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(54) **CLIP ON TORQUE DEVICE FOR ENDOVASCULAR PROCEDURES**

(71) Applicant: **Wisconsin Alumni Research Foundation**, Madison, WI (US)

(72) Inventors: **Dai Yamanouchi**, Madison, WI (US); **Isabelle Gundrum**, Northbrook, IL (US); **William Hayes**, Eau Claire, WI (US); **Anna Ankerstjerne**, Eagan, MN (US); **Eric Sagen**, Madison, WI (US); **Jakob Knauss**, Madison, WI (US)

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(57) **ABSTRACT**

A torque device employs a cylindrical housing surrounding a guidewire to provide concentric loading of the guidewire along a central axis of the housing attachable at any point along a length of the guidewire. Improved torsion of the guidewire is obtained by clamping the guidewire so that it runs along the center axis of the housing offering intuitive rotational handling (torque) of the guidewire along the torque axis.

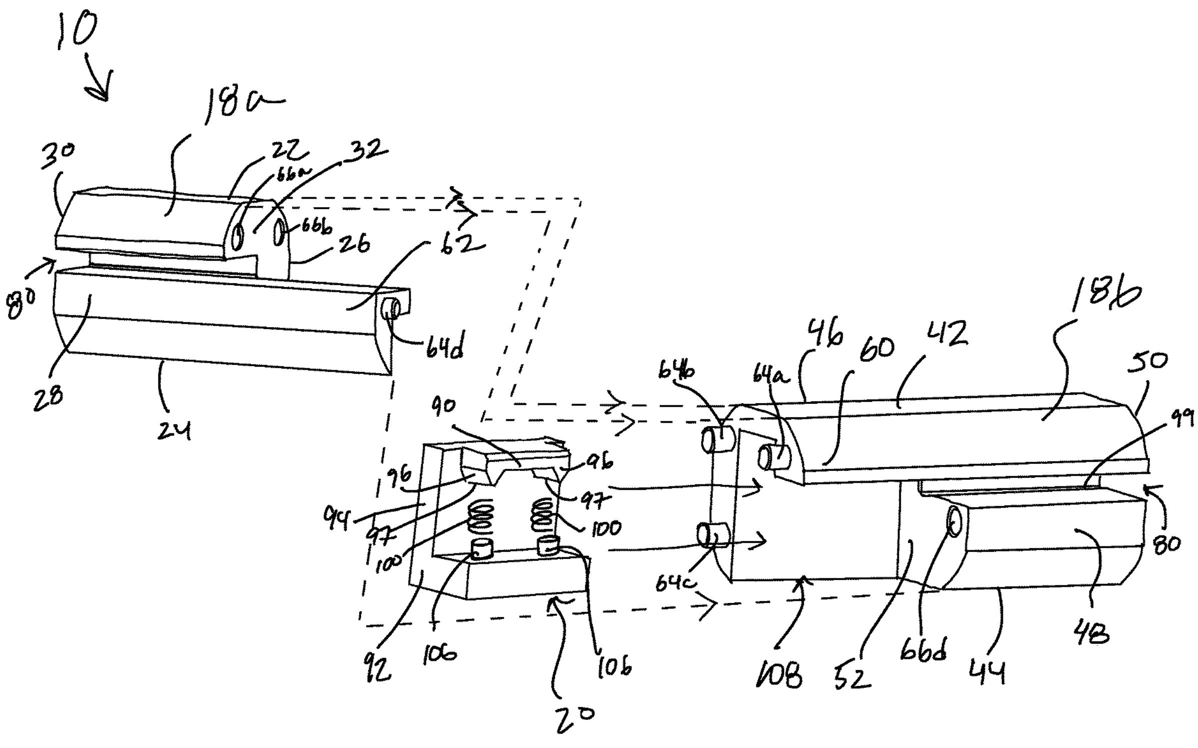
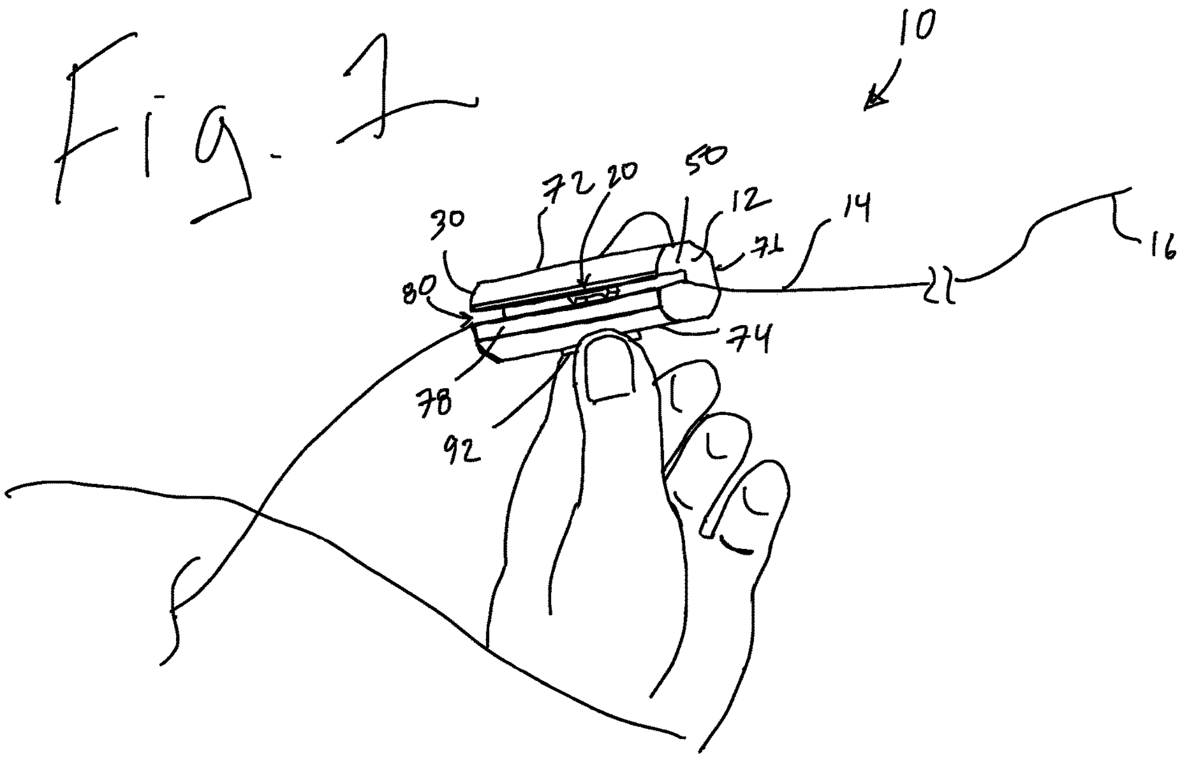


Fig. 1



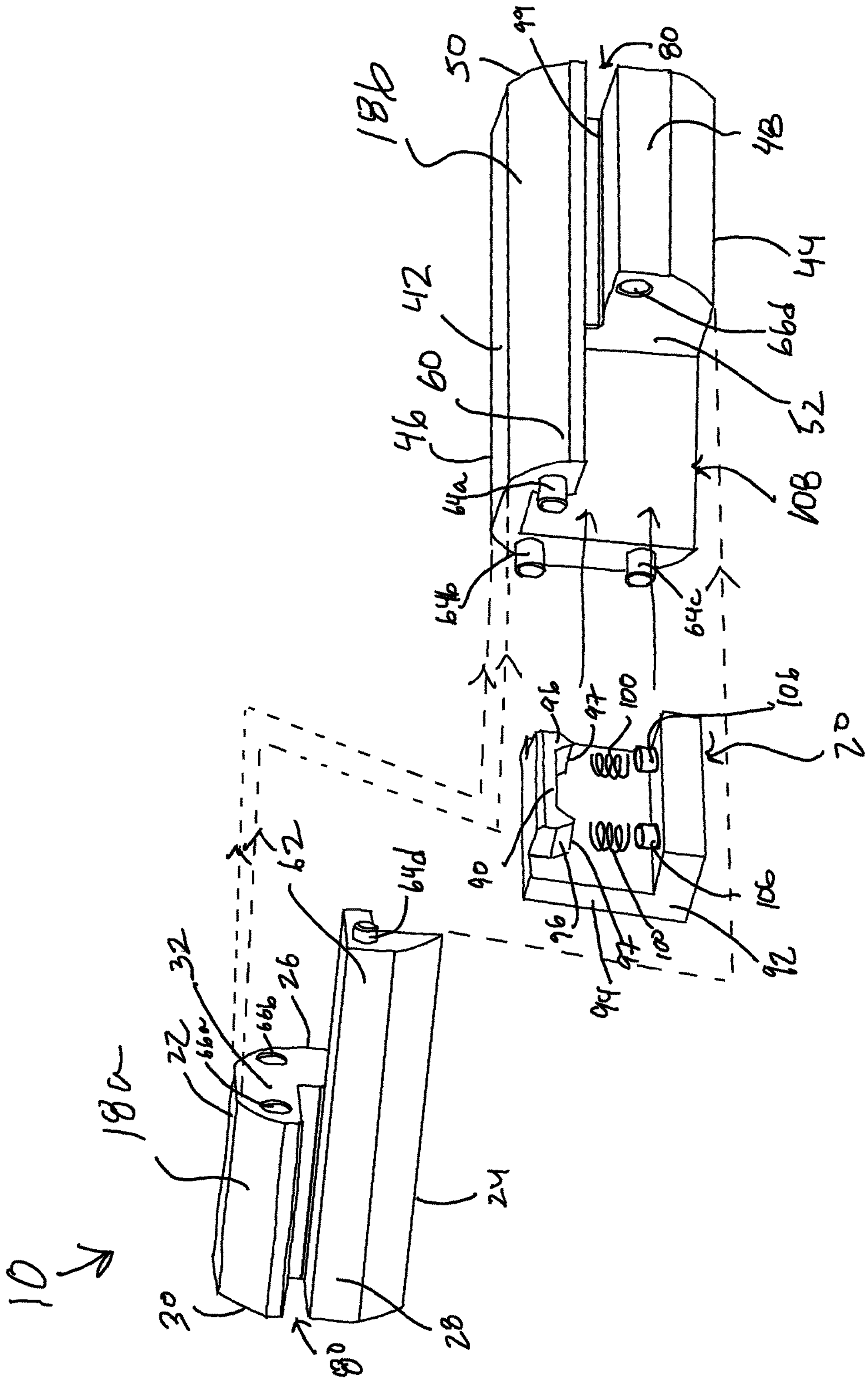

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Fig. 2

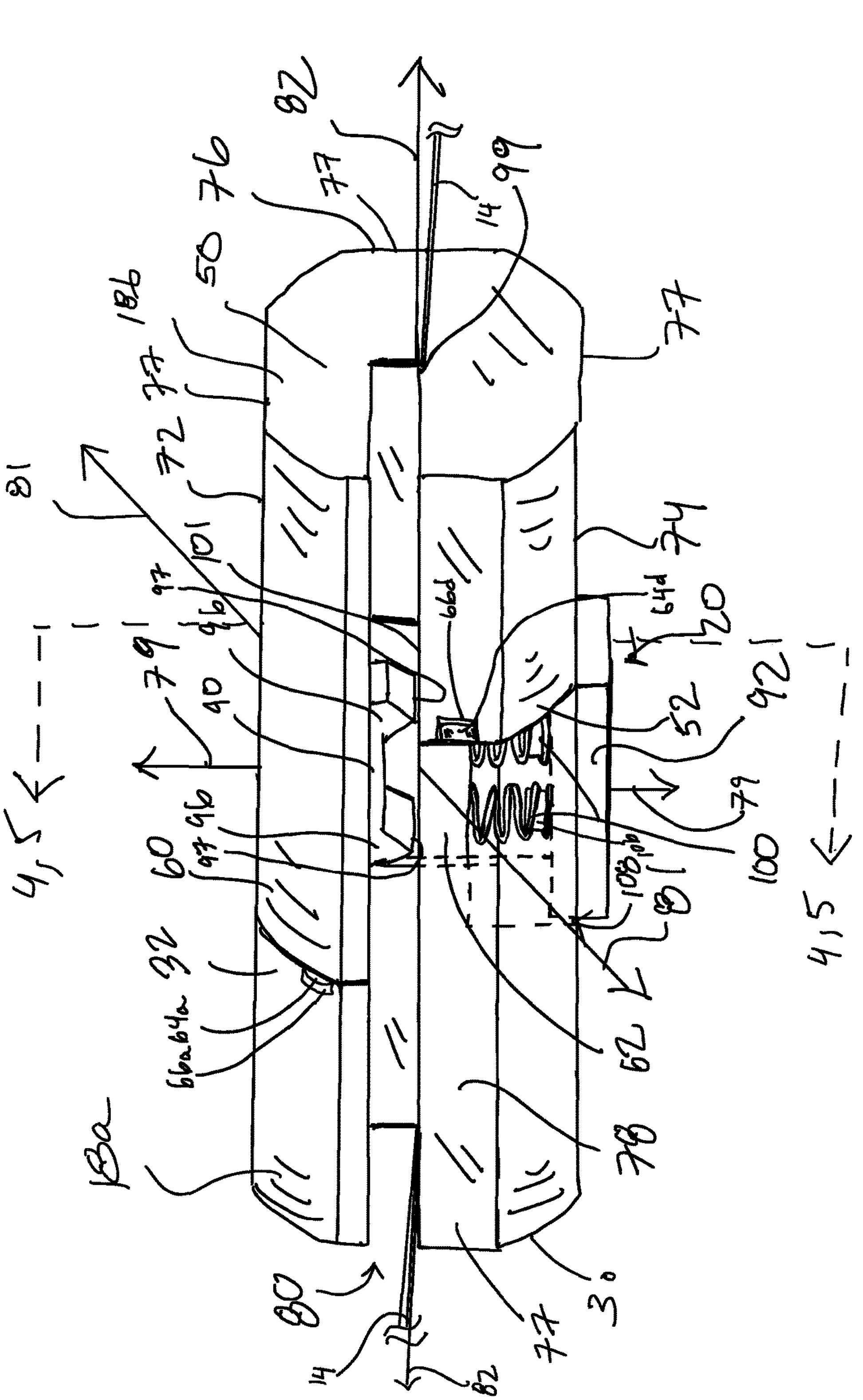

Fig. 3

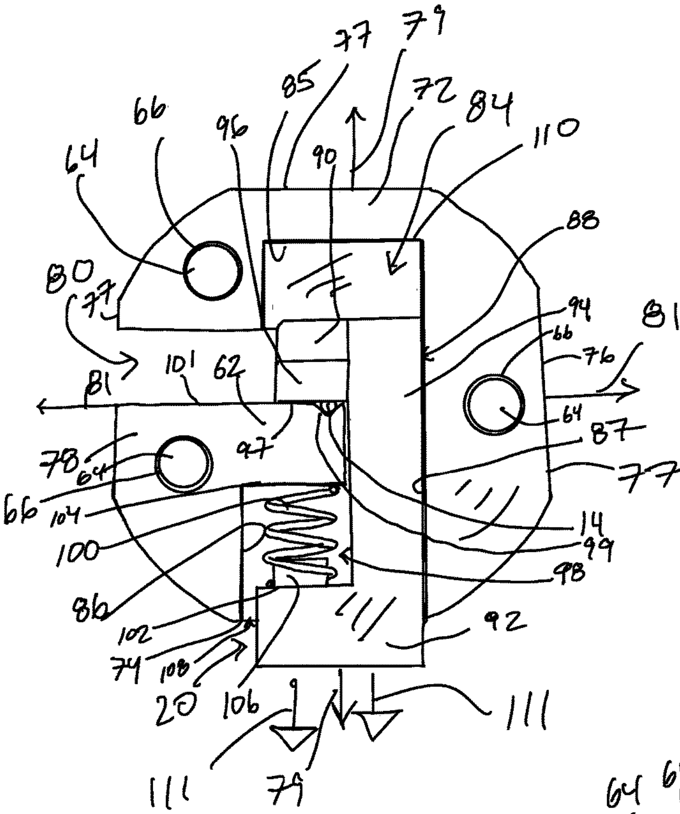

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Fig. 4

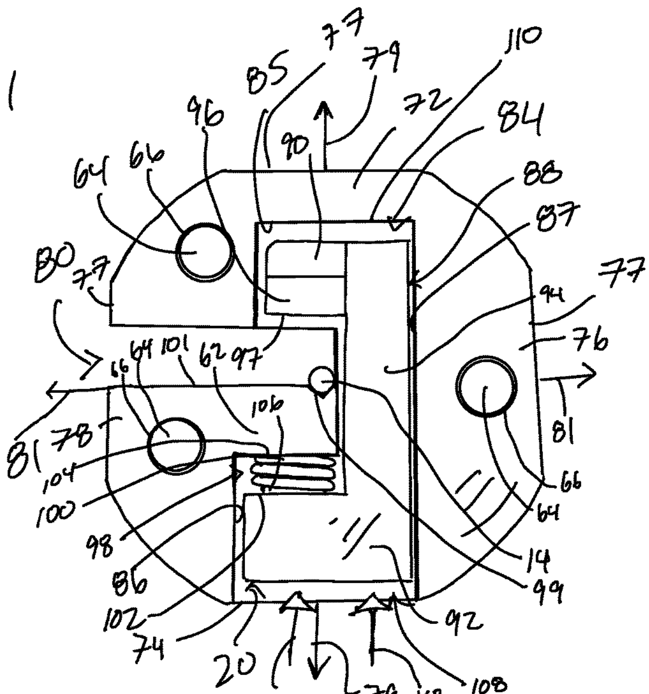

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Fig. 5

CLIP ON TORQUE DEVICE FOR ENDOVASCULAR PROCEDURES

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

CROSS REFERENCE TO RELATED APPLICATION

BACKGROUND OF THE INVENTION

[0001] The present invention relates to a medical wire manipulation device for controlling the linear and rotational (torque) motion of a wire and, in particular, to an improved torque device for making such controlling movements along the length of a guidewire during a minimally invasive procedure.

[0002] Spanning a broad range of medical disciplines including cardiology, neurology, urology, interventional radiology, and endovascular surgery, minimally invasive procedures have been on the rise and can range from treatment of narrowed arteries and veins, to insertion of drains and emergency hemorrhage control. Additionally, minimally invasive techniques can be used for diagnostic imaging, and interventional procedures or intervention focuses on performing minimally invasive, image-guided procedures throughout the body. The increasing number of these minimally invasive procedures indicates that small improvements in these procedures can have big impacts on improved surgical workflow and future patient outcomes.

[0003] In one non-limiting example, intervention for the treatment of cardiovascular disease has been gravitating towards minimally invasive methods. Endovascular procedures are increasingly common for minimally invasive treatment of conditions associated with cardiovascular disease, such as peripheral artery disease, deep vein thrombosis, coronary artery disease, and aneurysms. For example, there has been a significant shift in treating abdominal aortic aneurysms using minimally invasive endovascular procedures, with a 76% decrease in traditional open surgery. This increase in endovascular interventions, compared to open surgery, has resulted in lower associated costs, shorter recovery times, and reduced negative impact on the patient.

[0004] For many minimally invasive techniques, time-critical navigation of tortuous vasculature is required, demanding intricate manipulation of a guidewire. Torque devices are the ubiquitous method for providing fine-precision control of the guidewire. Torque devices help physicians advance, rotate, and grip the guidewire that is used to guide catheters to the desired location within the vascular system. Commonly used torque devices operate using a pin vise mechanism. This mechanism screws concentrically around the distal end of the guidewire and therefore must be loaded 180-300 cm from the incision. Overtightening may cause damage to the guidewire. Moreover, this cumbersome maneuver requires assistance from a second individual.

[0005] Any procedure change or additional tool available to the physician that aids in decreasing procedure times is an opportunity to improve patient outcomes. Thus, there is an opportunity to improve torque devices to increase usability for the physician and further reduce procedure times during minimally invasive procedures.

SUMMARY OF THE INVENTION

[0006] The current market leaves a gap that can be filled by a torque device that is attachable at any position along the length of the guidewire, not just the distal end, with a single hand and without assistance. This increases usability and further reduces procedure times during minimally invasive procedures such as endovascular interventions.

[0007] The present invention provides a torque device that employs a cylindrical housing surrounding a guidewire to provide concentric loading of the guidewire along a central axis of the housing and attachable at any point along a length of the guidewire. Improved torsion of the guidewire is obtained by clamping the guidewire so that it runs along the center axis of the housing offering intuitive rotational handling (torque) of the guidewire along the torque axis. The housing increases the grip diameter of the guidewire improving the handling and "torqueability" of the guidewire or the ability to apply rotational force at the distal end or along the guidewire and have that force transmitted efficiently to achieve proper control at the proximal (insertion) end. This is an improvement over torque devices that are attached at the distal end only or fail to provide concentric clamping of the guidewire.

[0008] Further, the present invention provides a spring loaded torque device that clamps the guidewire along the central axis of the housing without adding unnecessary side bulk to the device or presenting an asymmetry to the device providing a less intuitive handling.

[0009] Further, the present invention provides a sufficient clamping force on the guidewire regardless of wire size that minimizes slipping while mitigating damage to the guidewire.

[0010] In one embodiment, the invention provides a device for manipulating a guidewire for surgery, comprising a housing adapted to receive a wire, insertable into a patient at an incision site, the housing having a slot receiving a center portion of the wire between a proximal end and distal end of the wire wherein the wire is positionable to extend on a central axis of the housing; and the housing supporting a clamp assembly having a pincher and a biasing member configured to apply a biasing force on the pincher to bias the pincher to contact the wire at an at least one discrete pinch area to prevent movement of the wire with respect to the pincher.

[0011] It is thus a feature of at least one embodiment of the invention to create a concentric housing that provides a greater diameter grip section of the guidewire increasing torqueability.

[0012] The housing may be cylindrical in shape extending along the central axis of the housing.

[0013] It is thus a feature of at least one embodiment of the invention to facilitate rotation (torque) of the housing about the central axis by using a rounded cylindrical device that can be easily rotated between two fingers.

[0014] The housing may have at least two opposed flattened outer surfaces.

[0015] It is thus a feature of at least one embodiment of the invention to assist with gripping the cylindrical housing when the housing is slippery without adversely affecting the rotatability of the cylindrical housing.

[0016] The housing may be substantially concentric about an axis of the wire.

[0017] It is thus a feature of at least one embodiment of the invention to create intuitive rotation of the guidewire which corresponds to the rotation of the housing on the same axis where finely tuned torque precision is desired.

[0018] The slot may extend from a sidewall of the housing to the central axis. The slot has a height that is between 1 mm to 3 mm or between 1.9304 mm and 2.8956 mm.

[0019] It is thus a feature of at least one embodiment of the invention to allow the housing to be installed along the length of the guidewire so that the guidewire can be handled closer to the incision site/proximal end rather than at the distal end thus providing better hand control.

[0020] A groove may be formed on an inner wall of the slot receiving the wire substantially on the center axis. The groove may be V-shaped.

[0021] It is thus a feature of at least one embodiment of the invention to align the wire on the central axis regardless of the diameter of the wire and to position the wire along the pinch point locations where pinching contact can be confidently made.

[0022] At least one discrete pinch area may be discrete points on the wire. The pincher may include at least one outwardly extending pinching tooth. The pincher may include two pinching teeth.

[0023] It is thus a feature of at least one embodiment of the invention to minimize damage to the wire, caused by applying excessive force, and by limiting the force contact areas to discrete pinch points.

[0024] The biasing member may include at least one spring.

[0025] It is thus a feature of at least one embodiment of the invention to offload the desired pinching force to spring loaded clamps where the clamping force can be modified by changing the number of springs and/or the spring constant of the selected springs.

[0026] The clamp assembly may comprise a jaw supporting the pincher and movable against the biasing force of the biasing member. The jaw may comprise an upper arm opposite a lower arm. At least one of the upper arm and lower arm support the pincher and the other of the upper arm and lower arm support the biasing member.

[0027] It is thus a feature of at least one embodiment of the invention to reduce the number of separate parts by incorporating the push button and pincher into a single movable clamp assembly.

[0028] A button may be pressable by a human finger to move the pincher against the biasing force of the biasing member.

[0029] It is thus a feature of at least one embodiment of the invention to allow the housing to be installed on the guidewire at any location along the guidewire through one handed, one finger push button operation without the assistance of a second individual.

[0030] One embodiment of the present invention provides a method for manipulating a guidewire having a central portion between a proximal end and distal end of the wire for surgery comprising inserting the proximal end of the guidewire into a patient at an incision site, inserting the central portion of the guidewire into a slot of a housing wherein the guidewire is positionable to extend on a center axis of the housing; and clamping a clamp assembly to contact the guidewire at an at least one discrete pinch area.

[0031] The clamp assembly may apply a biasing force to contact the guidewire at the at least one discrete pinch area.

[0032] The method may further comprise pressing a button to apply an opposite force against the biasing force of the clamp assembly to release the guidewire at the at least one discrete pinch area.

[0033] The method may further comprise inserting the central portion of the guidewire into a groove of the slot of the housing wherein the groove extends on the center axis of the housing.

[0034] These particular objects and advantages may apply to only some embodiments falling within the claims and thus do not define the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] FIG. **1** is a perspective view of the torque device held by a hand of a physician in accordance with one embodiment of the present invention and may be positioned on a guidewire between the proximal end (inserted into a patient) and distal end to hold a guidewire on a central axis of a housing of the torque device;

[0036] FIG. **2** is an exploded view of the torque device of FIG. **1** showing the relative attachment of the left housing part and right housing part by corresponding pegs and holes to form an internal cavity for movably supporting a clamping device positioned therebetween;

[0037] FIG. **3** is a perspective view of the torque device of FIGS. **1** and **2** shown in partial phantom showing a push button protruding from the bottom of the housing and the clamping device spring biased in a "clamping position" to clamp the guidewire on the central axis;

[0038] FIG. **4** is a cross sectional view of the torque device of FIG. **3** showing the clamping device spring biased in the "clamping position" to clamp the guidewire on the central axis and the push button protruding from the bottom of the housing; and

[0039] FIG. **5** is a cross sectional view of the torque device similar to FIG. **4** showing the clamping device in a "non-clamping position" to allow the guidewire to be inserted along the central axis, or release the guidewire, when the push button is pressed into the housing.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0040] Referring now to FIG. **1**, a torque device **10** constructed according to one embodiment of the present invention may provide a torque housing **12**. The torque housing **12** is sized and shaped to receive a guidewire **14** therein, the guidewire **14** being further inserted into an opening or passage of a patient during a minimally invasive procedure. In use, a catheter may be guided over the guidewire **14** to assist with the minimally invasive interventional procedure as understood in the art. In one non-limiting example, the guidewire **14** is guided into a blood vessel to perform vascular and endovascular surgery, including complex stenting procedures, blood clot removal, and bypass surgery.

[0041] The guidewire **14** has a proximal end (not shown) inserted into the patient's body and an opposite distal end **16** with a length therebetween supporting the torque device **10** held and maneuvered by the physician's hand to advance and torque the guidewire **14**. The guidewire **14** may have an overall length ranging from 50 cm to 500 cm in length and have diameter sizes ranging from 0.3048 mm to 0.9652 mm (0.012 to 0.018 inches). The guidewire **14** has varied tensile strengths (e.g., at least 5 Newton (N)) and may be solid, braided, or coiled in construction. The guidewire **14** may include surface coatings that may increase lubricity and trackability, or assist with attracting or repelling water. Examples of guidewire coatings known in the art include polyvinylpyrrolidone (PVP), polytetrafluoroethylene (PTFE), polyacrylamides, hyaluronic acid, water-trapping hydrogels, and the like.

[0042] Referring also to FIG. **2**, the torque housing **12** may be defined by a cylindrical shell formed by joining two separate cylindrical connectable housing parts **18***a*, **18***b* along corresponding connectable side walls to produce a singular torque housing **12** further supporting a clamp assembly **20**. The connectable housing parts **18***a*, **18***b* may be manufactured of injection molded plastics such as polyethylene, polypropylene, polystyrene, polycarbonate, polyetheretherketone (PEEK), and the like.

[0043] A first housing part **18***a* includes an upper wall **22** opposite a lower wall **24** and flanking a rear wall **26** opposite a front wall **28**. An outer left sidewall **30** extends opposite a mating right sidewall **32**, with the mating right sidewall **32** couplable to the second housing part **18***b*. The second housing part **18***b* includes an upper wall **42** opposite a lower wall **44** and flanking a rear wall **46** opposite a front wall **48**. An outer right sidewall **50** extends opposite a mating left sidewall **52**, with the mating left sidewall **52** couplable to the first housing part **18***a*.

[0044] The mating right sidewall **32** of the first housing part **18***a* and the mating left sidewall **52** of the second housing part **18***b* interlock to provide an overlap of an upper projection **60** of the mating left sidewall **52** of the second housing part **18***b* over a lower projection **62** of the mating right sidewall **32** of the first housing part **18***a*. The upper projection **60** joins the mating right sidewall **32** and the lower projection **62** joins the mating left sidewall **52**. When joined, the connectable housing parts **18***a*, **18***b* leave hollow spaces therebetween that, when joined, form a cavity which permits the clamp assembly **20** to be supported therein, as further described below.

[0045] The upper projection **60** and the mating right sidewall **32**, and the lower projection **62** and the mating left sidewall **52**, respectively, may be joined by outwardly extending pegs **64** and corresponding holes **66**. The interlocking pegs **64** and holes **66** may be cylindrical pegs secured by an interference fit into corresponding cylindrical holes, and optionally, may be further secured by using an adhesive. For example, the pegs **64** may have a diameter of about 1.36 mm and the corresponding holes **66** may have a slightly larger diameter of about 1.72 mm. The corresponding pegs **64** and holes **66** may have lengths and depths, respectively, of about 1 mm.

[0046] In one embodiment, the outwardly extending pegs **64** may extend from the upper projection **60** and the lower projection **62** and the corresponding holes **66** may be formed in the mating right sidewall **32** and the mating left sidewall **52**, however, it is understood that the location of the outwardly extending pegs **64** and corresponding holes **66** may be reversed or may be positioned at any location on the mating right sidewall **32** and the mating left sidewall **52**.

[0047] The upper projection **60** and the mating right sidewall **32**, and the lower projection **62** and the mating left sidewall **52**, may include one or more corresponding pegs **64** and holes **66**. In one embodiment, as seen in FIGS. **2** and **3**, the upper projection **60** may support a first peg **64***a*, a second peg **64***b*, and third peg **64***c* insertable into a first hole **66***a*, a second hole **66***b*, and third hole (hidden from view), respectively, of the mating right sidewall **32**, and the lower projection **62** supports a fourth peg **64***d* insertable into a third hole **66***d* of the mating left sidewall **52**. It is understood that the number and configuration of the outwardly extending pegs **64** and corresponding holes **66** may vary, e.g., as seen in the alternative embodiment seen in FIGS. **4** and **5** showing three pegs **64** and three holes **66**, to secure the connectable housing parts **18***a*, **18***b* together.

[0048] Although outwardly extending pegs **64** and corresponding holes **66** are described herein, it is understood that the mating right sidewall **32** and the mating left sidewall **52**, may be joined by other attachment means known in the art such as using snap fits, mechanical fastening, welding, adhesive and solvent bonding, UV bonding, and the like. It is also understood that the torque housing **12** may be formed as a unitary structure instead of joinable parts without deviating from the spirit of the invention.

[0049] Referring now to FIG. **3**, upon joining the first housing part **18***a* and second housing part **18***b*, the torque housing **12** forms a generally cylindrical shell with a central axis **82** extending along a length of the housing **12** and having a housing upper wall **72** (formed by the joining of the upper wall **22** and upper wall **42**) opposite a housing lower wall **74** (formed by the joining of the lower wall **24** and lower wall **44**), and flanking a housing rear wall **76** (formed by the joining of the rear wall **26** and rear wall **46**) opposite a housing front wall **78** (formed by the joining of the front wall **28** and front wall **48**). The torque housing **12** has a height, extending along a vertical axis **79** and between the housing upper wall **72** and the housing lower wall **74** that is between 10 to 15 mm and about 11.4 mm. The torque housing **12** has a length, extending along the central axis **82** of the torque housing **12** and between the outer left sidewall **30** and the outer right sidewall **50**, that is between 30 to 50 mm and about 39 mm. The torque housing **12** has a depth, extending along a horizontal axis **81** and between the housing front wall **78** and housing rear wall **76**, that is between 10 to 15 mm and about 11.4 mm. The torque housing **12** may have dimensions that are less than 50 mm by 15 mm by 15 mm and less than 40 mm by 12 mm by 12 mm.

[0050] The housing upper wall **72**, housing lower wall **74**, housing rear wall **76**, and housing front wall **78** may be slightly flattened on its outer surfaces **77** to provide opposed gripping surfaces to receive the physician's opposed fingers and that minimize accidental slipping that may occur, for example, when the physician's fingers are slippery when wet.

[0051] Referring also to FIGS. **4** and **5**, the torque housing **12** may include a guidewire slot **80** extending along the central axis **82** allowing the guidewire **14** to be inserted into an interior of the torque housing **12** along the central axis **82**. The guidewire slot **80** may be a hollow channel formed in the housing front wall **78** and extending inwardly from the housing front wall **78** to the central axis **82** along a horizontal axis **81** terminating on the central axis **82**.

[0052] The guidewire slot **80** may be a rectangular channel having a height measured along the vertical axis **79** between 1.0 mm to 3.0 mm; and at least 1.0 mm and at least 1.5 mm and at least 1.6 mm and at least 1.7 mm and at least 1.8 mm and at least 1.9 mm; and less than 3.0 mm and less than 2.9 mm and less than 2.8 mm and less than 2.7 mm and less than

2.6 mm and less than 2.5 mm, and corresponding to about or at least twice the diameter of the largest anticipated guidewire **14** diameter and less than three times the diameter of the largest anticipated guidewire **14** diameter (the largest anticipated guidewire diameter is about 0.9652 mm) or between about 1.9304 mm and 2.8956 mm. The height of the guidewire slot 80 permits easy insertion of the guidewire **14** but is not too wide to diminish the stabilizing force on the peripheral areas of the guidewire **14** surrounding the pinch points. The guidewire slot **80** may have a length measured along the axis **82** between 30 to 50 mm and about 39 mm and corresponding to the length of the torque housing **12**. The guidewire slot **80** may have a depth measured along the horizontal axis **81** between 5 to 8 mm and about 6.11 mm and corresponding to about half the depth of the torque housing **12** and extending to the central axis **82**.

[0053] The guidewire slot **80** extends to the central axis **82** of the torque housing **12** thus allowing the guidewire **14** to be placed on and along the central axis **82**. The bottom wall **101** of the guidewire slot **80** may include an alignment groove **99** assisting with the positioning of the guidewire **14** within the guidewire slot **80** on and along the central axis **82**. The alignment groove **99** may have a V-shaped (like a V-block), round, or rectangular cut out or groove (when viewed in cross section as seen in FIGS. **4** and **5**) extending along the central axis **82** and receiving a bottom side of the guidewire **14** but permitting the top side of the guidewire **14** to project upwardly from the alignment groove **99** (even for the smallest anticipated guidewire diameter of 0.3048 mm). In this respect, the alignment groove **99** does not eliminate or reduce contact of the top side of the guidewire **14** with the clamp assembly **20** which is necessary to contact the guidewire **14** to prevent slipping (when linear and torque force is applied) as further discussed below.

[0054] The mating right sidewall **32** of the first housing part **18*a*** and the mating left sidewall **52** of the second housing part **18*b*** may include hollow spaces therebetween that join to form a clamp cavity **84** (see FIGS. **4** and **5** in cross section) between the first housing part **18*a*** and second housing part **18*b***. The clamp cavity **84** may be sized and shaped to receive the movable clamp assembly **20** and provide restricted linear vertical movement, as further described below.

[0055] The clamp assembly **20** includes a C-shaped jaw **88** having an upper horizontal arm **90** extending along the housing upper wall **72** and a lower horizontal arm **92** extending along the housing lower wall **74**. The upper horizontal arm **90** and lower horizontal arm **92** are joined by a vertical bridge **94** extending along the housing rear wall **76**.

[0056] The upper horizontal arm **90** has a length measured along the central axis **82** between 6 to 10 mm and about 8.10 mm and a height measured along the vertical axis between 1 to 3 mm and about 1.15 mm and a depth measured forwardly from the vertical bridge **94** between 1.5 to 3 mm and about 2.2 mm. The lower horizontal arm **92** has a length measured along the central axis **82** between 10 to 12 mm and about 11.7 mm and a height measured along the vertical axis between 1.5 to 3 mm and about 2.3 mm and a depth measured forwardly from the vertical bridge **94** between 1.5 to 4 mm and about 3.2 mm. The upper horizontal arm **90** may have a slightly shorter height, shorter depth, and shorter length than the lower horizontal arm **92**. The vertical bridge **94** has a length measured along the central axis **82** between 10 to 15 mm and about 11.7 mm and a height measured along the vertical axis **79** between 8 to 10 mm and about 9.15 mm and a depth measured along the horizontal axis **81** between 1 to 3 mm and about 1.8 mm.

[0057] The clamp cavity **84** is C-shaped with an upper horizontal cavity **85**, a lower horizontal cavity **86**, and a vertical cavity **87** receiving the upper horizontal arm **90**, lower horizontal arm **92** and vertical bridge **94**, respectively, of the C-shaped jaw **88**. The C-shaped jaw **88** is restrained from substantial movement along the central axis **82** by the mating right sidewall **32** and the mating left sidewall **52** (as best seen in FIG. **3**). The C-shaped jaw **88** is restrained from substantial movement along the horizontal axis **81** by the housing front wall **78** and the housing rear wall **76** (as best seen in FIGS. **4** and **5**). The C-shaped jaw **88** is movable along the vertical axis **79** but is restricted along the vertical axis **79** by the housing upper wall **72** on a top end and by the rightward extending lower projection **62** (separating the upper horizontal cavity **85** and lower horizontal cavity **86**) engaging the upper horizontal arm **90** on a lower end and preventing the upper horizontal arm **90** from moving further downward (as best seen in FIGS. **4** and **5**).

[0058] Generally, the clamp cavity **84** is sized and shaped to support the C-shaped jaw **88** and a biasing member **98** to permit the C-shaped jaw **88** to move between (1) a "clamping position" where the upper horizontal arm **90** is biased downward against a bottom wall **101** of the guidewire slot **80** and the lower horizontal arm **92** extends outwardly from a rectangular opening **108** of the housing lower wall **74** per FIGS. **4** and (2) a "non-clamping position" or "released position" where the upper horizontal arm **90** is raised above the bottom wall **101** and the lower horizontal arm **92** is pressed upwardly into the lower projection **62** of the housing lower wall **74** against the spring bias per FIG. **5**.

[0059] The upper horizontal arm **90** supports a pincher being a pair of downwardly extending teeth **96** for gripping the guidewire **14** extending within the alignment groove **99** of the guidewire slot **80** in the "clamping position." The downwardly extending teeth **96** may be a pair of triangular prisms with rectangular bases of the triangular prisms attached to the upper horizontal arm 90 with vertexes of the triangular prisms extending downwardly toward the bottom wall **101** of the guidewire slot **80** and forming a clamp edge **97** extending along the horizontal axis **81** and across (perpendicular to) the alignment groove **99**. The alignment groove **99** ensures that the clamp edges **97** of the downwardly extending teeth **96** will properly engage a top side of the guidewire **14** by maintaining the position of the guidewire **14** on and along the central axis **82**.

[0060] The bases of the triangular prisms may have a length measured along the central axis **82** between 1.5 to 3 mm and about 1.76 mm and spaced apart by a gap between 3 to 6 mm and about 4.74 mm, and a depth measured along the horizontal axis **81** between 1.5 to 3 mm and about 2.2 mm. Although the clamp edges **97** taper to tips, the clamp edges **97** may be slightly curved or rounded at the tips to increase the surface area contact on the guidewire **14** but minimizing damage to the guidewire **14**.

[0061] The clamp edges **97** of the downwardly extending teeth **96** will contact the guidewire **14** at two discrete contact areas or "pinch points" to hold the guidewire **14** against the bottom wall **101** of the guidewire slot **80**. It is understood that the number of downwardly extending teeth **96** and thus pinch points may be varied, for example, one, two or more pinch points. The pinch points minimize damage to the guidewire **14** by providing a greater downward point load on the wire at a small number of discrete points. However, it is understood that the downwardly extending teeth **96** may alternatively provide greater contact areas that are extended lengths of the guidewire **14** to increase the friction force on the guidewire **14**. In this respect, the length of the clamp edges **97** of the downwardly extending teeth **96** may be increased to increase the area of contact.

[0062] It is understood that the surface contact at the discrete contact areas between the guidewire **14** with the clamp edges **97** creates a friction force that will minimize slipping (when linear and torque force is applied) of the guidewire **14** with respect to the clamp edges **97**. The friction force is created through the biasing member **98** applying a force on the guidewire **14**, as further described below. Desirably, the clamped guidewire **14** can withstand an average tensile force (linear force) with a maximum value of 5 N for guidewires less than 0.762 mm diameter and 10 N for guidewires greater than 0.762 mm diameter without slipping. Desirably, the clamped guidewire **14** can withstand a torque force which avoids slipping during normal use.

[0063] Although it is contemplated that the C-shaped jaw **88** may be manufactured of an injection molded plastic similar to the torque housing **12**, the pair of downwardly extending teeth **96** could also be manufactured of a different material to assist with the clamping of the guidewire **14** such as a solid rubber or silicone which may produce an increased "flattened" contact area or may be roughened to increase the friction force on the guidewire **14**.

[0064] The C-shaped jaw **88** is biased to the "clamping position" which results in the downwardly extending teeth **96** clamping down on the guidewire **14** when an opposing force is not applied. A biasing force of the C-shaped jaw **88** is created by the biasing member **98** which may be springs, spring clips, spring steel, and the like. In one embodiment, the biasing member **98** may be a pair of springs **100** positioned between an upper surface **102** of the lower horizontal arm **92** and a lower surface **104** of the lower projection **62**. The pair of springs **100** may be spaced apart on the lower horizontal arm **92** to provide an equal distribution of spring force on the lower horizontal arm **92**.

[0065] The pair of springs **100** may be held in place by a pair of pegs **106** on at least one of the upper surface **102** of the lower horizontal arm **92** and the lower surface **104** of the lower projection **62** receiving the springs **100** thereon. The pair of pegs **106** may have a length of about 0.58 mm, and a diameter of about 1.20 mm, to support a length and diameter of the pair of springs **100** installed thereon to maintain a fixed position of the springs **100** along the length of the pegs **106** but allowing the springs to extend and compress.

[0066] In one embodiment, a first pair of pegs **106** may extend downwardly from the lower surface **104** of the lower projection **62** and/or a second pair of pegs **106** may extend upwardly from the upper surface **102** of the lower horizontal arm **92**, as shown, with the pair of springs **100** extending around and supported by the pairs of pegs **106**. It is understood that one or both of the lower surface **104** of the lower projection **62** and the upper surface **102** of the lower horizontal arm **92**, respectively, may support pegs **106**. It is also understood that the pair of springs **100** may be secured between the upper surface **102** of the lower horizontal arm **92** and the lower surface **104** of the lower projection **62** by other securing means known in the art such as spring stops, spring retainers, tape or zip ties, and the like.

[0067] Referring to FIG. **4**, when the pair of springs **100** is relaxed, the springs push the lower horizontal arm **92** downward along direction arrows **111** away from the lower projection **62**, thus moving the upper horizontal arm **90** downward against the bottom wall **101** to apply a pinching force on the guidewire **14**. The pair of springs **100** may be selected to provide a spring constant (k) with enough stiffness to apply enough force to retain the guidewire **14** within the alignment groove **99** without sliding but not too stiff to exert excessive force causing damage to the guidewire **14**. Further, the spring constant (k) is chosen to allow the physician to press against the pair of spring **100** with a single finger away from the "clamping position," as further discussed below. In one embodiment, the spring constant (k) is 1225.9 N/m to 5253.8 N/m (7 pounds per inch to 30 pounds per inch) and approximately 15 pounds per inch (2626.9 N/m).

[0068] When the lower horizontal arm **92** is spring biased to the "clamping position," the lower arm **92** extends downwardly and outwardly from the housing lower wall **74** along direction arrows **111** through a rectangular opening **108**. The lower horizontal arm **92** may extend outwardly approximately 1 to 2 mm from the housing lower wall **74** through the rectangular opening **108**.

[0069] Referring now to FIG. **5**, the lower horizontal arm **92** is accessible through the rectangular opening **108** in the housing lower wall **74** acting as a push button which allows the physician to finger press (without tools) the lower horizontal arm **92** upward along vertical axis **79** into the housing lower wall **74** to the "non-clamping position" or "released position" against the spring bias of the pair of springs **100** and thereby raising the upper horizontal arm **90** away from the bottom wall **101** releasing the downwardly extending teeth **96** from gripping or pinching the guidewire **14** or allowing a guidewire **14** to be inserted into the alignment groove **99**. The lower horizontal arm **92** may be pressed along direction arrows **112** into the housing lower wall **74**, for example, pressed approximately 2 to 4 mm upward along vertical axis **79** until the upper horizontal arm **90** abuts the upper wall **110** of the upper horizontal cavity **85**.

[0070] It is understood that the lower horizontal arm **92** acts as a push button that may be easily pressed along direction arrows **112** by the physician with one finger, for example, the torque housing **12** held between the thumb and index finger and the lower horizontal arm **92** pressed along direction arrows **112** by either the thumb or index finger. The button formed by the lower horizontal arm **92** may be sized approximately 11.7 mm by 5 mm which is approximately the same size as or slightly larger than the pad of a human finger thus permitting the pressure of the finger to evenly apply force onto the button. In this way, finger force is equally applied to the button so that both springs of the pair of springs **100** are compressed to avoid button tilt or slant and to maintain proper balance between springs.

[0071] Referring again to FIG. **1**, in operation, in a first step, during a minimally invasive surgical procedure the torque device **10** is held by the physician, for example, between their thumb and index finger. The physician may hold the guidewire **14** with their other hand to prepare for loading the torque device **10** onto the guidewire **14**.

[0072] Referring to FIG. **5**, in a second step, the physician uses their finger to press the lower horizontal arm **92** upward into housing lower wall **74** to move the upper horizontal arm **90** of the C-shaped jaw **88** upward away from the bottom wall **101** to the "non-clamping position" or "released position." The clearance between the downwardly extending teeth **96** and the bottom wall **101** permits the guidewire **14** to be inserted therebetween by the physician.

[0073] In a third step, the physician slides a short length of the guidewire **14** (at any position along the length of the guidewire **14**) into the guidewire slot **80** so that the guidewire **14** is positioned within the alignment groove **99** of the guidewire slot **80**. In one embodiment, the guidewire **14** may be inserted into the guidewire slot **80** at a position that is about 180 to 300 cm from the incision.

[0074] Referring now to FIG. **4**, in a fourth step, the physician releases the lower horizontal arm **92** to allow the C-shaped jaw **88** to move from the "non-clamping position" or "released position" to the "clamping position." Upon release of the lower horizontal arm **92**, the C-shaped jaw **88** is spring biased to clamp down on the guidewire **14** at the discrete contact areas or pinch points formed by the pair of downwardly extending teeth **96** to retain the guidewire **14** within the alignment groove **99** and on and along the central axis **82**.

[0075] Referring again to FIG. **1**, in a fifth step, the physician may move the torque housing **12** to manipulate the linear and rotational (torque) motion of the guidewire **14** with respect to the incision of the patient. The torque housing **12** provides intuitive handling by maintaining a concentric housing around the central axis **82** which increases a diameter of the guidewire **14** but leaves the central axis **82** of the torque housing **12** the same as an axis of the guidewire **14**. The cylindrical housing is easy to handle and rotate between the fingers without unwanted protrusions or asymmetry to the device. Further, the strong clamping of the guidewire **14** provided by the biasing member **98** minimizes unwanted slipping during maneuvering while still being usable with a range of guidewire **14** diameters.

[0076] Referring again to FIG. **5**, in a sixth step, the physician may remove the torque housing **12** from the guidewire **14** by pressing the lower horizontal arm **92** into the housing lower wall **74** to move the upper horizontal arm **90** of the C-shaped jaw **88** upward away from the bottom wall **101** to the "non-clamping position" or "released position."

[0077] In a final step, the physician slides the released guidewire **14** out of the guidewire slot **80** to remove the guidewire **14** from the torque housing **12**. The physician may desire to move the torque housing **12** to a different location along the guidewire **14** or may be ready to remove the guidewire **14** after use.

[0078] In certain embodiments, the torque housing **12** may be of various colors or include other visual identifiers to allow the physician to use the color of the torque device **10** as a visual indicator for identifying different guidewires **14**, e.g., differently sized guidewires **14**, used during surgery.

[0079] Further, the position of the torque housing **12** on the guidewire **14** may be used as a location marker to assist with visualizing the length of guidewire **14** inserted into the incision of the patient during the surgery.

[0080] In a non-limiting example, the torque device **10** may be used during endovascular surgery and open vascular surgery for conditions that affect the blood vessels and heart. In traditional open vascular surgery, incisions are made at the affected area, while endovascular surgery utilizes a minimally invasive approach. To perform an endovascular procedure, the physician punctures an artery using a needle and then navigates the vasculature to the affected area using a guidewire. The use of a catheter threaded over the guidewire delivers therapies to aid the patient, and this small incision results in minimal blood loss and a quicker recovery.

[0081] Certain terminology is used herein for purposes of reference only, and thus is not intended to be limiting. For example, terms such as "upper", "lower", "above", and "below" refer to directions in the drawings to which reference is made. Terms such as "front", "back", "rear", "bottom" and "side", describe the orientation of portions of the component within a consistent but arbitrary frame of reference which is made clear by reference to the text and the associated drawings describing the component under discussion. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import. Similarly, the terms "first", "second" and other such numerical terms referring to structures do not imply a sequence or order unless clearly indicated by the context.

[0082] When introducing elements or features of the present disclosure and the exemplary embodiments, the articles "a", "an", "the" and "said" are intended to mean that there are one or more of such elements or features. The terms "comprising", "including" and "having" are intended to be inclusive and mean that there may be additional elements or features other than those specifically noted. It is further to be understood that the method steps, processes, and operations described herein are not to be construed as necessarily requiring their performance in the particular order discussed or illustrated, unless specifically identified as an order of performance. It is also to be understood that additional or alternative steps may be employed.

[0083] It is specifically intended that the present invention not be limited to the embodiments and illustrations contained herein and the claims should be understood to include modified forms of those embodiments including portions of the embodiments and combinations of elements of different embodiments as come within the scope of the following claims. All of the publications described herein, including patents and non-patent publications, are hereby incorporated herein by reference in their entireties.

[0084] To aid the Patent Office and any readers of any patent issued on this application in interpreting the claims appended hereto, applicants wish to note that they do not intend any of the appended claims or claim elements to invoke 35 U.S.C. 112 (f) unless the words "means for" or "step for" are explicitly used in the particular claim.

What we claim is:

1. A device for manipulating a guidewire for surgery comprising:

a housing adapted to receive a wire partially insertable into a patient at an incision site, the housing having a slot receiving a center portion of the wire between a proximal end and distal end of the wire wherein the wire is positionable to extend on a central axis of the housing; the housing supporting

a clamp assembly having a pincher and a biasing member configured to apply a biasing force on the pincher to bias the pincher to contact the wire at an at least one discrete pinch area to prevent movement of the wire with respect to the pincher.

2. The device of claim **1** wherein the housing is substantially cylindrical extending along the central axis of the housing.

3. The device of claim **2** wherein the housing has at least two opposed flattened outer surfaces.

4. The device of claim **2** wherein the housing is substantially concentric about an axis of the wire.

5. The device of claim **1** wherein the slot extends from a sidewall of the housing to the central axis.

6. The device of claim **5** wherein the slot has a height that is between 1 mm to 3 mm.

7. The device of claim **1** further comprising a groove formed on an inner wall of the slot and receiving the wire substantially on the central axis.

8. The device of claim **7** wherein the groove is V-shaped.

9. The device of claim **1** wherein the at least one discrete pinch area are discrete points on the wire.

10. The device of claim **1** wherein the pincher includes at least one outwardly extending tooth.

11. The device of claim **10** wherein the pincher includes two teeth.

12. The device of claim **1** wherein the biasing member includes at least one spring.

13. The device of claim **1** wherein the clamp assembly comprises a jaw supporting the pincher and movable against the biasing force of the biasing member.

14. The device of claim **13** wherein the jaw comprises an upper arm opposite a lower arm.

15. The device of claim **14** wherein at least one of the upper arm and lower arm support the pincher and the other of the upper arm and lower arm support the biasing member.

16. The device of claim **1** further comprising a button pressable by a human finger to move the pincher against the biasing force of the biasing member.

17. A method for manipulating a guidewire having a central portion between a proximal end and distal end of the guidewire for surgery comprising:

inserting the proximal end of the guidewire into a patient at an incision site,

inserting the central portion of the guidewire into a slot of a housing wherein the guidewire is positionable to extend on a center axis of the housing; and

clamping a clamp assembly to contact the guidewire at an at least one discrete pinch area.

18. The method of claim **17** wherein the clamp assembly applies a biasing force to contact the guidewire at the at least one discrete pinch area.

19. The method of claim **18** further comprising pressing a button to apply a force against the biasing force of the clamp assembly to release the guidewire at the at least one discrete pinch area.

20. The method of claim **17** further comprising inserting the central portion of the guidewire into a groove of the slot of the housing wherein the groove extends on the center axis of the housing.

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