therapy structure moves along the guide. While illustrated as a single curved section, it is to be appreciated that multiple curves, compound curves or other shapes could be used to provide the desired functionality. For
example, the elongate element could be formed into an angled portion with more pronounced bends (i.e., as in a triangle or square) to accommodate the spacing between the channel and the movement of the therapy structure 50.

[0055] FIGs. 4A and 4B illustrate an elongate element 31 extending out of a channel 16 in an insertion instrument. The curved portion 33 bends back towards the insertion instrument to a position alongside the guide 43 in the housing 41. For clarity, the therapy structure 50 and connection 37 are omitted. As the knob 18 rotates, the elongate element 31 rotates so as to move along the insertion instrument 10 as shown in FIGs. 4A and 4B. Because the channel 16 is off center relative to the insertion instrument, the distance between the channel 16 and the therapy structure will change as the therapy structure moves along the guide. The curved portion 33 changes shape with the rotation of the elongate element 31 about the insertion instrument 10. The curved portion 33 has a smaller bend radius when the ablation structure is closer to the channel 16 (FIG. 4A) and a larger bend radius when farther away (FIG. 4B).

[0056] The elongate element 31 may be a stylet or alternatively, a wire, a rod, or other suitable flexible elongate torquable element to transmit force from the knob to the therapy structure. The portion extending from the end includes an angled portion 33 that radially extends past the outer diameter of the endoscope. By virtue of this angled portion of the stylet providing the slack or flexibility to accommodate variability in lateral dimension without compromise of function, this angled portion may also be understood as a service loop. The elongate element 31 is fully rotatable within the channel such that rotation of the element within the channel translates into rotation around the circumference of the instrument. In other embodiments, the rotation of the element may be limited to some fraction of a full circumference. Such a limitation to a partial circumference may be imposed by a feature that directly interacts with the element, the knob or within a guide.

[0057] As the channel hosting the stylet is typically eccentrically positioned within the endoscope, the radial distance from the channel to the circumferential edge of the endoscope varies from a minimum (FIG. 4A) to a maximum (FIG. 4B). The angled portion 33 of the stylet 31 is sufficiently flexible that it can flex outward to embrace the maximum distance (channel-to-edge) without stressing the stylet. The angled portion 33 is biased such that its distal end provides a pressure directed inward, back toward the instrument 10. A therapy structure coupled to the angled portion may thus be biased to move toward or away from the instrument 10. In some embodiments, the elongate element is a stylet or support wire formed from Nitinol or any other material having suitable super elastic and/or shape memory properties.
In one embodiment, the elongate element 31 is a stylet, wire, braid, or other structure having sufficient material strength to transmit the torsion from the knob 18 to the therapy structure 50. In some embodiments, there is a direct connection between the knob 18 and the elongate element 31 (FIG. 3). Alternatively, a gear train may be connected to the knob 18 to provide fine control of rotational movement or to increase torque applied to the elongate element or both. In one aspect, the elongate element 31 is a high-fidelity torque wire, for example, such that torque at the proximal end is immediately conveyed as torque at the distal end, without a delay or accumulation of torque force within the wire. In one illustrative embodiment, the elongate element 31 has a circular cross section with a diameter of 0.039 inches or less.

Alternatively, the diameter and cross section are selected based on the diameter of the channel available in the insertion instrument.

In one aspect, the fit between the elongate element and the insertion instrument channel is sized so that the channel provides additional support to the elongate element to help prevent buckling. Either the exterior of the elongate element 31 or the interior walls of the channel or both may be coated with or provided with a lubricious material to ensure rotation of the elongate element within the channel. The channel may also be sized based on the size and type connector 37 used. Additionally or alternatively, the connector 37 and or curved portion 33 may be removable so that only the straight portion of the elongate element need be passed through the channel. Alternatively, elongate element 31 is formed from shape memory material so that the connector 37 and curved portion 33 may be straightened for insertion through the channel 16 and then would assume the preformed shape (FIG. 3) once through the channel.

With reference to FIG. 2, the elongate element 31 is shown connected to the lower portion of both the therapy device 50 and the therapy element 21. The connection illustrated would be considered below the midline of both the therapy device and the therapy element.

While the relative position of the connection between the elongate element 31 and the therapy device and the therapy element may be the same, other configurations are possible as illustrated in FIGs. 5A, 5B and 5C. FIG. 5A illustrates a connection point 36 that occurs above the therapy device midline 46. FIG. 5B illustrates a connection point 36 that occurs at or near the therapy device midline 46. FIG. 5C illustrates a connection point 36 that occurs below the therapy device midline 46. In each of these embodiments, the connection point 36 is between the distal end of the elongate element 31 and the support 22. The connection point 36 may be in other positions such as on a connector or attached to a therapy element, for example.

While the previous embodiments have illustrated a single connection point between the elongate element and the therapy device, other configurations are possible. FIG. 6A illustrates...
an elongate element 31 having a distal end divided into connection points a and b. FIG. 6B illustrates one of several possible connection configurations (points 1 and 2) where the ends a and b may be coupled to the therapy device support 22. In this illustrative example, the connection points are above the midline 46 and symmetrically distributed. It is to be appreciated that the connection points may be in other configurations such as asymmetrical points of connection with regard to the midline 46, or in other distributions above or below the midline with respect to the therapy device or therapy element.

[0062] FIG. 7A illustrates an elongate element 31 having a distal end divided into connection points a, b and c. FIG. 7B illustrates one of several possible connection configurations (points 1, 2 and 3) where the ends a, b and c may be coupled to the therapy device support 22. In this illustrative example, the connection points are above the midline 46 and symmetrically distributed. It is to be appreciated that the connection points may be in other configurations such as asymmetrical points of connection with regard to the midline 46, or in other distributions above or below the midline with respect to the therapy device or therapy element.

[0063] FIG. 8A illustrates an elongate element 31 having a distal end divided into connection points a, b, c and d. FIG. 8B illustrates one of several possible connection configurations (points 1, 2, 3 and 4) where the ends a, b, c and d may be coupled to the therapy device support 22. In this illustrative example, the connection points are above the midline 46 and symmetrically distributed. It is to be appreciated that the connection points may be in other configurations such as asymmetrical points of connection with regard to the midline 46, or in other distributions above or below the midline with respect to the therapy device or therapy element.

[0064] FIGs. 9 and 10 depict section views of embodiments of the housing 41. The housing 41 is sized to fit over the insertion instrument 10 and provide a guide 43 in the exterior of the insertion instrument. The housing 41 may slip completely over the distal end of the insertion instrument as shown in the embodiments of FIGs. 1 and 10. Alternatively, the housing may be provided with a stop ring or block 42 to engage the housing 41 with the distal end of the insertion instrument as shown in FIG. 9. Additionally, the housing 41 position relative to the insertion instrument distal end may be adjusted to provide the desired orientation or relationship between the therapy structure and the insertion instrument or the guide 43 and the insertion instrument. As such, the housing may be positioned proximal to the insertion instrument distal end (FIGs. 2, 23 and 24), at or near the insertion instrument distal end (FIGs. 1, 4A, 4B, 11A, 11B, 15 and 16) or beyond the insertion instrument distal end (FIG. 10).

[0065] The guide 43 may take on any of a number of different forms or configurations. The guide 43 may take the form of an open recess as in FIG. 9 or with a narrowing provided by lips
or walls 44 as shown in FIGs. 2 and 10. Depending on the coupling technique used to couple the
therapy device to the insertion instrument and the desired amount of rotation to be provided, the
guide may extend completely around the circumference or only partially around the
circumference of the insertion instrument. Moreover, as illustrated below, the cross sectional
shape of the guide 43 may also change to complement the connector or other structure used to
couple the therapy device to the insertion instrument. For example, the rail 23c (see FIG. 18)
would be a complementary fit to the guide shape of FIG. 9. While both FIGs. 9 and 10 illustrate
guides having generally circular cross section shapes, other shapes are possible such as the
rounded rectangular shape 43 of FIG. 15 that complements the rail 23b of FIG. 17.

[0066] In some embodiments, the guide 43 has a small opening or is nearly enclosed so that
the connector will pass through the opening to snap-on the guide while the shape of the opening
helps maintain the connector in the guide and the therapy structure alongside the insertion
instrument. As best seen in FIG. 10, the guide 43 may be an annular groove or track with lips 44
that partially enclose the groove. Here the guide 43 circumscribes the outer periphery of the cap
41. In some embodiments, the track or groove is configured with lips 44 that partially enclose
the groove, and serve the purpose of securing the connector within the guide (see e.g., FIGs. 14
and 16).

[0067] The housing 41 may take the form of an open-face cap (FIG. 10) or one having an end
stop 42 (FIG. 9). The housing 41 may be formed from the same material or formed from a
compound material. In one aspect, the housing 41 is formed from a compliant and resilient
material such as silicone, such that the guide 43 may act as a female portion of a coupling
mechanism that can receive and clasp a male portion or embodiment of a connector 23 as
illustrated and described below. This second coupling mechanism thus may have a snap-in
character that relies on the resilient composition of the track, and the mutual fit of the first and
second coupling elements, and which by its snap-in quality allows an easy engagement and
disengagement, the engaged configuration nevertheless being secure. The embrace of the groove
43 around the connector 23 (such as, for example, a knob 23a in FIG. 14, rail 23b in FIG. 16,
ring 82 in FIG. 19 or clamp 87 in FIG. 20) is sufficiently constrained by the embracing lips of
the groove such that it prevents inadvertent escape of the connector from the guide while the
internal dimensions and clearance of the connector/guide relationship is sufficient to prevent
binding and ensure smooth motion.

[0068] FIGs. 11A and 11B a perspective and a longitudinal cross sectional view, respectively,
of another embodiment of the housing 41. In this embodiment, the housing 41 has a two part
construction. An in inner liner 53 has an opening 59 sized to accept an insertion instrument 10.
The material of the liner 53 is selected for ease of attachment to the instrument and to ensure a fit that will not slip under the forces applied in the operation of the therapy device. The outer sleeve 57 is formed from a rigid material that will provide a less compliant guide 43. FIG. 12 illustrates a section view of an alternative housing 41 where mechanical features 99 are provided to ensure that the outer sleeve 57 is joined to the inner sleeve 53.

[0069] It is to be appreciated that the housing 41 or the surfaces of the guide 43 or connector 23 may be a polymeric material that is doped with a lubricious material or features, such as glass beads or other material to ensure movement between the therapy structure and the insertion instrument. For example, a lubricious feature or treatment of the guide 43 is advantageous for the slidability of the engagement between the guide 43 and the engagement feature or connector on the therapy structure. A connector 23 may be shaped to fit into the groove 23 and may be formed from a high strength polymer, such as polyetheretherketone (PEEK). Additionally or alternatively, the connector material may be doped with a lubricious composition that includes glass beads or other friction reduction treatments.

[0070] FIG. 13 is a perspective view of a therapy structure 50. The therapy structure 50 includes a therapy element 21 on a support 22. A connector is provided to couple the therapy structure 50 to the insertion instrument as described above. In the illustrative embodiment of FIG. 13, the connector 23a is a shaft having a shaped head 239. The exterior of the shaped head 239 is sized and configured to cooperative placement within a guide 43 as shown in FIG. 14.

The relative position of the therapy structure and the insertion instrument as well as the relative motion between the therapy structure and the insertion instrument may be configured to provide a wide variety of therapy device operational characteristics. The spacing between the therapy device 50 and the insertion instrument 10 may be small (FIG. 14) so that there is little variation in the movement of the therapy structure as it rotates. Alternatively, the sides of the housing 41 may be modified to provide an offset so that the therapy structure may be permitted movement relative to the insertion instrument. FIG. 16 illustrates an offset provided by a raised portion 103 on either side of guide 43. In this illustrative embodiment, the raised portion 103 spaces the therapy structure away from the insertion instrument so that the ends of the support may move towards and away from the insertion instrument as indicated by the arrows. The length and shape of the connector 23 may also be used to provide an offset along or in cooperation with an offset provided on the instrument 10 or housing 41. Consider, for example, an alternative configuration of the embodiment of FIG. 14 having a longer connector 23a that would produce a spacing between the support 22 and the housing 41 to also permit a pivoting motion between the therapy structure and the insertion instrument 10.
FIG. 15 illustrates a housing 41 with a guide 43 having a cross section shape of rounded rectangle. It is to be appreciated that virtually any shape may be used for the guide to ensure cooperation between the connector and the guide that permits translation of the therapy structure relative to the insertion instrument. The connector shapes may also vary such as the rail 23b shown in FIG. 17. The guide of FIG. 15 would be complementary to the rail 23b of the therapy structure 50 shown in FIG. 17. Similarly, the semicircular connector 23c illustrated in FIG. 18 would be complementary to the guides 23 illustrated in FIGs. 9 and 22.

FIGs. 19 and 20 illustrate representative therapy devices 50 having connectors that completely encircle (23e) or nearly encircle (23f) the insertion instrument. FIG. 19 illustrates a therapy device 50 with a connector 23e having a ring 82. The ring 82 has a cross section shape selected for complementary engagement with a guide 43 that extends around the entire circumference of the insertion instrument. The ring 82 may be formed from any flexible material such as silicone or rubber that may be stretched to fit over the insertion instrument and then comply with the guide 23. The ring 82 may also be an o-ring sized to engage with a guide 43. The ring 82 is resilient enough to permit rotation of the therapy device relative to the insertion instrument. FIG. 20 illustrates a therapy device 50 with a connector 23f that includes a clamp 87. The clamp 87 is formed from a resilient material that may deflect to permit the clamp to engage with the guide 43. The clamp 87 may be formed from any suitable resilient material such as plastic. The connectors illustrated in FIG. 19 and 20 may also be doped or coated or the guide 23 may be doped or coated with a lubrication material to assist in rotation during use. In one aspect, the lubrication material is a biocompatible material used for lubrication that could be applied to the guide and/or connector prior to use. In addition, the cross section shape the ring 82 or the clamp 87 of the connectors 23e and 23f may be any shape suited to a particular guide cross section shape, such as a curvilinear shape or other shape to fit cooperatively within the guides 43 as shown in FIGs. 9, 10, 15 or 16.

While embodiments of the therapy device 50 have been described above, other additional embodiments and alternative configurations are possible. For example, the guide has been described and illustrated in a sidewall of a housing 41 at some spacing from the distal end of the instrument 10. Other guide configurations are possible. FIG. 21 illustrates a raised guide 41 on the distal most end of an insertion instrument 10. The therapy device 50 has a connector 23g. The connector 23g has complementary cross section shape to engage with the cross section shape of the raised guide 97. Rotation of the elongate element 31 produces rotational movement of the therapy device 50 along the raised guide 97 as indicated by the arrows. In addition, the sidewall of the insertion instrument may be modified directly to provide a guide 43 as shown in
FIG. 22. Such modification to the distal most section or a section of an insertion instrument eliminates the need for the housing 41 since the therapy device may be coupled directly to the insertion instrument directly. The guide 43 shown in FIG. 22 may take on any cross section shape as described herein or to complement the connector of a specific therapy device, such as those illustrated in FIGs. 19, 20, 23 and 24.

[0074] As described herein, the therapy device may be modified to use any of a number of convention therapy modalities using a wide variety different energy sources, energy levels and treatment times depending upon the desired therapeutic outcome. In one aspect, the therapy device is configured to provide radio frequency ablation therapy. In this case, the therapy element is an electrode array. The specific electrode configuration of the array and operation may change depending upon the action to be taken with the tissue as well as the desired therapeutic response. In some aspects, the desired response is provided by the method of energy delivery. In other aspects, the therapy element itself may have a different configuration. For example, the electrode array may be configured as a single uniform field or have different spacing between elements. Additionally or alternatively, the electrode may be configured as described and illustrated in FIGS. 48-56B of United States Patent Publication US 2009/0012513 entitled "ABLATION IN THE GASTROINTESTINAL TRACT TO ACHIEVE HOMEOSTASIS AND ERADICATE LESIONS WITH A PROPENSITY FOR BLEEDING," filed July 3, 2008 the entirety of which is incorporated herein by reference.

[0075] Additionally or alternatively, the therapy structure 50 may include a deflection mechanism to further alter the relationship between the therapy structure and the insertion instrument or between the therapy element and the tissue. FIG. 23 illustrates a perspective view of a therapy structure 50 attached to the distal end of an insertion device 10. The therapy structure 50 includes a pinned or hinged connector 23d between the support 22 and the guide 42 in the housing 41. In this alternative embodiment, the elongate element 31 is attached to the connector 23d but could also be connected to support 22 if desired. Also shown in this illustrative embodiment is the connection of appropriate power and control lines 62 on the outside of the insertion instrument 10. This configuration is in contrast to providing the power and control lines 62 along with the elongate element 31 though a channel of the insertion instrument 10 as illustrated and described elsewhere above such as in FIG. 1.

[0076] In another alternative aspect, the form of deflection involves the use of an expandable structure. The expandable structure may be an inflatable structure such as a balloon or other structure suited to moving from a stowed, compacted condition to an expanded condition during use. When expanded, the expandable structure assists in distal movement of the insertion device
and/or therapy structure to aid in therapy element positioning and or apposition to tissue. FIG.
24 illustrates a therapy device 50 within a bodily lumen 90. The therapy device 50 includes a
therapy element 21 on a support 22 and an expandable structure 72 on a connector 23e. The
connector 23e is coupled to the insertion instrument 10 using any of the techniques described
herein. As shown, the expandable structure 72 is a balloon is inflated into an expanded condition
to urge the therapy element 21 into apposition with the lumen inner wall 92.

[0077] Further alternative aspects for pinned, pivoting, biased and deflection capable therapy
structures are described in co-pending and commonly assigned United States Patent Application
Publications US 2007/018104 entitled "AUTO-ALIGNING ABLATING DEVICE AND
ABLATING DEVICE," filed on November 23, 2005, each of which are incorporated herein by
reference in its entirety.

[0078] Other modifications are possible, for example, see FIG. 6A where a raised groove is
formed on or added to the distal most end of the insertion instrument. Alternatively, the distal
section of an insertion instrument itself could be modified to provide one or more of the coupling
functionalities described herein. For example, the guide may be formed in or connected directly
onto the insertion instrument so that an ablation structure may be utilized with the rotating
element (stylet) without the need for a cap. For example, the guide may be formed at, near or
attached to the distal most end instead of the insertion instrument. FIG. 6A illustrates a guide
formed in the distal end of an insertion instrument. Alternately, could be formed in the wall of
the distal section as shown in FIG. 22.

[0079] Various alternative embodiments that provide coupling between the therapy structure
and the guide are included as alternative embodiments of the invention. The embodiments
depicted in FIGs. 2, 4A, 4B, 9, 10, 11A, and 14, for example, provide a female guide 43 and a
male connector 23. It is to be appreciated that other complementary relationships between the
connector and guide may be provided. For example, the guide 43 may have a male feature and
the connector 23 shaped to provide a complementing female feature. In addition, some
embodiments of the connector 23 may be double-ended shaped heads received into the support
22 and the guide 43. A doubled ended connector configuration would provide additional
pivoting freedom of movement between the therapy structure and the insertion instrument.

[0080] In one aspect of a therapy device according to the invention, a therapy structure having
a therapy element is rotationally-coupled to the distal end of an insertion instrument (such as an
endoscope, for example) by two coupling mechanisms. The first coupling mechanism refers to
the connection between the knob, the elongate element and the therapy structure. The second
coupling refers to the connection of the therapy structure to the insertion instrument. In one specific embodiment, the first coupling mechanism includes a stylet that is rotatable in a channel of the endoscope, and which is coupled to an operative element at an attachment site. The first coupling mechanism is capable of driving rotation of the operative element by way of torquing of the stylet. In one specific aspect, the second coupling mechanism includes a first feature, typically an annular groove on an open-faced cap that fits over the distal end of an endoscope, and a second feature, typically a knob, rail or connector attached to the operative element that fits into the groove within the open-faced cap. In contrast to the first coupling mechanism, the second coupling mechanism is rotationally passive in that it allows rotation but is not capable of driving rotation.

[0081] In one exemplary embodiment, the therapy device 50 includes a therapy element 21 on the surface of an appropriate substrate or support 22. The therapy element may include a radiofrequency electrode array supported on the surface of a housing, and supported at the distal end of an endoscope by a coupling arrangement that provides rotatability of the operative element around the endoscope. The coupling arrangement includes a first coupling mechanism and a second coupling mechanism that, together, cooperatively couple an ablation element to the distal end of an endoscope and provide rotational freedom of movement around the longitudinal axis of the endoscope. The first coupling mechanism may include a stylet disposed within an endoscope channel and rotatable therein; the stylet extends distally beyond the distal end of the endoscope, and an angled portion angles outward beyond the circumference of the endoscope and back to connect to the therapy structure. An ablation element is supported by a housing that is coupled to the end of the angled portion of the stylet at a site of mutual attachment, which may include features that allow the housing to swivel or pivot about the point of attachment. This first coupling mechanism can also convey rotational force to the housing. Such force originates as torque applied to the proximal end of the stylet by an actuator and is translated distally, manifesting as rotation of the therapy structure with respect to the longitudinal axis of the endoscope.

[0082] The second coupling mechanism may include two mutually engageable features, a first feature in the form of a circumferentially disposed track or groove within a housing disposed on the distal portion of an endoscope, and a second feature disposed on a portion of a therapy structure. The housing does not cover or interfere with any channel of the endoscope. It may, however, have a lip portion that fits over the distal end of the endoscope prevents that movement of the cap proximally along the endoscope from its distal end. As described herein, the housing is typically formed from a compliant material which gives it a snap-on character that allows it to
be easily stretched enough to slide over the distal end of the scope, but also with sufficient resilience that it then forms a very secure grasp on the endoscope.

[0083] The various alternative therapy devices described herein may be used to provide a variety of treatments to tissue within the body. In particular, in those areas of the body having large surface area where the benefits of a rotating therapy structure would be particularly beneficial. One method of providing therapy to tissue within a body may include coupling a therapy structure to an insertion instrument. Coupling may take on any of a number of different meanings depending upon the specific type of connector and guide in use. Thereafter, one would advance the elongate element along the insertion instrument to couple the distal end of the elongate element to the therapy structure. Here again, coupling may take on a number of different forms depending upon how the elongate element connects to and interacts with the therapy structure. Rotating the elongate element then moves the therapy structure relative to the insertion instrument.

[0084] Depending upon the therapy provided, there may also be the added step of connecting the therapy structure to a treatment source at the proximal end of the insertion instrument. In addition, there may also be using the therapy structure to provide a treatment from the treatment source to a portion of tissue in proximity to the therapy structure. As discussed above, the treatment source provides any appropriate energy or material based on the specific needs of the therapy to be performed. Examples include electromagnetic energy, photonic energy or cryogenic liquid or gas. In addition or alternatively, the method includes the step of inserting the insertion instrument into the body until the therapy device is adjacent to a tissue selected for treatment. This step may be confirmed using a visualization system on the insertion instrument or may be performed using an external medical imaging modality such as x-ray or other suitable means to image the position of the instrument within the body. In addition or alternatively, there may also be the step of deflecting the therapy structure relative to the insertion instrument. In addition or alternatively, there may also be the step of expanding a structure associated with the therapy structure before, during or after providing the therapy using the therapy device. In addition of alternatively, there may also be the step of rotating the therapy structure relative to the insertion instrument before, during or after using the therapy structure to provide a treatment.

[0085] Exemplary embodiments of the invention have been described as therapy devices, wherein a therapy element conveys energy to target tissue. Exemplary forms of energy include radiofrequency, laser, microwave, ultrasound, and cryogenic; all such forms of energy delivery may be provided by appropriately configured therapy structures and therapy elements, as understood by those of skill in the art and are also included in the scope of the invention. Further,
some forms of energy, if delivered at lower power ranges create thermal lesions which are not ablative but instead can effectively remodel tissue by way of altering the conformation of heat-sensitive structural proteins such as collagen. The delivery of energy at levels that remodel tissue by operative elements is also included within the scope of the invention.

What is claimed is:

1. A therapy device, comprising:
   An insertion instrument;
   A guide on the exterior of the insertion instrument;
   A therapy structure coupled to the guide, the therapy structure comprising a connector and an therapy element;
   An elongate element that extends along the insertion instrument and is connected to the therapy structure, the elongate element having a curved portion proximal to the connection between the therapy structure and the elongate element; and
   A handle connected to the elongate element, wherein rotation of the handle moves the therapy structure along the guide.

2. The therapy device of claim 1 wherein the insertion instrument is any one of: a catheter, a cannula, an endoscope or a colonscope.

3. The therapy device of claim 1 wherein the guide extends partially around the circumference of the insertion instrument.

4. The therapy device of claim 1 wherein the guide extends completely around the circumference of the insertion instrument.

5. The therapy device of claim 1 wherein the elongate element is connected to the therapy structure using the connector.

6. The therapy device of claim 1 wherein the connector couples the therapy structure to the guide.

7. The therapy device of claim 1 wherein the elongate element is connected to the ablation structure at the connector.

8. The therapy device of claim 1 wherein the connector comprises a shaped end.
9. The therapy device of claim 8 wherein the shaped end is a knob or a rail.

10. The therapy device of claim 8 wherein the shaped end has a length and curvature configured to conform to a partial circumference or a complete circumference of the insertion instrument.

11. The therapy device of claim 1 wherein the connector has an exterior surface that complements a shape of the guide.

12. The therapy device of claim 11 wherein when the exterior surface is engaged with the guide, the connector exterior surface is at least partially within the guide.

13. The therapy device of claim 1 wherein when the connector is engaged with the guide, the therapy structure is spaced apart from the insertion instrument.

14. The therapy device of claim 1 the therapy structure further comprising an expansion structure.

15. The therapy device of claim 1 the guide further comprising a recessed portion.

16. The therapy device of claim 15 wherein the recessed portion is shaped to accept a portion of the connector.

17. The therapy device of claim 1 wherein the guide is formed in a wall of the insertion instrument.

18. The therapy device of claim 1 wherein the elongate element connects to the therapy structure at more than one position.

19. The therapy device of claim 1 wherein the elongate element connects to the therapy structure above a midline of the therapy structure, at or near the midline of the therapy structure or below the midline of the therapy structure.
20. The therapy device of claim 1 wherein the connector is coupled to the insertion instrument the guide is positioned adjacent a portion of the therapy element above a midline of the therapy structure, at or near the midline of the therapy structure or below the midline of the therapy structure.

21. The therapy device of claim 1 wherein the guide is proximal to the distal end of the insertion instrument.

22. The therapy device of claim 1 wherein the guide is at or near the distal end of the insertion instrument.

23. The therapy device of claim 1 wherein the elongate instrument extends along the insertion instrument by passing through a working channel of the insertion instrument.

24. The therapy device of claim 1, further comprising: a housing shaped to fit onto or pass over the distal end the insertion instrument, wherein the guide is provided by the housing.

25. The therapy device of claim 1 further comprising: a treatment source that provides electromagnetic energy, photonic energy or cryogenic liquid or gas.

26. The therapy device of claim 25 wherein the therapy element is configured to provide electromagnetic energy, photonic energy or cryogenic liquid or gas depending upon the type of treatment source.

27. The therapy device of claim 1 further comprising: a radio frequency generator, wherein the therapy element is an electrode array connected to the radio frequency generator.

28. The therapy device of claim 1 wherein when the connector is engaged with the guide therapy structure is positioned to allow the therapy structure to pivot relative to the insertion instrument.

29. A method of providing therapy to tissue within a body, comprising:
   Coupling an therapy structure to an insertion instrument;
   Advancing an elongate element along the insertion instrument to couple the distal end of the elongate element to the therapy structure; and
   Rotating the elongate element to move the therapy structure relative to the insertion instrument.
30. The method of 29 further comprising:
Connecting the therapy structure to a treatment source at the proximal end of the insertion instrument.

31. The method of claim 29 further comprising:
Using the therapy structure to provide a treatment from the treatment source to a portion of tissue in proximity to the therapy structure.

32. The method of claim 31 wherein the treatment source provides one of: electromagnetic energy, photonic energy or cryogenic liquid or gas.

33. The method of any of claims 29, 30 or 31 further comprising: inserting the insertion instrument into the body until the therapy device is adjacent to a tissue selected for treatment.

34. The method of any of the above claims, further comprising: deflecting the therapy structure relative to the insertion instrument.

35. The method of any of the above claims, further comprising: expanding a structure associated with the therapy structure before, during or after providing the therapy using the therapy device.

36. The method of any of the above claims, further comprising: rotating the therapy structure relative to the insertion instrument before, during or after using the therapy structure to provide a treatment.