US 20110295267A1

(19) United States

(12) Patent Application Publication

(10) Pub. No.: US 2011/0295267 A1

(43) Pub. Date: Dec. 1, 2011

Tanner et al.

(54) SYSTEM AND METHOD FOR AUTOMATED TISSUE STRUCTURE TRAVERSAL

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(21) Appl. No.: **12/833,927**

(22) Filed: **Jul. 9, 2010**

Related U.S. Application Data

(60) Provisional application No. 61/349,690, filed on May 28, 2010.

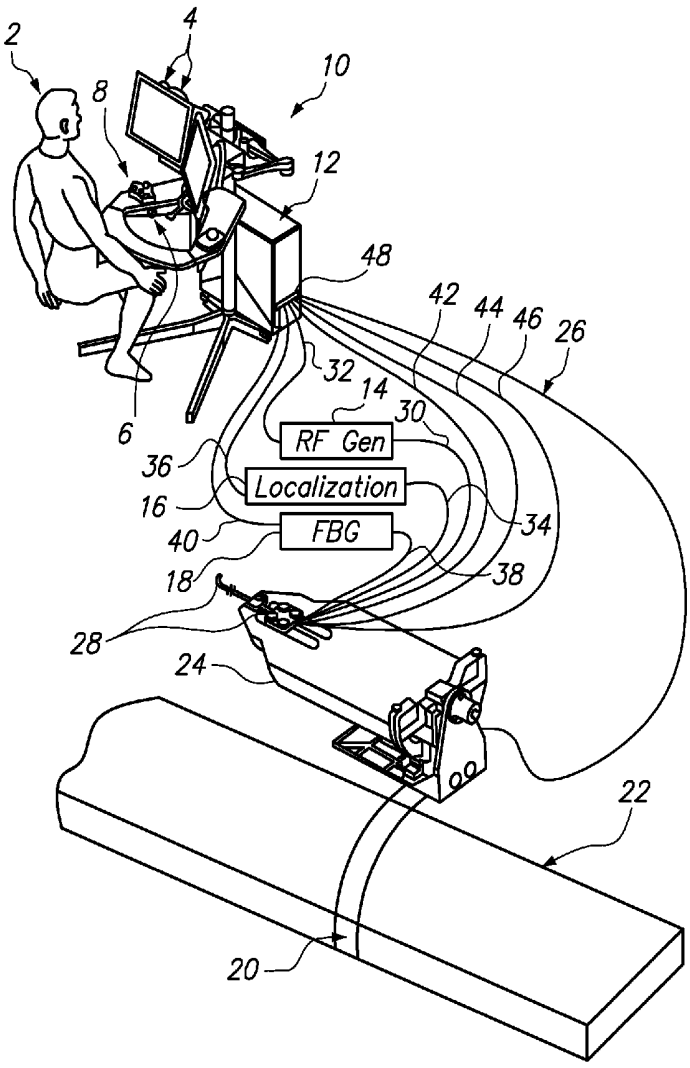
Publication Classification

(51) **Int. Cl.**
A61B 19/00 (2006.01)

(52) **U.S. Cl.** **606/130**

(57) **ABSTRACT**

Systems and methods are described for automating aspects of minimally invasive therapeutic treatment of patients. A robotic tissue structure traversal system may comprise a controller including a master input device, an electromechanically controlled elongate instrument having a proximal interface portion and a distal portion, the proximal interface portion being configured to be operatively coupled to an electromechanical instrument driver in communication with the controller, the distal portion comprising a traversing tip and being configured to be interactively navigated about internal structures of a patient's body in response to signals from the controller; and a load sensor operatively coupled between the distal portion of the elongate instrument and the controller; wherein the controller is configured to automatically advance the traversing tip through a thickness of an internal structure by observing loads from the load sensor.



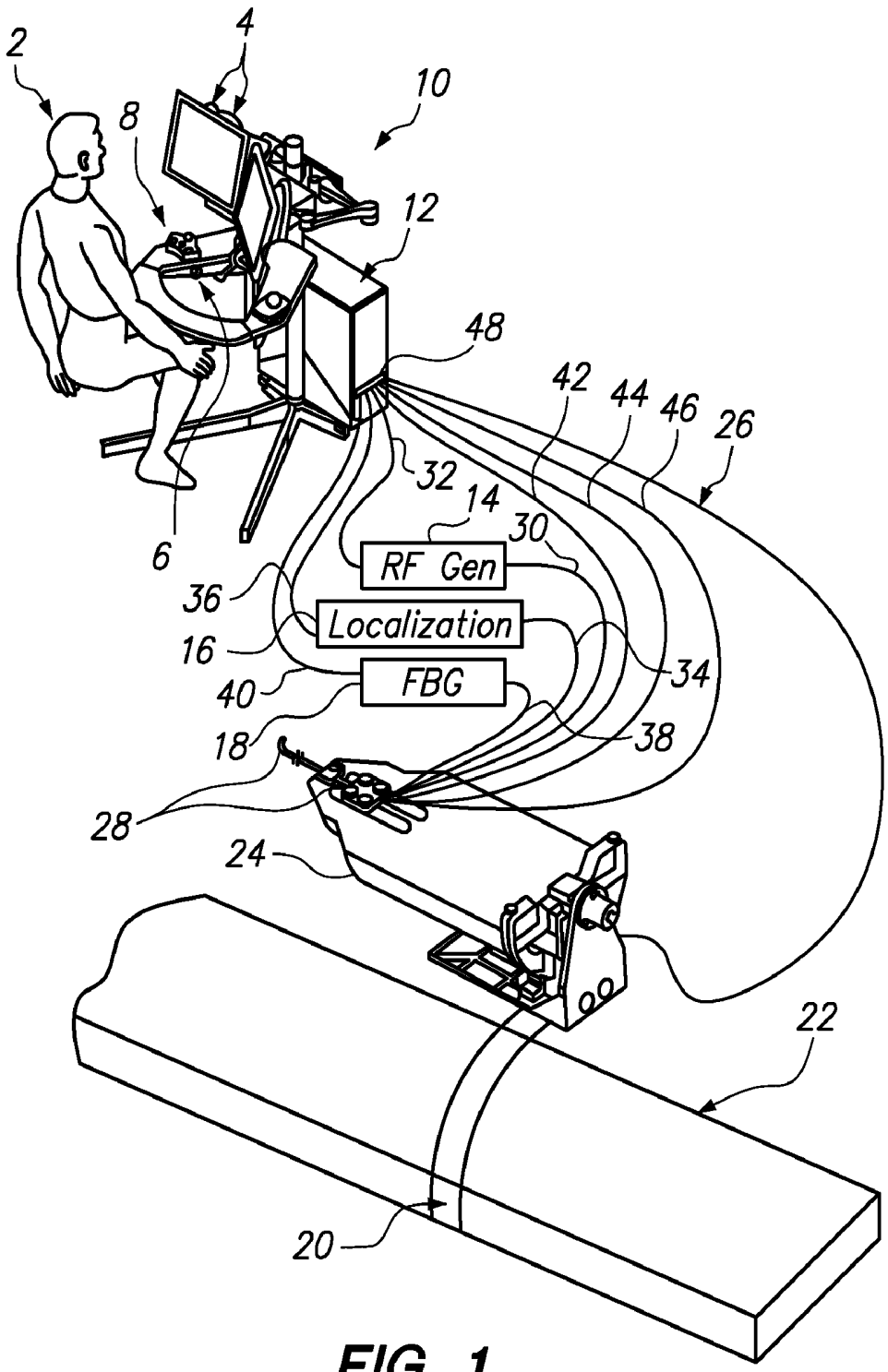

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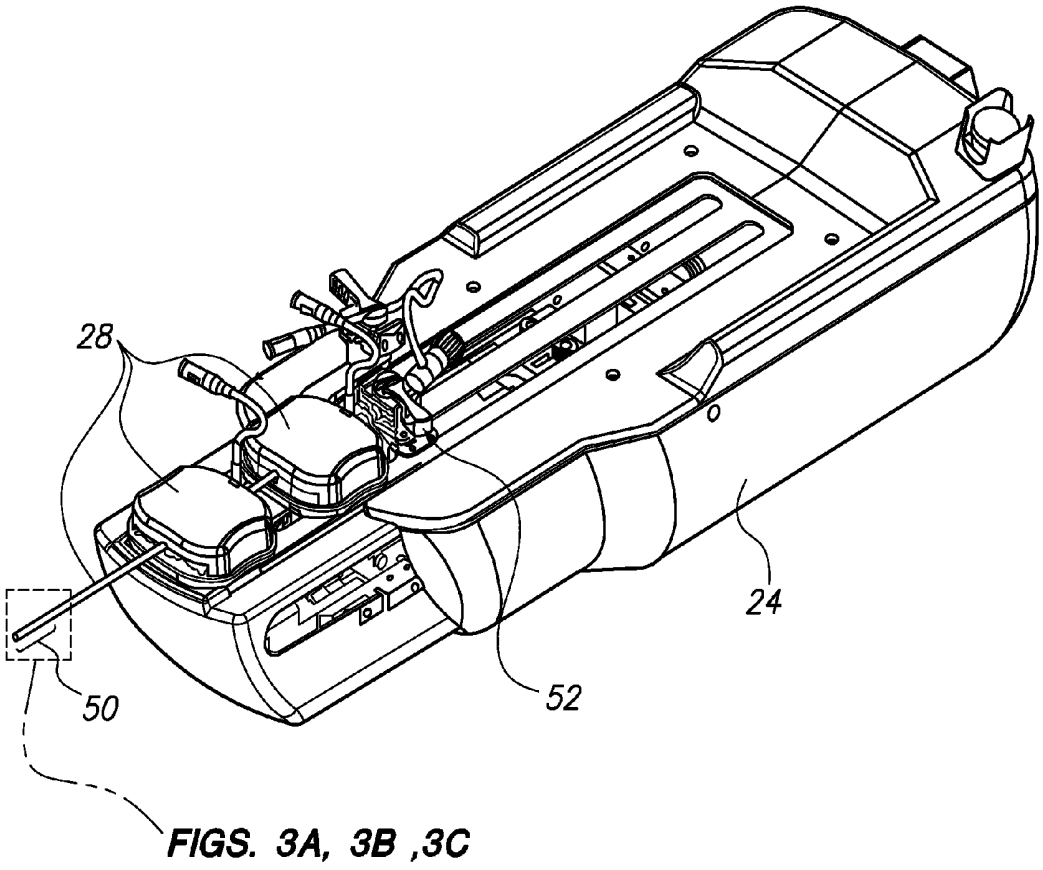
FIG. 1



FIGS. 3A, 3B ,3C

FIG. 2

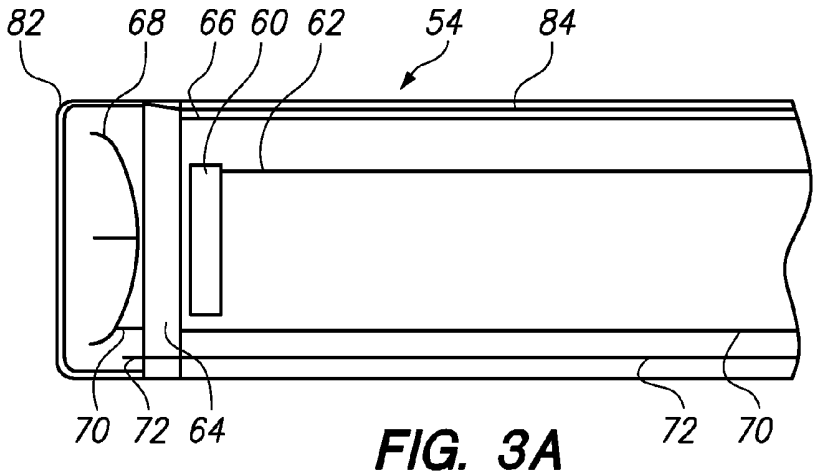


FIG. 3A

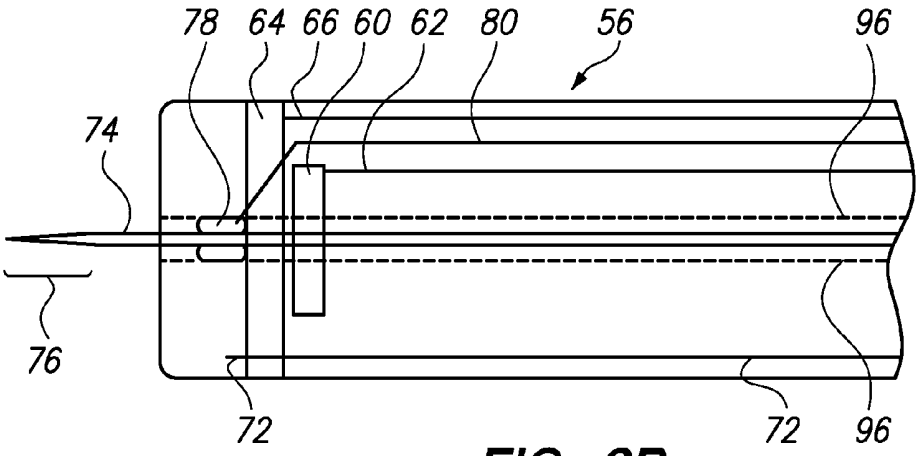


FIG. 3B

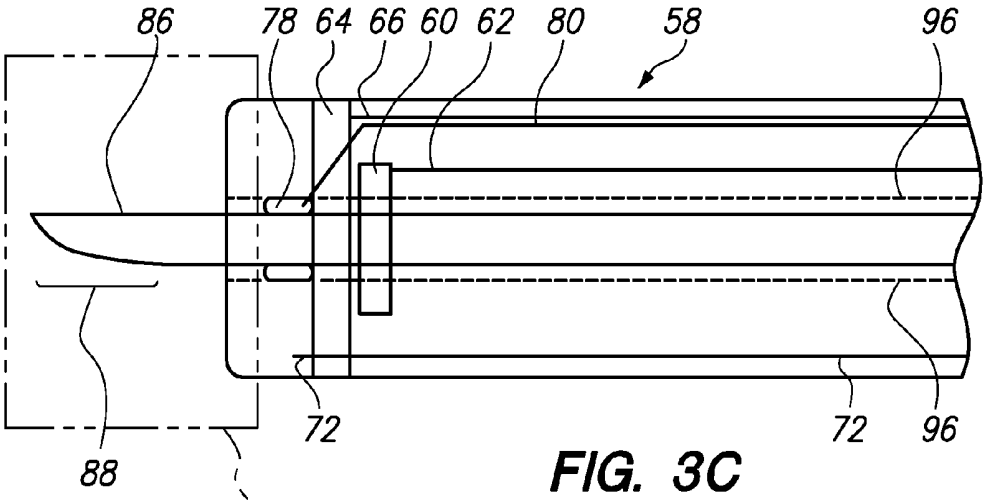


FIG. 3C

FIGS. 4A-E

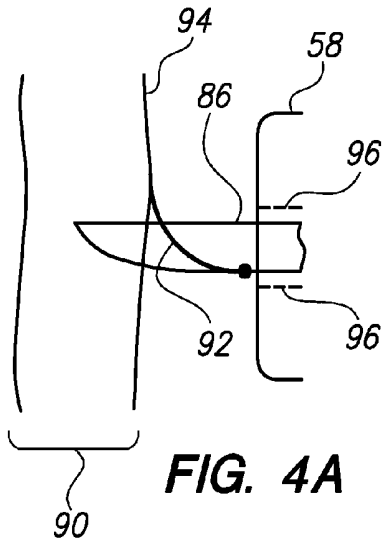


FIG. 4A

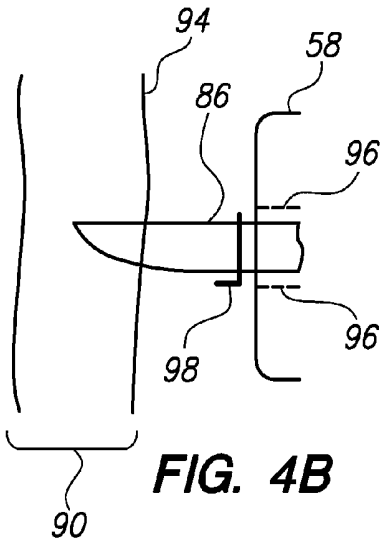


FIG. 4B

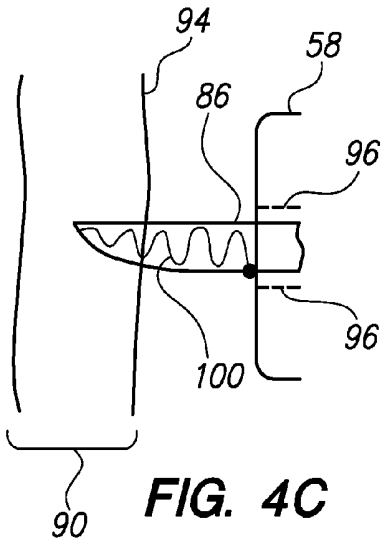


FIG. 4C

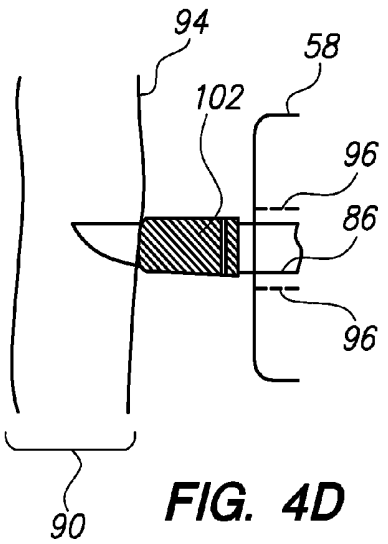


FIG. 4D

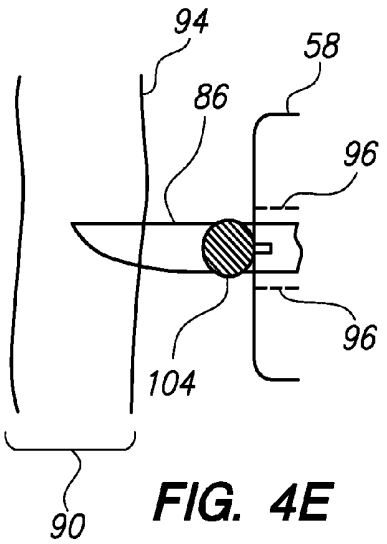


FIG. 4E

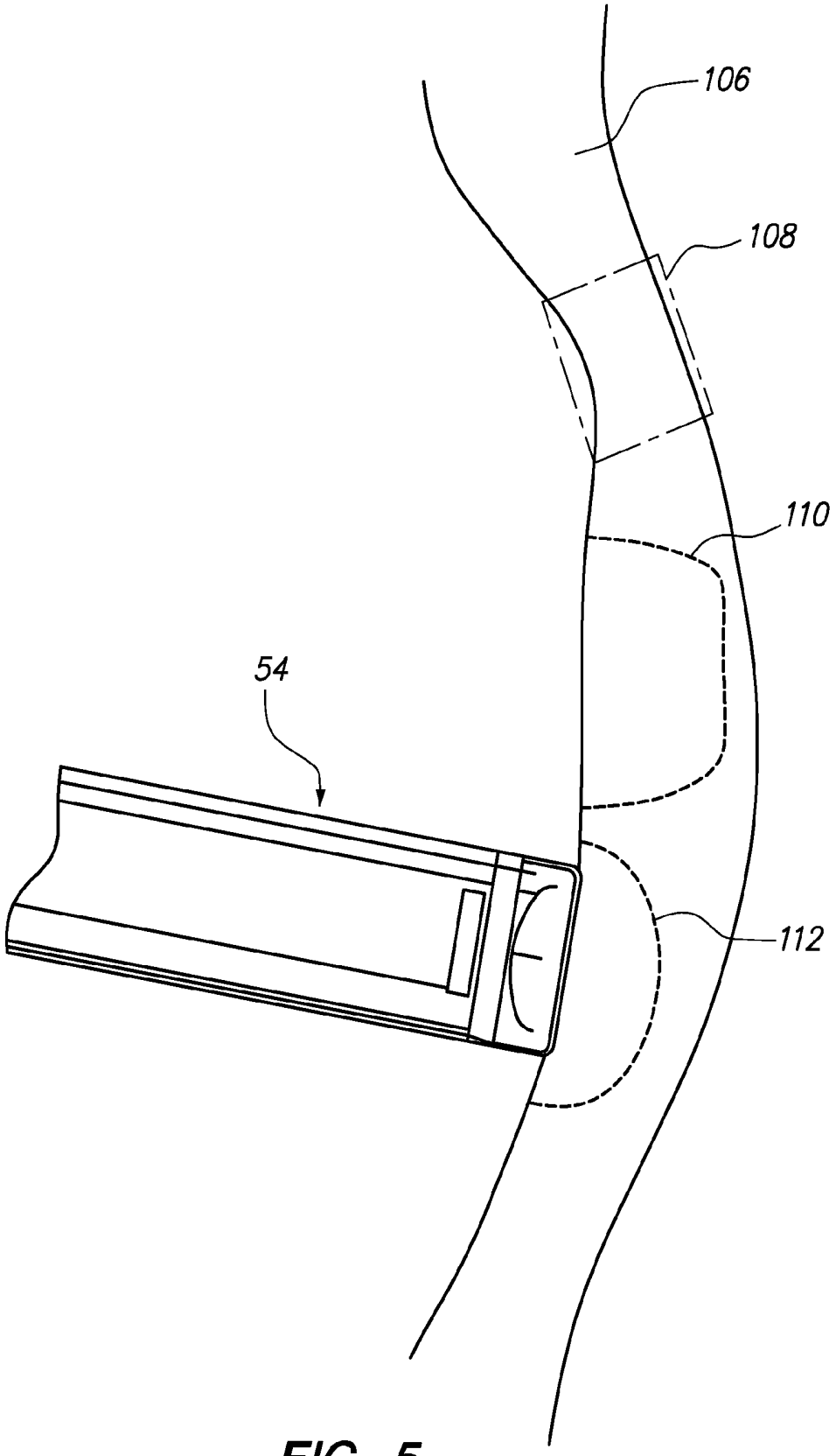
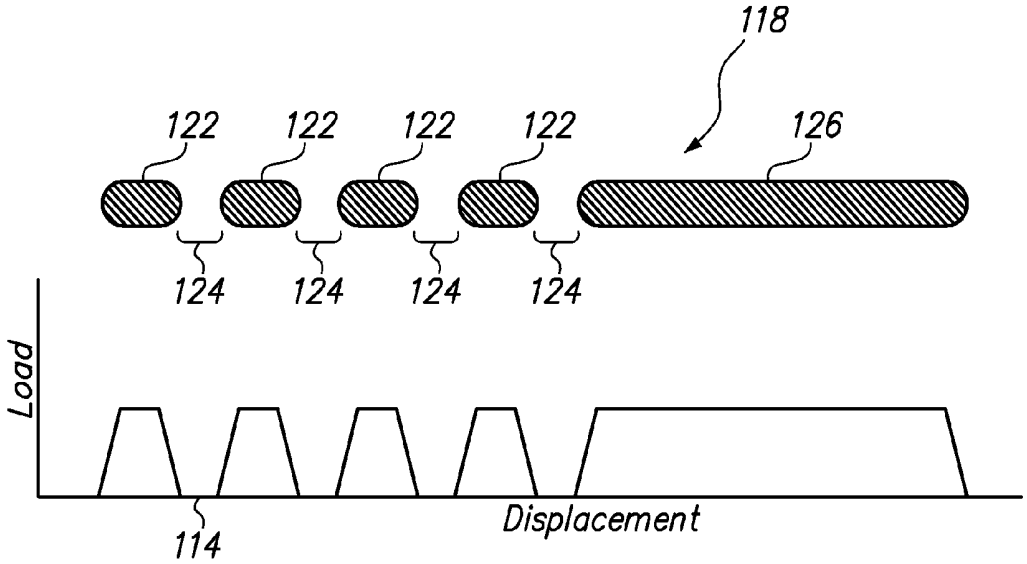


FIG. 5


118
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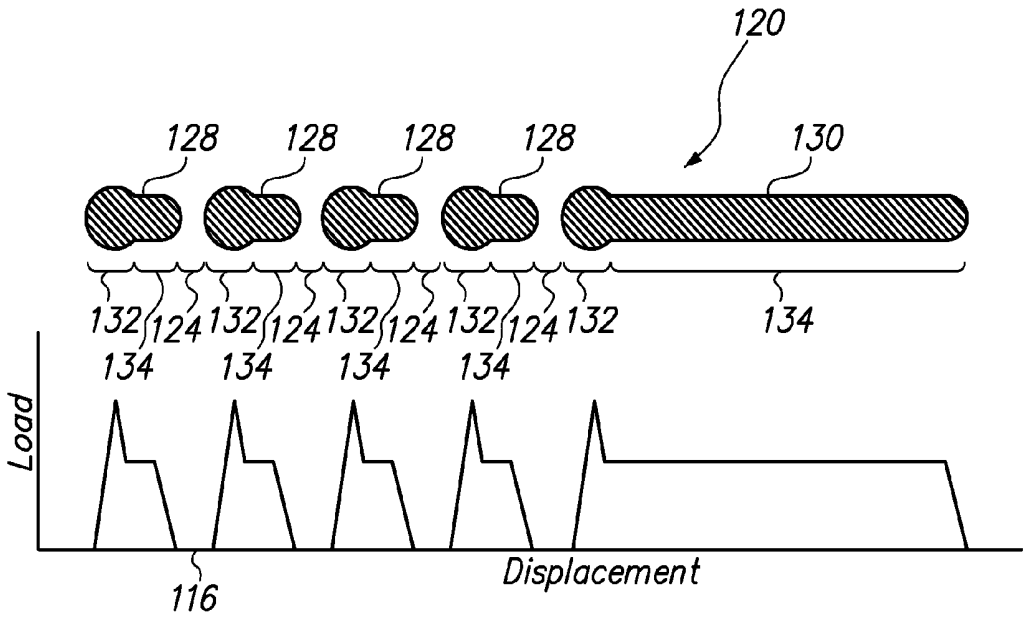
124
Load
Displacement
114

FIG. 6A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124
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134
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134
Load
Displacement
116

FIG. 6B

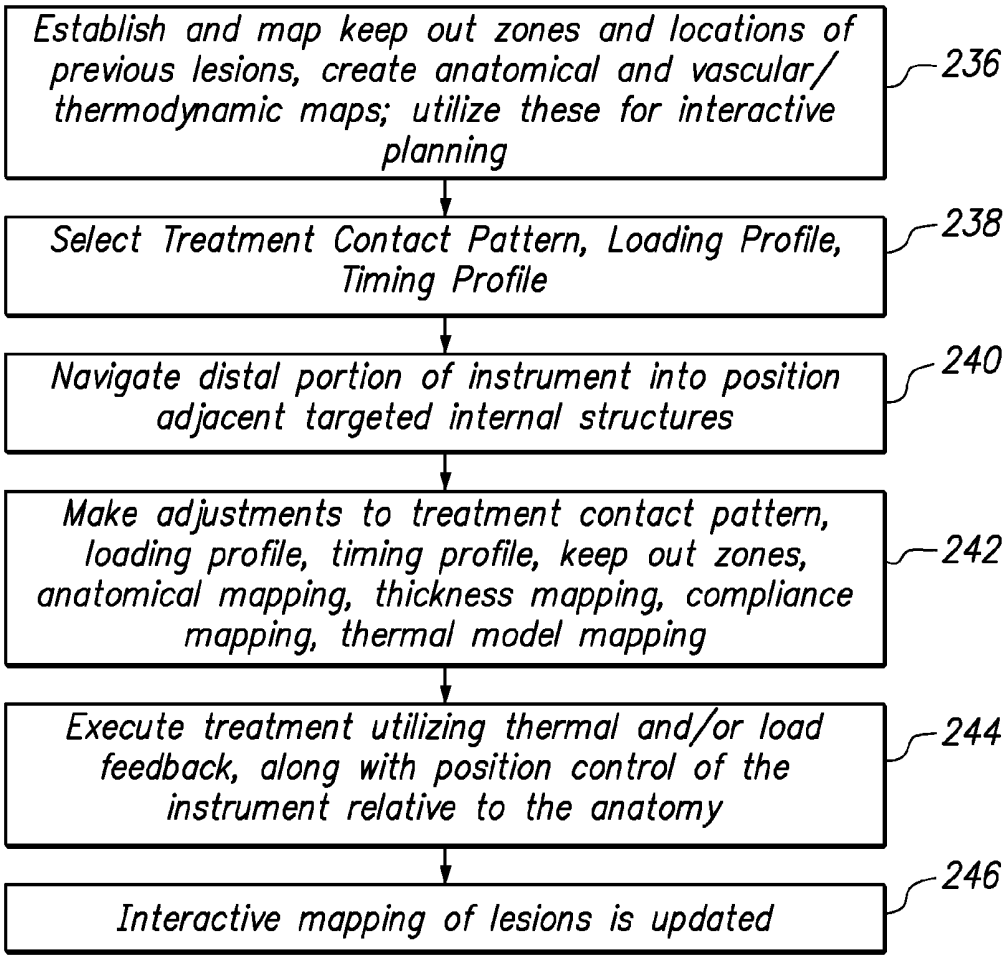
Establish and map keep out zones and locations of previous lesions, create anatomical and vascular/ thermodynamic maps; utilize these for interactive planning
236
Select Treatment Contact Pattern, Loading Profile, Timing Profile
238
Navigate distal portion of instrument into position adjacent targeted internal structures
240
Make adjustments to treatment contact pattern, loading profile, timing profile, keep out zones, anatomical mapping, thickness mapping, compliance mapping, thermal model mapping
242
Execute treatment utilizing thermal and/or load feedback, along with position control of the instrument relative to the anatomy
244
Interactive mapping of lesions is updated
246

FIG. 7

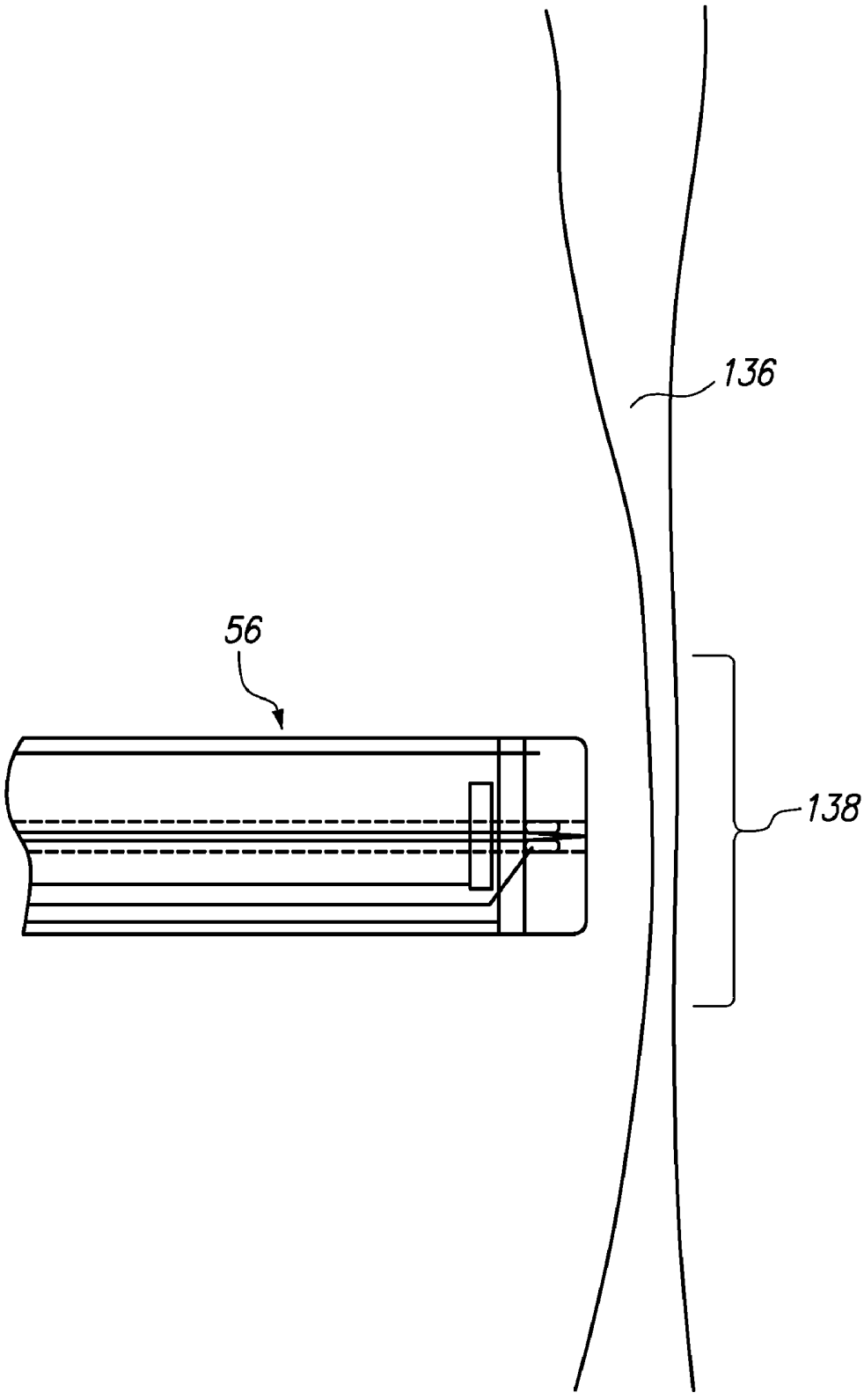

FIG. 8A

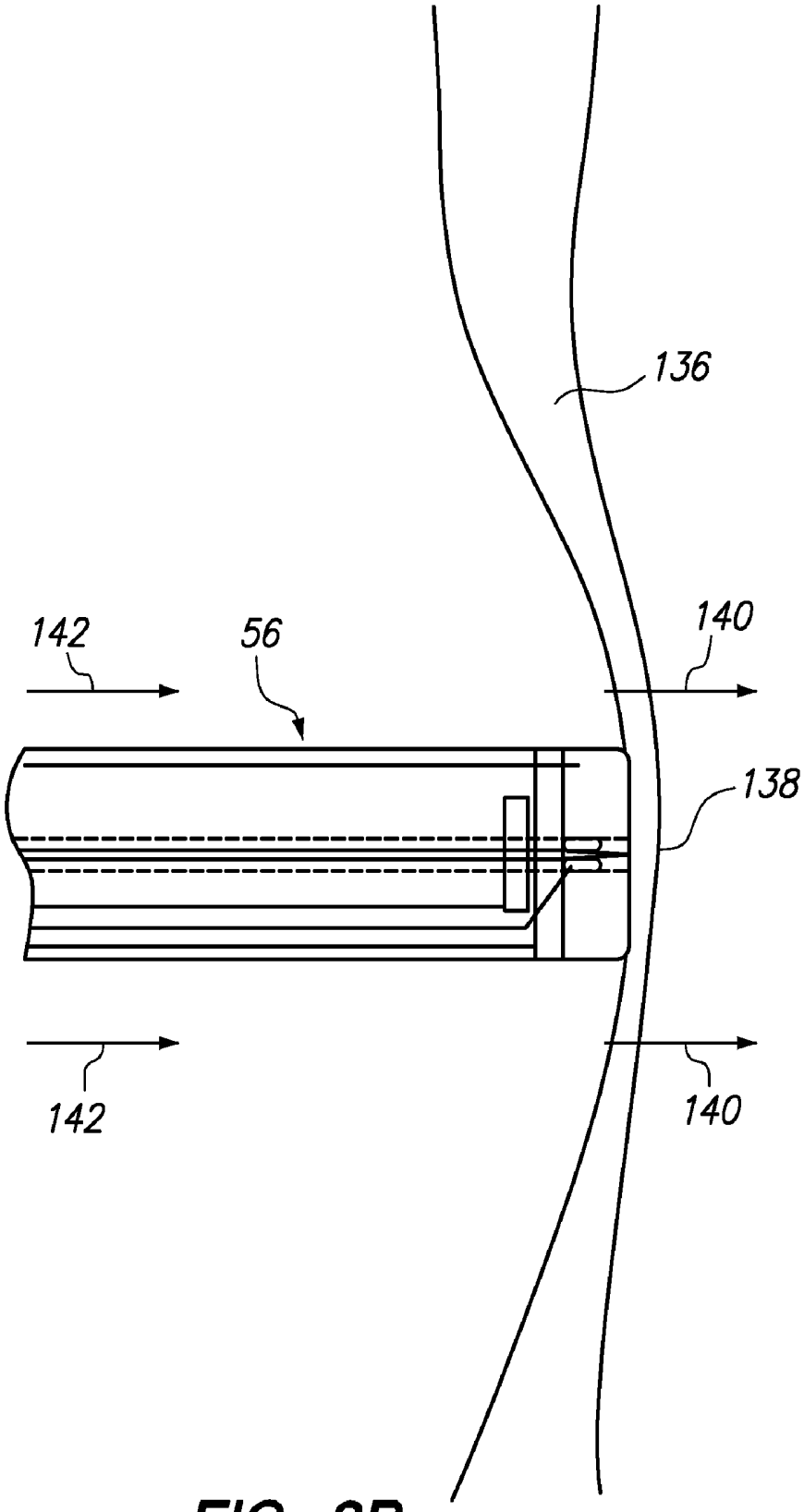

FIG. 8B

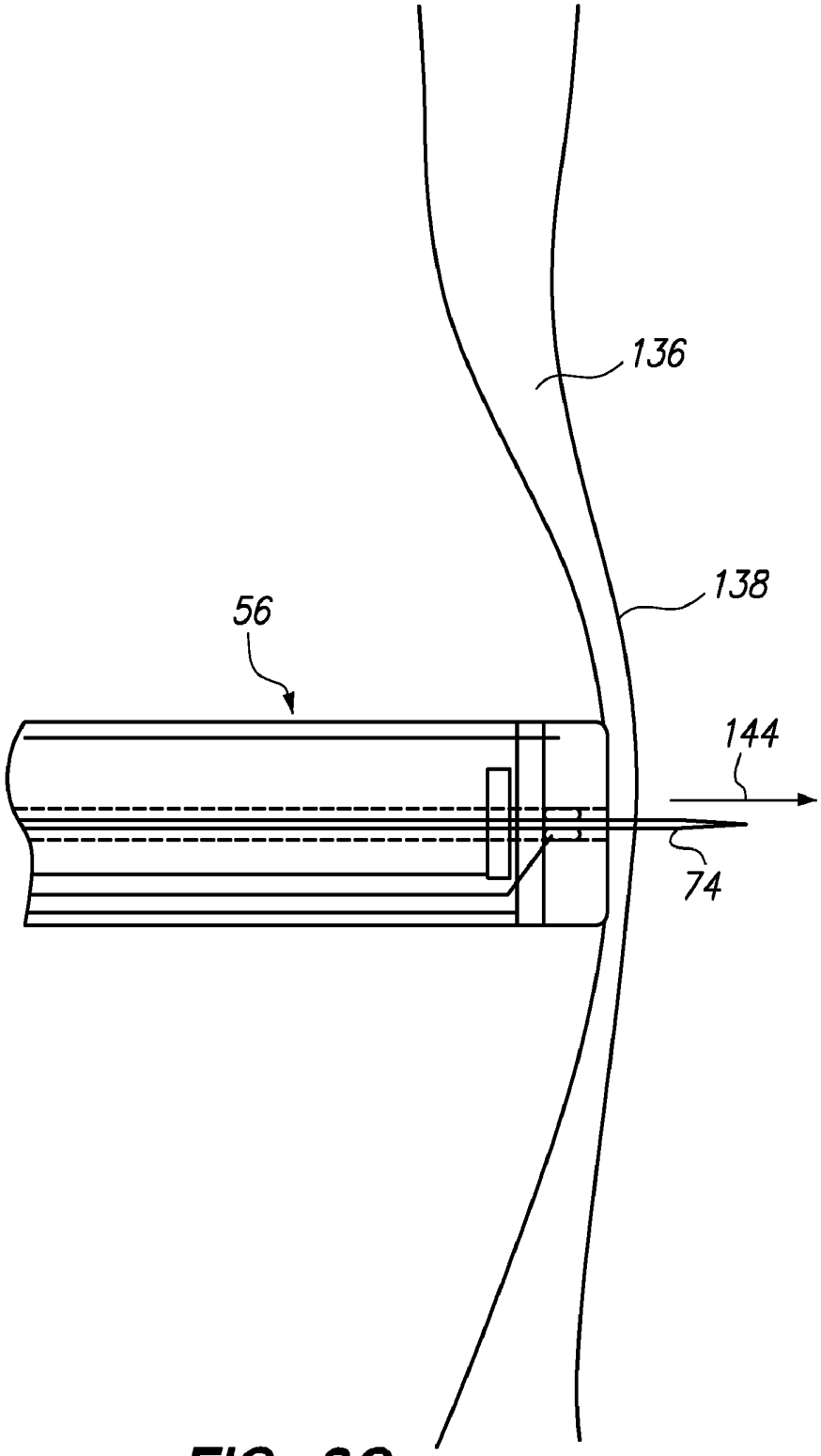

FIG. 8C

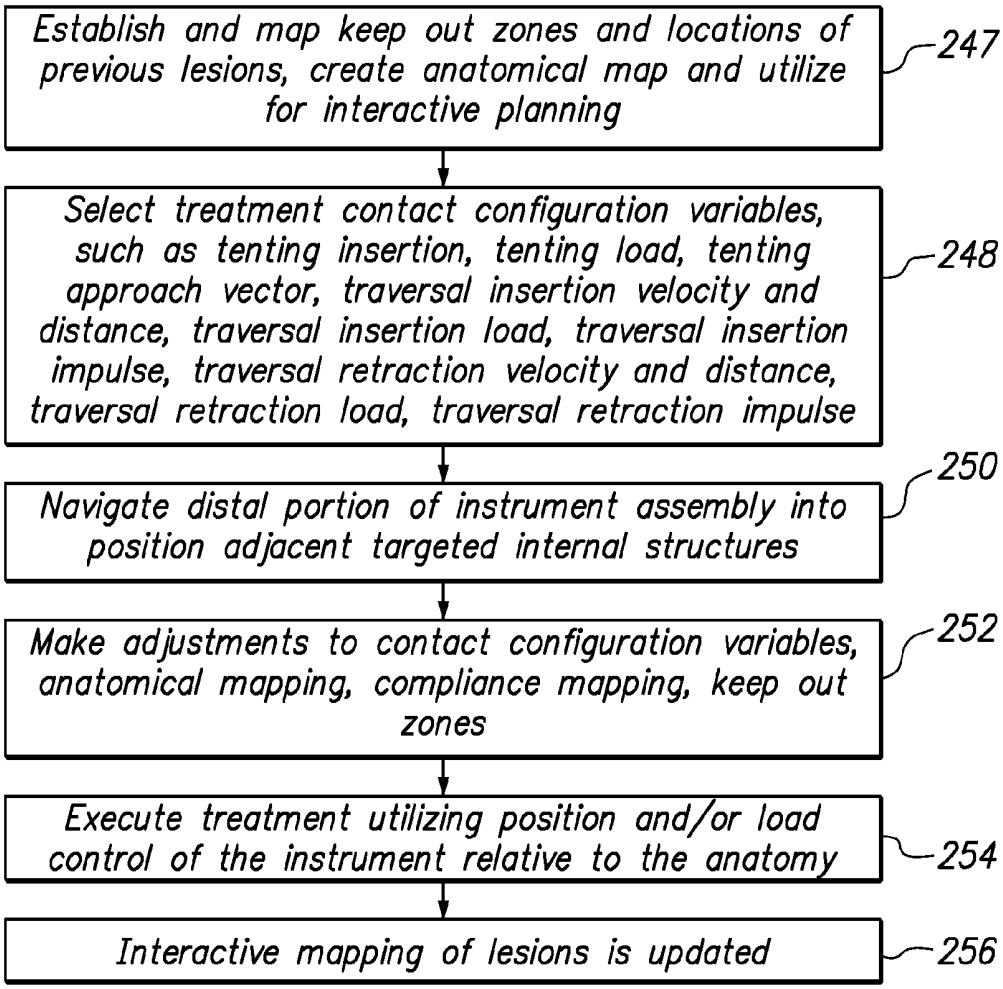
Establish and map keep out zones and locations of previous lesions, create anatomical map and utilize for interactive planning
247
Select treatment contact configuration variables, such as tenting insertion, tenting load, tenting approach vector, traversal insertion velocity and distance, traversal insertion load, traversal insertion impulse, traversal retraction velocity and distance, traversal retraction load, traversal retraction impulse
248
Navigate distal portion of instrument assembly into position adjacent targeted internal structures
250
Make adjustments to contact configuration variables, anatomical mapping, compliance mapping, keep out zones
252
Execute treatment utilizing position and/or load control of the instrument relative to the anatomy
254
Interactive mapping of lesions is updated
256

FIG. 9

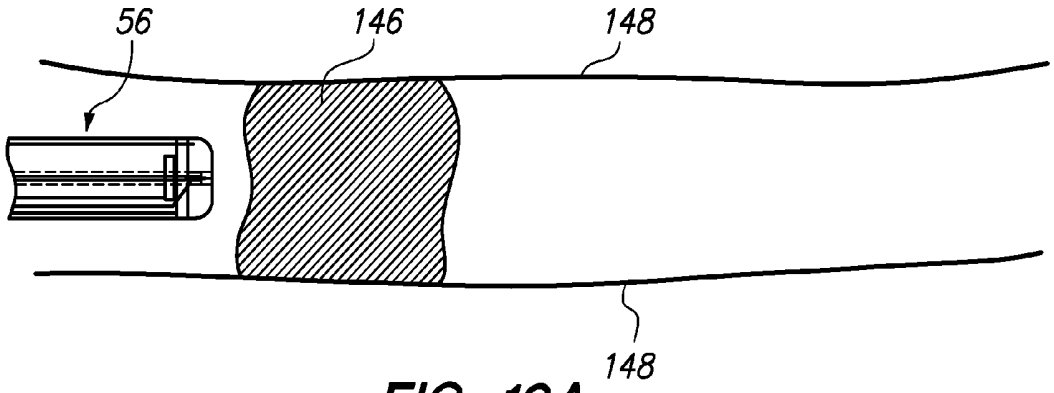

FIG. 10A

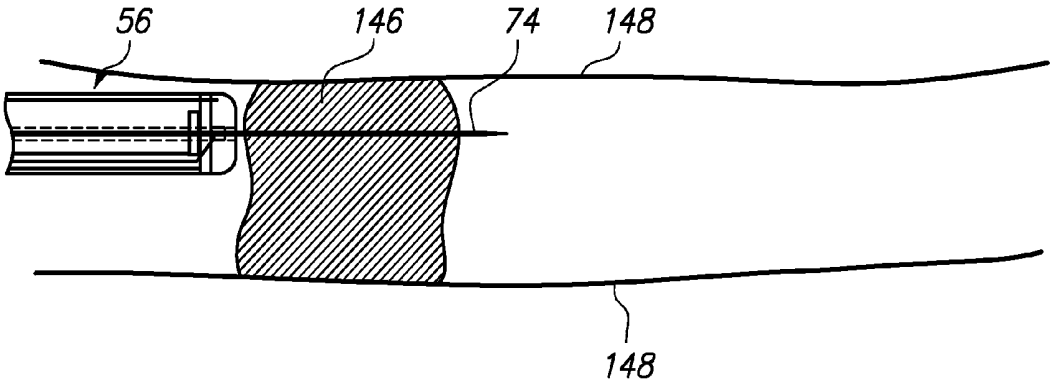

FIG. 10B

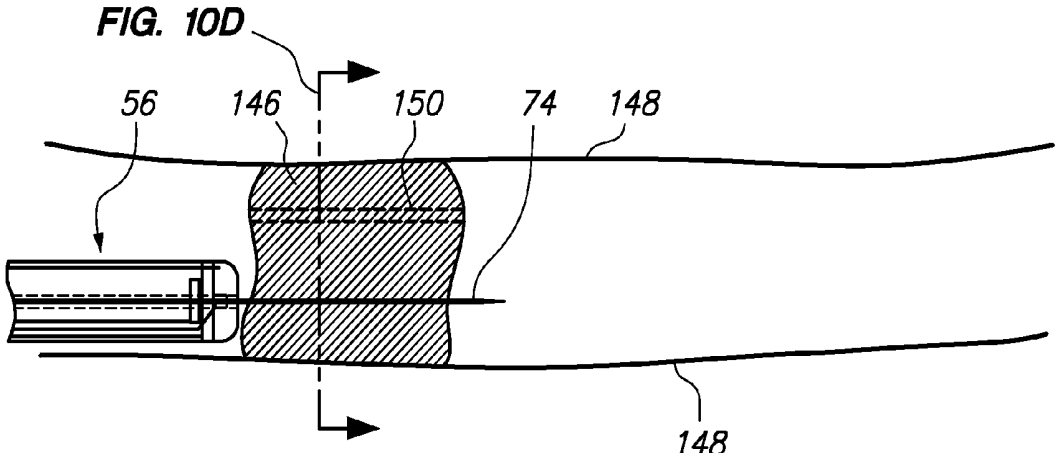

FIG. 10C

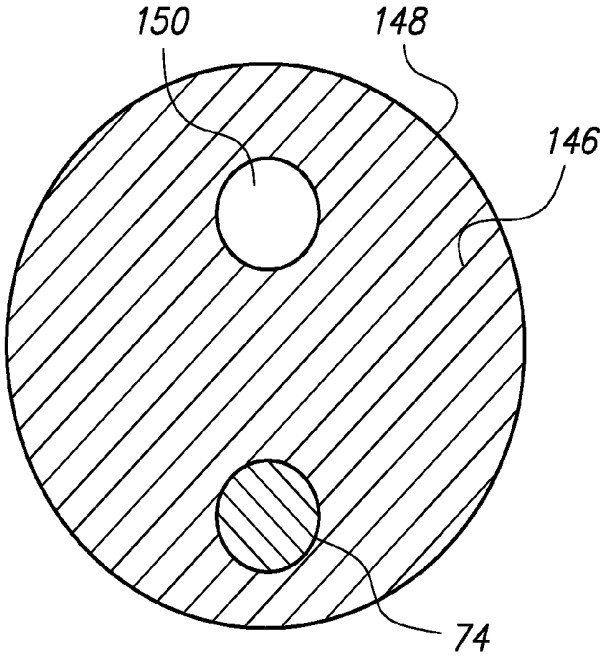

FIG. 10D

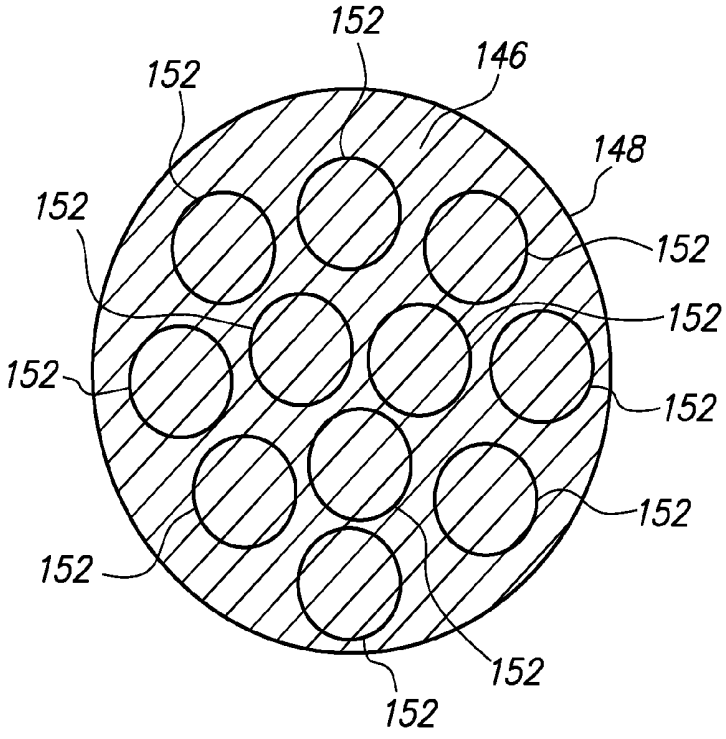

FIG. 10E

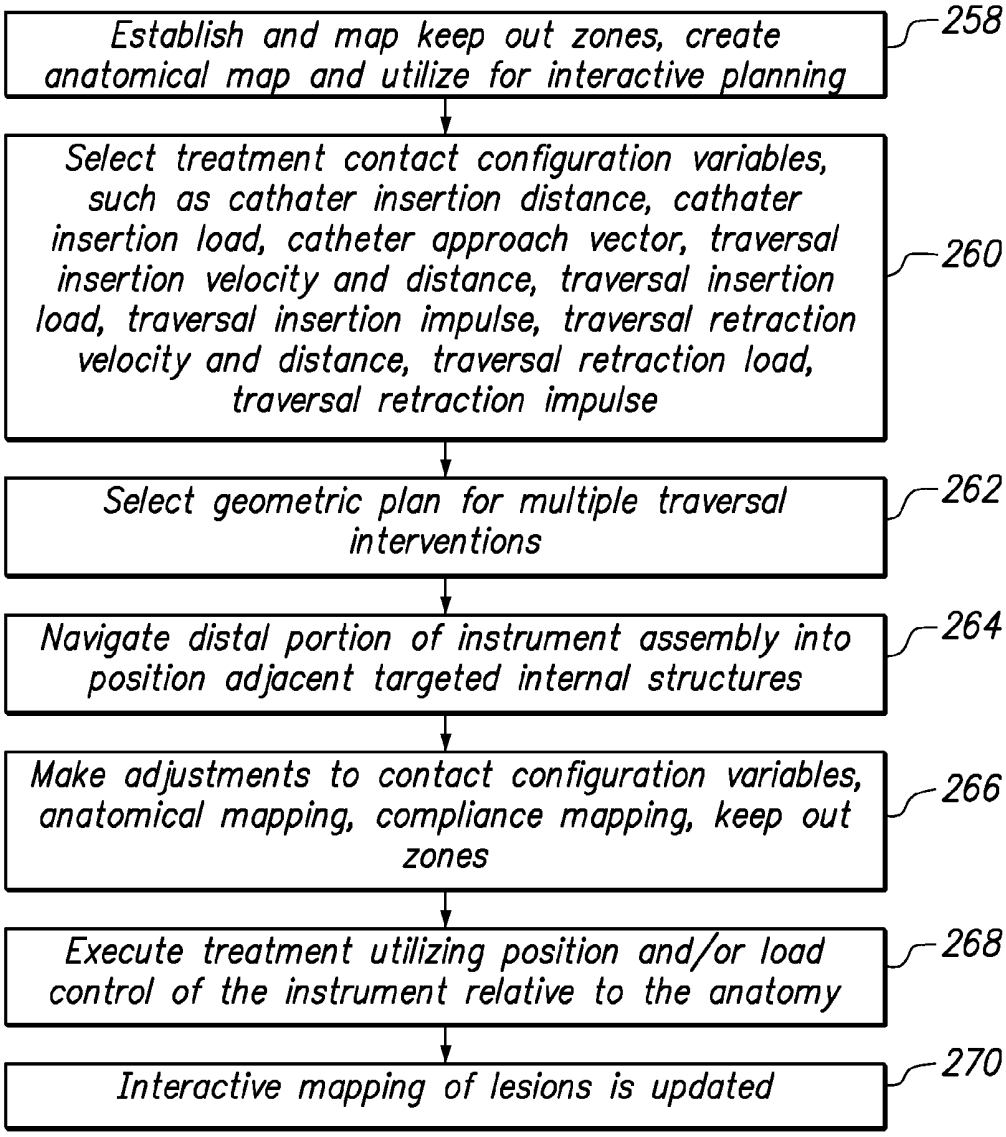
Establish and map keep out zones, create anatomical map and utilize for interactive planning
258
Select treatment contact configuration variables, such as cathater insertion distance, cathater insertion load, catheter approach vector, traversal insertion velocity and distance, traversal insertion load, traversal insertion impulse, traversal retraction velocity and distance, traversal retraction load, traversal retraction impulse
260
Select geometric plan for multiple traversal interventions
262
Navigate distal portion of instrument assembly into position adjacent targeted internal structures
264
Make adjustments to contact configuration variables, anatomical mapping, compliance mapping, keep out zones
266
Execute treatment utilizing position and/or load control of the instrument relative to the anatomy
268
Interactive mapping of lesions is updated
270

FIG. 11

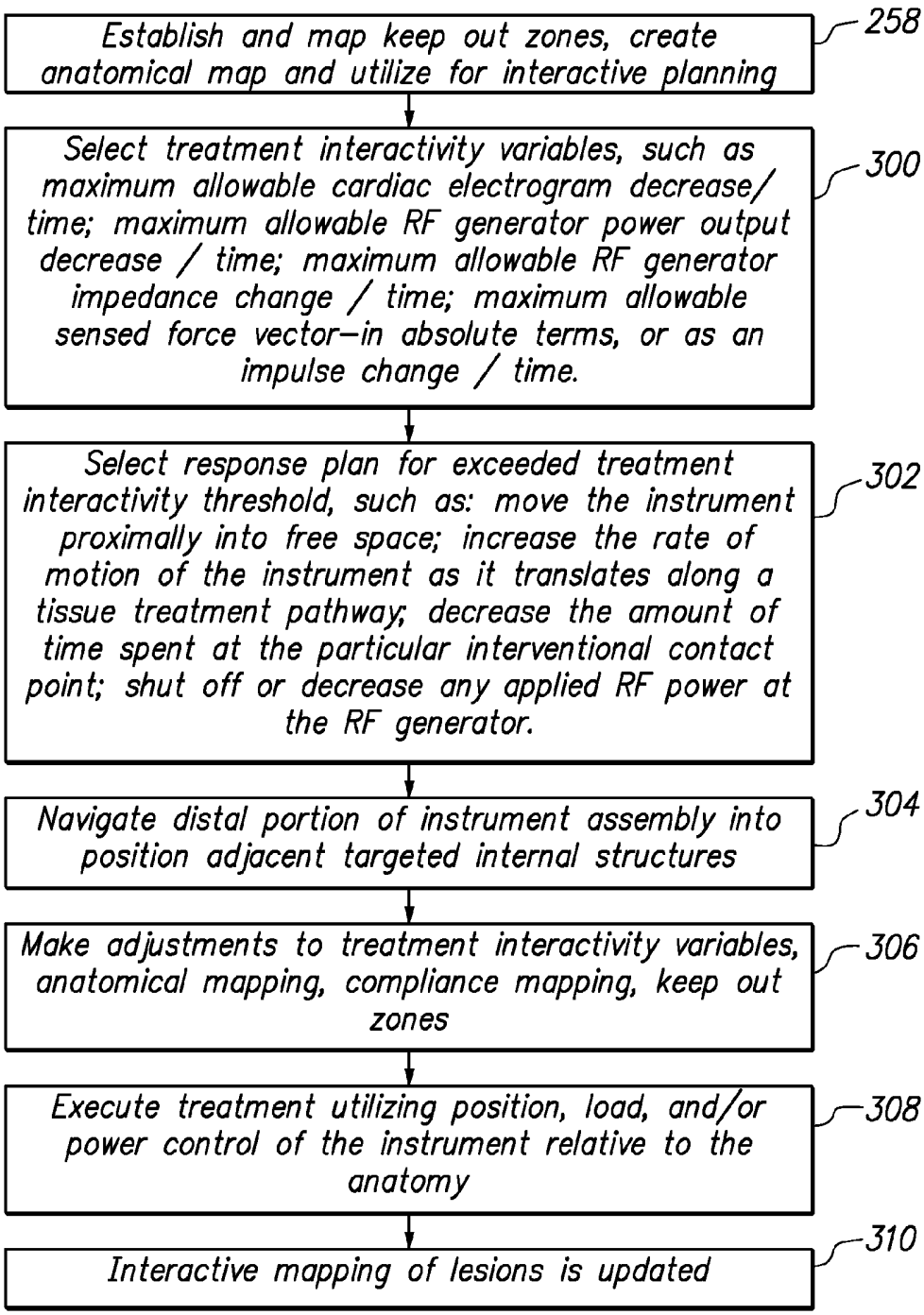
Establish and map keep out zones, create anatomical map and utilize for interactive planning
258
Select treatment interactivity variables, such as maximum allowable cardiac electrogram decrease/ time; maximum allowable RF generator power output decrease / time; maximum allowable RF generator impedance change / time; maximum allowable sensed force vector—in absolute terms, or as an impulse change / time.
300
Select response plan for exceeded treatment interactivity threshold, such as: move the instrument proximally into free space; increase the rate of motion of the instrument as it translates along a tissue treatment pathway; decrease the amount of time spent at the particular interventional contact point; shut off or decrease any applied RF power at the RF generator.
302
Navigate distal portion of instrument assembly into position adjacent targeted internal structures
304
Make adjustments to treatment interactivity variables, anatomical mapping, compliance mapping, keep out zones
306
Execute treatment utilizing position, load, and/or power control of the instrument relative to the anatomy
308
Interactive mapping of lesions is updated
310

FIG. 12

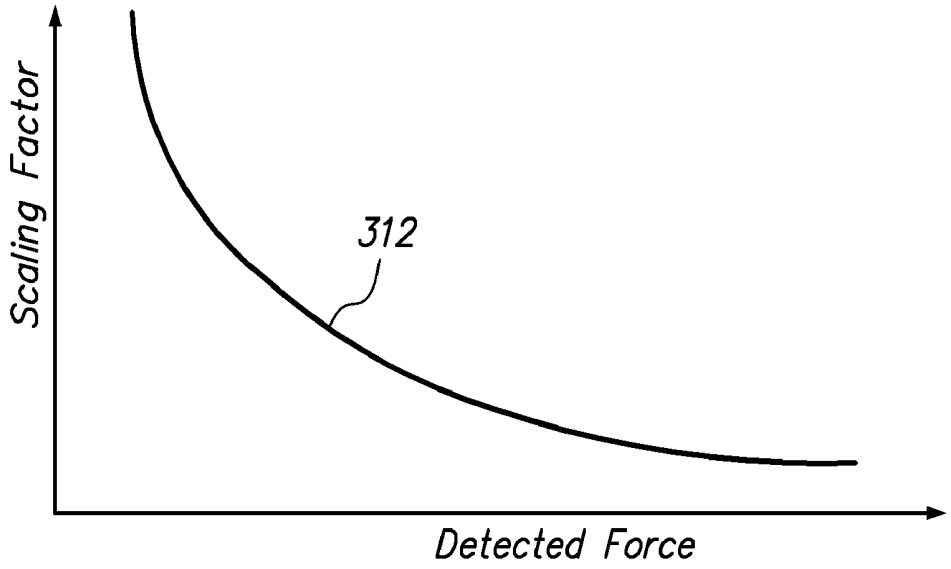

FIG. 13A

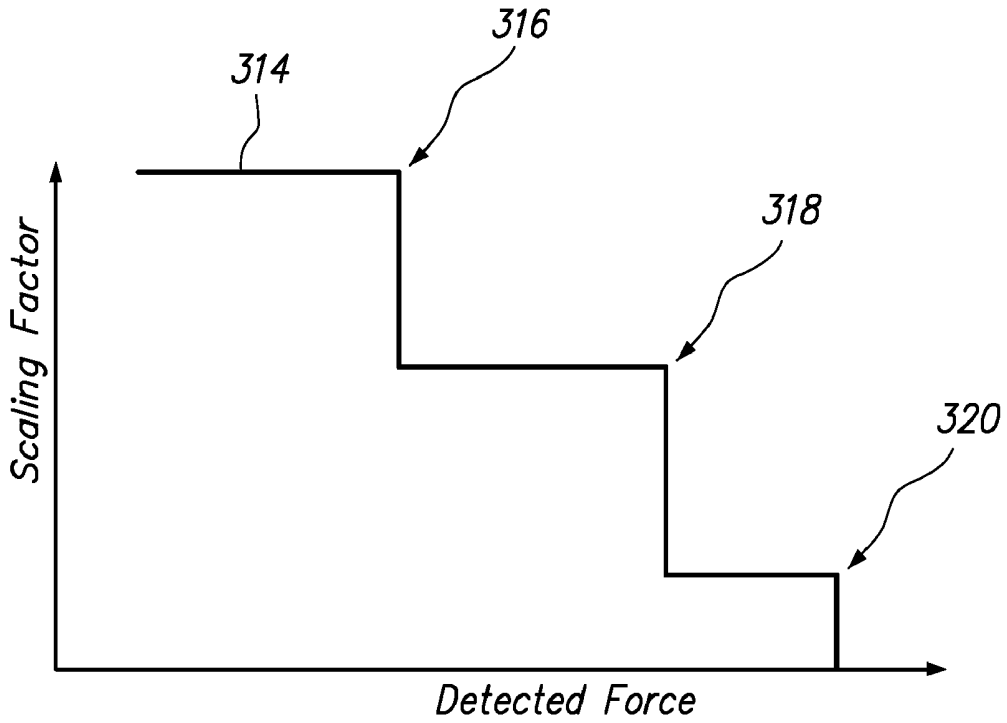

FIG. 13B

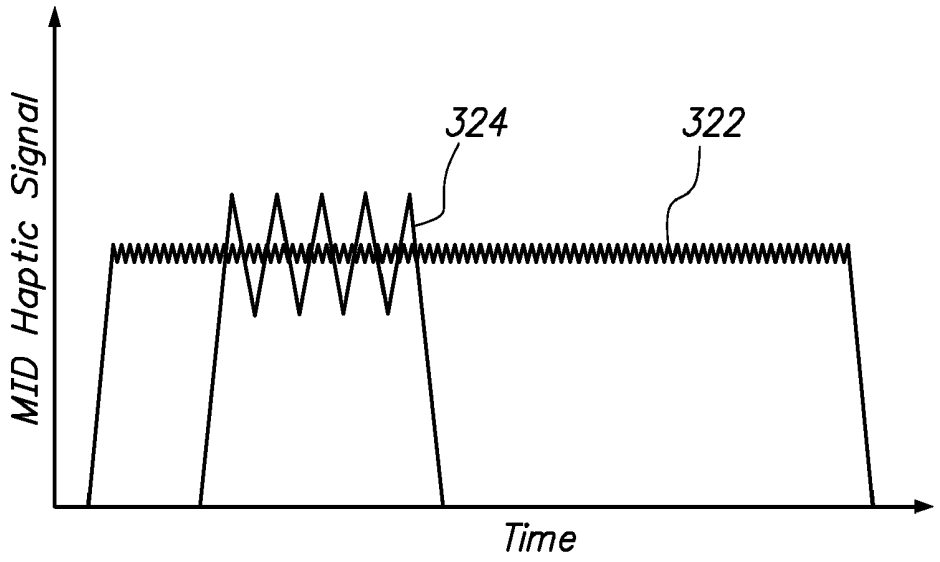

FIG. 14

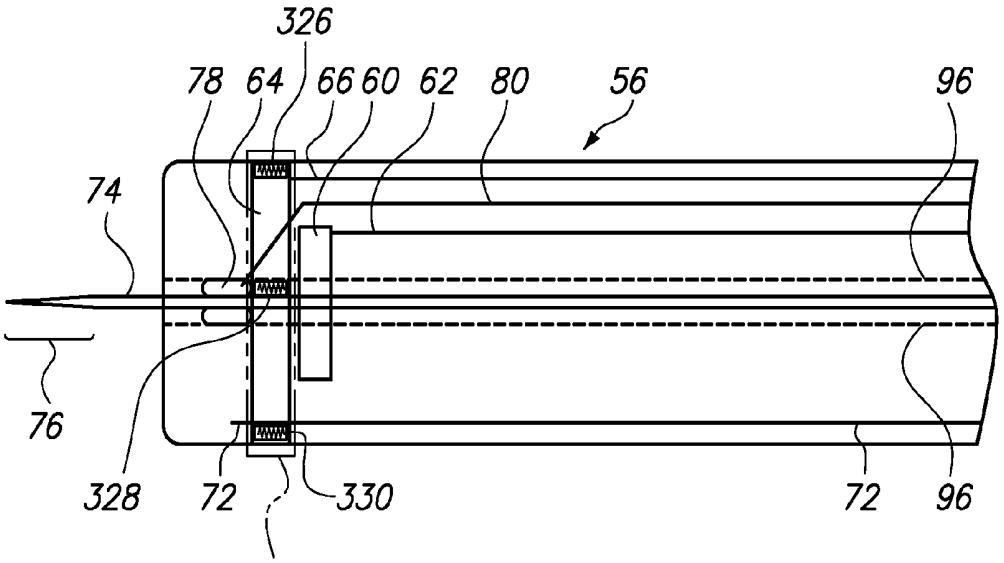

FIG. 15B

FIG. 15A

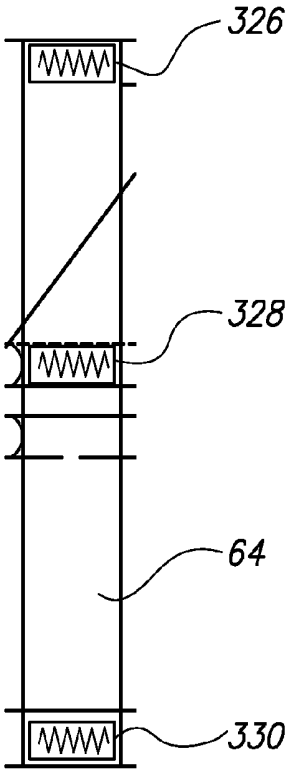

FIG. 15B

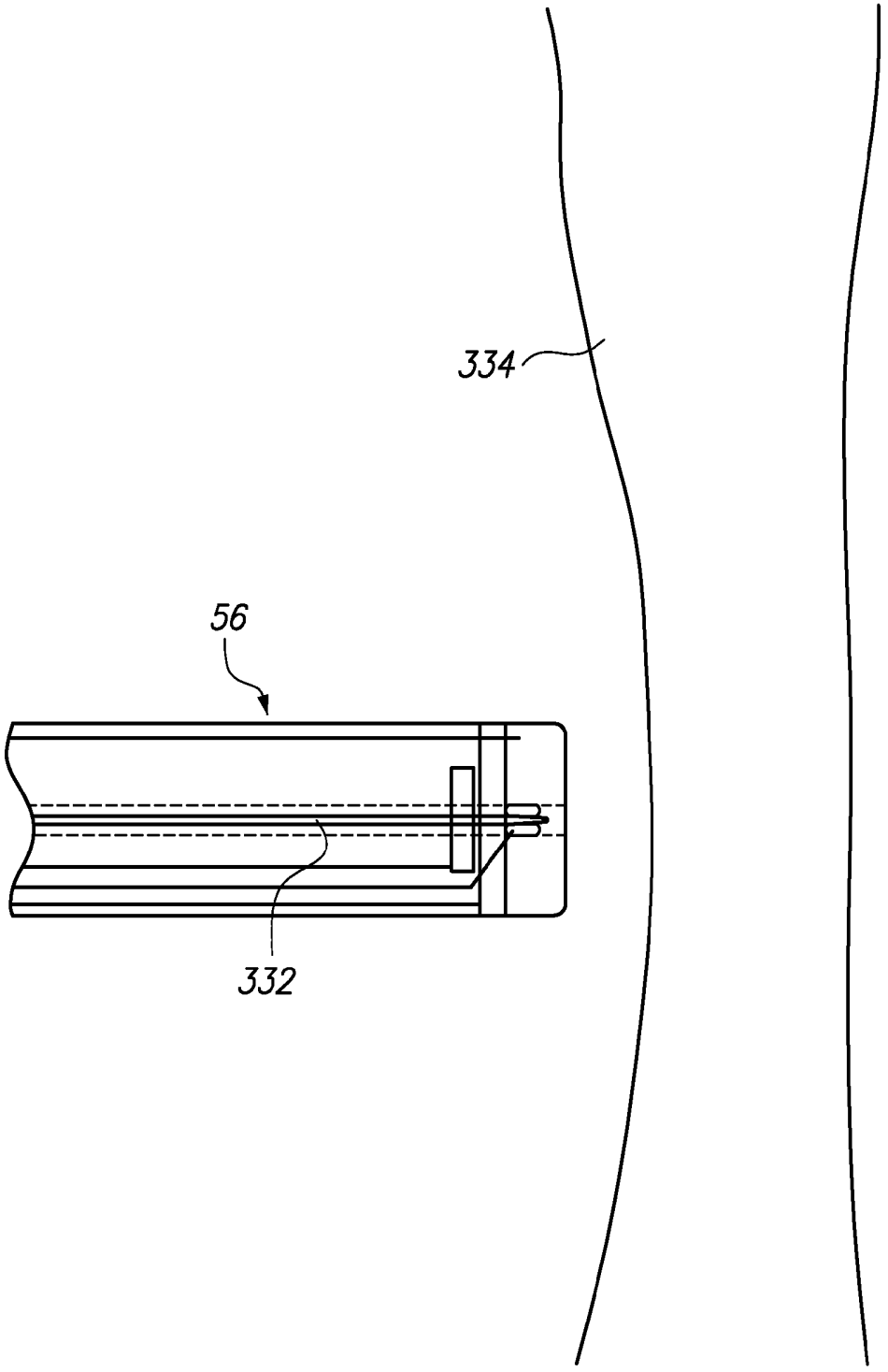

FIG. 16A

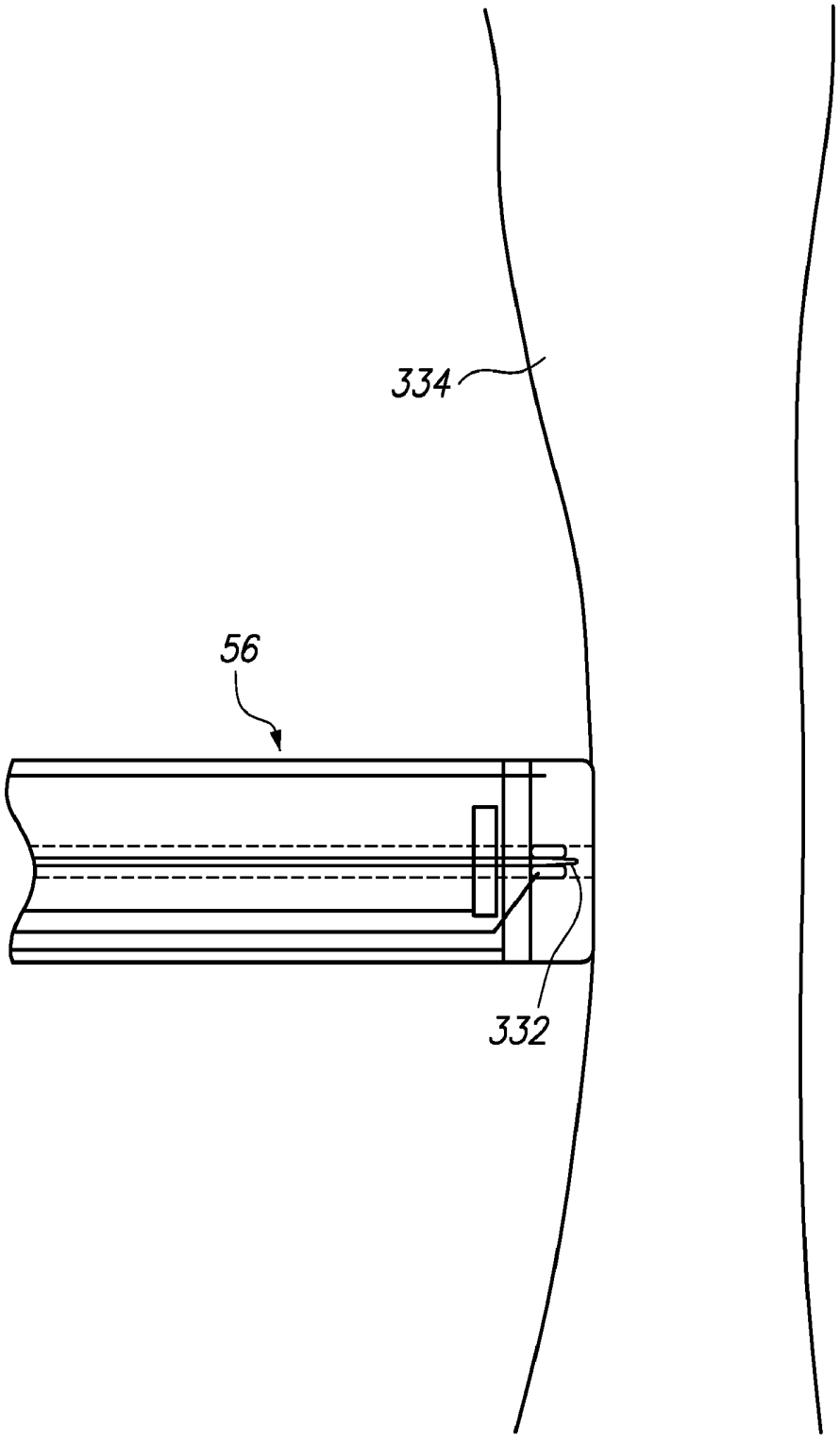

FIG. 16B

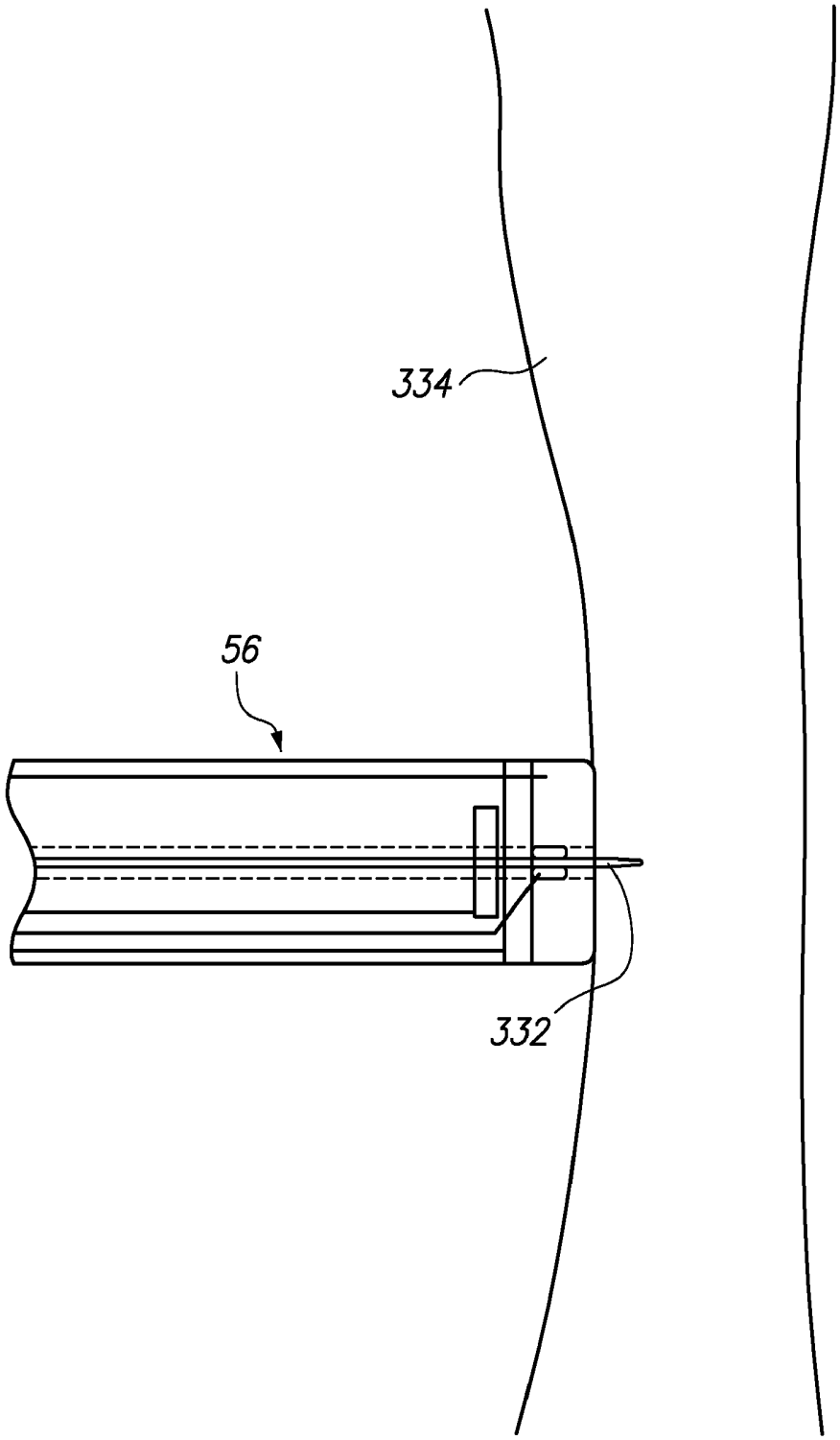

FIG. 16C

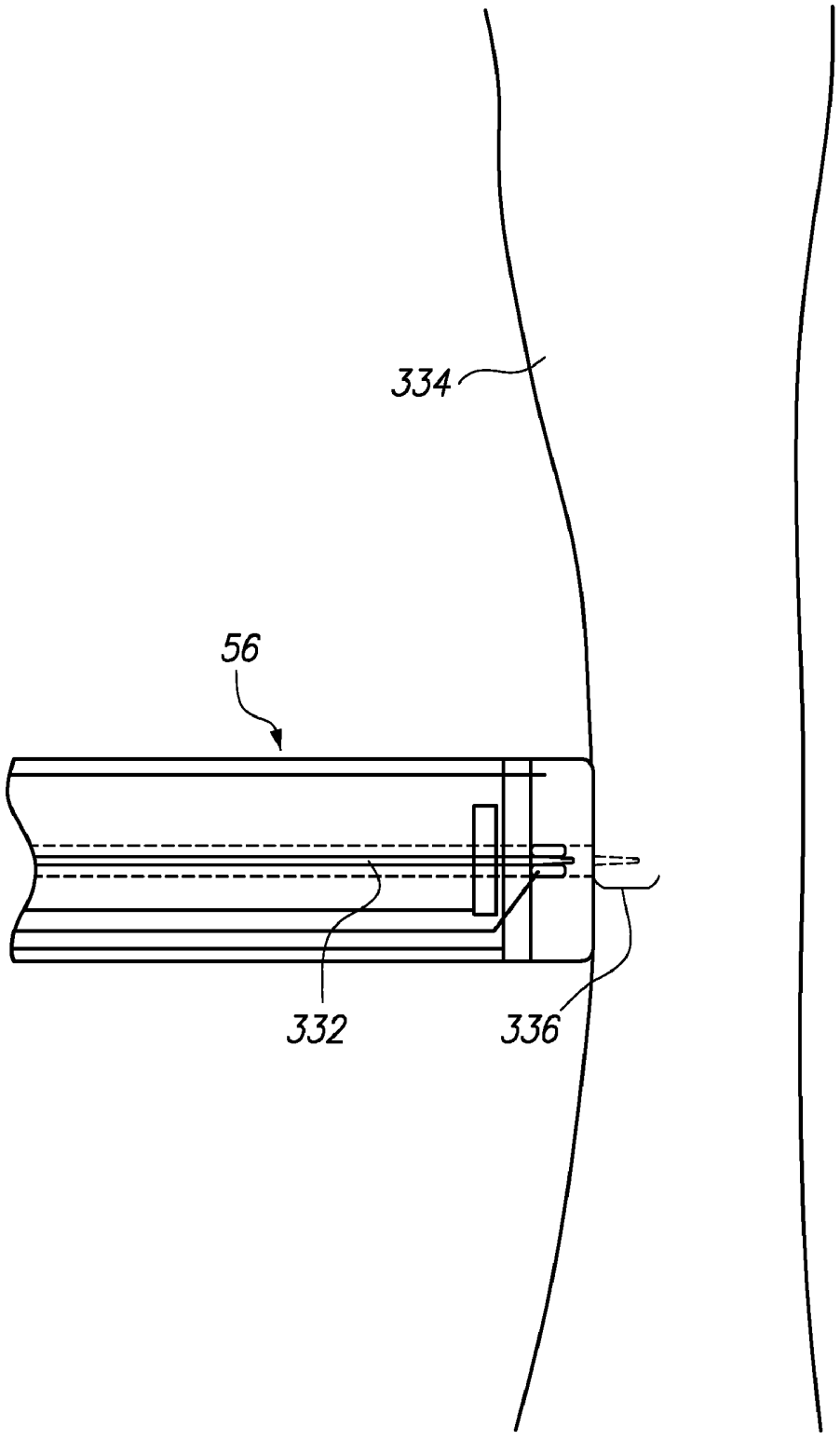

FIG. 16D

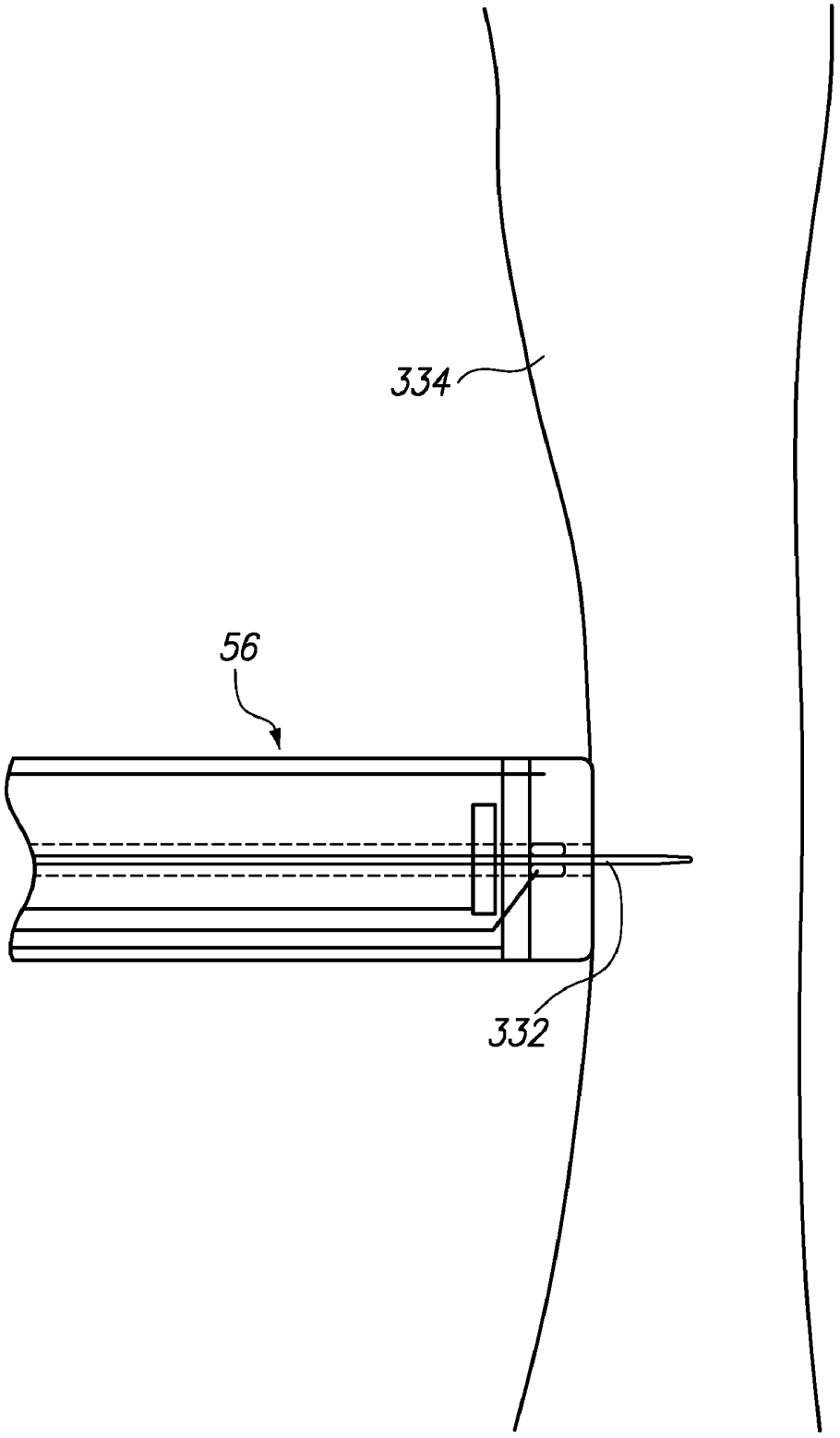

FIG. 16E

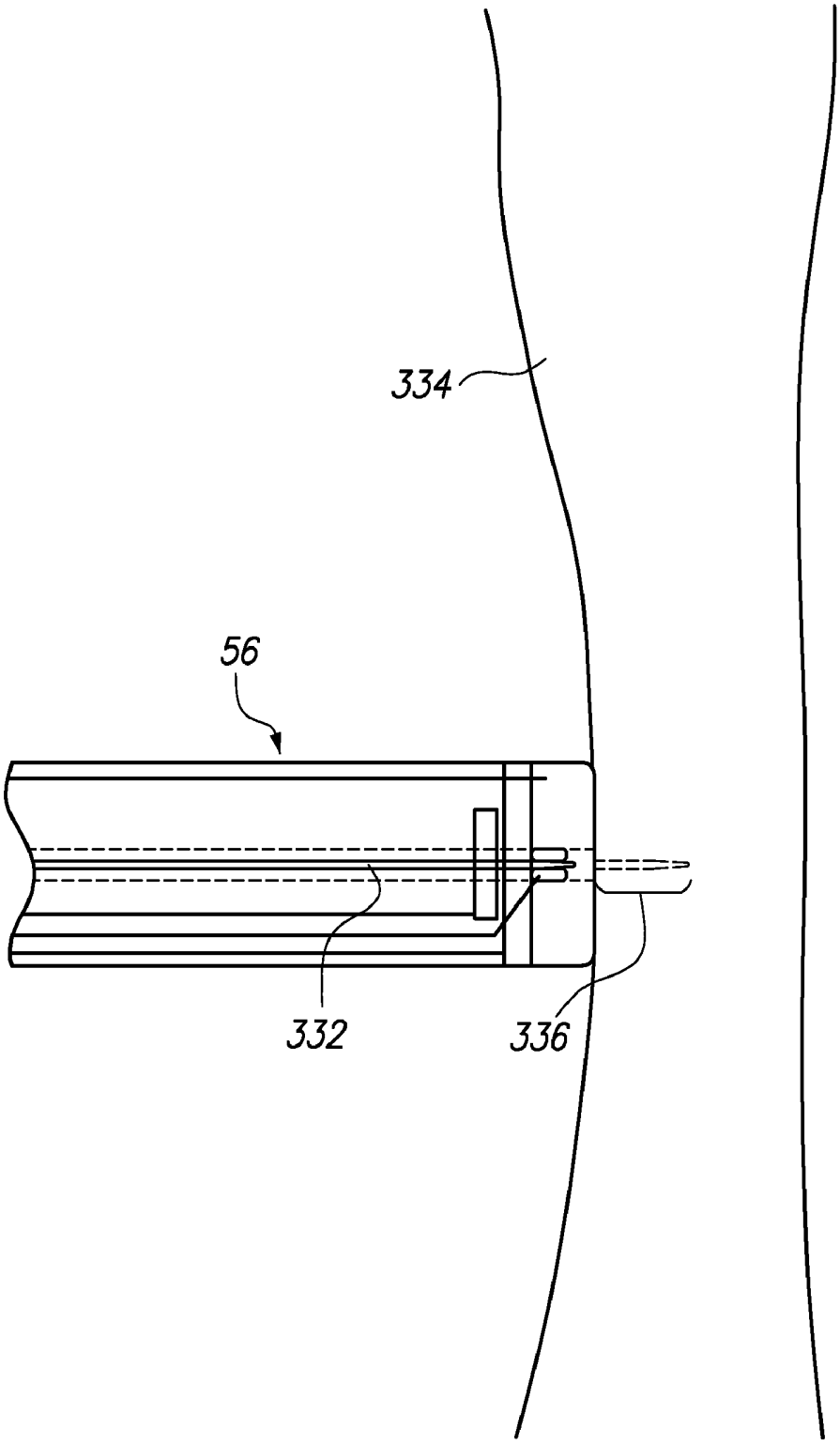

FIG. 16F

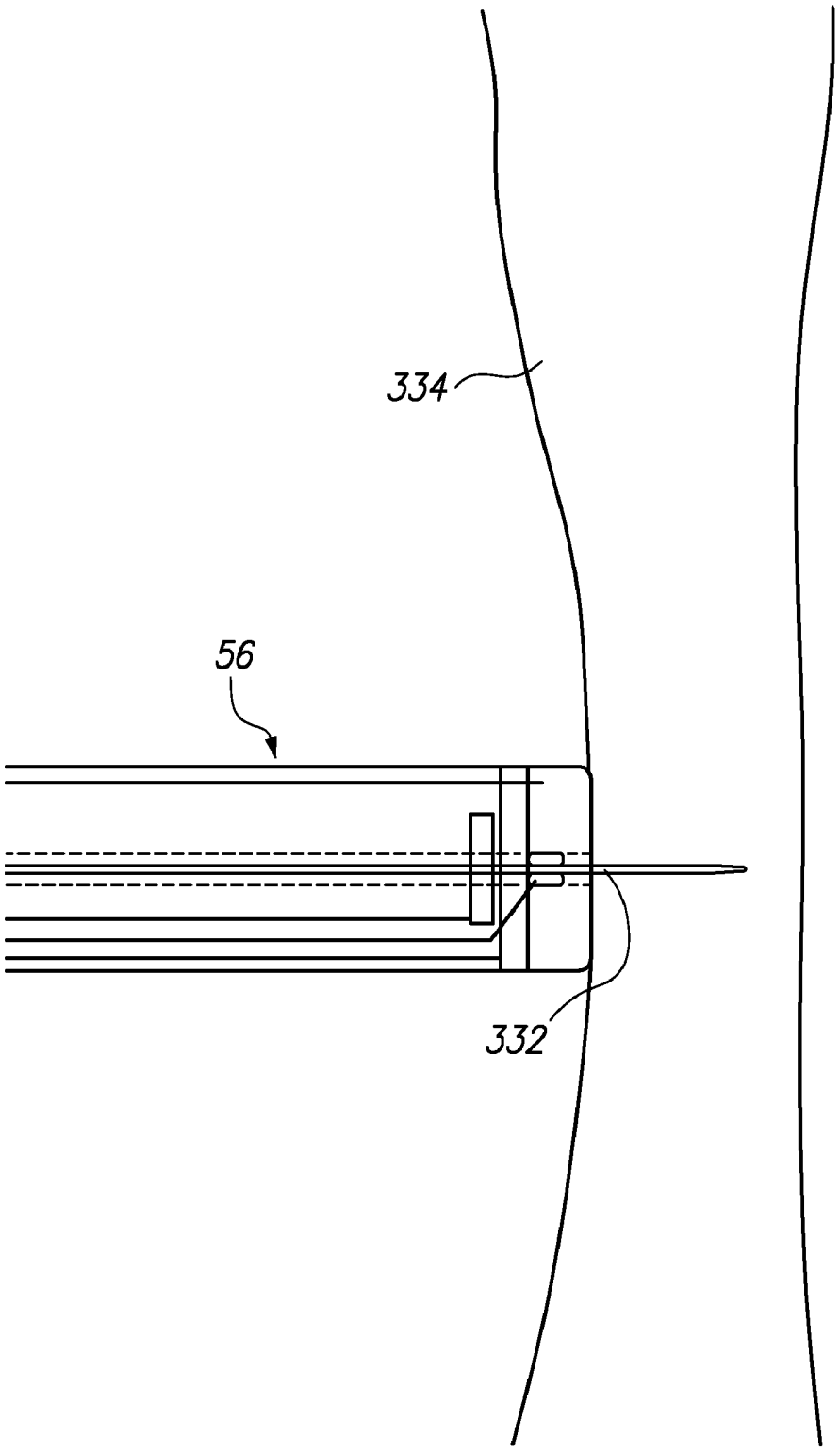

FIG. 16G

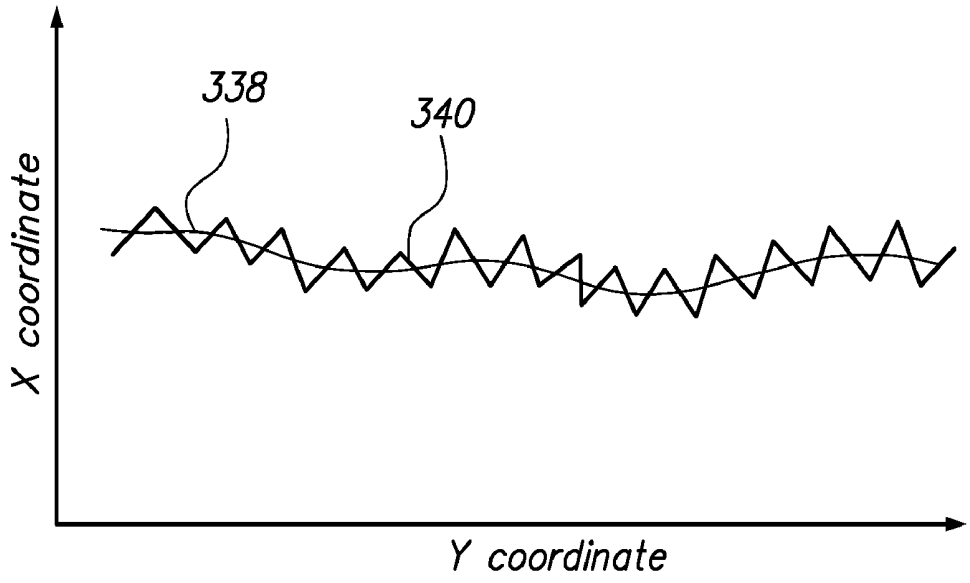

FIG. 17A

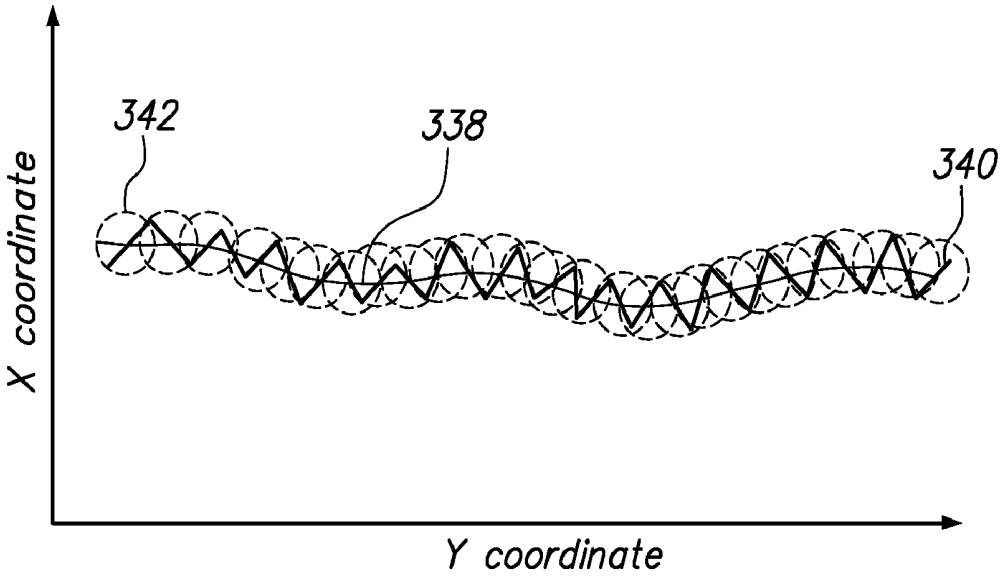

FIG. 17B

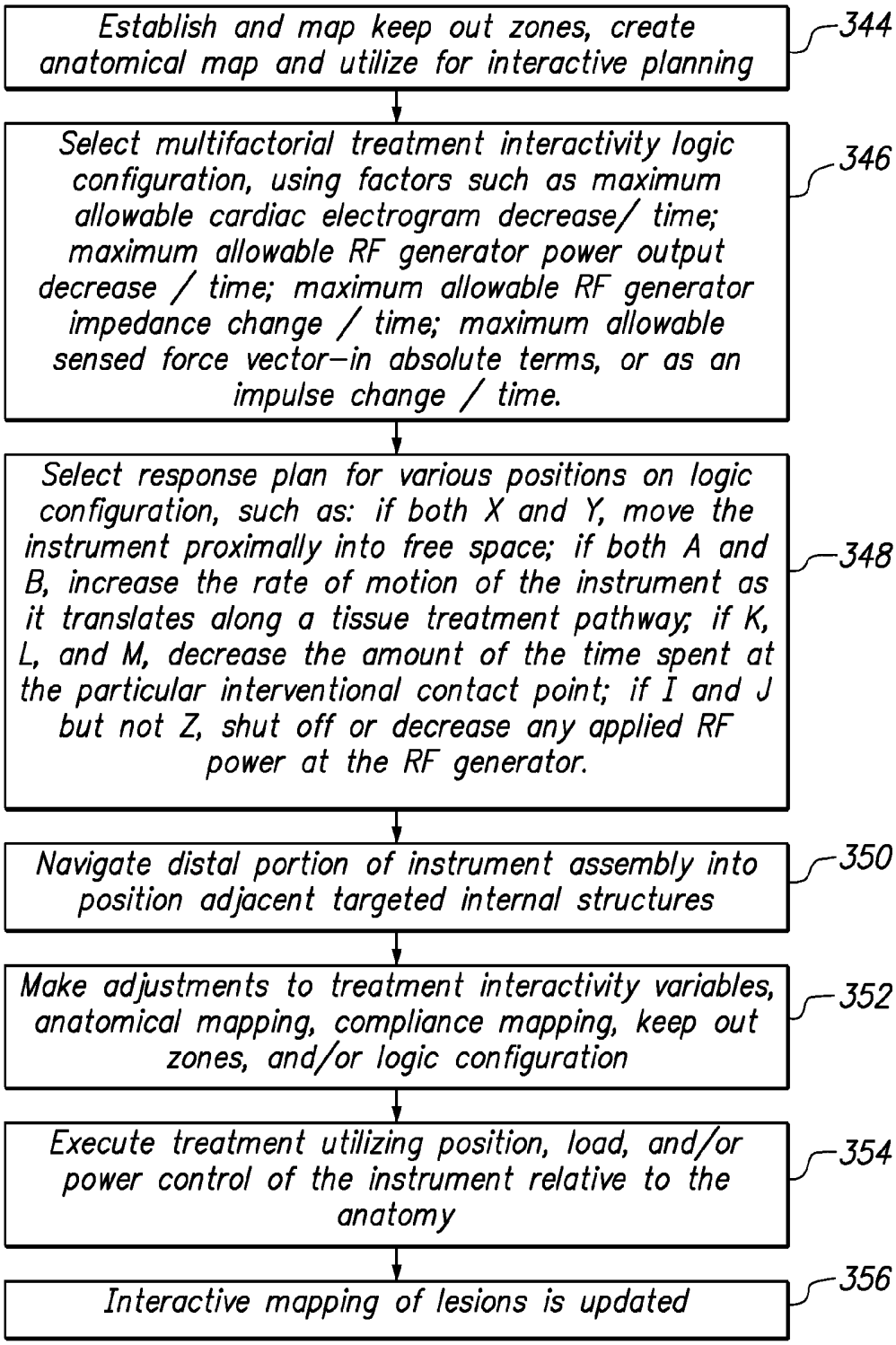
Establish and map keep out zones, create anatomical map and utilize for interactive planning
344
Select multifactorial treatment interactivity logic configuration, using factors such as maximum allowable cardiac electrogram decrease/ time; maximum allowable RF generator power output decrease / time; maximum allowable RF generator impedance change / time; maximum allowable sensed force vector—in absolute terms, or as an impulse change / time.
346
Select response plan for various positions on logic configuration, such as: if both X and Y, move the instrument proximally into free space; if both A and B, increase the rate of motion of the instrument as it translates along a tissue treatment pathway; if K, L, and M, decrease the amount of the time spent at the particular interventional contact point; if I and J but not Z, shut off or decrease any applied RF power at the RF generator.
348
Navigate distal portion of instrument assembly into position adjacent targeted internal structures
350
Make adjustments to treatment interactivity variables, anatomical mapping, compliance mapping, keep out zones, and/or logic configuration
352
Execute treatment utilizing position, load, and/or power control of the instrument relative to the anatomy
354
Interactive mapping of lesions is updated
356

FIG. 18

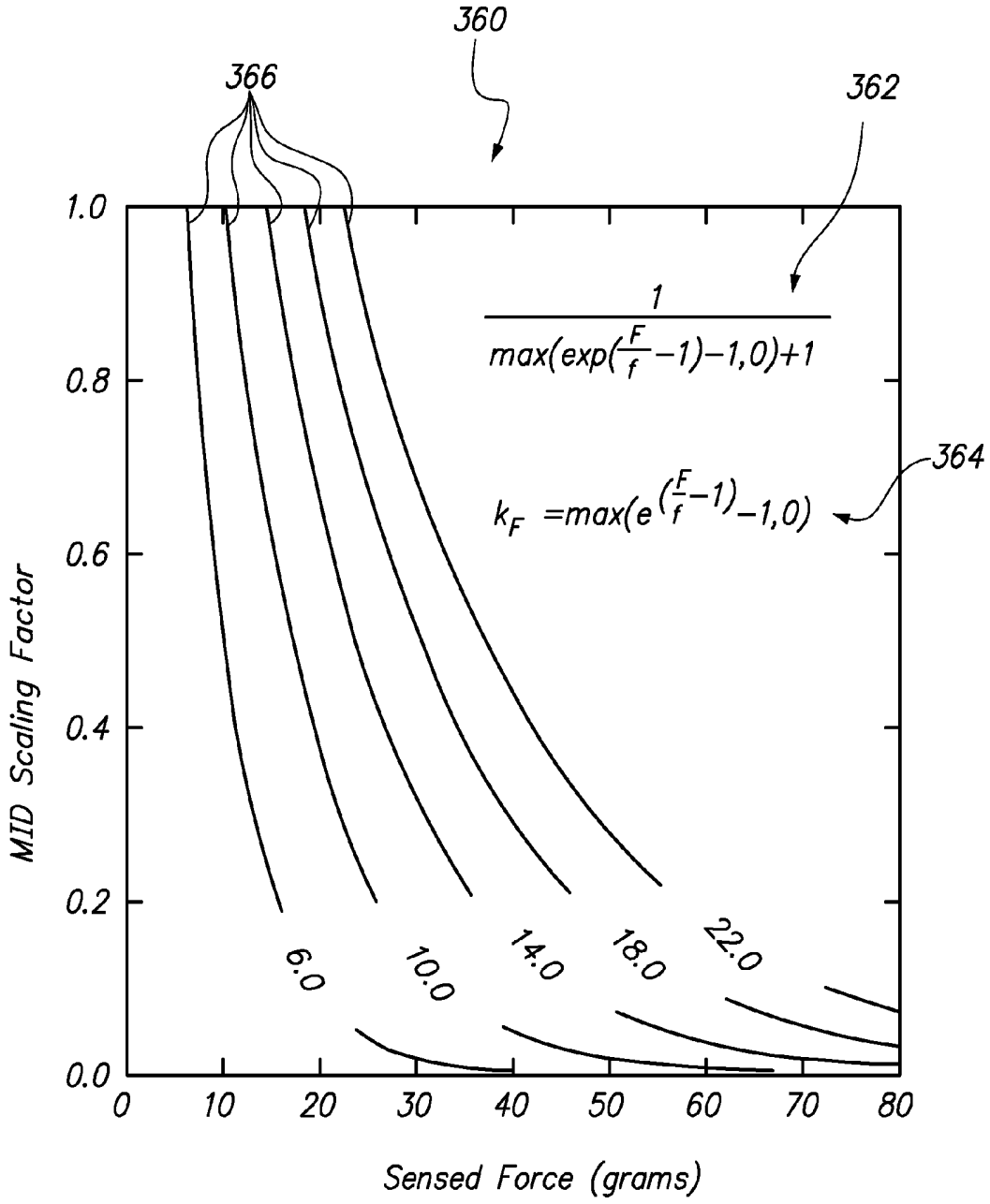
360
366
362
364
1.0
0.8
0.6
0.4
0.2
0.0
MID Scaling Factor
$\frac{1}{\max(\exp(\frac{F}{f}-1)-1,0)+1}$
$k_F = \max(e^{(\frac{F}{f}-1)}-1,0)$
6.0
10.0
14.0
18.0
22.0
0
10
20
30
40
50
60
70
80
Sensed Force (grams)

FIG. 19A

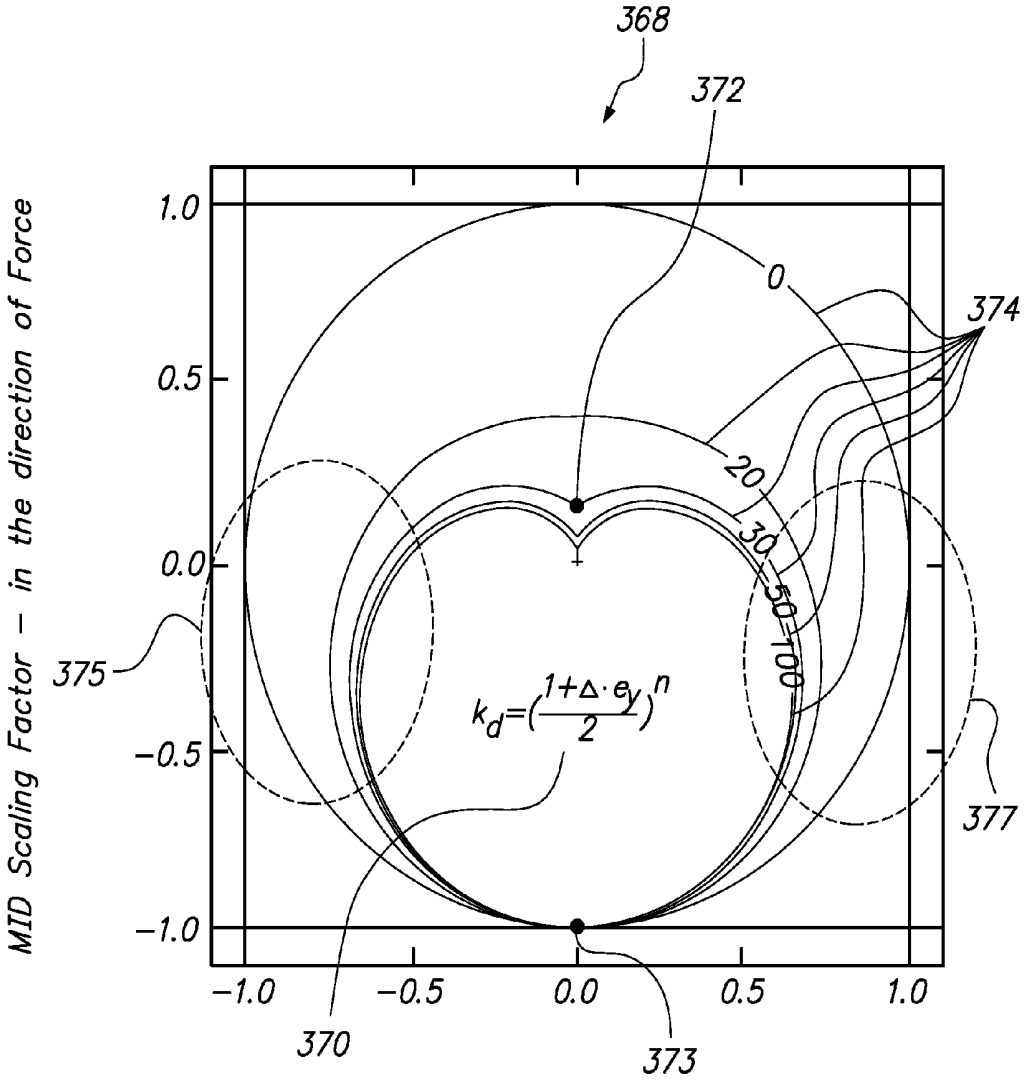
368
372
374
375
377
370
373
0
20
30
50
100
1.0
0.5
0.0
−0.5
−1.0
−1.0
−0.5
0.0
0.5
1.0
$k_d=(\frac{1+\Delta\cdot e_y}{2})^n$
MID Scaling Factor – in the direction of Force
MID Scaling Factor – in the direction orthogonal to Force

FIG. 19B

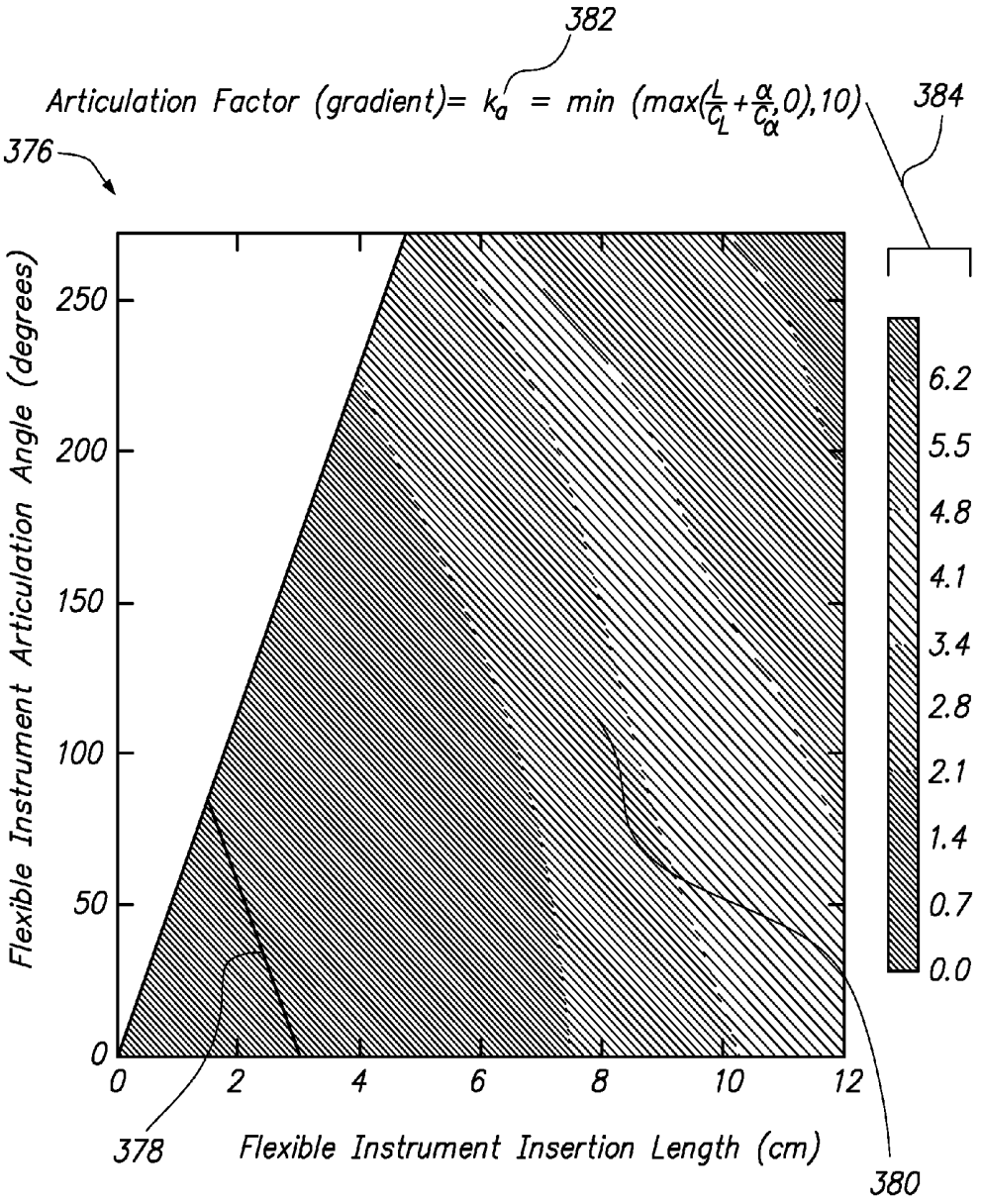
382
Articulation Factor (gradient)= k_a = min (max($\frac{L}{C_L}+\frac{\alpha}{C_\alpha}$,0),10)
384
376
Flexible Instrument Articulation Angle (degrees)
250
200
150
100
50
0
0
2
4
6
8
10
12
Flexible Instrument Insertion Length (cm)
6.2
5.5
4.8
4.1
3.4
2.8
2.1
1.4
0.7
0.0
378
380

FIG. 19C

SYSTEM AND METHOD FOR AUTOMATED TISSUE STRUCTURE TRAVERSAL

RELATED APPLICATION DATA

[0001] The present application claims the benefit under 35 U.S.C. §119 to U.S. Provisional Patent application Ser. No. 61/349,690, filed May 28, 2010. The foregoing application is hereby incorporated by reference into the present application in its entirety.

[0002] The present application is also related to application Ser. Nos. _____ (Attorney Docket No. HNMD-20072.01), _____ (Attorney Docket No. HNMD-20072.02), and _____ (Attorney Docket No. HNMD-20072.03), all of which are filed on the same date herewith. The disclosures of the foregoing applications are expressly incorporated herein by reference.

FIELD OF THE INVENTION

[0003] The invention relates generally to the minimally invasive medical techniques, and more particularly to the automation of certain aspects of therapeutic treatments using instruments such as electromechanically or robotically operated catheters.

BACKGROUND

[0004] Elongate medical instruments, such as catheters, are utilized in many types of medical interventions. Many such instruments are utilized in what have become known as "minimally invasive" diagnostic and interventional procedures, wherein small percutaneous incisions or natural orifices or utilized as entry points for instruments generally having minimized cross sectional profiles, to mitigate tissue trauma and enable access to and through small tissue structures. One of the challenges associated with minimizing the geometric constraints is retaining functionality and controllability. For example, some minimally invasive instruments designed to access the cavities of the blood vessels and/or heart have steerable distal portions or steerable distal tips, but may be relatively challenging to navigate through tortuous vascular pathways with varied tissue structure terrain due to their inherent compliance. Even smaller instruments, such as guidewires or distal protection devices for certain vascular and other interventions, may be difficult to position due to their relatively minimal navigation degrees of freedom from a proximal location, and the tortuous pathways through which operators attempt to navigate them. To provide additional navigation and operational functionality options for minimally invasive interventions, it is useful to have an instrument platform that may be remotely manipulated with precision, such as the robotic catheter system available from Hansen Medical, Inc. under the tradename Sensei™. It would be useful to have variations of such a platform that are configured for not only providing a navigable platform as an instrument or stepping off point for another associated instrument, but also configured to automate certain aspects of procedures of interest, such as RF ablation procedures, transseptal puncture or crossing procedures, and chronic total occlusion procedures.

SUMMARY

[0005] One embodiment is directed to a robotic medical patient structure traversal system comprising a controller including a master input device; an electromechanically controlled elongate instrument having a proximal interface portion and a distal portion, the proximal interface portion being configured to be operatively coupled to an electromechanical instrument driver in communication with the controller, the distal portion comprising a traversing tip and being configured to be interactively navigated about internal structures of a patient's body in response to signals from the controller; and a load sensor operatively coupled between the distal portion of the elongate instrument and the controller; wherein the controller is configured to automatically advance the traversing tip through a thickness of an internal structure by observing loads from the load sensor. The controller may be configured to stop advancing the traversing tip when a relative decrease in load observed with the load sensor is detected, indicating that the traversing tip has completed a traversal of at least a portion of the thickness of the internal structure. The elongate instrument may comprise a steerable catheter instrument movably coupled to an advanceable needle instrument comprising the traversing tip. The load sensor my be coupled to the distal portion and in electrical communication with the controller via a lead running proximally along the elongate instrument. The load sensor may be coupled to the traversing tip. The load sensor may be proximally coupled between the steerable catheter and the advanceable needle instrument. The traversing tip may comprise a scalpel. The distal portion may further comprise a traversal depth detector operatively coupled to the controller and configured to detect a depth to which the traversing tip has been protruded into the internal structure. The traversal depth detector may comprise a follower member coupled to the proximal portion of the scalpel and configured to remain at a surface of the internal structure as the scalpel traverses past such surface into said internal structure. The traversal depth detector may comprise a scalpel surface contact sensor configured to measure directly how much of the surface of the scalpel is encapsulated by the internal structure being traversed. The traversal depth detector may comprise a signal reflection based proximity sensor configured to determine how much of the scalpel is protruding into the internal structure relative to a detected position of a surface of the internal structure. The follower member may comprise a collar movably coupled about the scalpel. The follower member may comprise a bendable elongate member, and the depth detector may comprise a sensor configured to determine the amount of bend imparted to the bendable elongate member. The follower member may comprise a substantially rigid member rotatable relative to the scalpel, wherein the depth detector comprises a sensor configured to determine the amount of rotation imparted to the substantially rigid member. The internal structure may be a vascular plaque occluding at least a portion of a blood vessel of the patient, and the traversing tip may comprise an elongate flexible wire. The elongate flexible wire may comprise a tapered distal portion configured for insertion into and traversal of the vascular plaque. The controller may be configured to insert the elongate flexible wire across a full thickness of the vascular plaque in first insertion location, and to utilize data from an acquired medical image of the patient to automatically determine a trajectory for another insertion across another full thickness of the vascular plaque. The controller may be configured to repeatedly insert the elongate flexible wire across different trajectories through the vascular plaque until the vascular plaque is substantially mechanically disrupted, while tissue comprising a surrounding vessel remains intact.

[0006] Another embodiment is directed to a method of controllably traversing an internal structure of a patient, comprising: approaching a surface of an internal structure with a distal portion of an electromechanically controlled elongate instrument, the distal portion comprising a traversing tip configured to traverse at least a portion of a targeted internal structure; selecting a contact point and trajectory for traversing at least a portion of said internal structure with the traversing tip; controllably inserting at least a portion of the traversing tip into the internal structure while detecting loads imparted to the traversing tip by adjacent internal structures; and limiting the extent of insertion of the traversing tip based at least in part upon the loads detected. The method may further comprise stopping inserting of the traversing tip when a relative decrease in load is observed with the load sensor, indicating that the traversing tip has completed a traversal of at least a portion of the thickness of the internal structure. The method may further comprise observing the position of the distal portion of the elongate instrument relative to the targeted internal structure utilizing a medical imaging modality selected from the group consisting of: fluoroscopy, ultrasound, endoscopy, infrared imaging, and direct optical visualization. The method may further comprise simulating the position of the distal portion of the elongate instrument relative to the targeted internal structure utilizing models of the distal portion and targeted internal structure, wherein at least the model of the targeted internal structure is based at least in part upon a previously acquired medical image. The targeted internal structure may be a septal wall of the heart of the patient, and insertion of the traversing tip may be at least temporarily stopped subsequent to a drop in detected load indicative that the traversing tip has completely traversed the septal wall. The method may further comprise detecting traversing tip insertion depth into the targeted internal structure with a local depth detector. Detecting traversing tip insertion depth may comprise detecting movement or deflection of a follower member configured to remain at a surface of the internal structure as the traversing tip passes such surface into said internal structure. Detecting traversing tip insertion depth may comprise detecting traversing tip encapsulation with a surface contact sensor. Detecting traversing tip insertion depth may comprise detecting movement or deflection of a follower member configured to remain at a surface of the internal structure as the traversing tip passes such surface into said internal structure. Detecting traversing tip insertion depth may comprise detecting a signal reflected from a surface of the internal structure. The targeted internal structure may be a vascular plaque within a vessel of the patient, and inserting the traversing tip may comprise inserting a portion of an elongate flexible wire. The method may further comprise inserting the elongate flexible wire portion across a full thickness of the vascular plaque, retracting the elongate flexible wire portion, and utilizing data from an acquired medical image of the patient to automatically determine a trajectory for another insertion across another full thickness of the vascular plaque. A computerized controller may be configured to repeatedly insert the elongate flexible wire portion across different trajectories through the vascular plaque until the vascular plaque is substantially mechanically disrupted, while tissue comprising a surrounding vessel remains intact.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. **1** illustrates a robotic catheter system configured for conducting minimally invasive medical interventions.

[0008] FIG. **2** illustrates an instrument driver and instrument assembly of a robotic catheter system configured for conducting minimally invasive medical interventions.

[0009] FIG. **3**A illustrates a distal portion of an instrument assembly configured for conducting ablation treatments.

[0010] FIG. **3**B illustrates a distal portion of an instrument assembly configured for conducting treatments involving the traversal of a needle or wire-like instrument through at least a portion of a tissue structure.

[0011] FIG. **3**C illustrates a distal portion of an instrument assembly configured for conducting treatments involving the traversal of a scalpel type instrument portion through at least a portion of a tissue structure.

[0012] FIGS. **4**A-**4**D illustrate various embodiments for detecting an amount of instrument traversal into a tissue structure.

[0013] FIG. **4**E illustrates an instrument assembly wherein a scalpel tip is coupled to the remainder of the assembly with a joint.

[0014] FIG. **5** illustrates a cardiac ablation scenario employing an instrument assembly configured to sense temperature and load.

[0015] FIGS. **6**A and **6**B illustrate views of a user interface configured to facilitate customization of a tissue contact scenario.

[0016] FIG. **7** depicts a flow chart illustrating various aspects of an ablation treatment.

[0017] FIGS. **8**A-**8**C illustrate a tissue structure puncturing scenario employing an instrument assembly configured to sense loads of various aspects of the assembly.

[0018] FIG. **9** depicts a flow chart illustrating various aspects of a tissue wall traversal treatment.

[0019] FIGS. **10**A-**10**C illustrate a structure traversing scenario employing an instrument assembly configured to sense loads of various aspects of the assembly.

[0020] FIG. **10**D depicts a cross sectional view of structures depicted in FIG. **10**C.

[0021] FIG. **10**E illustrates an interventional planning scenario.

[0022] FIG. **11** depicts a flow chart illustrating various aspects of a structure traversal treatment.

[0023] FIG. **12** depicts a flow chart illustrating various aspects of a treatment interactivity variable based treatment.

[0024] FIGS. **13**A and **13**B illustrate plots of scaling versus detected force which may be utilized in accordance with the present invention.

[0025] FIG. **14** illustrates a haptic overlay plotting in accordance with one embodiment.

[0026] FIGS. **15**A and **15**B illustrate one embodiment of an instrument assembly in accordance with the present invention which comprises a plurality of strain gauges to detect a force vector.

[0027] FIGS. **16**A-**16**G illustrate one embodiment of a tissue intervention procedure in accordance with the present invention.

[0028] FIGS. **17**A and **17**B illustrate aspects of one embodiment of an intervention paradigm wherein a zig zag type pattern is utilized to create a substantially curvilinear lesion.

[0029] FIG. **18** depicts a flow chart illustrating various aspects of a multifactorial treatment technique in accordance with the present invention.

[0030] FIGS. **19**A-**19**C depict graphical representations of three relationships which may be utilized to vary master input device motion scaling.

DETAILED DESCRIPTION

[0031] Referring to FIG. **1**, a robotic catheter system is depicted having an operator workstation (**10**) comprising a master input device (**6**), control button console (**8**), and a display (**4**) for the operator (**2**) to engage. In the depicted embodiment, a controller or control computer configured to operate the various aspects of the system is also located near the operator (**2**). The controller (**12**) comprises an electronic interface, or bus (**48**), configured to operatively couple the controller (**12**) with other components, such as an electromechanical instrument driver (**24**), RF generator (**14**), localization system (**16**), or fiber bragg shape sensing and/or localization system (**18**), generally via electronic leads (**32**, **30**, **36**, **34**, **40**, **38**, **42**, **44**, **46**, **26**). Electromechanically or robotically controlled catheter systems similar to that depicted in FIG. **1** are available from Hansen Medical, Inc. under the tradename Sensei™, and described, for example, in U.S. patent application Ser. Nos. 11/073,363, 11/481,433, 11/678,001 ("Intellisense"), and 11/637,951, each of which is incorporated by reference in its entirety. In the depicted embodiment, the controller (**12**) preferably is operatively coupled (**32**) to the RF generator (**14**) and configured to control outputs of the RF generator (**14**), which may be dispatched via electronic lead (**30**) to the disposable instrument assembly (**28**). Similarly, the controller (**12**) preferably is operatively coupled (**36**) to a localization system, such as an electromagnetic or potential difference based localization system (**16**), such as those available under the tradenames CartoXP™ and EnSite™ from Biosense Webster, Inc., and St. Jude Medical, Inc., respectively. The localization system (**16**) preferably is operatively coupled via one or more leads (**34**) to the instrument assembly (**28**), and is configured to determine the three dimensional spatial position, and in certain embodiments orientation, of one or more sensors coupled to a distal portion of the instrument assembly relative to a coordinate system relevant to the controller and operator, such as a world coordinate system. Such position and/or orientation information may be communicated back to the controller (**12**) via the depicted electronic lead (**36**) or other signal communication configuration such as a wireless data communication system (not shown), to enable the controller (**12**) and operator (**2**) to understand where the distal portion of the instrument assembly (**28**) is in space—for control and safety purposes. Similarly, a fiber bragg localization and/or shape sensing system (**18**) may be coupled between the controller (**12**) and instrument assembly (**28**) to assist with the determination of position and shape of portions of the instrument assembly, thermal sensing, contact sensing, and load sensing, as described, for example, in the aforementioned incorporated patent applications. In one embodiment, a fiber (**38**) comprising Bragg gratings may be positioned between the distal tip of one or more instruments in the assembly and coupled proximally to the fiber bragg analysis system (**18**), and outputs from such system may be electronically communicated (**40**) to the controller (**12**) to facilitate control and safety features, such as closed loop shape control of one or more portions of the instrument assembly, as described, for example, in the aforementioned incorporated references. A feedback and control lead (**26**) is utilized to operatively couple the instrument driver (**24**) to the controller. This lead (**26**) carries control signals from the controller (**12**) to various components comprising the instrument driver (**24**), such as electric motors, and carries control signals from the various components of the instrument driver (**24**), such as encoder and other sensor signals, to the controller (**12**). The instrument driver (**24**) is coupled to the operating table (**22**) by a setup structure (**20**) which may be a simple structural member, as depicted, or a more complicated movable assembly, as described in the aforementioned incorporated references.

[0032] Referring to FIG. **2**, a close orthogonal view of an instrument driver (**24**) and instrument assembly (**28**) is depicted, this configuration having the ability to monitor loads applied to working members or tools placed through a working lumen defined by the instrument assembly (**28**). In this embodiment, such loads are determined with load sensors (**52**) located within the housing of the instrument driver, as described in the aforementioned incorporated references. In other embodiments, loads imparted to various tools or aspects of the instrument assembly (**28**) may be monitored using load sensors or components thereof which are embedded within or coupled to distal portions (**50**) of such tools or instrument assembly portions.

[0033] Referring to FIG. **3**A, an instrument assembly distal portion (**54**) configured for ablation therapy is depicted, comprising a distally located RF electrode (**82**) coupled to an RF generator (not shown in FIG. **3**A; element **14** of FIG. **1**). The depicted embodiment comprises a microwave antenna (**68**) distally coupled to the instrument portion and electronically coupled via a lead (**70**) back to the controller (not shown in FIG. **3**A; element **12** of FIG. **1**). Further, the depicted embodiment comprises a load sensor (**64**) mechanically positioned to sense loads applied to the most distal portion of the instrument assembly (**54**). Signals associated with loads are communicated via a lead (**66**) back to the controller for interpretation and analysis. The load sensor may, for example, comprise one or more strain gauges of various types, one or more localization sensors with a deflectable member of known spring constant in between, one or more fiber bragg sensors with fibers or other associated deflectable members of known spring constant, and/or movable fluid reservoir type pressure/load sensors. Further, the embodiment of FIG. **3**A may comprise one or more localization sensors (**60**) coupled via an electronic lead (**62**) to a localization system, as well as a fiber bragg shape and/or deflection sensing fiber (**72**) configured to assist in the determination of shape and bending deflection of the instrument assembly portion (**54**). In one embodiment, the microwave antenna (**68**) may be utilized to conduct radiometry analysis, such as black body radiometry analysis, of nearby structures, such as heated tissue structures, as described, for example in U.S. Pat. Nos. 5,683,382 and 6,932,776, both of which are incorporated by reference herein in their entirety. Utilization of such an embodiment is described below in reference to FIGS. **5**, **6**, and **7**.

[0034] Referring to FIG. **3**B, another embodiment of an instrument assembly distal portion (**56**) is depicted, this embodiment being configured for traversing or piercing a nearby structure, such as a tissue wall or endovascular plaque structure. As shown in FIG. **3**B, the instrument assembly may comprise a load sensor (**64**), localization sensor (**60**), and fiber bragg sensor (**72**), as with the embodiment of FIG. **3**A. A working lumen (**96**) is defined through the center of the assembly to accommodate a slender traversing tool (**74**), such as a wire, guidewire, or needle, which in the depicted embodiment has a sharpened tip (**76**). The traversing tool (**74**) and

working lumen (**96**) are sized to allow relative motion, such as rotational and/or translational motion, between the lumen and tool, and in the depicted embodiment, a braking mechanism is included to prevent relative motion between the two, such as in certain traversing scenarios, or situations wherein it is desirable to transfer loads imparted upon the traversing tool (**74**) to the very distal portion of the instrument assembly so that the load sensor (**64**) will read such loads. In the depicted embodiment, the braking mechanism comprises a controllably inflatable annular balloon (**78**) which may be remotely inflated using a fluid lumen (**80**). Utilization of such an embodiment is described below in reference to FIGS. **8**A through **11**.

[0035] Referring to FIG. **3**C, an instrument assembly distal portion (**58**) embodiment similar to that depicted in FIG. **3**B is depicted, with the exception that in the embodiment of FIG. **3**C, the working lumen (**96**) is larger and the traversing tool (**86**) comprises a scalpel cutting tip (**88**). Referring to FIG. **4**E, in one embodiment, it is desirable to have a jointed coupling (**104**) between the proximal and distal portions of the scalpel tipped traversing tool (**86**) to facilitate automatic following of the traversing or cutting surface with motion of the instrument assembly (**58**) as the nearby tissue structure (**90**) and surface thereof (**94**) is being cut or traversed.

[0036] Referring to FIGS. **4**A-**4**D, four variations of traversal depth sensing configurations are depicted which may be used with scalpel, needle, wire, or other type traversing tools to determine how much of such tool has been extended or traversed into the subject tissue structure (**90**), past the tissue structure outer surface (**94**). Referring to FIG. **4**A, in one embodiment, a flexible follower member (**92**) may be configured to bend through contact with the tissue structure (**90**) surface (**94**) as the traversing tool (**86**) is inserted past the surface (**94**). A bending sensor, such as a fiber bragg sensing fiber, strain gauge, or the like may be utilized along with known mechanics of such follower member (**92**) to determine how much the traversing tool (**86**) has extended into the tissue structure (**90**) past the surface (**94**). In another embodiment (not shown), the follower member may be rigid, and may rotate along with an encoder or other rotation sensor relative to the traversing tool (**86**), to allow for determination of traversal depth without flexion of the follower member. Referring to FIG. **4**B, a proximity sensor may be coupled to the traversing tool (**86**) and configured to transmit and receive reflected sound, light, or other radiation from the surface (**94**) to determine the traversal depth. Referring to FIG. **4**C, a surface contact sensor (**100**), such as one based upon an electronic lead coupled to the surface of the traversing tool (**86**) tip, may be utilized to sense traversal depth through direct contact with the traversed portions of the tissue structure (**90**). Referring to FIG. **4**D, a collar (**102**) may be configured to slide relative to the traversing tool (**86**) and remain at the surface (**94**) of the tissue structure (**90**), while a sensor such as a linear potentiometer may be utilized to determine how much the end of the collar (**102**) has moved relative to the end of the traversing tool (**86**), for determination of traversal depth.

[0037] Referring to FIG. **5**, an embodiment such as that depicted in FIGS. **1**, **2**, and **3**A is illustrated in situ adjacent a tissue structure (**106**) such as a heart cavity wall. In one embodiment, one or more medical imaging modalities, such as computed tomography ("CT"), magnetic resonance ("MRI"), or ultrasound, preferably are utilized preoperatively to understand the pertinent anatomy. Images from such modalities may be filtered and/or segmented to produce two or three dimensional surface models with which preoperative or intraoperative planning and instrument navigation may be conducted. In one embodiment, an operator may preoperatively mark certain portions of the tissue structure (**106**) as zones where contact should be avoided—these may be called "keep out zones" and labeled in a graphical user interface presented to the operator on a display as a dashed box (**108**), or otherwise highlighted area, and preferably the associated robotic catheter system controller is configured to not allow an instrument assembly which has a control system registered to such images and keep away zones (**108**) to move the distal portion of such instrument assembly (**54**) into such zone (**106**). In one embodiment, for example, such zones may be placed at thin walled areas, areas known to be at risk for possible fistulas, or areas of previous tissue damage or therapy. Indeed, in the depicted embodiment, a slightly different marker (**110**) is utilized to depict in the graphical user interface a previously heated or ablated volume. In one embodiment, volumes which have received previous therapy may be marked with graduations in color, shading, and/or highlighting to indicate different graduations of therapy. For example, cardiac muscle conduction blockage is generally associated with collagen denaturation of the such tissue. Such collagen denaturation can be created with applied heat, such as that applied with RF energy in an RF ablation procedure. In one embodiment, the operator may configure the controller to avoid volumes with the instruments which are known to have been heated at all. In another embodiment, the controller may be configured to only allow contact and associated delivery of RF energy to volumes known to have not received adequate energy for denaturation, and to stop the delivery of energy past a certain level of temperature and/or associated denaturation. Preferably the microwave antenna (shown as element **68** in FIG. **3**A) is utilized to determine the temperature of associated tissues in real or near-real time, along with microwave radiometry computer software operated by the controller (**12**) computer or other computing system, and preferably such temperature is depicted graphically (**112**) for the operator using gradients of colors, shading, and/or highlighting in real or near real time, to facilitate an actively monitored precision thermal intervention while the RF generator may be utilized to cause the RF electrode tip to emit RF energy to the adjacent tissue structure portion. In other words, RF may be used to interactively heat the tissue, and microwave radiometry may be utilized to observe the heating and/or modify the variables of the intervention, such as RF power, timing of RF emission, movement of the RF electrode, and the like. In one embodiment, a thermodynamic model may be utilized to understand the heating dynamics of the instrument and associated tissues. For example, preoperatively and/or intraoperatively, Doppler ultrasound analysis may be utilized along with the aforementioned anatomical images to map flow through the cardiac cavities, flow through the nearby vessels and sinuses, tissue density, tissue structure local thickness/volume and ability to handle and dissipate heat, and other factors pertinent to the denaturation conduction block electrophysiology therapy model. Computational fluid dynamics may be utilized to create thermodynamic models pertinent to localized RF-heat-based denaturation. In another embodiment, tissue structure thickness, volume, and thermal inertia qualities may be examined by applying small amounts of RF

energy, such as enough to heat a nearby tissue structure portion by about ten percent, and watching the decay of temperatures after such heating.

[0038] It has been found in various scientific studies that contact load is an important variable in RF-heat-based denaturation of cardiac tissue for aberrant conduction pathway blockage. Preferably the inventive system may be configured to customize many aspects of the physical contact scenario between instruments and tissue structures. For example, referring to FIG. **6**A, a graphical user interface control panel preferably is configured to allow an operator to custom tailor a contact scenario between instrument and tissue structure. A load-displacement graphical representation (**118**) is depicted alongside a plot of load versus displacement (**114**), and the operator is able to make adjustments through the graphical user interface to both. In the variation depicted in FIG. **6**A, the operator has configured the instrument to have four intermittent bouts of contact and dragging with the tissue structure, followed by a longer-in-distance bout of contact/dragging. The associated plot of load versus displacement (**114**) shows that as the instrument is placed into contact for each of the short (**122**) and long (**126**) drags, the load is taken up to a prescribed load amount and held until the end of such drag, after which the load goes to zero during one of the gaps in contact (**124**) between the instrument and tissue structure. This scenario is somewhat akin to drawing a dashed and then solid line with a pencil on a piece of paper—but in the subject clinical/instrumentation scenario, an RF electrode would be creating such a pattern on a selected tissue structure surface. Referring to FIG. **6**B, a contact configuration similar to that depicted in FIG. **6**A is depicted, with the exception that the operator has configured the instrument to start each drag (**128**, **120**) with an impulse of relatively higher load, and then to taper back to the load seen in the variation of FIG. **6**A for the remainder of each drag. The loading variations may be depicted in the load-displacement graphical representation (**120**) with the relatively high load drag portions (**132**) being highlighted with larger marking, and the remaining relatively low drag portions (**134**) being highlighted as in FIG. **6**A. The load versus displacement plot (**116**) is further illustrative of the loading and contact scenario. Again, there is a useful analogy to using a pencil on a piece of paper. One can see that many variations in loading, intermittence, and dragging patterns may be created and executed with such a control interface, to control not only contact, but also loads of contact, during interventional procedures.

[0039] Referring to FIG. **7**, various aspects of embodiments of treatment paradigms utilizing configurations such as those depicted in FIGS. **1**, **2**, **3**A, **5**, **6**A, and **6**B are illustrated with a flow chart. As shown in FIG. **7**, preoperative (or in another embodiment intraoperative) imaging studies may be utilized to map the anatomy, vasculature, and flow patterns. This information may be utilized to create thermodynamic models of portions of the tissue structure of interest. Further, keep out zones may be flagged using previous intervention data or imaging data. All of this information may be utilized for interactive planning purposes (**236**) along with three dimensional instrument simulation techniques described for the subject robotic catheter system in the aforementioned incorporated references. Next (**238**) an operator may select a treatment contact pattern for various planned lesions, as described, for example, in FIGS. **6**A and **6**B. A timing profile, including time to be spent at each location and related dragging velocity, may also be prescribed. Such a timing profile may be influenced by the models created in the previous step (**236**), such as tissue structure wall thickness and thermodynamic models. Intraoperatively, the instrument assembly may be navigated, such as by a robotic instrument driver, to desired positions adjacent targeted internal structures (**240**). Such navigation may be accomplished using open loop kinematic-based position control, or closed loop position control using sensor information from devices such as a fiber bragg shape and/or localization sensing configuration or localization system, as described above in reference to FIG. **1**, and in the aforementioned incorporated references. Given access to the anatomy intraoperatively, adjustments may be made to the treatment contact pattern, loading profile, timing profile, keep out zones, anatomical mapping, thickness mapping, compliance mapping, thermal model mapping, and general locations of desired contact between the instrument and anatomy (**242**). Subsequently the operator may execute the treatment (**244**) either manually or automatically using the robotic catheter system and a prescribed trajectory/position plan. Navigation may be controlled with position and/or load feedback using load sensors such as those described in relation to FIG. **3**A or **2**. A reference frame of a load sensor preferably is registered to a reference frame utilized by an operator to navigate the elongate instrument, such as a reference frame of a master input device or display utilized by the operator to visualize movement of the elongate instrument. New lesions preferably are observed in real or near-real time, as described in reference to FIG. **5**, and are mapped onto an updated lesion mapping.

[0040] Referring to FIGS. **8**A-**8**C, various aspects of a traversal intervention are illustrated, whereby an instrument or portion thereof may be controllably passed, or traversed, through at least a portion of a tissue structure. Referring to FIG. **8**A, a tissue structure (**136**) wall is depicted having a thinned region (**138**), which may, for example, represent a fossa ovalis portion of an atrial cardiac septum, which may be desirably traversed for a trans-septal procedure wherein instruments are to be utilized in the left atrium of the heart. The instrument assembly portion (**56**) depicted has been advanced toward the tissue structure (**136**) but has not yet contacted such tissue structure. Referring to FIG. **8**B, the instrument assembly (**56**) has been advanced (**142**) into contact with the targeted region (**138**) of the tissue structure (**136**), and this instrument advancement has caused a repositioning (**140**) and tensioning of the tissue structure, which may be called "tenting" of the tissue structure. Tenting may be desirable to assist with positioning and vectoring the instrument assembly distal portion (**56**) and to temporarily alter the mechanical properties of the tissue structure (for example, in tension, a thinned wall is not as likely to continue to deform and move away from the instrument assembly when a traversing instrument is advanced toward and into such wall relative to the rest of the instrument assembly; the viscoelastic performance may also be desirably altered by placing the structure under tented loading). Referring to FIG. **8**C, with the instrument assembly distal portion continuing to tent the targeted portion (**138**) of the tissue structure, the traversing member (**74**) may be inserted through the tissue structure. In one embodiment, such insertion may be conducted manually with a needle, guidewire, or similar working tool that extends proximally to a position wherein it may be manually manipulated by the hand of an operator. In another embodiment, insertion and retraction of such tool are controlled and actuated electromechanically, utilizing proximally positioned

actuation mechanisms such as those disclosed in the aforementioned incorporated references, or by proximally triggered but distally actuated (such as by a spring or other stored energy source) mechanisms, such as those described in U.S. Pat. Nos. 4,601,710, 4,654,030, and 5,474,539, each of which is incorporated by reference herein in its entirety.

[0041] Referring to FIG. **9**, a flowchart illustrates aspects of procedural embodiments for conducting a tissue traversal intervention. As shown in FIG. **9**, in a similar manner as described in reference to FIG. **7**, the system may be utilized along with preoperative imaging data to establish and map keep out zones and locations of previous lesions, for interactive planning purposes (**247**). The operator may configure the system with contact configuration variables such as tenting insertion load, velocity and impulse of tenting insertion, tenting approach vector with the instrumentation, traversal instrument velocity profile, traversal distance, traversal impulse and load profile, as well as traversal retraction velocity and distance, and traversal retraction load and impulse profile variables (**248**). The instrument assembly may be navigated into position adjacent targeted internal tissue structures (**250**), and adjustments may be made intraoperatively to contact configuration variables, anatomical mapping (such as with greater understanding of the thickness of various structures utilizing intraoperative imaging modalities such as in-situ instrument-based ultrasound), tissue structure compliance mapping, and keep out zones. Thickness mapping may be conducted using preoperative imaging to determine internal and external surface positions of various structures, or direct measurement of thicknesses from preoperative images. This information may be combined with further information gained from in-situ imaging techniques to increase the understanding of thickness, and also compliance of the tissue, as imaging and physical interaction may be utilized to understand compliance and density related variables, as described, for example, in the aforementioned incorporated references. Treatment may then be executed utilizing position and/or load control of the instrument portions relative to the anatomy, in accordance with the predetermined contact configuration variables (**254**), and the interactive mapping of lesions updated (**256**).

[0042] Referring to FIGS. **10**A-**10**C and **11**, various aspects of another traversal intervention are illustrated, featuring a traversal of an endovascular plaque, such as in a clinical condition known as chronic total occlusion, or "CTO". Referring to FIG. **10**A, a vascular plaque (**146**) structure occluding a vessel (**148**) is approached by an endovascular instrument assembly (**56**) configured for traversal. In a manner similar to that described in reference to FIG. **9**, the instrument assembly may be configured to approach, establish contact with, and traverse, with a traversing tool (**74**) the plaque, as shown in FIG. **10**B. Subsequently, the tool (**74**) may be retracted leaving a defect (**150**) in the plaque structure (**146**), the instrument assembly moved to a different location, and the plaque structure (**146**) readdressed and re-traversed with the traversing tool (**74**). FIG. **10**D depicts a cross sectional view of the activities illustrated in FIG. **10**C. Continued traversal may lead to dissolution or removal of the plaque, and referring to FIG. **10**E, a pattern of planned traversal defects (**152**) preferably may be preoperatively or intraoperatively planned utilizing images of the anatomy and an understanding of the geometry of the traversing tool.

[0043] Referring to FIG. **11**, a flowchart illustrates aspects of procedural embodiments for conducting a tissue traversal intervention; there are analogies to the procedures described in reference to FIGS. **7** and **9**. As shown in FIG. **11**, keep out zones may be established, an preoperative images may be utilized for interactive planning (**258**). Treatment contact configuration variables may be selected, such as the larger instrument subassembly (such as a catheter) insertion loads, velocity, approach vector, and the like (**260**). A geometric plan may be created for multiple traversals (**262**), as described above in reference to FIG. **10**E. The instrument assembly may then be navigated into position adjacent the targeted internal structures, such as vascular plaque structures (**264**), adjustments made intraoperatively (**266**), and the treatment executed using position and/or load control of the instrument portions relative to the anatomy (**268**). Then the interactive mapping of lesions, or destruction of lesions or structures, may be updated (**270**).

[0044] Referring to FIG. **12**, in another embodiment, treatment interactivity variables may be utilized in automated operation of an electromechanical interventional instrument system. Referring to FIG. **12**, subsequent to establishing and mapping keep out zones, creating an anatomical map for planning and the like (**258**), treatment interactivity variables may be selected (**300**) to match a particular hardware configuration, such as maximum allowable cardiac electrogram amplitude changes versus time in a hardware configuration featuring a cardiac electrogram sensor (such as one located distally on an elongate instrument), maximum allowable RF generator power output changes versus time in a hardware configuration featuring an RF generator which may be coupled to a distal treatment electrode, maximum allowable RF generator impedance change versus time in a hardware configuration featuring and RF generator and impedance monitoring capabilities, and maximum allowable sensed force vectors in absolute terms or as force change versus time (i.e., impulse) in hardware configurations wherein one or more force sensors may be utilized to detect loads imparted to an elongate instrument by surrounding structures, such as tissues or other instruments. A response plan paradigm may then be selected to direct a controller configured to operate the electromechanical elongate instrument in the instances wherein thresholds, such as those described above, are exceeded (**302**). For example, when a given threshold is exceeded, the controller may be configured to direct the instrument to move proximally into free space, to increase the rate of motion of the instrument as it translates adjacent or against the subject anatomy, to decrease the amount of time spent at any particular interventional contact location, or to shut off or decrease any applied RF power or other energy based treatment at its generator. Subsequently, the instrument distal portion navigation may be continued (**304**), adjustments may be made to operational variables (**306**), treatments may be executed (**308**), and interactive mapping of lesions continued (**310**).

[0045] As described above, various embodiments of the subject elongate instrument assemblies may comprise load or force sensing devices, such as those featuring strain gauges, fiber bragg sensors, or the like, as described above, or proximal interfacial load sensing assemblies such as that sold by Hansen Medical, Inc. under the tradename "Intellisense"™. Any of these configurations may be utilized by a robotic instrument controller to modify a scaling ratio associated with a master input device configured to allow an operator to move an instrument. For example, in one embodiment, at relatively minimal or nonexistent detected forces, such as

positions of the elongate instrument wherein the distal tip is in free space, the control system may be configured to move the instrument distal tip at a scaling ratio, such as 1:1, relative to master input device moves that the instrument is following. With larger detected forces, such scaling ratio may be decreased with a linear, curvilinear, or stepwise relationship, down to levels such as 1:0.5, 1:0.25, or less, to ensure that the instrument is moving in small increments relative to larger incremental commanded moves as the master input device when in the presence of other objects, such as tissue structures, as sensed through the force sensor. For example, a curvilinear relationship is illustrated by the plot (**312**) of FIG. **13**A. In accordance with such an embodiment, for example, a master-slave instrument being operated in free space would move with a significantly greater scaling factor of master move relative to slave move, as compared with the same master/slave configuration moving in a scenario wherein a significant load is detected at the instrument. In loading scenarios wherein loads are greater than zero but less than a maximum load, scaling would follow the plotted (**312**) configuration. FIG. **13**B illustrates a plot (**314**) wherein a stepwise decrease in scaling factor changes the scaling factor to a next step down in ratio at each of a series of predetermined loading threshold points (**316**, **318**, **320**). In the event of a quick loading past the third threshold point (**320**), in this embodiment, scaling would be taken to zero, and moves at the master input device would not result in moves at the slave.

[0046] As described in the aforementioned incorporated by reference disclosures, a haptically-enabled master input device may be utilized to navigate the subject elongate instruments while providing the operator with mechanical feedback through the master input device. In one embodiment, haptic sensations may be delivered to the operator through the master input device which are indicative of the presence and/or quantity of loads applied to the distal portion of the instrument. In one embodiment, wherein a uniaxial load is detected, such as in certain variations of the aforementioned and incorporated Intellisense™ technology, a vibration pattern may be delivered to the operator to indicate that a load is being applied, and amplitude and/or frequency of such vibration pattern may be varied in accordance with load quantity to provide the operator with indication of such quantity. For example, the following equations may be utilized to calculate a smooth sinusoidal force pattern in the presence of a shifting frequency:

$$\text{Theta}(t)=\text{integral of (theta}*2*pi*f(t)dt)$$

$$\text{Theta}[k]=\text{theta}[K-1]+\text{theta}*2*pi*f[k]Ts$$

$$F[k]=A[k]*\sin(\text{theta}[k])$$

Where f is the frequency, A is the desired amplitude, F is the force to be applied to the tool, Ts is the sample time, and theta is the phase through the current cycle. The frequency, amplitude, phase, and instantaneous force are all key attributes of the vibration object. In another embodiment, an additional vibratory pattern may be overlaid upon the first vibratory pattern, to indicate something else to the operator, such as current delivered through an instrument distal tip RF electrode, temperature sensed using one of the means described above, or other variables. Referring to FIG. **14**, such an overlaying configuration is illustrated, with a higher frequency, lower amplitude plot (**322**) representing a vibratory pattern delivered to the operator of a haptic input device based upon a constant force applied at an instrument distal tip, for example, while an additional pattern (plot **324**) may be also presented to the operator using the same master input device to provide an indication of some other treatment-related variable, such as sensed temperature, current delivery rate, power delivery, and the like, applied to tissues adjacent the distal instrument tip. Depending upon the quality and resolution of the haptic master input device, many variations of pluralities of vibratory feedback patterns may be imparted simultaneously to an operator of such a system to indicate the status of many states of variables such as load applied. For example, in one embodiment, a binary type of overlay signal may indicate merely the presence of a variable threshold crossing, such as a current density amount that is greater than a predetermined current density. In another embodiment, the overlay signal may not only indicate the existence of such variable, or variable threshold crossing, but also may be configured to scale with the quantification of such variable (i.e., greater current density, higher amplitude and/or frequency of the overlay signal). Other embodiments are described below in reference to FIGS. **19**A-**19**C, wherein master input device motion scaling may be varied in relation to directionality of the instrument positioning, articulation of the instrument, insertion length of the instrument, and/or forces applied to or sensed by the instrument.

[0047] Referring to FIG. **15**A, an instrument assembly (**56**) similar to that depicted in FIG. **3**B is depicted, with the addition of three or more small discrete load sensors (**326**, **328**, **330**), such as resistive type strain gauges or other small load sensors, as described above. Such sensors (**326**, **328**, **330**) are shown in greater detail in the magnified view of FIG. **15**B, and may be utilized to produce not only a reading of compressive or tensile forces applied to the distal tip of the instrument along the instrument's longitudinal axis, but also indications of force vectors for off axis loads applied, in three dimensions. Such three dimensional forces may be utilized in the determination and application of haptic feedback patterns and vectors thereof to the operator through a haptic master input device. Uniaxial force sensing, such as that featured in the aforementioned and incorporated Intellisense™ technology, or three dimensional force sensing using an embodiment such as that described above in reference to FIGS. **15**A and **15**B, may be utilized clinically to provide contact patterns, lines, or drags with predetermined loading configurations. For example, in one embodiment, a curvilinear line pattern may be selected for an RF ablation drag within a chamber of the heart, and a constant axial force application prescribed for the contact pattern along the drag; alternatively, a predetermined force contour or profile (such as one wherein the force is decreased for the portion of the curvilinear treatment pattern that crosses a particularly load sensitive portion of substrate tissue structure).

[0048] Referring to FIGS. **16**A-**16**G, one embodiment of a procedure for removing material from an in situ interventional site is depicted. Referring to FIG. **16**A, an instrument assembly similar to that depicted in FIG. **3**B is depicted, having a drilling type of elongate probe (**332**) rather than a needle-like device as shown in FIG. **3**B (element **74** of FIG. **3**B). The assembly is depicted approaching a calcified tissue structure (**334**), such as a portion of the human spine. Referring to FIG. **16**B, the instrument assembly is shown immediately adjacent the calcified tissue structure (**334**) where sensors comprising the instrument assembly may be utilized to detect information regarding the immediate portions of such tissue structure, such as compliance to applied low levels of

axial loading, conductivity, or temperature. Referring to FIG. **16**C, the drilling member (**332**) may be advanced into the calcified tissue structure (**334**), and later withdrawn, as shown in FIG. **16**D, leaving behind a defect (**336**). Referring to FIG. **16**D, the drilling instrument (**332**) may be advanced yet further, creating an opportunity to use sensing techniques, such as tissue compliance sensing, to analyze the scenario clinically from another deeper perspective. FIG. **16**F shows another cycle of withdrawal, and FIG. **16**G shows another cycle of insertion and further advancement. Such cyclic insertion and withdrawal, along with sensing during such intervention, may be highly advantageous in the case of a tissue removal intervention, such as one wherein cancerous or necrotic tissue is to be removed, and healthy substrate tissue left in place. Given a difference between the desirably removed tissue and the tissue to be left in place, that may be sensed with the instrument system, such procedures may be streamlined. For example, it may be known that necrosed bone material has a different conductivity, temperature, and/or mechanical compliance. In such a scenario, load sensing, temperature sensing, and or conductivity sensing at the distal tip of the instrument assembly may be used as tissue is incrementally removed. In other words, the instrument may be advanced, an incremental amount of material removed, and compliance (or whatever other variable may be sensed, analyzed, and correlated to a known tissue state) tested; if the tested compliance is greater than a threshold that is correlated with non-necrosed bone, another cycle of advancement, removal, and analysis is conducted—until less compliant bone, correlated with healthy bone, is reached, after which the advancement of the instrument may be ceased. Further, once the advancement has been ceased, the robotic instrument control system may be utilized to determined with reasonable precision the volume of the defect created, which may be useful for subsequent defect filling with materials such as poly methyl methacrylate or the like.

[0049] Referring to FIG. **17**A, when a fairly linear or curvilinear treatment pathway (**338**), such as a long linear lesion ablation "burn", has been selected, a zig zagging type of interventional pattern (**340**) may improve the knowledge of the anatomy, physiology, and treatment by allowing an instrument assembly comprising sensors, such as those depicted in FIGS. **3**A-**4**E, or **15**A-B, to gather more data regarding the region and treatment. In other words, if the instrument strictly follows the curvilinear pathway (**340**) during both treatment periods and non-treatment navigation periods, it is sampling data only from that area—whereas if it intentionally navigates a bit farther afield between treatments, it gathers more data to facilitate a more refined understanding of the clinical scenario. One advantage of an electromechanically controlled instrument is that such zig sagging, or other pattern, may be automated. For example, referring to FIG. **17**B, the zig sagging pattern of movement (**340**) may allow the distal tip of the instrument to encounter, and sense with pertinent sensor capabilities, three or more times the tissue swath, depending upon the amplitude of the zig sagging pattern (**340**), while also creating a curvilinear lesion sufficient to block aberrant conduction pathways from crossing the predetermined curvilinear path (**338**), the curvilinear lesion comprising an aggregation of smaller lesions (**342**) created, for example, at the intersections of the zig sagging pattern (**340**) with the predetermined curvilinear pattern (**338**). The widened swath essentially provides a larger sample size for pertinent analysis of the situation.

[0050] Referring to FIG. **18**, an embodiment is depicted to illustrate that multifactorial analysis may be conducted with treatments in situ, depending upon predetermined, and interactively adjustable, variable or factor interactivity logic. For example, after establishing keep out zones, creating an anatomical map, and generally creating an interventional plan to control tissue/instrument physical interaction (**344**), multifactorial logic may be configured (**346**) to utilize a plurality of sensed factors, such as those described in reference to FIG. **12** (**300**). A response plan (**348**) may also be selected or created, to control the interactivity of sensed factors and interventional variables. For example, one variable may be deemed controlling in certain situations, while another may become dominant from a controls perspective in another, such as in a scenario wherein if a sensed temperature is too high and a sensed force is too high, the instrument is to be pulled proximally into free space—but not if only one of these factors is higher than a predetermined threshold. Many combinations of variables may be coded into the logic and response plans. Subsequently, these configurations may be employed as the instrument assembly is navigated (**350**), and adjustments may be made (**352**) while treatment is executed (**354**) and interactive mapping is updated (**356**). For example, in one multivariate treatment embodiment, distal temperature, nearby tissue structure compliance, distal instrument load, and current delivery density per unit area of tissue structure may be simultaneously monitored, and the logic may be configured to stop application of treatment energy when a temperature, load, or current delivery density is exceeded, but not if a compliance threshold is exceed, unless the compliance threshold is crossed along with a significant decrease in detected distal load.

[0051] Instrument motion may be a scaled version of master device commanded motion based on a variety of other factors, e.g. forces, configurations and/or motion directions. Where force is measured, one embodiment would emulate a pre-determined motion-force relationship with the master. Alternatively, a more heuristic approach may be implemented. Referring to FIGS. **19**A-**19**C, in one embodiment, motion scaling at the master input device may be varied in accordance with the following relationship:

$$x_{catheter}=k_t x_{MID}$$

wherein Xcatheter represents commanded instrument (in one embodiment a steerable catheter) motion utilized by the system to move the instrument, Xmid represents motion commanded at the master input device ("MID") by the operator, and Kt represents a total scaling factor comprised of three components, per the equation below in one embodiment, including a force component Kf, an instrument direction component Kd, and an instrument articulation/insertion component Ka:

$$k_t = \frac{k_a k_d}{(1+k_F)} + 1 - k_d.$$

[0052] Referring to FIG. **19**A, MID motion scaling factor is plotted (**360**) versus sensed insertion axis force (measured, for example, using the Intellisense™ technology described above) for one implementation of a Kf relationship (**364**, **362**) wherein motion scaling is generally decreased as sensed force magnitude is increased for various quantitative levels of Kf (**366**); portions of the depicted relationships are linear, while

others are nonlinear. In other words, when a relatively high insertion (i.e., compressive) force is detected, motion scaling at the MID is generally decreased—to effectively "gear down" the MID-operator control relationship. In the depicted equation (**364**, **362**), "F" represents the measured force, and "f" represents the force scaling factor listed on each of the plots (**366**).

[0053] Referring to FIG. **19**B, MID scaling factor is plotted (**368**) versus the directionality of the force applied for one implementation embodiment. For example, in the depicted embodiment, with a sensed load equal to 30 grams (plots **374** are shown for sensed loads of 0 grams, 20 grams, 30 grams, 50 grams, and 100 grams), straight outward insertion (i.e., compressive along the load sensing axis—see point **372**) is scaled at approximately 0.2 (or twenty percent ratio of manually input command motion to output command motion to the system; geared down quite significantly), while straight withdrawal of the instrument (i.e., along the load sensing axis—see point **373**) is scaled at 1.0 (i.e., a 1:1 ratio of manually input command motion to output command motion to the system; effectively no scaling; the theory being that withdrawal generally is safe and should be able to be expediently directed by the MID). Motion in lateral directions orthogonal to the load sensing axis (for example, if the load sensing axis is "Z", lateral motion would be in the "X" and/or "Y" directions) may be scaled with a smooth connecting relationship (see plotted regions **375** and **377** in the exemplary embodiment) configured to avoid disjointed motion or any jumping or unpredictable instrument motion relative to commands at the MID. With a zero sensed load, scaling in the depicted embodiment is set at 1.0 in all directions; as load is increased, the most sensitivity (and most downscaling at the MID) in the depicted embodiment is for insertion type movements that are generally against the applied load (i.e., like to increase the sensed load). In the depicted Kd equation (**370**), the delta symbol represents the normalized direction of MID motion (a vector in R^3), and e_y is the unit vector in the direction of the instrument tip. Higher values of "n" will tighten the directionality of the scaling forward (i.e., lateral motion will be less scaled for higher values of "n").

[0054] Referring to FIG. **19**C, an articulation/insertion ("Ka") factor (**382**) embodiment is plotted (**376**) to show that a gradient (**380**) may be implemented wherein motion scaling (**384**) is highest when the instrument bending articulation angle is lowest, instrument insertion length (i.e., the amount of elongate instrument body that is inserted past structural support provided by other instrument-related structures such as introducer sheaths) is the lowest, or both. From a mechanics of materials perspective, the composite instrument generally is at its stiffest when it is maximally withdrawn and not bent (i.e., straight)—and this is when, in the depicted embodiment, motion at the MID is scaled down the most. When the instrument is maximally inserted, or when the instrument is maximally articulated (i.e., bent, in the scenario of a remotely controllable steerable catheter) the instrument is more highly compliant or flexible in relation to applied loads—and this is when, in the depicted embodiment, the motion scaling is minimized. Such configuration may be deemed a "virtual compliance" scaling modality, wherein the scaling is configured to have the instrument make only small incremental "soft touch" motions when the instrument is in a naturally stiffer configuration, and to be more quickly movable with less scaling when the instrument is in a configuration wherein it is naturally more akin to "soft touch"—thus providing the operator with a spectrum of "soft touch" operation. In the depicted equation (**382**), "L" represents the length of instrument insertion in centimeters, alpha is the instrument tip articulation in radians, and C_L and C_{alpha} are insertion and articulation factors, respectively. The plot (**380**) depicts the sample implementation wherein both of these factors are equal to 3.0, and the line (**378**) depicts unity scaling due to articulation (i.e., the scaling factor is neither increased nor decreased by the articulation or bending component).

[0055] While multiple embodiments and variations of the many aspects of the invention have been disclosed and described herein, such disclosure is provided for purposes of illustration only. For example, wherein methods and steps described above indicate certain events occurring in certain order, those of ordinary skill in the art having the benefit of this disclosure would recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of this invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially. Accordingly, embodiments are intended to exemplify alternatives, modifications, and equivalents that may fall within the scope of the claims.

1. A robotic medical patient structure traversal system comprising:

a. a controller including a master input device;

b. an electromechanically controlled elongate instrument having a proximal interface portion and a distal portion, the proximal interface portion being configured to be operatively coupled to an electromechanical instrument driver in communication with the controller, the distal portion comprising a traversing tip and being configured to be interactively navigated about internal structures of a patient's body in response to signals from the controller; and

c. a load sensor operatively coupled between the distal portion of the elongate instrument and the controller;

wherein the controller is configured to automatically advance the traversing tip through a thickness of an internal structure by observing loads from the load sensor.

2. The system of claim **1**, wherein the controller is configured to stop advancing the traversing tip when a relative decrease in load observed with the load sensor is detected, indicating that the traversing tip has completed a traversal of at least a portion of the thickness of the internal structure.

3. The system of claim **1**, wherein the elongate instrument comprises a steerable catheter instrument movably coupled to an advanceable needle instrument comprising the traversing tip.

4. The system of claim **1**, wherein the load sensor is coupled to the distal portion and in electrical communication with the controller via a lead running proximally along the elongate instrument.

5. The system of claim **4**, wherein the load sensor is coupled to the traversing tip.

6. The system of claim **3**, wherein the load sensor is proximally coupled between the steerable catheter and the advanceable needle instrument.

7. The system of claim **1**, wherein the traversing tip comprises a scalpel.

8. The system of claim **1**, wherein the distal portion further comprises a traversal depth detector operatively coupled to the controller and configured to detect a depth to which the traversing tip has been protruded into the internal structure.

9. The system of claim **8**, wherein the traversal depth detector comprises a follower member coupled to the proximal portion of the scalpel and configured to remain at a surface of the internal structure as the scalpel traverses past such surface into said internal structure.

10. The system of claim **8**, wherein the traversal depth detector comprises a scalpel surface contact sensor configured to measure directly how much of the surface of the scalpel is encapsulated by the internal structure being traversed.

11. The system of claim **8**, wherein said traversal depth detector comprises a signal reflection based proximity sensor configured to determine how much of the scalpel is protruding into the internal structure relative to a detected position of a surface of the internal structure.

12. The system of claim **9**, wherein the follower member comprises a collar movably coupled about the scalpel.

13. The system of claim **9**, wherein the follower member comprises a bendable elongate member, and wherein the depth detector comprises a sensor configured to determine the amount of bend imparted to the bendable elongate member.

14. The system of claim **9**, wherein the follower member comprises a substantially rigid member rotatable relative to the scalpel, and wherein the depth detector comprises a sensor configured to determine the amount of rotation imparted to the substantially rigid member.

15. The system of claim **1**, wherein the internal structure is a vascular plaque occluding at least a portion of a blood vessel of the patient, and wherein the traversing tip comprises an elongate flexible wire.

16. The system of claim **15**, wherein the elongate flexible wire comprises a tapered distal portion configured for insertion into and traversal of the vascular plaque.

17. The system of claim **15**, wherein the controller is configured to insert the elongate flexible wire across a full thickness of the vascular plaque in first insertion location, and utilize data from an acquired medical image of the patient to automatically determine a trajectory for another insertion across another full thickness of the vascular plaque.

18. The system of claim **17**, wherein the controller is configured to repeatedly insert the elongate flexible wire across different trajectories through the vascular plaque until the vascular plaque is substantially mechanically disrupted, while tissue comprising a surrounding vessel remains intact.

19. A method of controllably traversing an internal structure of a patient, comprising:

a. approaching a surface of an internal structure with a distal portion of an electromechanically controlled elongate instrument, the distal portion comprising a traversing tip configured to traverse at least a portion of a targeted internal structure;

b. selecting a contact point and trajectory for traversing at least a portion of said internal structure with the traversing tip;

c. controllably inserting at least a portion of the traversing tip into the internal structure while detecting loads imparted to the traversing tip by adjacent internal structures; and

d. limiting the extent of insertion of the traversing tip based at least in part upon the loads detected.

20. The method of claim **19**, further comprising stopping inserting of the traversing tip when a relative decrease in load is observed with the load sensor, indicating that the traversing tip has completed a traversal of at least a portion of the thickness of the internal structure.

21. The method of claim **19**, further comprising observing the position of the distal portion of the elongate instrument relative to the targeted internal structure utilizing a medical imaging modality selected from the group consisting of: fluoroscopy, ultrasound, endoscopy, infrared imaging, and direct optical visualization.

22. The method of claim **19**, further comprising simulating the position of the distal portion of the elongate instrument relative to the targeted internal structure utilizing models of the distal portion and targeted internal structure, wherein at least the model of the targeted internal structure is based at least in part upon a previously acquired medical image.

23. The method of claim **19**, wherein the targeted internal structure is a septal wall of the heart of the patient, and wherein insertion of the traversing tip is at least temporarily stopped subsequent to a drop in detected load indicative that the traversing tip has completely traversed the septal wall.

24. The method of claim **19**, further comprising detecting traversing tip insertion depth into the targeted internal structure with a local depth detector.

25. The method of claim **24**, wherein detecting traversing tip insertion depth comprises detecting movement or deflection of a follower member configured to remain at a surface of the internal structure as the traversing tip passes such surface into said internal structure.

26. The method of claim **24**, wherein detecting traversing tip insertion depth comprises detecting traversing tip encapsulation with a surface contact sensor.

27. The method of claim **24**, wherein detecting traversing tip insertion depth comprises detecting movement or deflection of a follower member configured to remain at a surface of the internal structure as the traversing tip passes such surface into said internal structure.

28. The method of claim **24**, wherein detecting traversing tip insertion depth comprises detecting a signal reflected from a surface of the internal structure.

29. The method of claim **19**, wherein the targeted internal structure is a vascular plaque within a vessel of the patient, and wherein inserting the traversing tip comprises inserting a portion of an elongate flexible wire.

30. The method of claim **29**, further comprising inserting the elongate flexible wire portion across a full thickness of the vascular plaque, retracting the elongate flexible wire portion, and utilizing data from an acquired medical image of the patient to automatically determine a trajectory for another insertion across another full thickness of the vascular plaque.

31. The method of claim **30**, wherein a computerized controller is configured to repeatedly insert the elongate flexible wire portion across different trajectories through the vascular plaque until the vascular plaque is substantially mechanically disrupted, while tissue comprising a surrounding vessel remains intact.

* * * * *

专利名称(译)	用于自动化组织结构遍历的系统和方法		
公开(公告)号	US20110295267A1	公开(公告)日	2011-12-01
申请号	US12/833927	申请日	2010-07-09
[标]申请(专利权)人(译)	航生医疗公司		
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IPC分类号	A61B19/00		
CPC分类号	A61B18/1492 A61B2019/465 A61B2017/0007 A61B2017/00084 A61B2017/00477 A61B2018/00678 A61B2018/00708 A61B2018/00791 A61B2019/2211 A61B2019/2223 A61B2019/464 A61B19/56 B25J9/1689 A61B2017/00057 A61B2017/00123 A61B2018/00702 A61B2018/00779 A61B2018/00839 A61B2019/2292 A61B2019/2296 A61B2019/462 A61B19/2203 A61B34/25 A61B34/30 A61B34/37 A61B34/76 A61B34/77 A61B2034/301 A61B2090/062 A61B2090/064 A61B2090/065		
优先权	61/349690 2010-05-28 US		
外部链接	Espacenet USPTO		

摘要(译)

描述了用于使患者的微创治疗处理的方面自动化的系统和方法。机器人组织结构遍历系统可包括控制器，该控制器包括主输入装置，具有近侧接口部分和远侧部分的机电控制细长器械，近侧接口部分构造成可操作地连接到与机械仪器驱动器连通的机电仪器驱动器。控制器，远端部分包括横向尖端，并且被配置为响应于来自控制器的信号，关于患者身体的内部结构交互地导航;负载传感器可操作地连接在细长器械的远端部分和控制器之间;其中控制器配置成通过观察来自负载传感器的负载自动推进横向尖端穿过内部结构的厚度。