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### CABLE ROUTING AND ASSEMBLIES FOR MEDICAL DEVICE HANDLES

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#### Abstract

Medical devices that include a medical tool, a handle and a flexible cable bundle passing through the handle. The handles and cable routing therethrough are adapted to reduce noise within the cable.

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#### Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation-in-part of Nonprovisional application Ser. No. 17/863,734, filed Jul. 13, 2022, which claims the benefit of and priority to provisional Application No. 63/222,799, filed Jul. 16, 2021, each of which are incorporated by reference in its entirety for any and all purposes.

## INCORPORATION BY REFERENCE

[0002] This application incorporates by reference herein the entire disclosures of the following applications, which are incorporated by reference herein for all purposes: U.S. Pat. Pub. No. 20230012775A1 filed Jul. 13, 2022, which claims priority to U.S. Prov. App. No. 63/222,799 filed Jul. 16, 2021.

[0003] 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

[0004] Medical devices, such as imaging catheters, may include flexible cable bundles extending therethrough that may be susceptible to noise along the cable line(s) in certain frequencies. Cable routing and handle assemblies through which the cables extend may be needed to reduce noise in the cables.

## SUMMARY

[0005] One aspect of the disclosure is a medical device that includes an elongate shaft sized and configured to be advanced within a patient. The medical device may include a handle sized and positioned to remain outside of the patient, and a flexible elongate cable bundle extending through the elongate shaft and into the handle. Within the handle, one or more shield layers of the cable bundle may be removed from the cable bundle before the remainder of the cable bundle passes through an electrical noise suppression member that is disposed within the handle.

[0006] In this embodiment, the medical device may include an ultrasound transducer that is in communication with the flexible cable bundle, optionally wherein ultrasound transducer is disposed in a distal tip of the medical device and optionally wherein the ultrasound transducer is used for medical imaging. The medical device may be used with other energy modalities as well.

[0007] In this aspect, the electrical noise suppression member may optionally comprise a ferrite bead.

[0008] In this aspect, the flexible cable bundle may be folded upon itself in an organized manner in a folded region within the handle, and wherein the shield layer may have been removed from the cable bundle before the folded region such that the shield layer is not folded within the handle.

[0009] In this aspect, the flexible cable bundle may be folded upon itself in an accordion style in a folded region.

[0010] In this aspect, the shield layer may be coupled to a receptacle at a proximal end of the handle.

[0011] In this aspect, the cable bundle may be coupled to a plurality of printed circuit boards that are secured within the handle, optionally after fanning out from a main cable bundle body.

[0012] In this aspect, the cable bundle may extend from a proximal end of an elongate shaft that is disposed within the handle.

[0013] In this aspect, the cable bundle may pass by and extend radially outside of a plurality of printed circuit boards that are disposed within the handle.

[0014] In this aspect, the cable bundle passes between first and second of a plurality of printed circuit boards that are disposed within the handle.

[0015] In this aspect, the cable bundle may include a movable portion that is axially moveable within the handle.

[0016] In this aspect, the cable bundle may not be adapted to be moved axially within the handle after the handle is assembled.

[0017] In this aspect, the electrical noise suppression member may comprise one or both of a material or configuration adapted to suppress electromagnetic interference from the elongate cable bundle.

[0018] In this aspect, the electrical noise suppression member may comprise one or both of a material or configuration to suppress electromagnetic interference into the elongate cable bundle.

[0019] One aspect of the disclosure is a medical device that includes an elongate shaft sized and configured to be advanced within a patient. The medical device may include a handle sized and positioned to remain outside of the patient, and a flexible elongate cable bundle extending through the elongate shaft and into the handle.

[0020] In this aspect, the flexible elongate cable bundle may be folded upon itself in an organized manner in a folded region within the handle, and wherein a shield layer of the cable bundle is removed from the cable bundle before the folded region such that the shield layer is not folded in the folded region.

[0021] This aspect may include any other suitable component, feature or functionality set forth herein, including any other feature of any other aspect in this Summary Section.

[0022] In this aspect, the medical device may include an ultrasound transducer that is in communication with the flexible cable bundle, optionally wherein ultrasound transducer is disposed in a distal tip of the medical device and optionally wherein the ultrasound transducer is used for medical imaging.

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## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

[0023] FIG. 1A illustrates an exemplary embodiment of a system that includes steering and a medical device.

[0024] FIG. 1B illustrates a cross-section A-A of the steering and device portion of the medical device of FIG. 1A.

[0025] FIG. 2 illustrates an exemplary system that includes a handle assembly with a plurality of actuators, a steerable sheath and medical tool.

[0026] FIGS. 3Ai, 3Aii and 3Aiii illustrate an exemplary steerable shaft with pull wires.

[0027] FIGS. 3Bi and 3Bii illustrate an exemplary steerable shaft with pull wires.

[0028] FIGS. 3Ci and 3Cii illustrate an exemplary steerable shaft with pull wires.

[0029] FIGS. 3Di-3Diiii illustrate an exemplary steerable shaft with pull wires.

[0030] FIG. 3E illustrates an exemplary steerable shaft with one or more pull wires circumferentially interwoven into braid wires of the shaft.

[0031] FIG. 3F illustrates an exemplary steerable shaft with a transition material between the tip and a deflection region.

[0032] FIG. 4 illustrates an exemplary portion of an exemplary system that includes a bundle.

[0033] FIG. 5 illustrates an exemplary proximal end of a medical tool, the tool including a conductor bundle that extends into a proximal connector within which is housed a printed circuit board (PCB).

[0034] FIG. 6A illustrates a portion of an exemplary medical tool that includes a flexible circuit strip.

[0035] FIG. 6B illustrates an exemplary proximal portion of a strip.

[0036] FIG. 6C illustrates a detailed view of an exemplary proximal portion of a strip.

[0037] FIG. 6D illustrates an end view of an exemplary flex strip.

[0038] FIG. 6E illustrates an exemplary stack of flex strips.

[0039] FIG. 6F illustrates an exemplary stack of flex strips and ground and shield strips.

[0040] FIG. 6G illustrates an exemplary bundle including a tubing material around a stack of strips

and shield and ground strips.

[0041] FIG. 7 illustrates an integrated system of the steerable sheath and medical tool wherein the system is connected to a console via a connector cable.

[0042] FIGS. 8A and 8B illustrate an exemplary handle assembly that can be used with any of the inner and outer elongate bodies or shafts herein.

[0043] FIG. 9A illustrates a portion of an exemplary inner elongate body, or inner shaft.

[0044] FIG. 9B illustrates a portion of an exemplary outer elongate body, or outer shaft.

[0045] FIG. 9C illustrates a portion of an exemplary medical device including the elongate bodies (or shafts) from FIGS. 9A and 9B.

[0046] FIG. 9D illustrates a section of the device in the deflectable portion from FIG. 9C.

[0047] FIG. 10A illustrates a portion of an exemplary handle assembly.

[0048] FIG. 10B is an exploded view illustrating an exemplary outer elongate body (or outer shaft) movement subassembly.

[0049] FIG. 10C illustrates a side sectional view of the handle assembly from FIG. 57A.

[0050] FIG. 11 illustrates an exemplary handle assembly that includes rotation indicators for first and second actuators.

[0051] FIG. 12A illustrates internal components of an exemplary handle assembly that includes a tensioning member, or flattening member.

[0052] FIG. 12B illustrates (in a side view) internal components of an exemplary handle assembly that includes a tensioning member, or flattening member.

[0053] FIG. 12C illustrates (in a side view that is the other side relative to FIG. 12B) internal components of an exemplary handle assembly that includes a tensioning member, or flattening member.

[0054] FIG. 12D illustrates internal components of an exemplary handle shell that include one or more guiding features positioned to help stabilize a tensioning member in the handle assembly.

[0055] FIG. 12E illustrates a side view of an exemplary handle shell.

[0056] FIG. 12F illustrates a side view of an exemplary handle shell.

[0057] FIG. 13A illustrates an exemplary flexible cable bundle with at least a portion that is twisted relative to a long axis.

[0058] FIG. 13B illustrates an exemplary flexible cable bundle with at least a portion that is twisted relative to a long axis.

[0059] FIG. 13C illustrates an exemplary flexible cable bundle with at least a portion that is twisted relative to a long axis.

[0060] FIG. 13D illustrates an exemplary flexible cable bundle with at least a portion that is twisted relative to a long axis.

[0061] FIG. 13E illustrates a detail from FIG. 13D.

[0062] FIGS. 14A and 14B illustrate an exemplary handle that includes a cable bundle shield layer removed before the bundle passes through a ferrite bead.

[0063] FIG. 14C illustrates an embodiment in which a shield and ground strip of the cable bundle layer are electrically joined at their distal termination.

[0064] FIG. 15 illustrates an exemplary handle that includes a cable bundle shield layer removed before the bundle passes through a ferrite bead.

[0065] FIG. 16 illustrates an exemplary handle that includes a cable bundle shield layer removed before the bundle passes through a ferrite bead.

[0066] FIG. 17A illustrates an exemplary schematic of cable routing.

[0067] FIGS. 17B and 17C illustrate shielding of the distal tip of the medical device.

[0068] FIG. 18 illustrates an exemplary handle that includes a cable bundle shield layer removed before the bundle passes through a ferrite bead.

[0069] FIG. 19 illustrates flexible cable folding within a handle of the medical device.

[0070] FIG. 20 illustrates an exemplary handle that includes a cable bundle shield layer removed

before the bundle passes through a ferrite bead

[0071] FIG. **21** illustrates a cross section of an exemplary handle.

#### DETAILED DESCRIPTION

[0072] The disclosure herein is related to cable routing and handle assemblies of medical devices that are configured and adapted to improve emission and/or immunity performance. FIGS. **1-13E** and the textual descriptions thereof illustrate exemplary features of imaging devices, systems, and methods of use, any of which may be incorporated with the cable routing concepts set forth herein with respect to FIGS. **14A-20**.

[0073] FIG. **1A** illustrates an exemplary embodiment of a system that integrates steering and a medical device. System **1000** includes handle assembly **1002** and steering and medical device portion **1004**. Steering and medical device portion **1004** includes a proximal portion **1006** and steerable portion **1008**. The system is adapted so that handle assembly **1002** can be actuated to cause steering of the steerable portion **1008**, and optionally can be further actuated to cause movement of medical device **1010** relative to steering and medical device portion **1004**. In this exemplary embodiment, handle assembly **1002** includes first actuator **1001**, second actuator **1003**, and third actuator **1005**. First actuator **1001** is adapted to be actuated (in this example rotated) relative to handle body **1007** to cause the steering of steerable portion **1008**, and specifically steering outer sheath **1102**. Steerable portion **1008** in this embodiment can be steered, or bent, into the configuration shown in FIG. **1A** in solid lines, and can also be steered into the configuration shown in dashed lines, or anywhere in between, and in some embodiments the opposite steering function is limited to simply straightening the shaft from an initial bent configuration, such as the solid line bent configuration in FIG. **1A**. The term “steer” in this disclosure means to deflect or bend, optionally via actuation of at least one pull wire, but in some instances the term can include shaft rotation (torqueing) and axial movement. The term “pull wire” herein refers to any element that may transmit a tensile force from the proximal end of the device to the distal end region. Pull wires may be comprised of metal wire such as stainless steel or nickel titanium, either solid or stranded/braided, or it may be comprised of a polymer such as aramid fiber (Kevlar®), polyethylene, ptfe, eptfe, etc., preferably stranded/braided, but also in monofilament form. In a preferred embodiment, the pull wire is constructed from an aramid fiber bundle having four 50 denier multifilament (approximately 25 filaments) threads braided together at a high picks per inch. The wire cross-sectional diameter is typically in the 0.005”-0.012” range, more preferably 0.008”-0.010”, although braided or stranded wire may flatten or ovalize in the device lumen. The preferred construction embodiments are believed to provide optimized strength and wear resistance for the size necessary to keep the shaft diameters to a minimum. Optional second actuator **1003** is adapted to be actuated relative to handle body **1007** (in this example rotated) to cause rotation of medical tool **1010** relative to shaft **1102** (labeled as rotation movement “R”), and optional actuator **1005** is adapted to be actuated relative to handle body **1007** (in this example axially) to cause axial (distal-proximal) movement of medical device **1010** relative the outer sheath **1102**. Proximal portion **1006** is not configured to bend significantly when steerable portion **1008** is steered (bent/deflected), although the proximal portion may flex and bend to conform to the anatomy within which it is used. In many embodiments, this is accomplished by constructing the steerable portion **1008** from a softer or less rigid material and/or composite construction than the proximal portion **1006**.

[0074] The embodiment shown in FIG. **1A** is an example of an apparatus that includes an integrated handle assembly that is in operable communication with both a steerable outer shaft and an inner medical tool. The handle assembly is integrated in that it is assembled and constructed to be in operable communication with the outer shaft and the inner medical tool prior to packaging and use. “Integrated” as that term is used in the context of an integrated handle assembly refers to a handle assembly in which at least one part of the handle assembly has to be broken or taken apart before the medical tool can be removed from within the outer shaft.

[0075] FIG. 1B illustrates an exemplary cross section A-A (shown in FIG. 1A) of the steering and device portion **1004**, and specifically in the steerable portion **1008**. In this embodiment medical device **1010** is sized and configured to be disposed within a steerable sheath. The steerable sheath includes an outer shaft **1102** and a set of pull wires **1104**, which are axially fixed in a distal region of steerable portion **1008**.

[0076] The medical tool in FIGS. 1A and 1B can be, for example, any medical tool herein, such as an ultrasound tool. When “ultrasound probe” is used herein, it generally refers to an elongate tool that includes at least one ultrasound transducer and one or more conductive elements that electrically connect the at least one ultrasound transducer to a proximal region of the elongate tool. A proximal region of the ultrasound probe includes, or is modified to include, at least one proximal contact, which is in electrical communication with the at least one ultrasound transducer, and which can be put into electrical communication with, optionally via attachment to, an electrical contact on another device, cable, or connector.

[0077] FIG. 2 illustrates an exemplary system **10** that is adapted to function similarly to the system in FIGS. 1A and 1B, and also illustrates exemplary internal components of handle assembly **12** (internal components shown as dashed lines). Handle assembly **12** is integrated and in operable communication with outer steerable shaft **20** and medical tool **30**. Handle assembly **12** includes actuator **14** that is adapted to, when actuated relative to handle body **15**, cause steering of steerable shaft **20**. Actuator **14** is in operable communication with steerable shaft **20** via steering control **16** disposed in handle assembly **12**. Medical tool **30** includes a proximal portion **18** disposed within and incorporated into handle assembly **12**. Actuator **13** is in operable communication with medical tool **30**, and actuation of actuator **13** (in this example rotation) relative to handle body **15**, causes rotation of medical tool **30** relative to outer shaft **20** via rotation control **1215**. Optional third actuator **17** is also in operable communication with medical tool **30**, and is adapted to be actuated, in this embodiment, axially (relative to handle body **15**), to cause axial movement of medical tool **30** relative to outer steerable shaft **20** via axial control **1217**.

[0078] The medical tool in FIG. 2 can be, for example, any medical tool herein, such as an ultrasound tool.

[0079] FIGS. 3A-3F represent exemplary embodiments of a distal region of the sheath portion **1208** of steerable sheath **1202** in system **1200**. For simplicity, the illustrated cross-sections show only the outer sheath **1208** and not the inner tool **1212**. The outer sheath **1208** preferably has a composite construction to improve torque transmission applied to the outside of the shaft from the proximal end, or to resist torque forces applied to it from within the shaft, such as from tool **1212**. As illustrated in FIG. 3Ai-iii, in order to form the composite, multiple braid elements **1250**, preferably formed from metal wire (round, pairs of round, or ribbon shaped) and/or multiple fibers (e.g., aramid or nylon), may be braided directly over a thin wall (e.g.,  $0.0010'' \pm 0.0005''$ ) lubricious liner tube **1251**, such as a PTFE or FEP material. A thermoplastic polymer **1252** (such as Pebax in a range of durometers from 25D-72D, or nylon, or other common catheter materials) may be laminated with heat using heat shrink tubing (such as FEP) to reflow the polymer over the braid elements **1250** and liner tube **1251** to form a uniform member. The thermoplastic polymer **1252** may also have radiopaque compounds that include materials such as bismuth, barium sulfate, or tungsten in order that the tip of the sheath be visible to the user under fluoroscopy. In the embodiment of FIG. 3Ai-iii, the pull wire **1104** is preferably parallel to the central access in the steerable (deflectable) portion **1222** of the sheath and also preferably provided in a lumen **1253** created within the wall of the steerable sheath **1208**. This lumen may be created during the thermoplastic polymer tubing extrusion process or during a shaft heat lamination fusing process with the aid of a removable mandrel. The pull wire lumen **1253** may further be created by incorporating a pull wire tube **1254**, preferably temporarily supported by a removable mandrel, within the wall. The removable mandrel may also be placed alongside the pull line **1104** or **1104'** during the fusing process, resulting in a somewhat ovalized lumen **1253** within which a fiber pull

wire may be allowed to flatten into, allowing space for free movement of the pull wire. The tube **1254** may include PTFE, FEP, polyimide, or another material which maintains its wall integrity during a heat lamination process up to approximately 500° F. The tube is preferably surrounded and supported by the thermoplastic polymer **1252** which is preferably heat laminated against the tube. In another embodiment, the pull wire lumen, preferably comprising the pull wire tube, is incorporated within the weave of the braid elements **1250**. For example, braid elements **1250** running in one direction would pass under the pull wire lumen, while those running in the opposite direction would pass over the pull wire lumen. The braid reinforcement provides a more dimensionally stable lumen during catheter manipulations and also helps assure the straightness of the lumen as needed. Proximal to the steerable portion, the pull wire may continue proximally parallel to the central axis on the same side of the outer sheath **1208**, such as is illustrated in FIG. 3Ai-iii. In this embodiment and others that follow, an additional pull wire **1104'** within an additional pull wire lumen routed within the wall of sheath **1208**, up through the steerable portion **1222**, may be required to straighten the steerable portion of the device. This straightening pull wire **1104'** is preferably routed within steerable portion **1222** on the side opposite from the pull wire(s) **1104** used for steering (deflection) in the steerable portion **1222**. In another embodiment, not shown, two lumens and two straightening pull wires **1104'** could be used, essentially mirroring the paired **1104** pull wire configuration. These straightening wires could also be constructed to allow deflection in the opposite direction by tensioning a greater distance (beyond just straightening) within the handle.

[0080] During use, a portion **1223** of the distal catheter just proximal to the steerable (deflectable) portion **1222** may be forced to conform to a curve based on the constraints of the anatomy in which it is used. For a specific embodiment where the device is advanced into the heart chambers from a groin access, the portion **1223** forced into a curve is expected to range from 5 to 25 cm in length. During rotation of the sheath shaft **1208** from the proximal end, torque is transmitted through this distal curved region **1223** to the catheter tip. A non-uniform cross section and/or tension of the device in this region **1223** may induce a tendency for the shaft to build up and suddenly release torque, causing a “whip” or sudden jerk in rotation as it is torqued. To minimize the potential for whip, it is optional to distribute the pull wire tension and construction material around the surface of the curved region **1223**. In one embodiment, such as is illustrated in FIG. 3Bi-iii, the pull wire **1104** may spiral around the central axis of the sheath in at least the curved region **1223** proximal to portion **1222**. The pull wire of this embodiment may make a full circumferential wrap over approximately 10 cm of length, with this value ranging 5-15 cm. The spiral may only need to be present in the curved region **1223**, continuing straight proximally thereafter through proximal portion **1224** (similar to **1006**), which may minimize the friction in the pull wire lumen and the associated pull wire force required to steer (deflect) the steerable portion **1222**. The spiral may also make a minimum of one turn before continuing straight, or spiral the full length of the shaft. In another embodiment to minimize whip, it may only be necessary to distribute the pull wire tension to opposite sides of the shaft. As illustrated in FIG. 3Ci-ii, deflection of the steerable section **1222** is accomplished with two parallel pull wires **1104** positioned adjacent one another on the same side of the sheath **1208**. In the curved region **1223** and proximal portion **1224** (similar to **1006**) proximal to the steerable section **1222**, the pull wires are routed to opposite sides of the shaft, each 90° from the position in the steerable section **1222**, to distribute the tension more evenly. While it is preferable to actuate the two parallel pull wires at the same time with equal force with the handle actuator, in other embodiments, a differential in force could be applied to steer the tip to one side or the other of the plane formed when the two are actuated with equal force. In other embodiments, any plurality of pull wires could be routed in the same configuration as illustrated in FIGS. 3B or FIG. 3C, with the multiple proximal pull wires distributed uniformly around the shaft circumference. Also, as illustrated in FIG. 3Ci-ii, the pull wires **1104** may be routed proximally along the opposite sides of the shaft for most of the shaft proximal portion **1124** length, but

preferably brought back together adjacent one another near the proximal end portion of the shaft to allow the wires to exit the same side of the proximal shaft together to facilitate them being secured together to a handle component for simultaneous actuation tension.

[0081] FIGS. 3Di-iv illustrate another embodiment of the distal region of catheter with construction similar to that previously described, but instead configured to provide a distal steerable portion **1222** which can be deflected into two different directions. As illustrated, a two pairs of pull wires **1105/1107** and **1106/1108** are along the proximal shaft region **1224** and curved region **1223**. This is similar to FIG. 3Ai-iii, except that the wires are paired on each side of the shaft. The routing could also be spiraled as in FIG. 3Bi-ii, or other configurations discussed. Within distal steerable portion **1222**, the wires are routed 90° from the proximal portions, although other angles are contemplated. At a junction **1225** within **1222** one or more of the pull wires (e.g., **1105** and **1107**) may be terminated and anchored to the shaft, with the remaining pull wires (e.g., **1106** and **1108**) continuing to a more distal tip location **1226** where they are anchored. This configuration allows independent actuation of pull wires terminated at **1225** and **1226** such that different shapes may be created during actuation. FIG. 3Dii shows both lines **1107** and **1108** tensioned to create a variable curve in the same direction. FIG. 3Diii shows lines **1107** and **1106** tensioned to create an “S” curve. Other configurations are also possible.

[0082] The pull wires (such as **1104** and **1104'**) must be terminated at their distal end in a manner that reliably affixes them to the wall of the distal steerable shaft portion **1222**, such that they do not break or pull free under repeated applications of tension. In a preferred embodiment, shown in FIG. 3E, the pull wires **1104** and **1104'**, upon exiting the distal pull wire lumen **1253**, are circumferentially interwoven into the braid wires **1250** of the distal shaft **1222** (shown without the thermoplastic polymer **1252**). One or more of the pull wires **1104** or **1104'** may also be additionally or instead wrapped and/or tied around the outside of the braid wires **1250** for additional securing. The braid wires **1250** may be then trimmed distal to the securing point, with the interwoven and/or wrapped pull wires preventing the braid wires from expanding and/or unraveling. Additional adhesives such as UV cured or cyanoacrylates may also be used to secure the pull wires to the braid wires. The weave and/or wrap of the pull wires and braid wires is then laminated with a thermoplastic polymer which melts within the space around the wires and cools to secure them in place. The thermoplastic polymer may also have radiopaque compounds that include materials such as bismuth, barium sulfate, or tungsten in order that the tip of the sheath be visible to the user under fluoroscopy.

[0083] In additional embodiments, the tool **1212** may also or alternatively be constructed with one or more pull wires to deflect the tip in a manner similar to any of the previous embodiments described for the outer sheath **1208**. In addition to routing the pull wires within the wall of the tubular member of the tool **1212**, the pull wires could be routed next to the conductors inside the lumen of the tubular element **1212**. Actuation of the pull wires could be from an actuator located in the proximal handle **1206**. The distal shaft of tool **1212** may also be formed into a particular shape (e.g., an arc) such that it bends into the shape as it exits the tip of the steerable portion **1222** of outer sheath **1208**. The stiffness of the distal shaft of tool **1212** is such that it does not substantially deform outer sheath **1208** while inside, but upon exiting is allowed to bend. The shape may be set by any one or combination of the following means: heat setting the polymeric material, using a moveable or fixed shaped stylet within the inner lumen of shaft **1212** or within a lumen within the wall of shaft **1212**. Such a stylet could be round, oval, or rectangular in cross section, and be formed of stainless steel, nitinol, or a rigid polymer such as PEEK, Vestamid, or similar. The outer steerable sheath could alternatively be made to bend with a similar method as above, with or without additional pull wire deflection, and with or without additional shape or deflection of the distal portion of tool shaft **1212**.

[0084] In some embodiments, it may be desirable to incorporate a transition region between the tip region and the steerable (deflection) region of the shaft. The inclusion of a transition region may



decrease the tendency of the shaft to deform, e.g., kink, at the transition between the relatively rigid tip material and the relatively flexible material along the shaft in the deflection region. In the example illustrated in FIG. 3F, the outer shaft of the deflection region may be formed of a 35D Pebax material and the distal tip formed of Vestamid polyamide. By introducing an additional material having an intermediate durometer between the two materials that form the tip and steerable regions, kinking between these sections may be avoided. In this example, a 63D Pebax region having a length of 19 mm was incorporated at the transition between the Vestamid nylon tip and 35D Pebax. A bonding post on the interior of the shaft may provide additional rigidity-in this example the post is formed of a Dymax adhesive and has a length of about 5 mm. The space between the post may be further reinforced with a spacer such as a polymer tube, such as 35D Pebax, or a coil formed from a metallic or insulated metallic wire or polymer strand. The spacer can also help ensure the inner shaft does not advance over portions of the inner flex circuit which are too wide for the inner diameter of the inner shaft.

[0085] One aspect of the disclosure includes methods of disassociating at least a portion of the system from other components, optionally as part of a reposing process. In some embodiments the medical tool includes one or more electrical contacts that are coupled to other electrical contacts, which are in electrical communication with an energy console, and examples of consoles are known in the ultrasound art.

[0086] FIG. 4 illustrates merely a portion of an exemplary medical tool, such as an ultrasound probe, that can be electrically coupled directly or indirectly to an energy console, such as an ultrasound console.

[0087] Reposing the device can involve disconnection of one or more proximal electrical contacts and moving the tool portion distally out of the distal end of the sheath portion. In this embodiment tool portion **1212** comprises at least a tool outer sheath or member **2010**, distal working end **1821** (which can include at least one ultrasound transducer), and conductor bundle **2020**. The conductor bundle **2020** extends from the distal working end **1821**, through the tool outer member **2010** to a proximal connector (the connector and handle mechanism are not shown in FIG. 18 for clarity). In some embodiments the medical tool is used for ultrasound imaging, optionally where the distal working end **1821** comprises a two-dimensional (2D) array of piezo electric components mounted on an ASIC (application specific integrated circuit).

[0088] FIG. 5 illustrates a merely exemplary proximal end of a medical device (the medical device is shown on the right), and in this embodiment the medical device is an ultrasound probe. The proximal end **2015** of the medical device is adapted to be electrically coupled to connector cable **270**, which is directly or adapted to be indirectly electrically coupled to an energy console, such as an ultrasound energy console. As illustrated in FIG. 5, flexible conductor bundle **2020** extends from a distal region of the medical tool (distal region not shown) into a proximal connector **2015** within which is housed a rigid or flexible printed circuit board (“PCB”) **2030**. The connector bundle **2020** includes a plurality of contacts **2024** (examples of which are described below) that are attached to PCB board contacts **2031**. Each individual trace from each contact **2031** is linked to individual exposed contacts **2050** on another portion, optionally more proximal, of the PCB. The individual PCB traces may also pass through other useful circuitry on the PCB. The exposed contacts **2050** are configured for a mechanical mating for electrical conduction to similar contacts **2060** on mating connector cable **2070**, similar in concept to the proximal tool connector **1990** described previously, which links the tool **1204** to a user-interface console. Proximal connector **2015** can be incorporated into any of the systems, handles, steerable sheaths, medical tools, etc., herein.

[0089] “Conductor bundle” as that term is used herein may be interchangeably used with “flexible conductor bundle” unless indicated to the contrary herein.

[0090] FIGS. 6A and 6B illustrate an exemplary conductor strip (also referred to herein as a flexible circuit strip) **2021** that can be included in any of the conductor bundles herein. The embodiment in FIGS. 6A and 6B is an example of a conductor strip that can be included in bundle

**2020** from FIGS. **4** and **5**. The embodiment in FIGS. **6A** and **6B** can be incorporated into any other system herein.

[0091] As shown in FIGS. **6A**, **6B** and **6G**, conductor bundle **2020** comprises a plurality of flex circuit strips, including multi-trace strips **2021**, as well as conductive strips for grounding **2022** and shielding **2023** (only a portion of which are shown). Each multi-trace strip comprises a plurality of conductive traces **2025**, which can be seen clearly in FIGS. **6B**, **6C** and **6D**. The number traces **2025** in FIGS. **6D-G** is twelve, and the number of traces in FIGS. **6A-6C** is sixteen, and they are both exemplary as to the number of traces **2025** that can be used. Each strip **2021** can be approximately 0.072" wide and 0.0022" thick, and can optionally comprise sixteen 0.0022" wide×about 0.0007" thick conductive (e.g., copper) traces, each spaced approximately 0.0022" apart. The traces are disposed on an insulating substrate layer **2027**, such as a polyimide substrate, and the traces can be at least partly covered by a cover layer **2026**, such as a photoimageable film cover ("PIC") layer or other dry film solder mask (DFSM) or other similar material. The cover layer generally extends along most of the bundle, except at discrete locations in proximal and distal regions for electrical coupling. In other embodiments, the strip **2021** is approximately 0.055" wide and comprises twelve conductive traces (see FIGS. **6D-G**). In other embodiments, the strip **2021** is approximately 0.037" wide and comprises eight copper conductive traces. The outer strips **2022** and **2023** used for grounding and shielding may have a similar construction and dimension except they can comprise a single full width strip of copper. As optimized for a 2D piezo array, a stack of approximately seven 16-trace strips **2021** would be required (or nine 12-trace, or fourteen 8-trace), along with one each of strips **2022** and **2023** on each side of the stack of multi-trace strips. FIG. **6E** illustrates a portion of an exemplary bundle **2020** with nine strips **2021** stacked together. FIG. **6F** illustrates a portion of the bundle that includes nine strips **2021** stacked, as well as ground strip **2022** and shield strip **2023** (only those on top are labeled). The complete bundle may optionally be held together with a, for example without limitation, about 0.001" wall thickness shrink tube, such as the tubing **2028** in FIG. **6G**. The flex circuit dimensions and number of traces discussed above are for a particular configuration of a piezo-electric array (and/or an ASIC controller thereof) and may be varied depending on how the number and size of array elements are optimized for the particular application.

[0092] The proximal end of each flex circuit strip has the conductive material (e.g., gold-plated copper) exposed over a length of approximately, for example, 3 mm through removal of the cover layer **2026** at location **2024**. Location **2024**, and other exposed locations **2024'**, **2024''**, **2024'''**, **2024''''** described herein, is generally referred to as a "contact." It is understood that when used in this context, the contact actually includes a plurality of separated conductive traces (such as shown in region location), each of which is adapted to be in electrical communication with its own corresponding conductive element. "Contact" is therefore not limited to mean only a single electrical connection between two conductive elements. While FIG. **6A** shows a plurality of exposed regions **2024**, the embodiment in FIG. **6A** will first be described herein as if there is only one exposed region (i.e., region **2024** at the proximal end). The strip **2021** can be made to create an electrical connection to matching exposed contacts **2031**, shown in FIGS. **6A-C**, for conductive traces on the PCB **2030**. In some embodiments, sixteen individual traces, sized and spaced to match sixteen traces in the multi-trace strip **2021**, would be provided within a given contact **2031**. An ACF (anisotropic conductive film), soldering, conductive adhesive, mechanical connection, or any combination of these may be used to achieve a suitable electrical connection (electrical coupling) between the strip traces and the PCB contacts.

[0093] FIG. **7** illustrates the integrated system **1200** of the steerable sheath **1202** and medical tool **1204** wherein the system **1200** is connected to console **4000** via the connector cable **2070**. As previously described, such as for FIG. **5**, the tool **1204** comprises a proximal connector **2015** which forms a mating connection to cable **2070**. As previously described, it is desirable to repose (e.g., reprocess and reuse) the system **1200**. It is further desirable to ensure that the system is reposed

only by the original manufacturer and not an unaffiliated third-party, and to ensure the device is only reused a specified number of times. To control the reposing process, a crypto-authentication chip (crypto-chip) is incorporated into the tool **1204**, preferably on the PCB **2030**, although other locations, such as within the steerable handle **1206**, or within the tip **3000**, are contemplated. The crypto-chip is programmable only by the original manufacturer who controls the authentication keys. The console **4000** to which the system **1200** is connected has a Trusted Platform Module (TPM) which also has the authentication keys. During use of the system **1200**, the console **4000** is able to authenticate the system **1200** via the crypto-chip and as desired may read and write information to the chip (e.g., via an EEPROM feature). In any of the scenarios discussed, RFID chips, preferably encrypted, may be used to read and transmit data between the console, connector, and the device.

[0094] As used herein, “cleaning” can refer to any type of cleaning, such as without limitation: cleaning an interior of an outer shaft using a flushing system of cleaner and/or disinfectant and optionally mechanical scrubbing with small brushes; mechanical cleaning (e.g., wipes, brushes) an outer portion of an outer shaft and/or outer portion of a medical device shaft (e.g., ultrasound probe) with a cleaner/disinfectant, and optionally submerging the shaft in an ultrasound bath of cleaner/disinfectant for a specified period of time; and optical cleaning methods such as comprising using UV light. “Cleaning” as used here does not refer to a specific cleaning process, but rather refers to the general idea of cleaning an object.

[0095] The disclosure herein also includes methods of assembling or reassembling any of the subassemblies or assemblies herein, including any of the subassemblies within any of the handle assemblies herein. For example without limitation, the disclosure here includes methods of spooling one or more pull wires over a bearing surface in a spindle support and then around the spindle.

[0096] The methods herein also include manufacturing or constructing any of the individual components of any of the subassemblies or assemblies herein. For example, the disclosure includes methods of manufacturing handle shell components that have particular configurations (e.g., guides, walls, etc.) that can accommodate the internal parts that allow the assemblies or subassemblies herein to function as intended.

[0097] Regardless of the reference number with which they are labeled, any of the handle assemblies, medical tools, steerable sheaths, and electrical connections herein can be used together in a system in any combination with each other.

[0098] Any of the technology, including ultrasound and steering technology, in any of the following U.S. pat. no. references may be incorporated into any of the medical tools, devices, systems, or methods of use thereof herein, the disclosures of which are incorporated by reference herein:

6,100,626, 6,537,217, 6,559,389, 7,257,051, 7,297,118, 7,331,927, 7,338,450, 7,451,650, 7,451,650, 7,527,591, 7,527,592, 7,569,015, 7,621,028, 7,731,516, 7,740,584, 7,766,833, 7,783,339, 7,791,252, 7,791,252, 7,819,802, 7,824,335, 7,966,058, 8,057,397, 8,096,951, 8,207,652, 8,207,652, 8,213,693, 8,364,242, 8,428,690, 8,451,155, 8,527,032, 8,659,212, 8,721,553, 8,727,993, 8,742,646, 8,742,646, 8,776,335, 8,790,262, 8,933,613, 8,978,216, 8,989,842, 9,055,883, 9,439,625, 9,575,165, 9,639,056, and 20080287783.

[0099] Any suitable disclosure above can be incorporated into any of the embodiments below. For example, aspects of devices, systems, and methods of manufacture and use are incorporated herein and can be incorporated into any of the embodiments below unless specifically indicated to the contrary.

[0100] FIGS. **8A** and **8B** illustrate a merely exemplary handle assembly that may be in operable communication with outer shaft **131** and inner shaft **132**. In this exemplary implementation, handle assembly **120** includes handle body **123** that has an outer surface that can be gripped by a user, first actuator **121**, and second actuator **122**. Actuator **121** can be in operable communication with outer shaft **131**, and actuator **122** can be in operable communication with inner shaft **132**. Actuator **121** is

adapted to be both rotated and moved axially relative to handle body **123** (and relative to second actuator **122**). This allows actuator **121** to cause axial movement of the medical tool **103** and rotation of the medical tool **103** relative to a distal end of inner shaft **132**. Second actuator **122** is adapted to be actuated (e.g., rotated in this embodiment) relative to handle body **123** to cause deflection of the inner shaft **132**. For example, the handle assembly can have internal components that interface with proximal ends of pull wires such that actuation of actuator **122** tensions one or more pull wires to cause deflection of the inner shaft. In this embodiment actuator **121** is distal to actuator **122**, but in other designs their relative positions could be reversed. FIG. **8B** shows handle assembly **120** after actuator **121** has been advanced distally relative to its position in FIG. **8A**. This distal advancement causes outer shaft **131** to be advanced distally, and thus causes the medical tool to be advanced distally. Actuator **121** can similarly be retracted proximally relative to its position in FIG. **8B**. Tensioning members described further below are referenced with respect to actuator **121** being retracted proximally.

[0101] In other designs, actuator **121** could be in operable communication with an inner shaft and actuator **122** may be in operable communication with an outer shaft.

[0102] As described herein, the outer shaft can be moved axially relative to the inner deflectable shaft. The outer shaft may be constructed with sections of materials that vary in stiffness (e.g., durometer) along the length of at least a portion of the outer shaft. For example, a first portion that is distal to a second portion can have a lower durometer than the second portion. Because the outer shaft can be moved axially relative to the deflectable inner shaft, and because the stiffness of the outer shaft can vary along its length, the deflection, including the degree (or amount), of the overall device can be selectively controlled by controlling the axial position of the outer shaft (relative to the inner shaft). Axial movement of the outer shaft can thus selectively control deflection of the device. For example, a user (e.g., physician) can change or control where the bend occurs along the length of the device (measured from the distal end) by axially moving the outer shaft relative to the inner shaft. Additionally, for example, sections of varying stiffness in the outer shaft can allow for more or less deflection depending on the relative position of the outer shaft relative to the deflectable inner shaft. For example, deflecting the inner shaft at a region where the outer shaft has a relatively higher stiffness can result in less deflection than when the inner shaft is deflected at a region where the outer shaft has less stiffness.

[0103] FIG. **9C** shows exemplary apparatus medical apparatus **130**, which includes elongate inner shaft **132** (see FIG. **9A**) and elongate outer shaft **131** (see FIG. **9B**). Medical apparatus **130** may also be referred to herein as a “catheter,” or other medical device that includes at least one elongate shaft.

[0104] FIG. **9D** illustrates Section A-A shown in the assembly in FIG. **9C**, which is a section in the deflectable section of the device. Parts from FIGS. **9A-9C** are similarly labeled. As can be seen in FIG. **9D**, pull wires **111** and **112** are very near to one another and about 180 degrees away from straightening pull wire **116**.

[0105] As is also shown in FIG. **9D**, elongate inner shaft **132** includes two layers of braided material **119**, and the pull wires are, at least at the location of this section, essentially sandwiched between the two layers of braided material. Annular spaces **118** allow freedom of movement and space for optional lubricant. Inner shaft **132** may be made from, for example without limitation, a polymeric material such as Pebax, optionally with a lubricious additive. Inner shaft **132** may include liner **125**, such as a PTFE liner. The flexible cable bundle **105** may be surrounded by one or more layers of insulation **126**, such as PTFE insulation. Outer shaft **131** may comprise a polymeric material **127**, such as Pebax. Outer shaft **131** may also include a radially inner liner **128**, such as a PTFE liner. Any of the pullwires (e.g., **111**, **112**, **116**) may be disposed in a lumen with a liner, such as PTFE liner **129**.

[0106] Medical apparatus **130** (or either of elongate shaft **132** and elongate shaft **131**, individually) can be in operable communication with any of the handle assemblies herein, including handle

assembly **120** shown in FIGS. **8A** and **8B**.

[0107] FIGS. **10A-10C** and FIG. **11** illustrate an additional exemplary handle assembly that can be in operable communication with any of the medical devices, including ultrasound probes, herein. For example, the exemplary handle assembly shown in FIGS. **10A-10C** can be coupled to (directly or indirectly) and in operable communication with medical apparatus **130** shown in FIGS. **9A-9D**. In a particular embodiment, both elongate outer shaft **131** and elongate inner shaft **132** are coupled to and in operable communication with the handle assembly shown in FIGS. **10A-10C**.

[0108] The handle assembly in FIGS. **10A-10C** and FIG. **11** has some similarities to the handle assemblies, the individual components, and subassemblies that are shown in FIGS. **8A** and **8B**. Unless indicated to the contrary, concepts, features and methods of use from FIGS. **8A** and **8B** that can be incorporated into the handle assembly in FIGS. **10A-C** are hereby incorporated by reference for all purposes into the disclosure of the handle assembly shown in, and described with respect to, FIGS. **10A-C**. Similarly, concepts, features and methods of use that are shown in, and described with respect to, FIGS. **10A-C** that can be incorporated into other handle assemblies herein are hereby incorporated by reference for all purposes into the disclosure of any of the handle assemblies set forth herein.

[0109] FIG. **10A** is side view of handle assembly **140** with a portion of handle body **141** removed so that some internal components of the handle assembly can be seen. Handle assembly **140** includes first actuator **143** and second actuator **142**, and in this embodiment first actuator **143** is distal to second actuator **142**. First actuator **143** can be both moved axially and rotated relative to the handle body and relative to a second actuator (in this embodiment actuator **142**). First actuator **143** is in operable communication with an outer elongate body, such as outer shaft **131** (see FIG. **9B**). Axial movement of actuator **143** (distally or proximally) causes axial movement of the outer shaft **131**, while rotation of actuator **143** causes rotation of the outer shaft. Second actuator **142** is in operable communication with an inner shaft, such as inner shaft **132** (FIG. **9A**). Actuation of second actuator **142**, in this embodiment rotation, causes deflection of the inner shaft. In this embodiment a rotatable and axially movable actuator (i.e., first actuator **143**) is in operable communication with an outer shaft.

[0110] First actuator **143** is coupled to elongate outer shaft movement assembly **150** shown in the exploded view in FIG. **10B**, such that movement of first actuator **143** causes movement of assembly **150**. Elongate outer shaft movement assembly **150** is similarly coupled to the elongate outer shaft so that movement of first actuator also causes movement of the elongate outer shaft. In this embodiment, the outer elongate shaft is attached to removable part **153** after it is inserted into channel **156**. Removable part **153** and channel **156** are configured so that removable part **153** is constrained by at least one inner surface of channel **156** when it is inserted therein. Elongate outer shaft movement assembly **150** also includes a distal head portion **151** that is secured to first actuator. Elongate outer shaft movement assembly **150** also includes a rotation limiting mechanism similar to that which is described herein, which limits the rotation of first actuator **143**, and thereby limits the rotation of the outer elongate shaft. Any of the disclosure above related to rotation limiting subassemblies, functionality, and use, is incorporated into this embodiment for all purposes and may be incorporated into this and similar designs. During rotation, part **157** (see FIG. **10B**) interacts with part **161**, and part **162** interacts with part **158**. The physical interactions of these two sets of parts limits rotation to the desired rotation limit, e.g., such as limiting rotation up to 630 degrees of rotation of the outer body (in other embodiments the allowed rotation could be more than 630 degrees, such as up to and including 720 degrees).

[0111] If it is desired to clean the outer shaft, for example after use, removable part **153** can be detached from the outer shaft to allow the outer shaft to be removed from the handle assembly and cleaned, before being reinserted and reattached to removable part **153** or a new removable part if part **153** is damaged or broken.

[0112] Handle assembly **140** also includes inner shaft deflection assembly **146**, which is in

operable communication with second actuator **142**. Inner shaft deflection assembly **146** includes central gear **147** adapted and configured to rotate when second actuator **142** is rotated. Central gear **147** interfaces first spindle **148** and second spindle **149** via a geared interface, such that rotation of central gear **147** causes rotation of the spindles in the opposite direction. The inner shaft deflection assembly **146**, including the spindles, extends further proximally than the elongate outer body movement assembly **150**. The inner shaft extends through the outer shaft and extends further proximally than the outer shaft within handle assembly **150**. This allows one or more pullwires that are part of the inner shaft to extend radially outward and interface with reels **160**.

[0113] The lack of interaction between elongate outer shaft movement assembly **150** and elongate inner shaft movement assembly **146** allows for the inner and outer elongate shaft to be independently controlled by first actuator **143** and second actuator **142**.

[0114] Handle assembly **140** also includes printed circuit board (“PCB”) **170** disposed within handle body **141**, the PCB being in electrical communication with a cable bundle, such as flexible cable bundle **105** in FIG. **53**, or any of the cable bundles herein that are in communication with the medical tool, such as an ultrasound transducer.

[0115] Handle assembly **140** also includes a rotation indicator **180** that can be used to show a user the extent to which at least one of the first actuator and the second actuator are rotated relative to a home, or neutral position. First actuator **143** can include a rotation indicator **181** that is aligned along an axis with rotation indicator **180** when first actuator **143** is in a neutral position, as shown in FIG. **11**. When first actuator **143** is rotated, rotation indicator **181** is rotated relative to the axis along which rotation indicator **180** extends, which enables the user to visually understand that first actuator **143**, and thus the outer shaft, is rotated to some extent relative to the neutral position. Similarly, second actuator **142** can also have rotation indicator **182** that is aligned along an axis with rotation indicator **180** when second actuator **142** is in a neutral position, as shown in FIG. **11**. When second actuator **143** is rotated, rotation indicator **182** is rotated relative to the axis along which rotation indicator **180** extends, which enables the user to visually understand that second actuator **143**, and thus the inner shaft, is deflected to some extent relative to its neutral position.

[0116] In some alternative embodiments, the handle assembly can include one or more sensors to track how much rotation has occurred for the outer shaft, or how much deflection has occurred in the inner shaft. In some embodiments the handle assembly can include an encoder for each actuator.

[0117] In any of the embodiments herein that include an outer shaft and an inner shaft, the device can include one or more lubricants between the inner and outer shafts to make it easier to move the inner and outer shafts relative to one another by reducing friction between the two. If the medical device needs to be cleaned for reuse, additional lubricant can be added between the inner and outer shafts after the cleaning process.

[0118] In some embodiments herein the medical device may include a flexible member, such as a flexible conductor bundle (which may be referred to herein as a conductor bundle, flex bundle or other similar derivative thereof), coupled to and extending from a distal region (e.g., probe tip) towards a proximal region of the medical device (see, for example, conductor bundle **2020** shown in exemplary FIGS. **4-6G**; or bundle **105** from FIG. **9B**). A probe tip may include an ultrasound transducer in electrical communication with a flexible conductor bundle. In some embodiments herein (e.g., FIGS. **9A-11**), the probe tip and conductor bundle can be axially displaced (proximally and/or distally) by actuation of a handle actuator (e.g., actuator **143** as shown in FIG. **10A**). In some instances, the conductor bundle is disposed within an elongate member (e.g., steerable inner elongate body **132**; or elongate member **131**) and moves axially relative thereto when the probe tip is advanced distally or retracted proximally. When the distal region (e.g., ultrasound probe) and conductor bundle are retracted proximally (after being advanced distally), the conductor bundle may tend to fold up, bunch up, or otherwise bend, near or adjacent to its distal end due to friction between the bundle and, for example, the elongate member (e.g., steerable inner shaft **132**) in

which the conductor bundle is disposed. Bunching may occur if the medical device is in a straight configuration as well as if the medical device has some degree of bend (e.g., after being deflected from a straight or linear configuration).

[0119] To reduce the degree of, or even prevent completely, a tendency to bunch up or bend, any of the medical devices herein may include a structural tensioning member that is adapted and configured to apply or maintain tension on the flexible member, such as a flexible conductor bundle, at a location that is proximal to where the conductor bundle is coupled to the distal medical tool. By tensioning the flexible member, folding or bunching up of the flexible member can be minimized or even prevented. When used in this context, the “tensioning” member is adapted and configured to reduce distal region(s) of the flexible conductor from bunching (compared to a device without a tensioning member) by proximally moving at least a distal portion of the flexible conductor bundle as the distal probe is retracted proximally. In some embodiments, the structural tensioning member (e.g., a tensioning bar) may be physically secured to the flexible conductor bundle (e.g., direct or indirect attachment). In general, the tensioning members herein are in operable communication with the flexible members (e.g., a flex conductor bundle) such that movement or actuation of the tensioning member applies some force to the flexible member, and may cause movement (e.g., proximal) of the flexible member. In some exemplary embodiments the structural tensioning member may be disposed in or carried by the handle assembly of the medical device. Structural tensioning member in this context may be a single component or an assembly of separate components.

[0120] FIGS. 12A-12F illustrate a handle assembly portion of an exemplary medical device, which may be incorporated into any suitable medical device herein. For example, the handle assembly in FIGS. 12A-12F may be part of a medical device that includes a medical tool (e.g., an ultrasound imaging probe) at its distal end or near its distal end, examples of which are described herein. Any other embodiment or feature herein is incorporated by reference into the exemplary handle assembly shown in FIGS. 12A-12F.

[0121] Exemplary handle assembly 310 includes first actuator 314 and second actuator 322, where first actuator 314 is distal to proximal actuator 322. First actuator 314 is adapted and configured to be moved axially (distally and proximally) relative to second actuator 322 (and optionally also rotatable relative thereto), and may be in operable communication with an elongate body (e.g., 131 or 132) that may include a medical tool (e.g., 103) in a distal region. Handle assembly 310 (including actuators) may incorporate any of the relevant disclosure from any other handle assembly herein. The medical device of which handle assembly 310 is a part also includes a flexible member (e.g., flexible conductor bundle 105 in FIG. 9B) securely coupled to (directly or indirectly) the medical tool at a first distal location (e.g., as shown in FIGS. 9B and 9C where medical tool 103 is secured to flexible member 105) and extends proximally from the medical tool towards handle assembly 310. The flexible member may be a flexible conductor bundle and can extend into handle assembly 310, as shown. A portion of the flexible member is disposed within an outer surface of the elongate body (e.g., within 131 and/or 132). The medical device also includes tensioning member that is secured to the flexible member at a second location 316, which is proximal to the first location (“first location” in this context may be referred to as a first distal location or derivative thereof). FIG. 12A illustrates exemplary tensioning member 312, while reference number 312 in FIG. 12A also points to an optional elongate rigid member (in this embodiment the elongate rigid member is linear and extending axially) of the tensioning member. Tensioning member 312 is adapted and configured to tension the flexible member as the medical tool is retracted proximally. This may be referred herein as applying a tensile force to the flexible member, or tensioning the flexible member, or maintaining tension in the flexible member. In this exemplary embodiment, tensioning member 312 is adapted and configured to tension the flexible member as the medical tool is retracted proximally, which in this embodiment occurs when first actuator 314 is retracted proximally from its position shown in FIG. 12A-C. The tensioning

members herein can apply tension when the medical device is in a straight configuration and when the medical device is in a non-straight (linear) configuration, such as when the device may be deflected or bent.

[0122] In this embodiment, tensioning member **312** (which may include the tensioning bar shown in FIG. **12A**) is secured to (e.g., attached directly) the flexible conductor bundle at location **316**, the location of which is inside the handle assembly in this embodiment. In another embodiment, the tensioning member **312** may be secured to the flexible conductor bundle at an alternate location **317**. A tensioning member may alternatively be secured to the flexible member at a location that is inside a handle or outside of the handle, such as inside one or both of outer and inner shafts. In this embodiment the tensioning member is also axially secured relative to first actuator **314**, such that axial movement of first actuator **314** causes axial movement of tensioning member **312** (which may be in a 1:1 movement ratio). Because tensioning member **312** is also secured to the flexible member (e.g., at location **316**), axially movement of tensioning member **312** also causes axial movement of the flexible member at location **316**. By securing tensioning member **312** to the flexible member, the flexible member is tensioned distal to where the tensioning member is secured to the flexible member when first actuator **314** is retracted proximally, which prevents the flexible member from folding or bunching up at its distal region near or adjacent to the medical tool (or at least reduces the extent of folding/bunching up compared to a device without a tensioning member).

[0123] The flexible member may include a flexible conductor bundle, such as any of the flexible conductor bundles herein. In FIGS. **12A-F**, the tensioning member comprises a rigid elongate member (generally referred to as **312** in FIG. **12A**) with a fixed length. The rigid tensioning member as shown has a general longitudinal axis, which in this embodiment is parallel with a longitudinal axis of the medical device and/or a longitudinal axis of the handle assembly. The rigid tensioning member may be made of a variety of materials, such as a rigid plastic member.

[0124] The tensioning members herein can ensure that the distance traveled by the medical tool is the same as the distance traveled by any point on the flexible member between the first and second locations. The tensioning members herein can ensure that the distance traveled by the medical tool is the same as the distance traveled by the location where the tensioning member is secured to the flexible member (e.g., location **316** in FIG. **12A**).

[0125] The secured relationship between the tensioning member and the flexible member maintains the flexible member in a substantially flat or straight configuration between the first and second locations as the medical tool is retracted proximally (when the medical device is a straight configuration). A flat configuration in this context can include embodiments in which the flexible member may also be twisted (i.e., the flexible member can be flat and still be twisted, but not bunched/folded). A flattened configuration as used herein indicates a lack of a fold or bunching of the flexible member.

[0126] Medical devices in which a tensioning member is incorporated may also be steerable or deflectable. The tensioning members herein can be adapted and configured to apply a tensile force to the flexible member even if the medical device, including the flexible member, are in non-straight (e.g., deflected, steered, bent) configurations. When this disclosure refers to maintaining a substantially flat configuration in the flexible member, it refers to instances where the medical device may be in a straight configuration, which need not be the case, such as when a medical device has been steered, bent, or deflected.

[0127] The secured relationship between the tensioning members and the flexible members herein prevents the flexible member from forming a fold (i.e., bending, or bunching up) between the first and second locations as the medical tool is retracted proximally. Folding, bending, and bunching-up in this context includes a first region of the flexible member axially overlapping with a second region of the flexible member, and also includes general bending and bunching of the flexible member, such as regions of the flexible member that are not flat and, for example, form a bend,



curved region, and/or meander back and forth.

[0128] The flexible member may have flat top and bottom surfaces (e.g., a conductor bundle with one or more flat surfaces), and optionally the tensioning member may be secured to at least one of the top and bottom surfaces. For example, FIGS. 6A-6G illustrate a flexible member with flat or generally flat first and second surface (e.g., top and bottom surfaces), and a tensioning member may be secured to one or both of the flat or generally flat surfaces (e.g., such as at location **316**). They may be secured using a variety of techniques, such as using adhesive, welding, or other bonding techniques.

[0129] The tensioning member may be in operative communication (directly or indirectly) with a handle actuator such that axial movement of the actuator axially moves the tensioning member. The handle actuator may be further adapted and configured to be rotated (e.g., actuator **314**) to cause rotation of the medical tool, and optionally wherein rotation of the actuator does not cause rotation of the tensioning member. The tensioning member can thus be adapted to be moved axially when the actuator is moved axially, but not to rotate when the actuator is rotated. This can be accomplished by the manner in which the tensioning member is operatively in communication (directly or indirectly) with the actuator.

[0130] The medical device may include an inner elongate body (e.g., **132**) including a lumen in which at least a portion of the flexible member is disposed. An inner elongate body may be independently steerable, such as with a separate independently actuatable handle actuator (e.g., actuator **322**). Aspects of other embodiments herein in which the medical device includes an inner member and outer member, the inner member independently controllable (e.g., axially and rotationally) are fully incorporated in any of the embodiments herein.

[0131] The flexible member may be coupled to a printed circuit board (e.g., **321** “boards” as shown in FIG. 12A) in the handle assembly. The tensioning member may be coupled to a flexible member proximal to a printed circuit board. In alternative embodiments the tensioning member may be coupled to a flexible member distal to a printed circuit board.

[0132] FIGS. 12A-12F is an example of a portion of a medical device that includes an elongate outer body (e.g., **131**) including a probe tip in a distal region of the elongate body; a flexible conductor bundle (e.g., **105**) securely coupled to the probe tip at a first location (shown in figure FIGS. 9B and 9C) and extending proximally from the medical tool and into a handle assembly, the flexible member disposed within an outer surface of the elongate body; an inner elongate body (e.g., **131**), at least a portion of which is disposed within the elongate outer body, the inner elongate body optionally steerable, wherein at least a portion of the flexible conductor bundle is disposed within the inner elongate body and configured to be axially movable relative to the inner elongate body; a tensioning member secured to the flexible member at a second location in the handle assembly, the tensioning member adapted and configured to apply tension on the flexible member as the probe tip is retracted proximally. Probe tips as used herein may include one or more ultrasound transducers.

[0133] FIGS. 12E-F illustrate a half of a handle outer shell **320**, two of which form a portion of the outer surfaces of the handle assembly **310**. Handle shells **320** include radially inwardly extending features **315** that are adapted to interface with a control the movement of the tensioning member **312**. Features **315** can include guides that are configured to interface with the tensioning member at one or more locations and help stabilize the tensioning member.

[0134] Any other handle assembly component in any other embodiment herein that can be suitably integrated into handle assembly **310** is incorporated by reference herein.

[0135] In any of the embodiments and claims herein, the phrase “tensioning member” may be replaced with “straightening member,” “flattening member,” or a derivative thereof. As described herein, a straightening member or flattening member refers to maintaining a substantially straight or flattened configuration in the flexible member when the medical device is in a straightened configuration, and does not require that the device always has a straightened configuration. Thus,

even if the flexible member is not necessarily being placed under tension, it may still be maintained in a straightened (i.e., not folded configuration) along at least a portion of its length due to a straightening member. Member **312** in FIG. **12A**, for example, is an example of a straightening member, even if it also functions as a tensioning member. This applies to all tensioning members described, shown, and claimed herein. In some embodiments herein, the “member” can be a straightening member (or flattening member) and can also function as a tensioning member. Additionally, the phrase “tensioning member” herein may be replaced with “fold-prevention member,” “bend-prevention member,” “bunching-prevention member,” or a derivative thereof. [0136] The disclosure above describes that in some embodiments the flexible member, such as conductor bundle **2010**, may be twisted along a portion of its length. For example, a conductor bundle may be twisted to provide a more balanced cross-section along a portion of the length of the medical device. A conductor bundle may be twisted only in a portion of the medical device that will experience deflection.

[0137] FIGS. **13A-13E** illustrate a portion of an exemplary medical device that includes a twisted flexible member, such as a flexible conductor bundle. The embodiment in FIGS. **13A-E** may be incorporated with any other suitable feature and/or medical device described herein.

[0138] The portion **330** of the medical device shown in FIGS. **13A-E** includes a medical tool **332** at a distal region, a flexible member **331** coupled thereto and extending proximally therefrom, and a proximal end region **333** comprising a plurality of electrical connectors. Flexible member **331** may be a flexible conductor bundle, such as any of the bundles herein. Medical tool **332** may include an ultrasound imaging transducer **339**. Flexible conductor bundle **331** has a region **338** in which the conductor bundle is twisted, the twisted region **338** having a distal end and a proximal end. Flexible conductor bundle **331** also includes a region **336** distal to twisted region **334** that is not twisted, and a region **340** proximal to twisted region **336** that is not twisted. Medical tool **332** may be coupled to an outer shaft, such as outer shaft **131** shown in FIG. **9B**.

[0139] The length of twisted region **338** from its distal end to its proximal end can vary, and in some embodiments is from 5-15 cm, such as from 8-15 cm, such as 11 cm. The length over which a complete turn is formed can vary well, such as from 1-5 cm, such as 3 cm.

[0140] The number of twists over the length of the twisted region can vary as well, such as, for example without limitation, 7-9 full twists.

[0141] An exemplary manner in which to form the twisted region of the flexible member (e.g., flexible conductor bundle) is to couple the flexible member to the medical tool at the distal end (e.g., probe tip). A thin section of PET heat shrink may then be advanced over the flexible conductor bundle. A portion of the device can be held in place while another portion is twisted to the desired number of turns to form the twisted region. While the twisted configuration is maintained, the PET can be heat shrunk over the twisted bundle region. Additional layers of PET may be subsequently added. An elongate member (e.g., shaft **131**) may then be placed over the bundle, including the twisted region, and the elongate member can be bonded to the medical tool.

[0142] The concepts that follow may be applied to any suitable device, system, and/or method of use set forth above. While the disclosure that follows is described generally in the context of imaging catheters, and in particular ultrasound imaging catheters, the concepts that follow may be applied to any type of suitable medical device that includes a cable through which electrical signals are transmitted. One merely exemplary illustrative medical device is an ultrasound imaging catheter, which includes a cable bundle in electrical communication with one more ultrasound transducers, wherein the cable bundle transmits signals to and/or from the ultrasound transducers. Exemplary ultrasound imaging devices, including handles thereof, are shown and described with respect to FIGS. **1-13E** herein, the disclosures of which are fully incorporated by reference into the disclosure that follows. For example, the handle assemblies shown in FIGS. **14-20** and descriptions thereof may incorporate any of the disclosure herein related to the handle assemblies in any of FIGS. **1-13E** herein.

[0143] FIGS. **14A** and **14B** illustrate an exemplary handle **1400** of a medical device, with half of a handle shell removed to show internal handle components. Any of the components in any of the handle assemblies herein may have exemplary designs described in more detail with respect to embodiments in FIGS. **1-13E**. For example, flex bundle **1402** in FIGS. **14A** and **14B** may include any of the disclosure of any of the electrical flexible bundles herein. Additionally, for example, the push arm **1404** in FIG. **1** may include any of the disclosure with respect to any tensioning members herein adapted for maintaining tensioning in the cable bundle. Additionally still, the inner shaft **1406** in FIGS. **14A** and **14B** may be any of the inner members (or any derivative thereof) herein. Additionally, the device medical extending distally from handle **1400** in FIGS. **14A-20** may also include an outer member or outer shaft, such as any of those described herein. It is further understood that “inner” shaft is illustrative and the medical device shaft does not necessary require an inner shaft and an outer shaft. In embodiments that include an inner shaft and an outer shaft, the two shafts may be axially movable relative to one other to allow for a telescoping probe tip, while in any embodiments herein an inner shaft and an outer shaft may be immovable relative to each other, such as in the example shown in FIG. **20**.

[0144] Some medical device cables may be susceptible to noise along the cable line(s) in the frequencies of interest. One aspect of the disclosure is related to immunity performance to reduce or minimize noise. FIG. **14A** illustrates an exemplary handle that includes therein an exemplary electrical noise suppression member **1408** that includes a lumen through which a flexible cable bundle **1402** passes. By way of example only, any of the electrical noise suppression members herein may comprise a ferrite bead, general examples of which are known. This disclosure may refer to a ferrite bead in the context of certain embodiments, but it is understood to be illustrative only and other materials and/or configurations of an electrical noise suppression member may be used. A noise suppression member herein may include one or both of a material or configuration such that it is adapted to increase impedance to any RF noise coupled into sensitive analog lines. It is of note that a cable bundle shield **1410**, an example of which is shown in FIG. **18**, has been removed from the cable bundle **1402** within the handle before the cable bundle **1402** passes through the electrical noise suppression member **1408** so as not to cause a reduction in the shield **1410** impedance.

[0145] While ferrite beads are described in examples herein, these are understood to be examples and other materials and/or configurations may be used. In general, the noise suppression members herein include a material that is configured to surround one or more signal line conductors such that the surrounding material provides a high impedance pathway intended to dissipate frequencies in a targeted range that are induced in the surrounding material from the signal line. The dissipation of the frequencies provides a filtering or noise-suppression effect. The surrounding material may comprise sintered powders and may be formed into a hollow cylindrical or similar extruded polygonal shape. The material may be formed as one piece with the signal line conductor running through the middle, and in some embodiments include two halves clamped together over the signal line conductor. The impedance and filtering effects of the surrounding material may be optimized based on the selection, size, and relative amounts of the sintered powders. The powders are typically formed into a ceramic compound comprising a mix of iron oxide and other materials such as cobalt, copper, manganese, magnesium, nickel, and zinc. The circumference, thickness, and length of the surrounding material may also be optimized for the desired effect. The signal line (e.g., cable bundles herein) may pass once through the middle or, after passing through once, may be routed around the outside of the surrounding material and back through the center in the same direction as the first pass (forming a winding) multiple times. The various constructions and configurations allow optimization of the impedance at a given frequency range. In some applications of intracardiac ultrasound imaging, ferrite construction may be selected to provide enhanced immunity from frequencies <10 MHz and to suppress radiation of frequencies >100 MHz. Different surrounding material embodiments may be employed at different locations along

the pathway of the signal line conductor (cable bundles herein) to achieve different noise suppression effects.

[0146] One aspect of this disclosure is related to improving emissions within a handle of a medical device. FIGS. **14A** and **18** illustrate examples in which excess flex cable bundle **1402** is disposed in the handle and is folded in folded region **1412** in an organized manner in the handle, and in this embodiment is folded in an accordion style configuration as shown against an inner surface of a shell of handle **1400**. As shown, cable bundle shield **1410** is routed out of the cable bundle **1402** before the bundle assumes its folded configuration in region **1412**, as shown. Separating the shield layer **1410** from the rest of the bundle **1402** before folding in region **1412** minimizes inductance of shield layer **1410** while increasing impedance of signal cables in the frequencies of interest. Folding the excess cable length in an accordion style fold as shown can reduce unit to unit variation, minimizes self-inductance of the signal cable and can help reduce or minimize radiated emissions. In some embodiments herein, however, the cable bundle may not be folded within the handle, an example of which is shown in the exemplary embodiment in FIG. **20**.

[0147] A ferrite bead **1408** in FIG. **14A** that is disposed within the handle **1400** is positioned about or around the portion of the flex cable bundle **1402** that contains the signal lines and grounds, but not the shield **1410**, as shown. An exemplary advantage to this construction may be to increase impedance to RF entering the cable bundle (for noise reduction) without increasing impedance to the shield **1410**. The shield impedance should be as low as possible to shunt out any RF current picked up. By removing the shield **1410** from the cable bundle **1402** in the handle before it passes through the ferrite bead **1408**, the ferrite bead **1408** does not increase the impedance of the cable bundle shield **1410**. Section of the cable bundle **1402'** are shown fanned out to attachment locations on the printed circuit boards ("PCBs") with the handle. A receptacle flex **1414** is also shown coupled to the receptacle at the handle proximal end. FIG. **14B** illustrate the handle and labels noise suppression member **1410** without showing the cable bundle for clarity.

[0148] The ferrite (or other suitable noise suppression member/material) can improve immunity to outside noise, such as in the 5-10 MHz imaging frequency if the system is so configured. A ferrite bead can be selected to maximize impedance in a desired frequency range (e.g., 5-10 MHz), while allowing it to fit in the handle shell. An exemplary impedance obtained is ~90-102 ohms in the range of interest. The impedance can be increased by increasing the number of "turns", or "T", defined as how many times the cable passes through the inside of the ferrite. The impedance increases with the square of the number of turns. The cable may pass IT through the ferrite, although it could be turned 2, 3, or 4, up to the limit of the ferrite ID. An alternative to the solid ferrite is to have a "split" ferrite which is clamped around the cable. This could allow ACF bonding and then wrapping of the cable. IT within a solid ferrite may be adequate to adequately improve noise immunity. Additionally, for a solid core, if the cable is wrapped around the ferrite, there may not have enough slack for an ACF bonding process. In an exemplary implementation, too much impedance in the desired frequency may have a negative effect on, for example, image quality.

[0149] As shown in FIG. **14A**, excess cable bundle may be folded in a controlled and organized manner or configuration within the handle. For example, an "accordion" style fold as shown in FIG. **14A** may minimize looping and any RF being inducted back into the flex bundle. Ribs or other protruding members may be added directly into (e.g. formed integrally with) the inner surface of the handle shell to facilitate folding of the flex cable bundle. An alternative embodiment is a separate non-integral handle component to facilitate the flex cable folding.

[0150] As noted above, the shield is pulled out of or removed from the cable bundle, as shown in exemplary FIGS. **14A** and FIG. **17A**. Both the top and bottom shield strip are shorted to a single wire, which is soldered to the plated surface of the receptacle, as shown in FIGS. **14A** and **15** (at location **1511**). This plating makes the shield connection to the umbilical cable plug. Exemplary benefits of this approach can include one or more of the following: transmitting RF out of the device in as low an impedance path as possible; preventing the shield from entering the ferrite; or

minimize looping of the shield near the other conductors which would provide more noise inductance into the conductors.

[0151] In some embodiments, a ground line strip, similar in construction to the shield line strip in the catheter body, may be run adjacent to the shield strip on each side of the conductor bundle or more preferably as shown may be formed of a common strip that is folded over to form both the ground and shield strips as illustrated in FIG. 14C. Experimental data have shown that combining the ground and shield strips lowered the overall impedance and resulted in better noise suppression. As illustrated in FIG. 14C, a single material strip twice the desired length may be folded over on itself (insulation on the inside, copper on the outside), with the folded side at the distal end. In this embodiment, the ground and shield strips are positioned on both sides (top and bottom) of the conductor bundle. Accordingly, in this preferred embodiment the top and bottom strips do not require a connection between them. It will be appreciated however that in other embodiments (not illustrated) the two separate strips of material for the ground and shield may be electrically joined at their distal end. The ground strips in yet other embodiments (not illustrated) may have a conductive pathway isolated from the shield strip.

[0152] The ground strips are attached to ground connections in the distal catheter tip and run parallel with other ground pathways (lines) in the conductor bundle back to the PCBs where they are again joined with other ground lines from the conductor bundle. These ground lines continue through the flex which is integrated with the electrical contacts on the catheter receptacle connector. The shield strips may be electrically joined with the grounds at the distal tip. This allows sharing of the shield strip pathway with the ground lines back to the proximal end of the catheter. This sharing of the pathway lowers the overall shield impedance and improves the effectiveness of the shield. The ground strip pathway may still route with the cable bundle through the ferrite to the PCBs and receptacle connections, but may also share a lower impedance path with the shield wire bypassing the ferrite, PCBs and receptacle contacts. Preferably the ground strips do not require an electrical connection again to the shield where the shield exits the conductor bundle, but this connection may be made if a performance benefit is realized.

[0153] To further lower the impedance of the shield, a thicker strip of copper (e.g., a 28 AWG wire flattened to 0.0035"), which may be referred to as a "drain wire" may be added to the top and/or bottom of the conductor bundle as shown in FIG. 14C. The drain wire is electrically coupled (e.g., soldered) to the outer shield strip. The drain wire may run the full length of the device or, as in the preferred embodiment shown, the wire may terminate proximal to the deflection region (e.g., ~12 cm from the distal tip), so that the added stiffness of the strip does not impede deflection and tip rotation performance.

[0154] The drain wire may be isolated from the ground and/or the shield strip. The ground may be isolated from the shield strip and/or the drain wire. The shield strip may be isolated from the ground and/or the drain wire. The isolated drain wire may run from the distal tip to the catheter receptacle connector. Isolating the drain wire and/or the ground and/or the shield strip may reduce or minimize noise in images produced by the catheter. Isolating the drain wire may prevent the drain wire from interfering with the ground and/or the shield strip. Of the ground, the isolated drain wire, and the shield strip, the isolated drain wire may provide a least resistive route for noise. The least resistive route may facilitate picking up noise and routing noise away independently, without being shorted to or meeting the ground and/or the shield strip. The drain wire may be implemented in conjunction with shield strip braiding over the cable bundle. The isolated drain wire may reduce a centerline and grating lobe noise artifact on an image captured by the catheter. Reduction of noise may be determined based on the difference between the inclusion of one or more of the shield strip or isolated drain wire from a configuration without the prescribed shield strip or drain wire.

[0155] FIGS. 14A and 15 illustrate an exemplary embodiment of an imaging catheter with optional tensioning controlling push arm, which may include any of the disclosure of the tensioning members set forth herein (e.g., with respect to any of FIGS. 1-13). A push arm may be present in

catheter designs in which an inner shaft and an outer shaft are movable relative to each other. In these embodiments, the cable bundle may be left intact (shields and remainder of flexes) between the exit out of the inner shaft and the push arm attachment to allow the bundle to telescope back and forth with the distal tip (2.5-3.0 cm), which may have an ultrasound transducer therein. Tension to the bundle is provided from the tip during advancement, while tension during retraction is provided from the point of push arm attachment. An additional intact portion (another 2-3 cm) proximal to the push arm attachment can be provided to allow changing of the bundle radius during advancement and retraction. While the shield could be pulled out of the bundle at the push arm attachment, it may be preferred to pull it out after the additional 2-3 cm to prevent it from having to move. The shield exit can be secured, and the remaining cable immediately routed into the noise suppression member.

[0156] As noted above, it may be desirable to reduce the amount of cable shield impedance. In some embodiments, the cable bundle can include an additional shield wire on either or both sides of the flex bundle running the full length, or nearly the full length of the catheter shaft, terminating in the handle where the shield exits the cable bundle. In a preferred embodiment, the additional shield wire(s) terminate at the distal end, proximal of the deflection region of the shaft. This may help to minimize the stiffness of the deflection region and prevent any compromise in mechanical deflection and torque response in this region. If the cable bundle has a rectangular configuration and is disposed in a circular space, an extra wire may not be as wide as existing copper strips such that the fit of this cable bundle “rectangle” in the shaft “circle” can be optimized. The shield wire(s) are preferably as large as can fit in the available space to provide the minimal impedance possible. Shorting the top and bottom shields together at the tip may provide for a more even impedance distribution and reduce any dipole antennae effects.

[0157] distal tip of the medical device, such as any of the distal tips herein that include an ultrasound probe and ultrasound transducer may be the source of outside noise pickup. To mitigate this noise, the distal tip may include shielding. As shown in FIG. 17B, shield strips may be extended around the tip (along the existing short flex strips), except for where the acoustic window is. The shield may also be wrapped around the sides of the transducer. Tip flex strips may also be plated or coated in a conductive material connected to the shield conductors. A very thin shield coating could be provided over the transducer at least  $\frac{1}{4}$ - $\frac{1}{8}$  the ultrasound wavelength. In some embodiments in which the distal tip includes a molded tip that surrounds the ultrasound transducer, the outer molding may be shielded with a shield strip material such as illustrated in FIG. 17C. The shield tip material preferably coats as much of the surface area of the transducer as possible without impeding the ultrasound beams emitted from the acoustic window. The shield material may be the same or similar to that of the shield strips of the cable bundling internal to the device or may be implemented using other materials and techniques such as gold plating, painted silver, copper taper or other layering, conductive ink or the like. Where shielding is disposed on the outer molding of the tip, the shield material should be insulated from the patient by lamination, polymer spray coating, or other dielectric.

[0158] Some embodiments may include additional shield layers incorporated into the layers of the PCBs and flex circuit extending between the PCBs and catheter connector. The shielding may also be applied externally to the PCBs and flex circuit using copper tape or other similar construction. The additional shielding layers can be connected to the catheter connector shield directly, or via the low impedance shield connection wire (FIG. 18). In another embodiment, the low impedance shield connection wire may terminate in the distal side of the additional shielding layers and the proximal end of the additional shielding layers terminated to the connector shield layer. Terminations may be made through the use of solder, welding, a mechanical contact, or other conventional techniques.

[0159] Some embodiments may include an umbilical connector shielding. A connection may be made between the catheter and cable shield through a plated surface of the catheter receptacle and umbilical plug. A lower impedance connection may be preferred to be added to or provided instead

of the existing plated connection. For example, the central core of the receptacle and plug could be adapted to provide a direct electrical connection to one another. A “banana style” connection could be made or other pogo-pin, c-pin, or lever arm metal-metal mechanical connection made. In lieu or in addition to shield plating, directed braided wire (flat shield wire preferred) could be electrically attached (solder, crimp, or the like) between the connector pins and the shields in the umbilical cable and catheter. The umbilical cable plug could have a recessed, touch proof receptacle for a male-style pin from the catheter receptacle connector. This could be positioned on the central axis, but could also be on the inner circumference or integrated into the cable.

[0160] Some embodiments may include an umbilical ferrite. A clamp on ferrite may be used over the outside of the umbilical cable to improve noise immunity. A 3T or 4T may be used on the cable. This use is common in the art. However, an appropriately sized ferrite may be used under the shield and have it integrated in the design. This may be located at the DLP (console connector) side, outside the DLP, or actually inside the housing (and inside the shielded cage), of the DLP. It may also be incorporated near the plug (catheter connector) side, although the extra weight in this location may not be as desirable and should be considered.

[0161] FIGS. **15** and **16** illustrate photographs of a portion an exemplary handle shown in FIG. **14A**, whereas FIG. **16** additionally highlights an exemplary cable bundle **1602** pathway within the handle, with components similarly labeled with respect to FIGS. **14A**, **15**, **17A**, **18** and **19**.

[0162] FIG. **17** schematically illustrates an exemplary cable bundle **1702** routing within a handle (handle housing not shown) that is shown in FIGS. **14A-16**. FIG. **17** excludes the handle housing to provide a more clarified routing pathway. Shield **1710** is removed from cable bundle **1702** before it passes through noise suppression member **1708** (e.g., ferrite bead) and the cable bundle is shown folded in folding region **1712**. Sections of the cable bundle are fanned out to attachment locations on the printed circuit boards **711** as shown. Receptacle **1713** is also shown.

[0163] FIG. **18** illustrates an exemplary embodiment of an imaging catheter in which handle **1800** does not include a noise suppression member (e.g., ferrite bead) therein. Handle **1800** may include any other handle component or functionality described in any of the other handles herein. For example, exemplary inner shaft **1806** is shown. In this example, shield layers **1810** are routed directly from the cable bundle to the receptacle **1813**, as shown. The cable bundle is folded accordion style in folded region **1812**. After the shield layers are removed from the bundle, cable bundle **1802** is routed directly to the PCBs as shown, and are fanned out at locations **1803** to the PCB attachment points.

[0164] Additional exemplary details and parts are shown, which may be the same or similar to the handle components shown the embodiments in FIGS. **14A-17A**. Any suitable disclosure from the embodiments from FIGS. **14A-17** may be incorporated by reference into the disclosure of the embodiment shown in FIG. **18**. FIG. **18** also illustrates an exemplary cable bundle cross section, wherein any of the embodiments herein may include such as cable bundle. The cable bundle is exemplary, however, and not every layer need be included, in this embodiment or any other embodiment.

[0165] FIG. **19** illustrates an exemplary embodiment of an imaging catheter in which handle **1900** does not include a ferrite bead, and wherein excess cable bundle **1902** is looped in looped region **1905**. The handle shown in FIGS. **19** may incorporate any suitable feature of any of the other handles and imaging catheters herein. Handle **1900** has inner shaft **1906** extending therein, from which cable bundle **1902** extends as shown. The cable bundle is fanned out at locations **1903** for attachment to the PCBs as shown. Handle **1900** may include any other suitable component or functionality described or shown with respect to other handles herein.

[0166] FIG. **20** illustrates an exemplary handle **2000**, with half of handle housing **2005** removed to illustrate internal components therein. Handle includes catheter shaft control system **2010**, which may include any suitable features herein to cause the deflection of a deflectable shaft herein, such as one or more pull wires routed through an elongate deflectable shaft. In this example, flexible

cable bundle **2002** extends around a plurality of printed circuit boards **2004**. This in contrast to FIG. **14A-19** herein, in which the flexible cable bundle passed between first and second of a plurality of printed circuit boards. In this example, shield **2002** is removed from the cable bundle within the handle before the remainder of the cable bundle passes through ferrite bead **2006**, as shown. The bundle **2007** with the shield removed then extends proximally and is coupled to the printed circuit boards **2004**, as shown. In the example of FIG. **20**, an inner and outer catheter shafts are not axially movable relative to each other (not telescoping) and the cable bundle is not axially movable within the handle after the handle is assembled. The flexible bundle may pass around the printed circuit boards **2004** as shown as the flexible cable bundle does not need to follow a straight axial path for easy axially movement, as may be beneficial in some examples that includes a telescoping probe tip. Routing the flexible cable bundle around the printed circuit boards **2004** may help increase the distance between the signal lines in the cable bundle **2002** and the signal lines (particularly the analog signal lines) in the printed circuit boards **2004** so as to minimize noise pickup.

[0167] In some embodiments, the handle may include a tongue-and-groove construction as illustrated in cross section in FIG. **21**. In this example, the handle is formed of two halves wherein each half mates at a via male tongue on one half and a female groove on the other half. The tongue-and-groove construction increases the mating surface area between handle parts, provides a more secure connection, and permits cleaner bonding without the creation of an exterior glue seam.

[0168] In an embodiment, the handle may be sized and positioned to remain outside of the patient. Being sized and positioned to remain outside of the patient may comprise configuring the handle to a size to be disposed in one or more hands of a physician.

## Claims

1. An ultrasound imaging catheter, comprising: an elongate shaft sized and configured to be advanced within a patient; a handle sized and positioned to remain outside of the patient; a distal tip including an ultrasound transducer; an elongate cable bundle in communication with the ultrasound transducer, the elongate cable bundle passing through the elongate shaft and extending into the handle, wherein the elongate cable bundle comprises a shield strip, a ground, and a drain wire, wherein the drain wire is configured to comprise a less restrictive route than the shield strip, wherein the drain wire is configured to comprise a less restrictive route than the ground, wherein the drain wire is isolated from the ground, and wherein the drain wire is isolated from the shield strip.
2. The ultrasound imaging catheter of claim 1, wherein the shield strip is isolated from the ground.
3. The ultrasound imaging catheter of claim 1, wherein the shield strip is braided.
4. The ultrasound imaging catheter of claim 3, wherein the shield strip is disposed over the elongate cable bundle.
5. The ultrasound imaging catheter of claim 1, wherein the elongate cable bundle is coupled to a plurality of printed circuit boards that are secured within the handle.
6. The ultrasound imaging catheter of claim 1, wherein the elongate cable bundle extends from a proximal end of an elongate shaft that is disposed within the handle.
7. The ultrasound imaging catheter of claim 1, wherein the elongate cable bundle extends radially outside of a plurality of printed circuit boards that are disposed within the handle.
8. The ultrasound imaging catheter of claim 1, wherein the elongate cable bundle passes between first and second of a plurality of printed circuit boards that are disposed within the handle.
9. The ultrasound imaging catheter of claim 1, wherein the cable bundle includes a movable portion that is axially moveable within the handle.
10. The ultrasound imaging catheter of claim 1, wherein the cable bundle is not adapted to be moved axially within the handle after the handle is assembled.



- 11.** The ultrasound imaging catheter of claim 1, wherein the drain wire is configured to reduce a centerline on an image captured by the ultrasound transducer.
  - 12.** The ultrasound imaging catheter of claim 1, wherein the drain wire is configured to reduce grating lobe noise artifact on an image captured by the ultrasound transducer.
  - 13.** An ultrasound imaging catheter, comprising: an elongate shaft sized and configured to be advanced within a patient; a handle sized and positioned to remain outside of the patient; a distal tip including an ultrasound transducer; an elongate cable bundle in communication with the ultrasound transducer, the elongate cable bundle passing proximally through the elongate shaft and extending into the handle, wherein the elongate cable bundle comprises a shield strip, a ground, and a drain wire, wherein the drain wire is configured to attract noise away from the ground and the shield strip, wherein the drain wire is isolated from the ground, and wherein the drain wire is isolated from the shield strip.
  - 14.** The ultrasound imaging catheter of claim 13, wherein the cable bundle is coupled to a plurality of printed circuit boards that are disposed within the handle.
  - 15.** The ultrasound imaging catheter of claim 13, wherein the cable bundle extends from a proximal end of an elongate shaft within the handle.
  - 16.** The ultrasound imaging catheter of claim 15, wherein the cable bundle extends radially outside of a plurality of printed circuit boards that are disposed within the handle.
  - 17.** The ultrasound imaging catheter of claim 15, wherein the cable bundle passes between first and second of a plurality of printed circuit boards that are disposed within the handle.
  - 18.** The ultrasound imaging catheter of claim 13, wherein the cable bundle is axially moveable within the handle.
  - 19.** The ultrasound imaging catheter of claim 13, wherein the cable bundle is axially immovable within the handle.
  - 20.** The ultrasound imaging catheter of claim 13, wherein the drain wire is configured to reduce a centerline on an image captured by the ultrasound transducer.
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