United States Patent Application Publication	20250262444
Kind Code	A1
Publication Date	August 21, 2025
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BIOSTIMULATOR TRANSPORT SYSTEM HAVING SWAGED TORQUE SHAFT

Abstract

A biostimulator transport system, such as a biostimulator delivery system, having a swaged torque shaft, is described. The torque shaft includes an outer cable coaxially arranged with an inner coil. The inner coil has a single wire coil extending around a central axis in a first helical direction, and the outer cable has several outer strands that extend around the central axis in a second helical direction that is different than the first helical direction. The outer cable can be swaged to form a close fit to the inner coil. The close fit of the swaged coaxial torque shaft structure can track to a target site through tortuous vessels and efficiently transfer torque from a handle to a docking cap of the biostimulator transport system to drive a biostimulator into the target site. Other embodiments are also described and claimed.

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Family ID: **1000008586667**

Appl. No.: **19/199257**

Filed: **May 05, 2025**

Related U.S. Application Data

parent US continuation 16859706 20200427 parent-grant-document US 12296181 child US 19199257
us-provisional-application US 62933084 20191108

Publication Classification

Int. Cl.: **A61N1/375** (20060101); **A61M25/01** (20060101); **A61N1/05** (20060101); **F16C1/02** (20060101)

U.S. Cl.:

CPC **A61N1/3756** (20130101); **A61M25/0113** (20130101); **A61N1/0573** (20130101); **A61N1/37512** (20170801); **F16C1/02** (20130101); A61N2001/0578 (20130101); A61N2001/058 (20130101)

Background/Summary

[0001] This application is a continuation of co-pending U.S. patent application Ser. No. 16/859,706, filed on Apr. 27, 2020, which claims the benefit of priority of U.S. Provisional Patent Application No. 62/933,084, filed on Nov. 8, 2019, entitled “Biostimulator Transport System Having Swaged Torque Shaft,” and these patent applications are incorporated herein by reference in their entirety to provide continuity of disclosure.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND

Field

[0003] The present disclosure relates to biostimulators and related delivery and retrieval systems and methods. More specifically, the present disclosure relates to transport systems for delivery or retrieval of leadless biostimulators.

BACKGROUND INFORMATION

[0004] Cardiac pacing by an artificial pacemaker provides an electrical stimulation of the heart when its own natural pacemaker and/or conduction system fails to provide synchronized atrial and ventricular contractions at rates and intervals sufficient for a patient's health. Such antibradycardial pacing provides relief from symptoms and even life support for hundreds of thousands of patients. Cardiac pacing may also provide electrical overdrive stimulation to suppress or convert tachyarrhythmias, again supplying relief from symptoms and preventing or terminating arrhythmias that could lead to sudden cardiac death.

[0005] Cardiac pacing by currently available or conventional pacemakers is usually performed by a pulse generator implanted subcutaneously or sub-muscularly in or near a patient's pectoral region. The generator usually connects to a proximal end of one or more implanted leads, the distal end of which contains one or more electrodes for positioning adjacent to the inside or outside wall of a cardiac chamber. Although more than one hundred thousand conventional cardiac pacing systems are implanted annually, various well-known difficulties exist, of which a few will be cited. For example, a pulse generator, when located subcutaneously, presents a bulge in the skin that patients can find unsightly, unpleasant, or irritating, and which patients can subconsciously or obsessively manipulate or “twiddle.” Even without persistent manipulation, subcutaneous pulse generators can exhibit erosion, extrusion, infection, disconnection, insulation damage, or conductor breakage at the wire leads. Although sub-muscular or abdominal placement can address some concerns, such placement involves a more difficult surgical procedure for implantation and adjustment, which can prolong patient recovery.

[0006] Leadless cardiac pacemakers incorporate electronic circuitry at the pacing site and eliminate leads, and thus, avoid the above-mentioned shortcomings of conventional cardiac pacing systems.

Leadless cardiac pacemakers can be anchored at the pacing site by an anchor. During delivery or retrieval of a leadless cardiac pacemaker, a transport system can apply torque to the leadless cardiac pacemaker via a docking cap to screw the anchor into, or out of, the target tissue.

SUMMARY

[0007] Existing transport systems used for delivery or retrieval of leadless cardiac pacemakers may have a torque transmission component to apply torque to a leadless cardiac pacemaker. For example, the torque transmission component may be an elongated cable that connects a docking cap to a handle of the transport system. The handle can be rotated to transmit torque through the cable to rotate the leadless cardiac pacemaker when it is attached to the docking cap. The torque transmission component may transmit torque, however, an efficiency of that torque transfer may be less than optimal. For example, the torque transmission component may be rotationally soft such that, as an input rotation is applied at an input end, energy is stored in the elongated cable without resulting in an output rotation at the docking cap. This phenomenon is referred to as “wind up.” Wind up can occur until an angular (or energy) threshold is met, at which point an output end of the cable can quickly rotate or whip to a new angular position that may or may not match an angular position of an input end of the cable. This phenomenon is referred to as “unloading” or “whip.” In other words, the output twist may lag the input twist in existing torque transmission components, which can result in poor torque transmission and a lack of correspondence between the input end and the output end of the torque transmission component. In short, correspondence between the input end and the output end is ideally a direct correlation (1:1 ratio) to ensure that rotation at the handle of the transport system matches rotation of the biostimulator within a patient, and this ideal is not met by existing transport systems.

[0008] A biostimulator transport system having a swaged torque shaft that promotes a direct correlation between an input rotation at a handle and an output rotation at a docking cap, is provided. The biostimulator transport system can be a catheter-based system for delivering or retrieving a leadless pacemaker. In an embodiment, the biostimulator transport system includes the handle coupled to a proximal end of the torque shaft, and the docking cap coupled to a distal end of the torque shaft. An intermediate component, such as a hypotube, can connect the proximal end of the torque shaft to the handle. The handle can have one or more portions, e.g., a proximal handle portion and a distal handle portion, and at least one of the handle portions can be twisted to impart the input rotation to the torque shaft. For example, the proximal handle portion can be rotated relative to the distal handle portion to twist the hypotube and transmit torque to and through the torque shaft.

[0009] The torque shaft can have a swaged, dual-layer, coaxial construction. More particularly, an outer cable having several strands can be coaxially arranged about an inner coil having a wire coil. The outer strands and the wire coil can extend helically around a central axis. For example, the outer strands can spiral about the central axis in a first helical direction, e.g., right handed rotation, and the wire coil can spiral about the central axis in a second helical direction, e.g., left handed rotation.

[0010] The outer cable can be swaged over at least a portion of a length of the torque shaft. For example, the outer cable can be swaged and then loaded onto the inner coil, or the outer cable can be swaged directly onto the inner coil. In either case, the outer cable can be swaged over a portion of, or an entirety, of a coil length of the inner coil. The swaged outer strands can form a friction fit or a slip fit with the wire coil, and thus, torque transmission through the torque shaft can be improved. More particularly, when torque is applied to a proximal end of the torque shaft, one layer of the torque shaft can limit expansion and or contraction of the other layer, and thus, energy storage within the layers can be mitigated. As a result, the torque shaft experiences less wind up and can achieve direct correlation between an input torsional angle of the input torque at the proximal shaft end and an output torsional angle of the output torque at the distal shaft end. The swaged torque shaft can reduce wind up even under objectively challenging scenarios. For

example, in one use case, the torque shaft can experience multiple loading conditions at once, e.g., may transmit torque while under a varying compressive load. By way of example and not limitation, the torque shaft can transmit 100 oz-in while under a 5 lbf compressive load. Even under such conditions, the swaged torque shaft can experience reduced wind up and can achieve direct correlation between the input torsional angle and the output torsional angle.

[0011] A method of manufacturing the torque shaft is also described. The method includes loading the outer cable over the inner coil. The outer cable can be a in a pre-swaged state such that the outer strands are undeformed, e.g., round wires, or in a post-swaged state such that the outer strands are deformed, e.g., flattened wires. Accordingly, the pre-swaged outer cable can be swaged directly onto the inner coil to form a friction fit, or the post-swaged outer cable can be loaded over the inner coil to form a slip fit. The layers can be attached to each other at the ends of the tubular layers to form the torque shaft. The swaged torque shaft can be connected to the hypotube and/or the docking cap to form the torque shaft assembly. The torque shaft assembly can then be incorporated as a subcomponent of the biostimulator transport system.

[0012] In an embodiment, an outer sleeve is used to constrain the inner coil and the outer cable in a mating relationship, in addition to or instead swaging the outer cable. For example, the outer sleeve can be a thin-walled tubular component that surrounds and contains the inner coil and the outer cable. The outer sleeve can have an inner diameter that matches, e.g., is equal to, an outer diameter of the outer cable. For example, the outer sleeve can form a slip, friction, or press fit with the outer sleeve. Accordingly, expansion of the outer cable due to twisting of the torque shaft can be resisted by the hoop strength of the outer sleeve to maintain the inner coil and the outer cable in contact with each other.

[0013] The above summary does not include an exhaustive list of all aspects of the present invention. It is contemplated that the invention includes all devices, systems, and methods that can be practiced from all suitable combinations of the various aspects summarized above, as well as those disclosed in the Detailed Description below and particularly pointed out in the claims filed with the application. Such combinations have particular advantages not specifically recited in the above summary.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0015] FIG. **1** is a diagrammatic medial-lateral cross section of a patient heart illustrating an example implantation of biostimulators in the patient heart, in accordance with an embodiment.

[0016] FIGS. **2**A-**2**B are, respectively, side and end views of a biostimulator, in accordance with an embodiment.

[0017] FIG. **3** is a perspective view of a biostimulator transport system, in accordance with an embodiment.

[0018] FIG. **4** is a distal perspective view of a biostimulator transport system having a docking cap to receive a biostimulator, in accordance with an embodiment.

[0019] FIG. **5** is a cross-sectional view of a biostimulator transport system having a torque shaft assembly, in accordance with an embodiment.

[0020] FIG. **6** is a pictorial view of a torque shaft, in accordance with an embodiment.

[0021] FIG. **7** is a side view of a torque shaft, in accordance with an embodiment.

[0022] FIG. **8** is a cross-sectional side view of a torque shaft, in accordance with an embodiment.

[0023] FIGS. **9**A-**9**B are cross-sectional end views of a torque shaft in pre-swaged and post-swaged states, in accordance with an embodiment.
[0024] FIG. **10** is a detail view of a torque shaft in a post-swaged state in which outer strands form a friction fit with a wire coil, in accordance with an embodiment.
[0025] FIG. **11** is a flowchart of a method of manufacturing a torque shaft assembly, in accordance with an embodiment.
[0026] FIG. **12** is a perspective view of a handle having a rotation feedback mechanism, in accordance with an embodiment.

DETAILED DESCRIPTION

[0027] Embodiments describe a biostimulator transport system, such as a biostimulator delivery system, having a swaged torque shaft. As described below, the biostimulator transport system can be used to deliver a biostimulator into a heart of a patient to pace cardiac tissue. The biostimulator may, however, be used in other applications, such as deep brain stimulation. Thus, reference to the biostimulator as being a cardiac pacemaker is not limiting.
[0028] In various embodiments, description is made with reference to the figures. However, certain embodiments may be practiced without one or more of these specific details, or in combination with other known methods and configurations. In the following description, numerous specific details are set forth, such as specific configurations, dimensions, and processes, in order to provide a thorough understanding of the embodiments. In other instances, well-known processes and manufacturing techniques have not been described in particular detail in order to not unnecessarily obscure the description. Reference throughout this specification to “one embodiment,” “an embodiment,” or the like, means that a particular feature, structure, configuration, or characteristic described is included in at least one embodiment. Thus, the appearance of the phrase “one embodiment,” “an embodiment,” or the like, in various places throughout this specification are not necessarily referring to the same embodiment. Furthermore, the particular features, structures, configurations, or characteristics may be combined in any suitable manner in one or more embodiments.
[0029] The use of relative terms throughout the description may denote a relative position or direction. For example, “distal” may indicate a first direction along a central axis of a torque shaft assembly. Similarly, “proximal” may indicate a second direction opposite to the first direction. Such terms are provided to establish relative frames of reference, however, and are not intended to limit the use or orientation of a biostimulator transport system to a specific configuration described in the various embodiments below.
[0030] In an aspect, a torque shaft having coaxially arranged and swaged inner and outer layers is provided to improve torque transmission. The inner layer may be an inner coil including a single wire coil wound about a central axis, e.g., as a stacked coil tube. The outer layer may be an outer cable including several outer strands wound about the inner coil and the central axis. The inner layer and the outer layer can be wound about the central axis in opposite directions, and furthermore, one or more of the layers can be swaged to form one or more of a friction fit or a slip fit between the outer strands and the wire coil. Accordingly, the inner coil and the outer cable can cooperate to reduce wind up and enhance torque transmission. More particularly, as torque is applied to an input end of the torque shaft, the inner and outer layers can cinch against each other to limit an amount of torque-loading in the torque shaft. By limiting torque-loading in the torque shaft, the swaged dual-layer torque shaft can reduce a likelihood of torque “wind up” that can lead to “unloading” and over-rotation of a biostimulator. More particularly, the swaged, coaxial construction of the torque shaft can improve torque transmission to provide a direct correlation between rotations at a handle and rotations at an output end of the torque shaft and/or a docking cap of a biostimulator transport system. As described below, the swaged, coaxial construction also provides adequate column strength and axial rigidity to engage tissue while still being flexible enough in bending to prevent tissue trauma during delivery of the biostimulator to a target site.

[0031] Referring to FIG. **1**, a diagrammatic medial-lateral cross section of a patient heart illustrating an example implantation of biostimulator in the patient heart is shown in accordance with an embodiment. A cardiac pacing system includes one or more biostimulator **100**. The biostimulator(s) **100** can be implanted at respective target sites in a patient heart **104**. The biostimulator(s) **100** can be leadless, and thus, may be leadless cardiac pacemakers **102**. Each biostimulator **100** can be placed in a cardiac chamber, such as a right atrium and/or right ventricle of the patient heart **104**, or attached to an inside or outside of the cardiac chamber. Attachment of the biostimulator **100** to the target tissue can be accomplished via one or more fixation elements **106**, such as helical anchors. In a particular embodiment, the leadless pacemaker can use two or more electrodes located on or within a housing of the leadless pacemaker for pacing the cardiac chamber upon receiving a triggering signal from internal circuitry and/or from at least one other device within the body.
[0032] Referring to FIG. **2**A, a side view of a biostimulator is shown in accordance with an embodiment. The biostimulator **100** can be a leadless cardiac pacemaker **102** that can perform cardiac pacing and that has many of the advantages of conventional cardiac pacemakers while extending performance, functionality, and operating characteristics. The biostimulator **100** can have two or more electrodes, e.g., a distal electrode **202** and a proximal electrode **204**, located within, on, or near a housing **206** of the biostimulator **100**. In an embodiment, the fixation element **106** forms a portion of the distal electrode **202**. The electrodes can deliver pacing pulses to muscle of the cardiac chamber, and optionally, can sense electrical activity from the muscle. The electrodes may also communicate bidirectionally with at least one other device within or outside the body.
[0033] In an embodiment, the housing **206** has a longitudinal axis **208**, and the distal electrode **202** can be a distal pacing electrode mounted on the housing **206** along the longitudinal axis **208**. The housing **206** can contain a primary battery to provide power for pacing, sensing, and communication, which may include, for example, bidirectional communication. The housing **206** can optionally contain an electronics compartment **210** to hold circuitry adapted for different functionality. For example, the electronics compartment **210** can contain circuits for sensing cardiac activity from the electrodes, circuits for receiving information from at least one other device via the electrodes, circuits for generating pacing pulses for delivery via the electrodes, or other circuitry. The electronics compartment **210** may contain circuits for transmitting information to at least one other device via the electrodes and can optionally contain circuits for monitoring device health. The circuit of the biostimulator **100** can control these operations in a predetermined manner. In some implementations of a cardiac pacing system, cardiac pacing is provided without a pulse generator located in the pectoral region or abdomen, without an electrode-lead separate from the pulse generator, without a communication coil or antenna, and without an additional requirement of battery power for transmitted communication.
[0034] Leadless pacemakers or other leadless biostimulators **100** can be fixed to an intracardial implant site by one or more actively engaging mechanisms or fixation mechanisms, such as a screw or helical member that screws into the myocardium. In an embodiment, the biostimulator **100** includes the fixation element **106** coupled to the housing **206**. The fixation element **106** can be a helical element to screw into target tissue. More particularly, the fixation element **106** can extend helically from a flange **214** of the biostimulator **100**, which is mounted on the housing **206**, to a distal tip at a helix distal end **216**.
[0035] Referring to FIG. **2**B, an end view of a biostimulator is shown in accordance with an embodiment. The helix distal end **216** can be located distal to the distal electrode **202** (a centrally located electrode). Accordingly, when the biostimulator **100** contacts the target tissue, the distal tip can pierce the tissue and the housing **206** can be rotated to screw the fixation element **106** into the target tissue to pull the distal electrode **202** into contact with the tissue. By contrast, the housing **206** can be rotated to unscrew the fixation element **106** from the target tissue to retrieve the biostimulator **100**.

[0036] Leadless pacemakers or other leadless biostimulators **100** can be delivered to and retrieved from a patient using a transport system, as described below. In some implementations, the transport system is a delivery system for delivering the leadless pacemaker to the target tissue. In some implementations, the transport system is a retrieval system for retrieving the leadless pacemaker from the target tissue. Such delivery systems and retrieval systems can incorporate common components, such as a torque shaft or torque shaft assembly as described below.

[0037] Referring to FIG. **3**, a perspective view of a biostimulator transport system is shown in accordance with an embodiment. A biostimulator transport system **300** may be used for delivery and/or retrieval of the biostimulator **100**, e.g., a leadless pacemaker, into or from a patient. For example, the biostimulator transport system can be a biostimulator delivery system used for delivery of the biostimulator **100** into a patient. Alternatively, the biostimulator transport system can be a biostimulator retrieval system. The transport system is primarily referred to as being a delivery system for brevity below, however, such reference is non-limiting.

[0038] The biostimulator transport system **300** can include a handle **302**, and an elongated catheter **304** extending distally from the handle **302** to a distal catheter end **306**. The handle **302** can include several portions and features that allow a user to provide inputs at a proximal end of the system that translate to outputs at the distal end of the system. For example, the elongated catheter **304** can be a deflectable catheter, and an operator can use the handle **302** to steer the distal catheter end **306** in the patient. In an embodiment, the handle **302** includes a deflection lever **303** that can be used to deflect the distal catheter end **306**. By pivoting the deflection lever **303** toward a distal handle portion **350** of the handle **302**, the operator can cause a pull ring assembly (FIG. **5**) to apply off-axis compression to the elongated catheter **304**, resulting in lateral deflection of the distal catheter end **306**. The handle **302** can be used to apply a torque to a docking cap **320** at the distal end of the system. In an embodiment, the handle **302** includes proximal handle portion **352**. The proximal handle portion **352** can be rotationally and/or longitudinally moveable relative to the distal handle portion **350**. For example, the distal handle portion **350** can be coupled to the elongated catheter **304** and the proximal handle portion **352** can be coupled to a hypotube (FIG. **5**), and an operator can rotate the proximal handle portion **352** relative to the distal handle portion **350** to cause the docking cap **320**, which is rotationally linked to the proximal handle portion **352**, to rotate relative to the elongated catheter **304**, which is rotationally linked to the distal handle portion **350**. More information about the handle **302** and the handle functionality is described in the publications and patent applications that are incorporated by reference below.

[0039] In an embodiment, the biostimulator transport system **300** includes a protective sheath **308** mounted on the elongated catheter **304**. The protective sheath **308** can be slidably disposed on the elongated catheter **304**. The protective sheath **308** can include an atraumatic end **310**, e.g., a soft, funnel-shaped distal portion, that can slide distally over the distal catheter end **306** of the elongated catheter **304** and/or the biostimulator **100** (not shown). The atraumatic end **310** can have an outer dimension, which may be larger than a proximal portion of the protective sheath **308**. For example, the atraumatic end **310** may flare in a distal direction to a funnel opening that can advance over a docking cap **320** of the biostimulator transport system **300**. An outer dimension of the atraumatic end **310** can be larger than a region of the protective sheath **308** supporting a valve bypass tool **312**.

[0040] The valve bypass tool **312** can be slidably disposed on the protective sheath **308** such that a distal portion of the valve bypass tool **312** can slide distally over the distal catheter end **306** of the elongated catheter **304** and/or the atraumatic end **310** of the protective sheath **308**. More particularly, the valve bypass tool **312** can be inserted into an access introducer to gain access to the patient vasculature, and after access is established, the distal portion of the protective sheath **308** and/or the distal end of the elongated catheter **304** can be advanced through the valve bypass tool **312** into the patient.

[0041] The valve bypass tool **312**, the protective sheath **308**, and the elongated catheter **304** can have respective flush ports **322***a*, **322***b*, and **322***c* extending respectively therefrom. Each of the longitudinal bodies are displaceable proximal-distal relative to each other, and thus, the flush ports can be used to introduce and/or flush saline or other fluids between the longitudinal bodies or through the respective components in different relative positions.

[0042] Referring to FIG. **4**, a distal perspective view of a biostimulator transport system having a docking cap to receive a biostimulator is shown in accordance with an embodiment. The distal catheter end **306** of the elongated catheter **304** may be selectively connectable to the biostimulator **100**. More particularly, the biostimulator **100** can be mounted on the distal catheter end **306** of the elongated catheter **304**. In an embodiment, the biostimulator **100** includes an attachment feature **402**. The attachment feature **402** can be, for example, a protuberance extending proximally from the housing **206**. In an embodiment, the attachment feature **402** includes a channel (not shown) shaped and sized to receive one or more tethers **406**. The tethers **406** can comprise wires, shafts, tubes, cords, ropes, strings, or other similar structures that can extend throughout the catheter shaft **304**. For example, the tethers **406** can extend through a central lumen of a torque shaft assembly. In an embodiment, the tethers **406** include one or more snare wires having loops that can wrap or grasp around the attachment feature **402**. In some embodiments, the tethers comprise a shape memory material, such as nickel-titanium. In other embodiments, the tethers comprise stainless steel wires or braids. The tethers **406** can be inserted into and locked within the attachment feature **402** to connect the biostimulator **100** to the biostimulator transport system **300**. In other embodiments, the tethers **406** can be formed from wire or mechanical linkages created by processes such as machining, molding (metallic or polymer materials), or other fabrication processes.

[0043] The attachment feature **402** can have a shape and size that fits within a docking cavity **404** of the docking cap **320**. When the tethers **406** are locked within the attachment feature **402**, the tethers **406** can be retracted to pull the biostimulator **100** toward the docking cap **320**. As the biostimulator **100** moves toward the docking cap **320**, the attachment feature **402** can insert into the docking cavity **404**. Accordingly, the docking cavity **404** can receive the attachment feature **402** to dock the biostimulator **100** to the biostimulator transport system **300** for delivery or retrieval from the patient.

[0044] The biostimulator **100** can be protected by the atraumatic end **310** of the protective sheath **308** during delivery and/or retrieval of the biostimulator **100** from the patient. The atraumatic end **310** can have a braided or woven tubular construction. The atraumatic end **310** can therefore be advanced over the biostimulator **100** and may expand radially over the biostimulator **100** in the case where an outer dimension of the biostimulator **100** is greater than the inner diameter of the atraumatic end **310**. Accordingly, the atraumatic end **310** can cover the biostimulator **100** to protect the biostimulator during advancement into the patient.

[0045] While delivering the biostimulator **100** to the target tissue, the elongated catheter **304** is likely to encounter several reaction forces. For example, when the biostimulator transport system **300** is “loaded” with a biostimulator, the system undergoes a large, mostly static compressive force to maintain intimate coupling of the biostimulator to the transport system. This compressive force resists de-coupling of the biostimulator from the transport system as it is tracked through the venous system into the patient heart. The transport system may be deflected via an integrated catheter pullwire (FIG. **5**) to sweep the entire system through a deflection angle, e.g., 120 degrees, into a heart chamber from an inferior approach. Such deflection can be caused by pulling on the pullwire, and thus, a compressive force can be applied to the elongated catheter **304**. The atraumatic end **310** may also track along tortuous vessels that will apply compressive forces to the distal catheter end **306**. Similarly, when the biostimulator **100** is advanced toward the heart tissue to engage the tissue with the fixation element **106**, the heart tissue will apply axial or lateral loads to the distal catheter end **306**. Furthermore, rotation of the proximal handle portion **352** to screw the fixation element **106** into the heart tissue will be countered by resistance forces applied by the tissue to the fixation element **106**. Therefore, to promote effective tracking and implantation of the biostimulator **100**, the biostimulator transport system **300** can: have column strength and/or rigidity in an axial direction to promote trackability through tortuous vessels, be supple and flexible to allow deflection in bending such that tissue trauma is avoided either during tracking or engagement with the heart tissue, and transmit torque efficiently from the handle **302** to the docking cap **320** to drive the biostimulator **100** into the heart tissue.

[0046] Referring to FIG. **5**, a cross-sectional view of a biostimulator transport system having a torque shaft assembly is shown in accordance with an embodiment. The elongated catheter **304** of the biostimulator delivery system can include a torque shaft assembly **502** to transmit torque from the handle **302** to the docking cap **320**. More particularly, the torque shaft assembly **502** is torqueable and can be used to rotate the biostimulator **100** in a first direction, e.g., clockwise. Rotating the biostimulator in a first direction when the fixation element **106** is in contact with the heart tissue can cause the fixation element **106** to screw into the heart tissue and affix the biostimulator **100** to the heart tissue. By contrast, rotating the biostimulator **100** in a second direction opposite to the first direction when the fixation element **106** is affixed to the heart tissue can cause the fixation element **106** to unscrew from the heart tissue.

[0047] In an embodiment, the torque shaft assembly **502** includes a torque shaft **504**, the docking cap **320**, and a hypotube **506**. The torque shaft assembly **502** components transmit torque from the handle **302** to the biostimulator **100**, and can each function to facilitate that objective. As discussed above, the docking cap **320** can include a docking cavity **404** to receive the attachment feature **402** of the biostimulator **100** when the biostimulator is retracted against the docking cap **320** by the tethers **406**. In an embodiment, the docking cap **320** further includes one or more key features **508** that interfere with a surface of the attachment feature **402** when torque is transmitted through the torque shaft **504** to the docking cap **320**. Accordingly, the transmitted torque can be applied to the biostimulator **100** via the key feature **508** to cause the biostimulator **100** to rotate into, or out of, the target tissue.

[0048] The docking cap **320** can be mounted on the torque shaft **504**. More particularly, the torque shaft **504** can have a distal shaft end **510** coupled to the docking cap **320**, e.g., via a weld or adhesive joint. The torque shaft **504** can extend proximally from the docking cap **320** at the distal shaft end **510**, which may be near, e.g., within 25 mm, of the distal catheter end **306**, to a proximal shaft end **512** at a location intermediate between the distal shaft end **510** and the handle **302**. The hypotube **506** can connect the proximal shaft end **512** to the handle **302**, and thus, the proximal shaft end **512** may be coupled to the handle **302**.

[0049] In an embodiment, the hypotube **506** is a solid, thin-walled tube having a distal tube end **514** joined to the proximal shaft end **512**, and a proximal tube end **516** joined to the proximal handle portion **352** (not shown). The hypotube **506** can be cylindrical and extend over a proximal region of the elongated catheter **304**, and thus, is primarily used in relatively straight segments of the patient anatomy. Accordingly, the hypotube **506** primarily requires axial stiffness and 1:1 torque transmission. As a result, the thin-walled tubular structure of the hypotube **506** can achieve the functional objectives of the system component. In an embodiment, the hypotube **506** has a length of at least 60 mm, and has a wall thickness of 0.005-0.010 inches. The hypotube **506** may be fabricated from a stiff, biocompatible material, such as full hard **304** stainless steel.

[0050] Interaction between the torque shaft assembly **502** and the handle **302** can be achieved in numerous manners. For example, the hypotube **506** can be directly connected to the proximal handle portion **352**, which is rotatably coupled to the distal handle portion **350**, as described above. For the sake of brevity, reference is made to previously filed patent applications that describe biostimulator transport systems **300** having a torque shaft **504** that interacts with a handle **302**. The following publications include disclosures that are incorporated herein by reference: (1) U.S. application Ser. No. 15/783,454, filed on Oct. 13, 2017, entitled “CATHETER-BASED SYSTEM FOR DELIVERY AND RETRIEVAL OF A LEADLESS PACEMAKER” and published as US2018/0303514A1 on Oct. 25, 2018; (2) U.S. application Ser. No. 15/783,406, filed on Oct. 13, 2017, entitled “CATHETER-BASED SYSTEM FOR DELIVERY AND RETRIEVAL OF A

LEADLESS PACEMAKER" and published as US2018/0303513A1 on Oct. 25, 2018; (3) U.S. application Ser. No. 15/942,105, filed on Mar. 30, 2018, entitled "CATHETER-BASED DELIVERY SYSTEM FOR DELIVERING A LEADLESS PACEMAKER AND EMPLOYING A LOCKING HUB" and published as US2018/0280703A1 on Apr. 29, 2018; (4) U.S. application Ser. No. 15/783,475, filed on Oct. 13, 2017, entitled "CATHETER-BASED SYSTEM FOR DELIVERY AND RETRIEVAL OF A LEADLESS PACEMAKER" and published as US2018/0104452A1 on Apr. 19, 2018; (5) U.S. application Ser. No. 15/783,430, filed on Oct. 13, 2017, entitled "CATHETER-BASED SYSTEM FOR DELIVERY AND RETRIEVAL OF A LEADLESS PACEMAKER" and published as US2018/0104451A1 on Apr. 19, 2018; (6) U.S. application Ser. No. 15/783,363, filed on Oct. 13, 2017, entitled "CATHETER-BASED SYSTEM FOR DELIVERY AND RETRIEVAL OF A LEADLESS PACEMAKER" and published as US2018/0104450A1 on Apr. 19, 2018; and (7) U.S. application Ser. No. 15/783,298, filed on Oct. 13, 2017, entitled "CATHETER-BASED SYSTEM FOR DELIVERY AND RETRIEVAL OF A LEADLESS PACEMAKER" and published as US2018/0104449A1 on Apr. 19, 2018.

[0051] The biostimulator transport system **300** may include components that couple the torque shaft assembly **502** to the elongated catheter **304**. In an embodiment, a bearing **520** supports the docking cap **320** and/or the torque shaft **504** relative to a docking hub **522**. The bearing **520** can be a roller bearing **520**, for example, and can provide smooth supported rotational motion between the docking cap **320** and the docking hub **522**. The docking hub **522** can encase the distal end of the torque shaft **504**. The docking hub **522** may be a collar component that mounts on and attaches to the distal catheter end **306** of the elongated catheter **304**. Accordingly, when the torque shaft **504** is rotated, torque is transmitted to the docking cap **320** to allow it to spin freely relative to the docking hub **522**, and related to an outer sheath of the elongated catheter **304** on which the docking hub **522** is mounted.

[0052] In an embodiment, the biostimulator transport system **300** is steerable. More particularly, by pivoting the deflection lever **303** toward a distal handle portion **350** of the handle **302**, the operator can cause a pull ring assembly **550** to apply off-axis compression to the elongated catheter **304**, resulting in lateral deflection of the distal catheter end **306**. The pull ring assembly **550** can include a pull ring **552** attached to a distal end of a pull wire **554**. The components may be attached by a weld or adhesive bond, for example. The pull ring **552** may, for example, be a metallic or polymeric annulus that fits within an interior of the docking hub **522**. The pull ring **522** can interfere with a proximal portion of the interior, such that a proximal load applied to the pull ring **522** is transferred to the docking hub **522** and applies compression to the elongated catheter **304**. In an embodiment, the pull wire **554** is a metallic or polymeric wire extending through the elongated catheter **304**, e.g., between the outer sheath of the elongated catheter **304** and the torque shaft **502**. The pull wire **554** can connect to the deflection lever **303**, such that pivoting the lever applies an axial tension to the wire that pulls the pull ring **552** against the docking hub **522** to cause the biostimulator transport system **300** to deflect laterally and be steered to the target tissue.

[0053] Referring to FIG. **6**, a pictorial view of a torque shaft is shown in accordance with an embodiment. Whereas the hypotube **506** is primarily structured to maximize axial and torsional stiffness, the functional demands on the torque shaft **504** are different, and thus, the torque shaft **504** has a more complex structure. The torque shaft **504** is required to provide as close to 1:1 direct drive of the biostimulator as possible, however, the torque shaft **504** must also balance axial stiffness and suppleness to absorb compressive or bending loads during tracking. In an embodiment, a balance between torque transmission, axial stiffness, and suppleness is achieved using a swaged dual-layer construction. The torque shaft **504** can be fabricated from a same material as the hypotube **506**, e.g., 304 stainless steel, or from another biocompatible material, such as nickel titanium. The dual-layer construction can improve torque transmission and can achieve the required column strength/rigidity while also being very flexible in bending (for deflection).

[0054] The torque shaft **504** having the swaged dual-layer construction includes an inner layer, e.g., an inner coil **602**, within an outer layer, e.g., an outer cable **604**. The inner coil **602** can be coaxially arranged with the outer cable **604** along a central axis **606**. For example, the inner coil **602** can include one or more wire coils **608** wrapping around the central axis **606**, and the outer cable **604** can include several outer strands **610** wrapping around the central axis **606**. The wire coil(s) **608** can extend around the central axis **606** in a first helical direction **612**, and the outer strands **610** can extend around the inner coil **602** in a second helical direction **614**. In an embodiment, the first helical direction **612** is opposite to the second helical direction **614**. For example, whereas the first helical direction **612** may be a right-handed rotational direction around the central axis **606**, the second helical direction **614** may be a left-handed rotational direction around the central axis **606**. The torque shaft **504** can be flexible due to the coiled structure of the wire coil(s) **608** and the outer strands **610**, however, the dual-layer structure can support axial compression and torque transmission. To achieve such function, the inner and outer layers can compensate for and complement each other under axial and torsional loading. Under axial loading, the layers can stabilize each other to prevent buckling while still allowing some amount of give, e.g., when the biostimulator engages the target tissue. Under torsion, the layers can constrain diametric changes in each other to reduce wind up that may otherwise occur, e.g., in a single-layered torsional cable.

[0055] Referring to FIG. **7**, a side view of a torque shaft is shown in accordance with an embodiment. The inner coil **602** (hidden within the outer cable **604**) can include a wire coil **608** extending about the central axis **606** over a coil length **702**. More particularly, the inner coil **602** can extend through the outer cable **604** from a proximal coil end **704** to a distal coil end **706**. Similarly, the outer cable **604** can extend helically around the central axis **606** from the proximal coil end **704** to the distal coil end **706**.

[0056] The coil length **702** may be similar, but not necessarily identical, to a shaft length **708** of the torque shaft **504**. More particularly, the shaft length **708** can be between the proximal shaft end **512** and the distal shaft end **510**, and may be slightly longer than the coil length **702**. The difference between these lengths can stem from one or more welds between the inner coil **602** and the outer strands **610** at the extremities of the torque shaft **504**, e.g., at the ends of the tubular layers of the torque shaft **504**. For example, a proximal weld **710** can join the inner coil **602** to the outer cable **604** at the proximal coil end **704** and/or a distal weld **712** can join the inner coil **602** to the outer cable **604** at the distal coil end **706**. Accordingly, the shaft length **708** may be an entire length of the torque shaft **504**, including the weld zones, and the coil length **702** may be a portion of the shaft length **708** over which the inner coil **602** and the outer cable **604** are not directly joined by a bond, but may nevertheless be indirectly joined, e.g., via swaging, as described below.

[0057] In an embodiment, the welds at the extremities of the torque shaft **504** extend circumferentially around the torque shaft **504**. More particularly, the proximal weld **710** and/or the distal weld **712** can fuse the inner layer and the outer layer around an entire circumference of the torque shaft **504** about the central axis **606**. The circumferential welds can form collar sections, e.g., tubular sections, having lengths of 0.02-0.25 inches in length, e.g., 0.04 inches long. The collar sections may be entirely fused, e.g., there may be no gaps or holes visible in the collar sections under magnification. The welds can be formed using known welding processes, e.g., laser welding. The welded collars can provide attachment points to join the torque shaft **502** to the docking cap **320** and/or the hypotube **506**.

[0058] Referring to FIG. **8**, a cross-sectional side view of a torque shaft is shown in accordance with an embodiment. The inner coil **602** can include a single wire coil **608**, e.g., a single wound wire, wound in the first helical direction **612**. For example, the single wire coil **608** can be right hand wound. In an embodiment, the wire coil **608** has a quadrilateral cross-sectional profile. For example, the wire coil **608** can include a rectangular wire having a rectangular cross-sectional profile including height and width dimensions in a range of 0.1 to 0.5 mm, e.g., 0.15 mm by 0.3 mm. The rectangular cross-sectional profile allows the individual turns of the wire coil **608** to stack on each other, which can provide a stable columnar structure. For example, the wire coil **608** can have several turns that are in contact with each other such that the inner coil **602** is a stacked coil tube **802**. The stacked coil tube **802** may have no gaps between the turns, as shown in FIG. **8**, in an undeformed state. Accordingly, the inner coil **602** can have high columnar strength, yet can be flexible in bending, e.g., when a lateral load is applied to the stacked coil tube **802** the coil can bend and gaps can occur between the turns in the deformed state.

[0059] In an embodiment, the outer cable **604** is swaged, either before or after loading the outer cable onto the inner coil **602**. For example, the outer cable **604** can be swaged directly onto the inner coil **602**. Alternatively, the outer cable **604** can be swaged and then loaded onto the inner coil **602**. Swaging refers to a process in which one or more of the outer cable **604** or the inner coil **602** are radially compressed between surfaces, e.g., a mandrel and an outer die, to cause the compressed layer(s) to be cold-worked. The assembled layers can therefore be tightly-formed relative to each other. As described below, the cold-working can cause a cold-forming reduction in diameter of the outer cable **604** around the inner coil **602** to form a friction fit between the outer strands **610** and the wire coil **608**. Alternatively, the outer cable **604** can be cold-worked onto a mandrel, and then the post-swaged outer cable **604** can be loaded onto the inner coil **602** to form a slip fit. In an embodiment, the outer cable **604** is swaged, e.g., onto the inner coil **602**, over an entirety of the coil length **702** from the distal coil end **706** to the proximal coil end **704**. Alternatively, the outer cable **604** may be swaged over only a portion of the coil length **702**. For example, a stitch-swaging process may be used to swage the layers over several segments intermittently spaced between the distal coil end **706** and the proximal coil end **704**.

[0060] Referring to FIGS. **9**A, a cross-sectional end view of a torque shaft **504** in a pre-swaged state is shown in accordance with an embodiment. As compared to the single-stranded structure of the wire coil **608**, the outer cable **604** includes several outer strands **610** that are wound in a predominantly axial direction around the central axis **606**. For example, the outer cable **604** may include 15 outer strands **610** wound in the second helical direction **614**, e.g., the strands can be left hand wound. The strands **610** can overlay the wire coil **608**, and an angle formed between a helical axis of the wire coil **608** and a helical axis of each of the strands may be orthogonal, or nearly orthogonal. More particularly, a direction of the helical axis of the wire coil **608** can be predominantly circumferential and a direction of the helical axis of the outer strands **610** can be predominantly axial.

[0061] The outer strands **610** may have a pre-swaged cross-sectional profile (FIG. **9**A) and a post-swaged cross-sectional profile (FIG. **9**B). The pre-swaged and post-swaged cross-sectional profiles can differ because the swaging process can deform the outer strands **610** to reduce and conform the outer cable **604** to the inner coil **602**. In an embodiment, the pre-swaged cross-sectional profile is round. For example, the outer strands **610** can be formed from round wire stock, such as 0.2 mm diameter round wire, that is formed into a helically stranded tube prior to swaging. In the pre-swaged state, one or more circumferential gaps **902** may be located between adjacent outer strands **610**. Furthermore, the pre-swaged outer cable may fit over the pre-swaged inner coil **602** in a sliding fit, e.g., a radial gap can be present between the layers at locations along the torque shaft **504**.

[0062] Referring to FIG. **9**B, a cross-sectional end view of a torque shaft in a post-swaged state is shown in accordance with an embodiment. The post-swaged cross-sectional profile of the outer strands **610** and/or the wire coil **608** can be non-round. For example, each of the outer strands **610** may have, after swaging, an oblong or elliptical outer profile. The elliptical profile can result from the squeezing of the round profile into a post-swaged state. In the post-swaged state, the outer strands **610** can be in contact with each other such that the outer cable **604** is tubular. More particularly, there may be no gaps greater than 0.01 inches between the outer strands **610** over the length of the swaged regions. Accordingly, the pre-swaged helically-stranded tube having openings through the tube wall can become the post-swaged helically-stranded tube having a closed wall.

[0063] The illustrated cross-sectional profiles of the outer cable **604** and the inner coil **602** in the pre-swaged and post-swaged states are provided by way of example, and other cross-sectional profiles and profile combinations are within the scope of this description. For example, the single wire coil **608** may have a round, e.g., circular or elliptical, cross-sectional profile in the pre-swaged and/or post-swaged state. By contrast, the outer strands **610** of the outer cable **604** may have rectangular cross-sectional profiles in the pre-swaged and/or post-swaged state. Furthermore, the cross-sectional profiles of the wire coil **608** and the outer strands **610** may be the same, and the profiles may be round or non-round, e.g., elliptical, polygonal, etc. Accordingly, the respective profiles of the inner and outer layers may be varied within the scope of this description, and are not limited by the embodiments provided.

[0064] Referring to FIG. **10**, a detail view of a torque shaft in a post-swaged state in which outer strands form a friction fit with a wire coil is shown in accordance with an embodiment. The swaged layers of the torque shaft **504** can form a friction fit that resists relative motion between the outer cable **604** and the inner coil **602**. The friction fit can be caused in part by squeezing the coil and strand materials together. For example, the wire coil **608** can bulge into the remaining circumferential gaps **902** of the outer strands **610** and/or the outer strands **610** can embed in a radially outward surface of the inner coil **602**. The friction fit can support axial loading, e.g., the torque shaft **504** may resist at least **30** lbf of axial compression without separating the inner coil **602** from the outer cable **604**. Furthermore, the friction fit can support torque transmission, e.g., the swaged regions have layers that resist movement of each other and therefore reduce a likelihood of wind up in the torque shaft structure. Accordingly, the coaxial swaged torque shaft **504** provides good trackability and direct correlation between input rotation at the proximal shaft end **512** and outer rotation at the distal shaft end **510**.

[0065] In an embodiment, one or more of the layers can be swaged to form a slip fit between the outer strands **604** and the wire coil **608**. For example, the outer cable **604** may be swaged onto a mandrel having an outer diameter that is the same or slightly larger than an outer dimension of the inner coil **602**. Similarly, the wire coil **608** may be swaged onto a respective mandrel. The layer(s) can be removed from their respective mandrels, and the outer cable **604** can then be slipped onto the inner coil **602** in the post-swaged state such that the outer strands **604** form a slip fit with the wire coil **608**. The inner and outer layers can be attached to each other via weld(s) **710**, **712** to form the torque shaft **504** having a slip fit configuration. It will be appreciated that the slip fit configuration can have sufficient interference between the layers to reduce a likelihood of wind up during torque transmission, and thus, can improve torque transmission through the torque shaft **504**. More particularly, the slip fit can support axial compression and torque transmission, as described above.

[0066] Referring to FIG. **11**, a flowchart of a method of manufacturing a torque shaft assembly is shown in accordance with an embodiment. The torque shaft assembly **502** can be fabricated in a variety of manners, and one such process is described below. At operation **1102**, the outer cable **604** is loaded over the inner coil **602**. The assembled layers can be in a coaxial relationship. Optionally, one or more welds can be formed at the extremities of the inner and outer layers to form the torque shaft **504**. For example, a laser welding process can form the distal weld **712** and the proximal weld **710**. The welds may be circumferentially continuous to fuse the torque shaft layers around the entire shaft perimeter. The torque shaft **504** can therefore include the distal shaft end **510** and the proximal shaft end **512**.

[0067] At operation **1104**, the outer cable **604** is swaged. Swaging of the outer cable **604** can occur before or after operation **1102**. For example, when the outer cable **604** is swaged and then loaded onto the inner coil **602** to form a slip fit, operation **1104** can precede operation **1102**. By contrast, when the outer cable **604** is swaged directly onto the inner coil **602** to form a friction fit, operation **1102** can precede operation **1104**.

[0068] In an embodiment, operation **1104** precedes **1102**. The outer cable **604** and/or the inner coil **602** can be placed on respective mandrels. The layer(s) may be swaged over an entirety of the shaft length **708** or only a portion of the shaft length **708**. For example, the outer cable **604** and the inner coil **602** may be swaged to respective diameters such that, when the outer cable **604** is loaded onto the inner coil **602**, the layers form a slip fit.

[0069] In an embodiment, operation **1102** precedes **1104**. As a preliminary operation, the inner coil **602** may be placed on a mandrel having an outer diameter that is the same size as a desired inner diameter of the torque shaft **504**. The outer cable **604** can be loaded over the inner coil **602**. Optionally, the outer cable **604** can be pre-swaged. More particularly, the helically-stranded tubular structure of the outer cable **604** can be swaged to transition the cable from the pre-swaged state (FIG. **9**A) to the post-swaged state (FIG. **9**B). In either case, the outer cable **604** can be placed on the inner coil **602**, and the dual-layer pre-assembly can be supported on the mandrel. The outer cable **604** may then be swaged directly onto the inner coil **602** to form a friction fit between the layers.

[0070] In the swaging processes described above, the swaged component (the outer cable **604** and/or the inner coil **602**) can be swaged to varying degrees at discrete locations between the proximal shaft end **512** and the distal shaft end **510**. In an embodiment, the outer cable **604** is swaged to a greater degree, e.g., to a smaller outer diameter, at a location near the proximal shaft end **512** than at a location near the distal shaft end **510**. This variation in swaging over the length of the torque shaft **504** can include swaging more near the proximal end near the handle **302**. The swaging at the proximal end can form a stiffness that more closely matches the hypotube stiffness at that location. The increased stiffness can facilitate axial stiffness and torque transmission. By contrast, swaging less near the distal end can provide a more flexible region at that location, which may be better for tracking through tortuous vessels and absorbing impacts with the target tissue.

[0071] At operation **1106**, the proximal shaft end **512** may be attached to the hypotube **506**. A bonding process, such as welding, may be used to attach the torque shaft **504** to the hypotube **506**. Similarly, at operation **1108**, the distal shaft end **510** may be attached to the docking cap **320**. A bonding process, such as welding, may be used to attach the torque shaft **504** to the docking cap **320**. Accordingly, a torque shaft assembly **502** can be provided for integration in the biostimulator transport system **300**. The torque shaft assembly **502** can improve torque transmission from the handle **302** to the docking cap **320** by providing a 1:1 direct drive transmission shaft, and the torque shaft **504** can be trackable and supple.

[0072] Referring to FIG. **12**, a perspective view of a handle having a rotation feedback mechanism is shown in accordance with an embodiment. As described above, the swaged coaxial torque shaft **504** improves torque transmission and can reduce wind up in the shaft, which translates to 1:1 (or near 1:1) correspondence between input rotations at the handle **302** and output rotations at the docking cap **320**. The improved correspondence between input and output rotation can allow for improved granularity of device control by an operator. More particularly, the operator can rotate the input control of the handle **302** over a smaller angle and have increased confidence that the same small angle will be reproduced at the output of the docking cap **320**, rather than being absorbed in torsion of the shaft. The input control can include a feedback mechanism to indicate to the operator that a particular amount of rotation has been input to the torque shaft. A particular embodiment of the input control is described below.

[0073] In an embodiment, the handle **302** includes the distal handle portion **350** and the proximal handle portion **352**. The proximal handle portion **352** can be rotated about the central axis **606** to rotate relative to the distal handle portion **350**. Furthermore, rotation of the torque shaft **504** can be fixed to rotation of the proximal handle portion **352**. More particularly, when the operator rotates the proximal handle portion **352** relative to the distal handle portion **350**, the torque shaft **504** can also rotate relative to the distal handle portion **350**. The torque shaft **504** can be coupled to the proximal handle portion **352**. For example, a distal end of the proximal handle portion **352** can be mounted on the proximal shaft end **512**. Accordingly, rotation of the proximal handle portion **352** is an input rotation to the proximal shaft end **512**.

[0074] In an embodiment, the handle **302** includes a detent ring **1202**. The detent ring provides feedback to the operator that indicates an amount of input rotation applied to the torque shaft **504**. The detent ring **1202** can be mounted on a distal end of the proximal handle portion **352**, such that, as the proximal handle portion **352** rotates, the detent ring **1202** rotates. In an embodiment, the detent ring **1202** has a disc-shaped head having a circumferential outer surface **1204**. The circumferential outer surface **1204** includes one or more detents **1206**, which are recessed in the circumferential outer surface **1204**. More particularly, a radial distance between the central axis **606** and the detents **1206** is less than a radial distance between the central axis **606** and the outermost surfaces of the circumferential outer surface **1204**. The detents **1206** cause the circumferential outer surface **1204** to be bumpy, and more particularly, the detents **1206** cause intermittent recesses around the circumference of the detent ring **1202**. For example, there may be 8 detents evenly spaced around the circumferential outer surface **1204**.

[0075] The detent ring **1202**, which is mounted on the proximal handle portion **352**, can interface with a snick clip **1210**. In an embodiment, the snick clip **1210** is fixed to the distal handle portion **350**. For example, the snick clip **1210** can be mounted within a slot formed in the wall of the distal handle portion **350**, and optionally, may be bonded to the distal handle portion **350**. The snick clip **1210** can have an inner arc that receives the detent ring **1202**. The detent ring **1202** can be aligned to the inner arc, and thus, can rotate about the central axis **606** within the inner arc. In an embodiment, the snick clip **1210** includes one or more protrusions **1212** extending radially inward from the inner arc. For example, the snick clip **1210** can have a pair of protrusions diametrically opposed to each other about the circumferential outer surface **1204** of the detent ring **1202**. The protrusions **1212** can extend into contact with the detent ring **1202**. For example, as the detent ring **1202** rotates within the snick clip **1210**, the protrusions can ride over the bumpy surface of the circumferential outer surface **1204**. More particularly, the protrusions can ride over the outermost portions of the surface **1204**, and ride over the detents **1206**. As the protrusions **1206** transition into the detents **1206**, a tactile click can be felt in the handle **302**. This click is the result of the protrusions **1212** snapping into the detents **1204**. Accordingly, the engagement of the detent ring **1202** and snick clip **1210** can provide tactile feedback to a user indicating that a particular input rotation has been transmitted to the torque shaft **504**.

[0076] In an embodiment, the detent ring **1202** includes at least 4, e.g., 8, evenly spaced detents **1204**. Thus, each click of the snick clip **1210** corresponds to at least 90 degrees, e.g., 45 degrees, of rotation input to the torque shaft **504**. That is, in the case of 8 detents, as the protrusions **1212** exit a first detent, ride over the outermost surface of the detent ring **1202**, and click into place within a second adjacent detent, the input rotation will have been 45 degrees.

[0077] It will be appreciated that 1:1 correspondence between the input to the torque shaft **504** and the output of the torque shaft **504** allows for more detents **1204** to be included on the detent ring **1202**, and thus, improves the granularity of feedback to the operator. For example, when torque transmission is worse than 1:1, e.g., when 90 degrees of input is required to overcome wind up and cause rotation at the output, the detent spacing must be at least 90 degrees or else the operator will receive a tactile click that indicates a degree of rotation at the input end that does not correspond to an actual rotation at the output end. By contrast, as torque transmission approaches 1:1, there is less wind up and the tactile clicks associated with closely spaced detents can actually correspond to an output rotation. For example, the biostimulator transport system **300** including the swaged coaxial torque shaft **504** can have 8 detents, and each time the operator receives a click when rotating the proximal handle portion **352** relative to the distal handle portion **350**, a 45 degree output can result at the docking cap **320**.

[0078] Referring again to FIG. **8**, optionally, an outer sleeve **850** may be used in addition to or instead of swaging the outer cable **604**. Such optional feature may be omitted, however, as is clear from the illustrations of FIGS. **9**A-**9**B, which do not show the outer sleeve **850**. The outer sleeve **850** can reduce a likelihood that the outer strands **610** of the outer cable **604** will expand during

use. More particularly, the sleeve **850** can be a thin-walled tubular component that contains the inner coil **602** and the outer cable **604** of the torque shaft assembly **502**. The sleeve **850** can be fabricated from a material that facilitate a thin wall, such as polyethylene terephthalate or polyimide. The sleeve **850** can extend over at least a portion of, e.g., an entire length or less than an entire length of, the outer cable **604**. For example, the outer sleeve **850** can extend from a proximal sleeve end to a distal sleeve end, and be attached at the sleeve ends to the outer cable **604**.
[0079] The tubular sleeve **850** can have an inner diameter that matches, e.g., equals, the outer diameter of the outer cable **604**. More particularly, the sleeve **850** can form a sliding or friction fit with the outer cable **604**. In an embodiment, the sleeve is formed from a heat shrinkable material, e.g., polyolefin. Accordingly, a press fit between the sleeve **850** and the outer cable **604** can be thermally induced. The close fit between the sleeve **850** and the outer cable **604** can limit expansion of the outer strands **610**. For example, when torque is applied to the torque shaft **504**, the outer strands **610** may be urged to unwind and expand in diameter, as previously discussed. The sleeve **850**, however, may have a solid or semi-solid wall that does not expand, and thus, the outer strands **610** can expand against an interior surface of the sleeve **850**. More particularly, the interior surface of the sleeve **850** can constrain the outer strands **610**. The outer cable **604** may therefore remain at an initial diameter. The constrained strands can remain in contact with the inner coil **602**, and thus, torque transmission can be efficiently transferred as described above. Accordingly, the sleeve **850** can facilitate torque transmission through the torque shaft **504**.
[0080] In the foregoing specification, the invention has been described with reference to specific exemplary embodiments thereof. It will be evident that various modifications may be made thereto without departing from the broader spirit and scope of the invention as set forth in the following claims. The specification and drawings are, accordingly, to be regarded in an illustrative sense rather than a restrictive sense.

Claims

1. A torque shaft assembly, comprising: an inner coil including a wire coil extending about a central axis in a first helical direction over a coil length between a proximal coil end and a distal coil end; and an outer cable including a plurality of outer strands extending helically around the inner coil in a second helical direction from the proximal coil end to the distal coil end, wherein the plurality of outer strands extend in a predominantly axial direction.
2. The torque shaft assembly of claim 1, wherein the outer cable is swaged onto the inner coil between the proximal coil end and the distal coil end such that an outer surface of the outer cable is flattened and the wire coil bulges into circumferential gaps between the plurality of outer strands to form an annular wall around a central lumen.
3. The torque shaft assembly of claim 1, wherein the inner coil has a single wire coil.
4. The torque shaft assembly of claim 3, wherein the single wire coil includes a plurality of turns in contact with each other to form a stacked coil tube.
5. The torque shaft assembly of claim 1, wherein the first helical direction is opposite to the second helical direction.
6. The torque shaft assembly of claim 5, wherein the first helical direction is a right hand direction, and wherein the second helical direction is a left hand direction.
7. The torque shaft assembly of claim 1, wherein the outer cable is swaged over an entirety of the coil length.
8. The torque shaft assembly of claim 1, wherein the outer cable is swaged over only a portion of the coil length.
9. The torque shaft assembly of claim 1, wherein the plurality of outer strands are in contact with each other such that the outer cable is tubular.
10. The torque shaft assembly of claim 1 further comprising an outer sleeve containing the inner

coil and the outer cable.
11. The torque shaft assembly of claim 10, wherein the outer sleeve is a tubular component having an inner diameter equal to an outer diameter of the outer cable.
12. The torque shaft assembly of claim 11, wherein the outer sleeve is attached to the outer cable at a proximal sleeve end and a distal sleeve end.
13. A biostimulator transport system, comprising: a handle; a docking cap having a docking cavity to receive an attachment feature of a biostimulator; and a torque shaft having a proximal shaft end coupled to the handle and a distal shaft end coupled to the docking cap, wherein the torque shaft includes an inner coil including a wire coil extending about a central axis in a first helical direction over a coil length between the proximal shaft end and the distal shaft end, and an outer cable including a plurality of outer strands extending helically around the inner coil in a second helical direction from the proximal shaft end to the distal shaft end, and wherein the plurality of outer strands extend in a predominantly axial direction.
14. The biostimulator transport system of claim 13, wherein the outer cable is swaged onto the inner coil between the proximal coil end and the distal coil end such that an outer surface of the outer cable is flattened and the wire coil bulges into circumferential gaps between the plurality of outer strands to form an annular wall around a central lumen.
15. The biostimulator transport system of claim 13 further comprising a hypotube connecting the proximal shaft end to the handle.
16. The biostimulator transport system of claim 15, wherein the handle includes a proximal handle portion that is rotationally moveable relative to a distal handle portion, and wherein the proximal handle portion is coupled to the hypotube.
17. A method, comprising: loading an outer cable over an inner coil to form a torque shaft having a proximal shaft end and a distal shaft end, wherein the inner coil includes a wire coil extending about a central axis in a first helical direction, wherein the outer cable includes a plurality of outer strands extending helically around the inner coil in a second helical direction, and wherein the plurality of outer strands extend in a predominantly axial direction; and welding the outer cable to the inner coil at the proximal shaft end and the distal shaft end.
18. The method of claim 17 further comprising swaging the outer cable onto the inner coil between the proximal shaft end and the distal shaft end such that an outer surface of the outer cable is flattened and the wire coil bulges into circumferential gaps between the plurality of outer strands to form an annular wall around a central lumen.
19. The method of claim 17 further comprising attaching the proximal shaft end to a hypotube.
20. The method of claim 17 further comprising mounting a docking cap on the distal shaft end, wherein the docking cap has a docking cavity to receive an attachment feature of a biostimulator.