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Chen et al.

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(54) **MEDICAL DEVICE AND SYSTEM AND METHOD FOR GUIDING POSITIONING OF SAME**

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G01K 11/3206 (2021.01)

(52) **U.S. Cl.**
CPC ***G01D 5/35316*** (2013.01); ***G01K 11/3206*** (2013.01); *A61B 2562/0266* (2013.01)

(58) **Field of Classification Search**
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(Continued)

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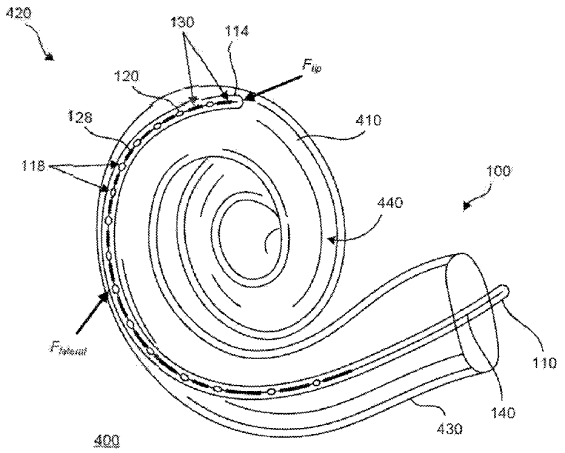
(57) **ABSTRACT**

A medical device that includes a carrier member, one or more operative components disposed in the carrier member, an optical fiber at least partly disposed in the carrier member, and at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and disposed in the carrier member. The carrier member includes an insertion end and side walls that contact the subject's body during positioning of the carrier member in the subject's body. The at least one FBG sensor array measures contact forces at one or both of the insertion end and along the side walls of the carrier member during positioning of the carrier member in the subject's body. A multi-core optical fiber configured for use in a medical device for positioning in a subject's body is also
(Continued)



provided. A system and method for guiding positioning of a medical device in a subject's body is also provided.

25 Claims, 10 Drawing Sheets

(58) **Field of Classification Search**
CPC A61B 2018/00267; A61B 2018/00327; A61B 2018/00577; A61B 2034/2061; A61B 2034/256; A61B 2090/065; A61B 2218/002; A61B 2218/007; A61B 34/20; A61B 2090/062; A61B 2090/374; A61B 2090/376; A61B 2090/378; A61B 2560/0468; A61B 2562/04; A61B 90/06; G01L 1/246; A61N 5/0601; A61N 5/0603; A61N 2005/0605; A61N 2005/0626; A61N 2005/0652; A61N 5/0622; A61N 1/0541; G02B 6/02042; G02B 6/02076; G02B 6/02314; G02B 6/3624; G02B 6/02
See application file for complete search history.

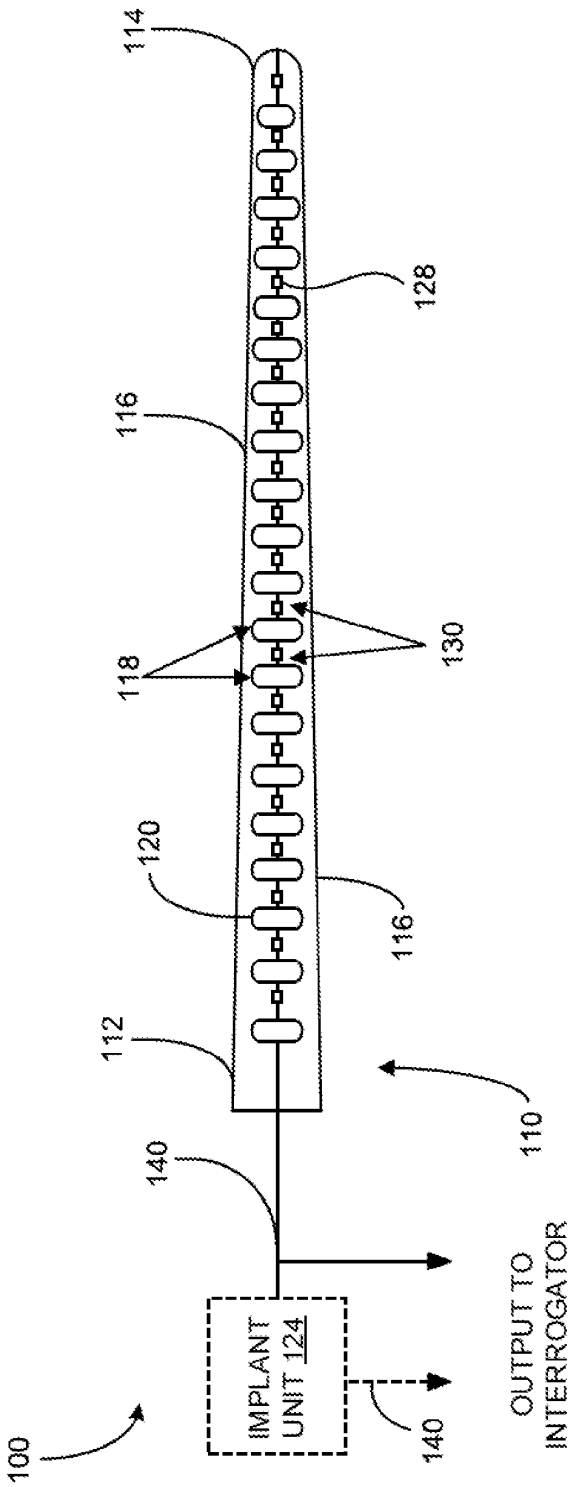

114
128
116
118
130
120
116
112
110
140
IMPLANT UNIT 124
140
OUTPUT TO INTERROGATOR
100

Figure 1

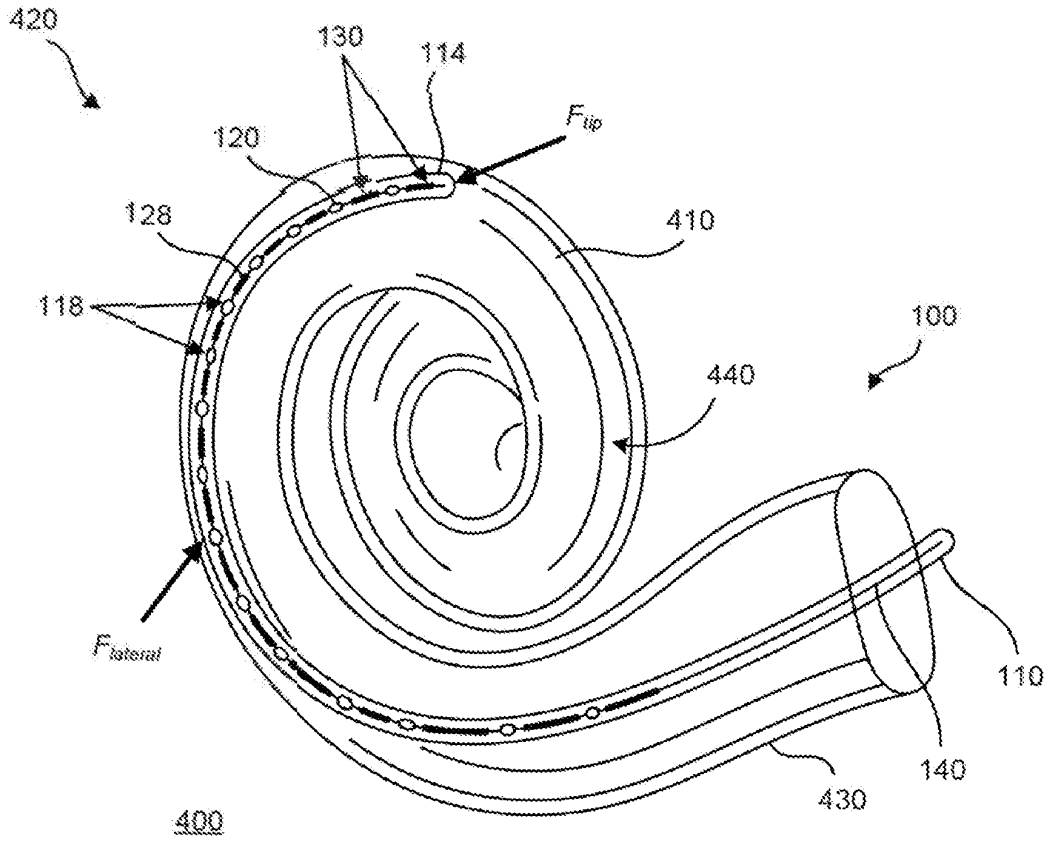


Figure 2

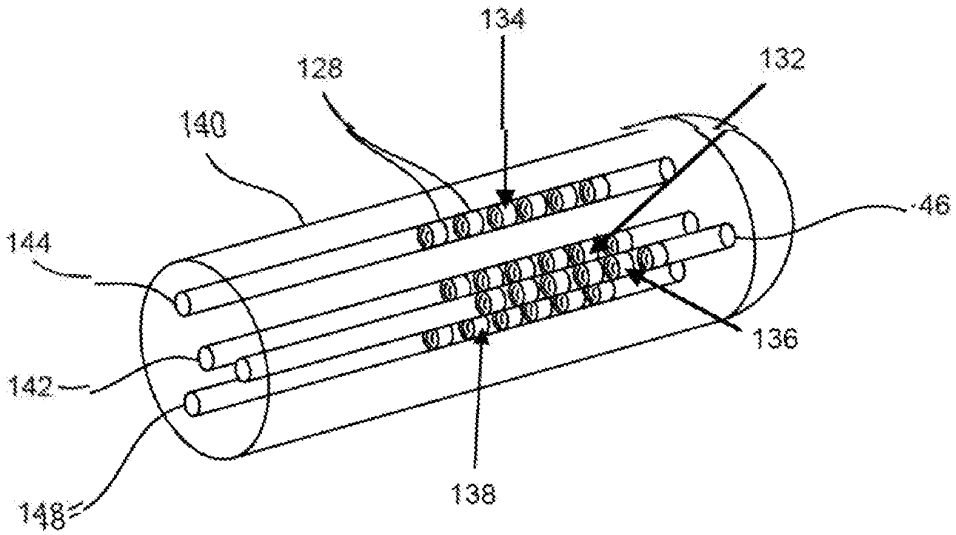


Figure 3

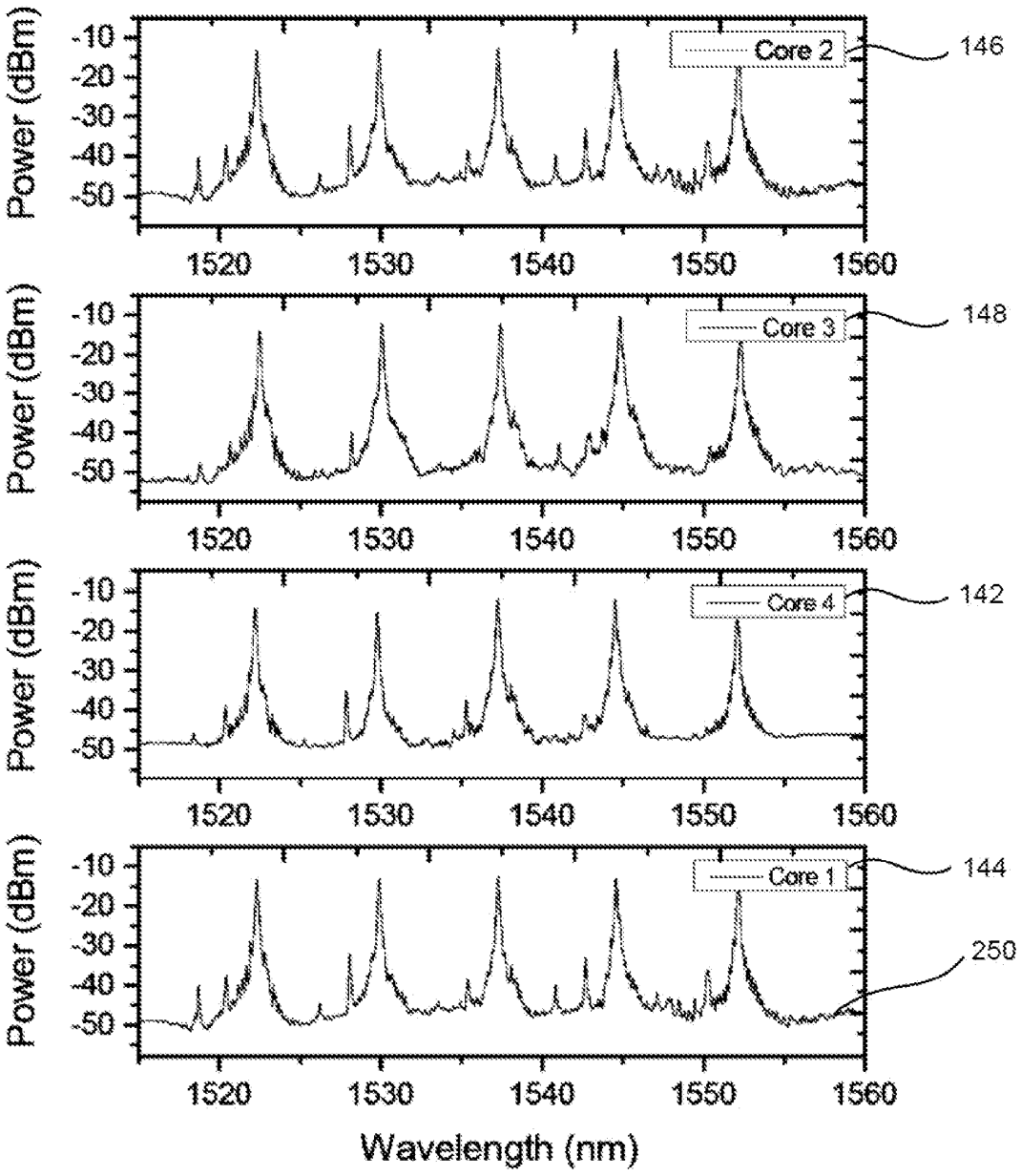

Power (dBm)
-10
-20
-30
-40
-50
Core 2
146
Core 3
148
Core 4
142
Core 1
144
250
1520
1530
1540
1550
1560
Wavelength (nm)

Figure 4

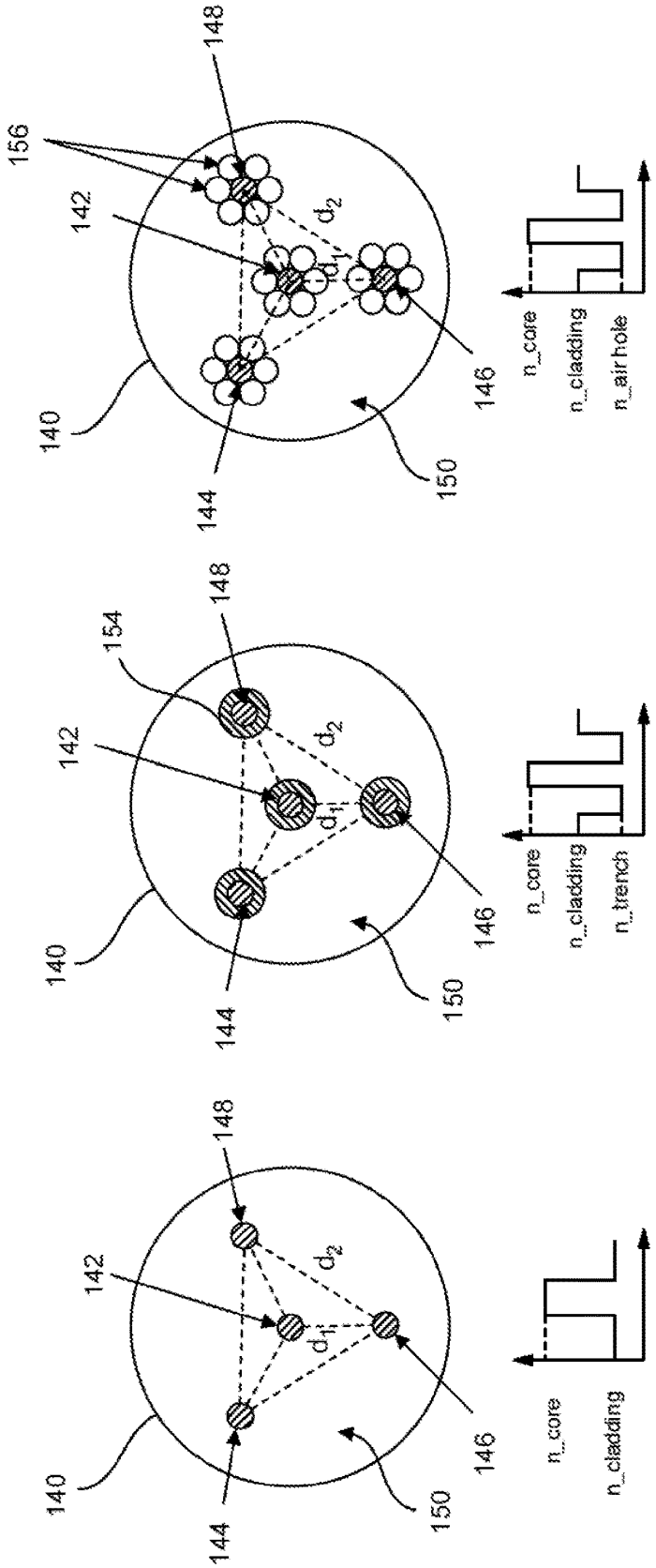


Figure 5C

Figure 5B

Figure 5A

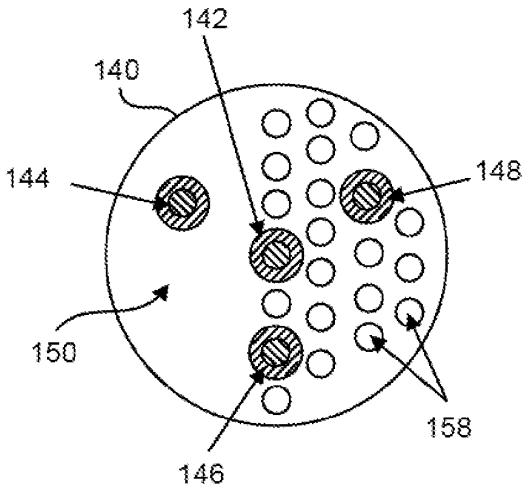


Figure 6A

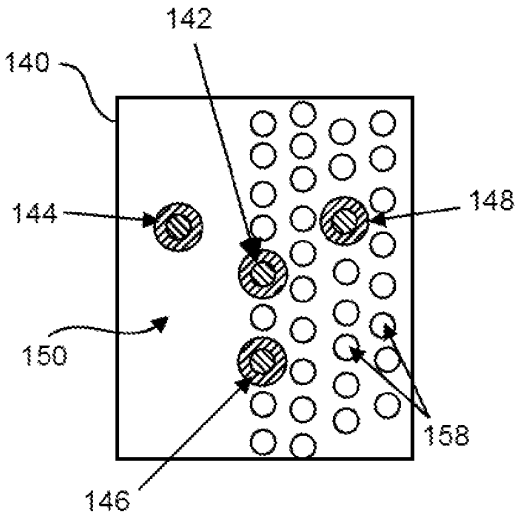


Figure 6B

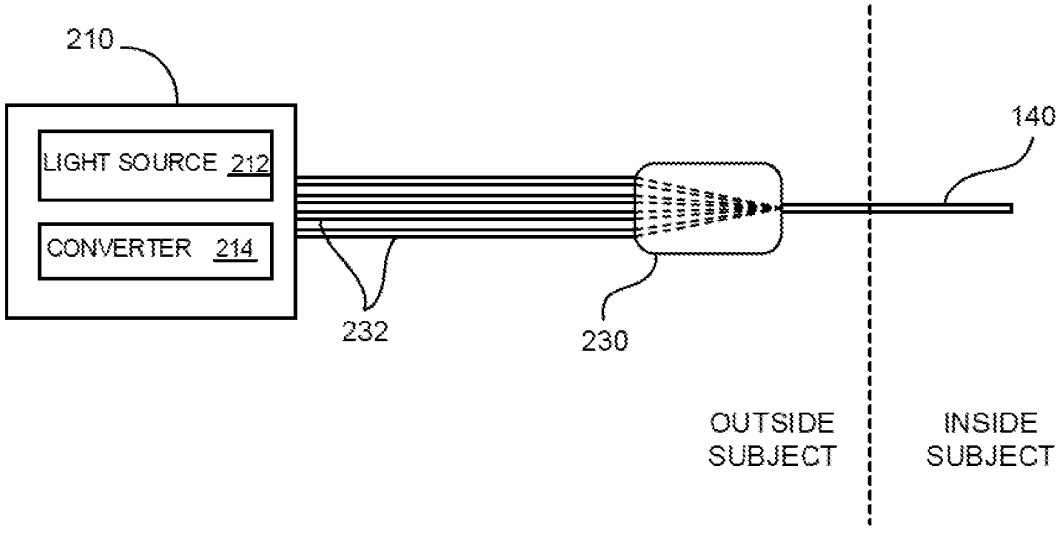


Figure 7

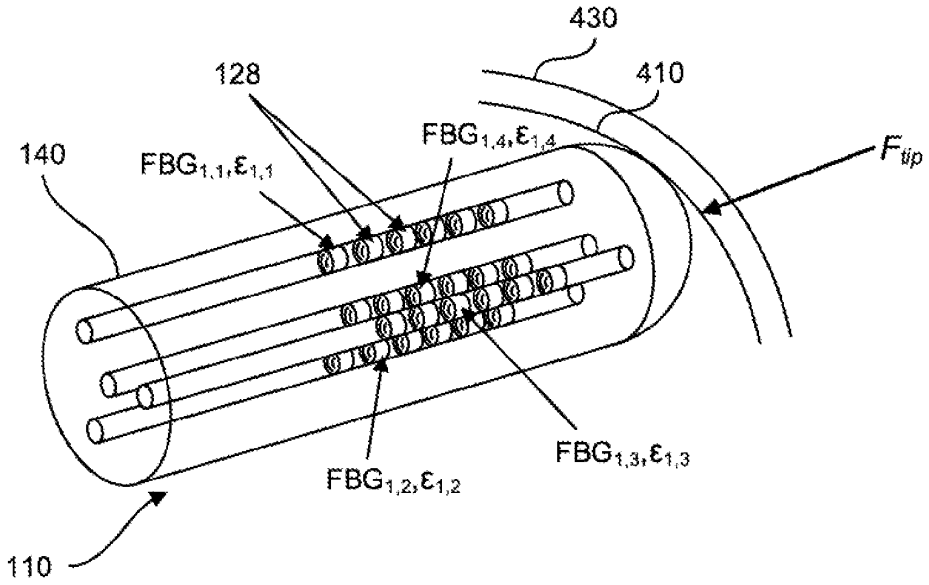


Figure 8

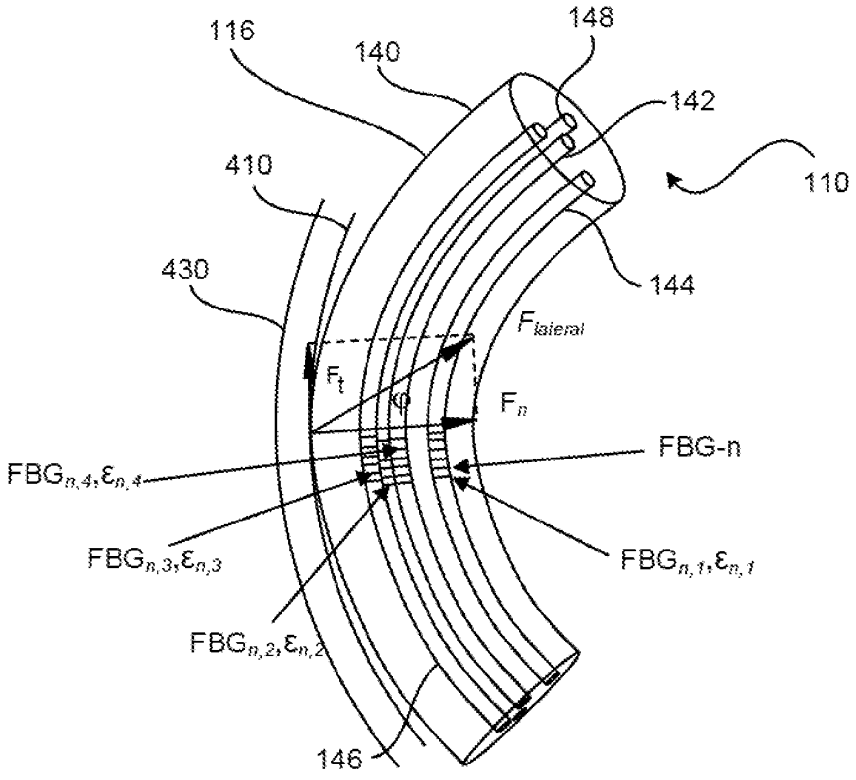


Figure 9

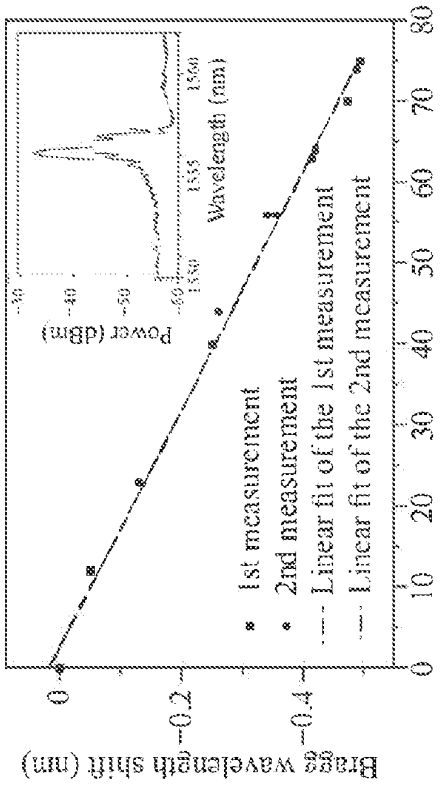


Figure 11

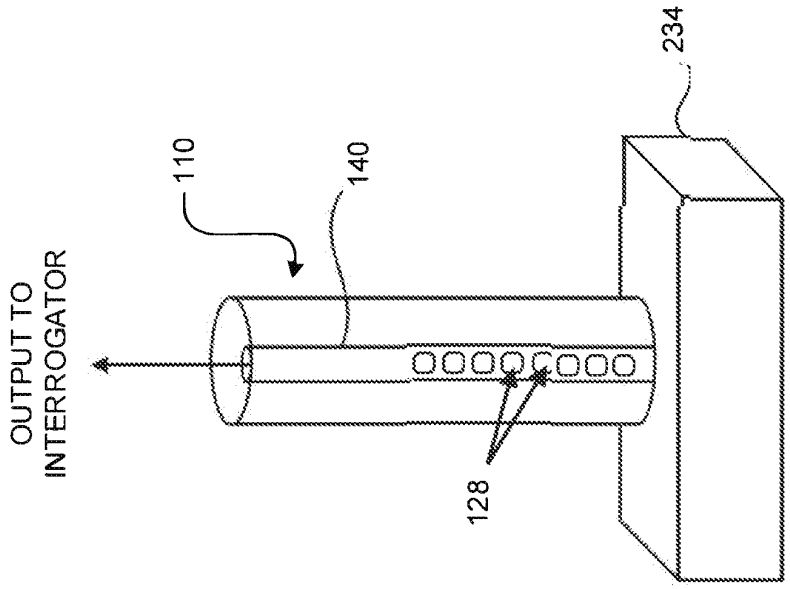


Figure 10

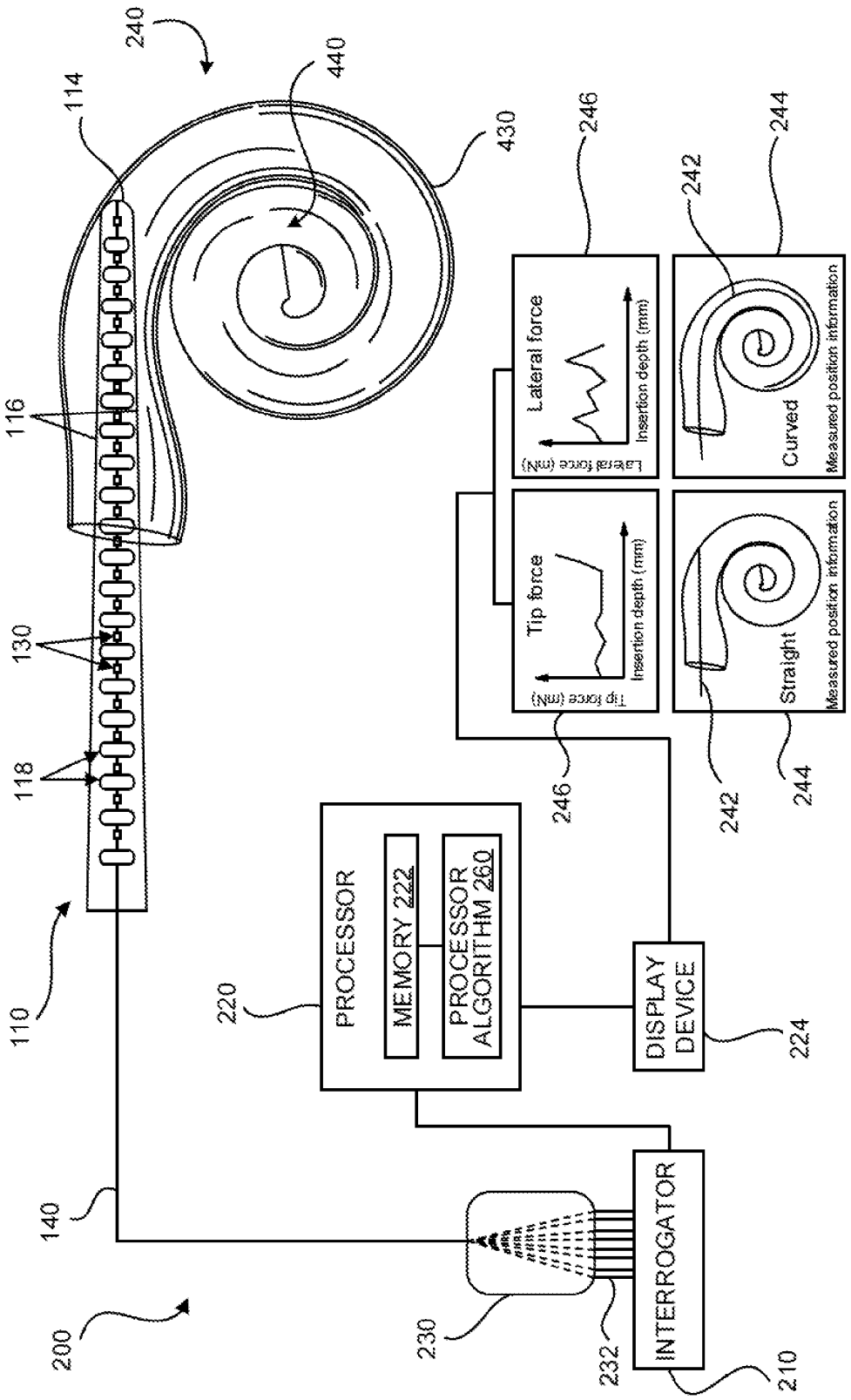

240
440
114
430
246
242
244
116
Lateral force
Lateral force (mN)
Insertion depth (mm)
Curved
Measured position information
130
Tip force
Tip force (mN)
Insertion depth (mm)
Straight
Measured position information
118
246
242
244
110
220
PROCESSOR
MEMORY 222
PROCESSOR ALGORITHM 260
DISPLAY DEVICE
224
140
200
230
232
INTERROGATOR
210

Figure 12

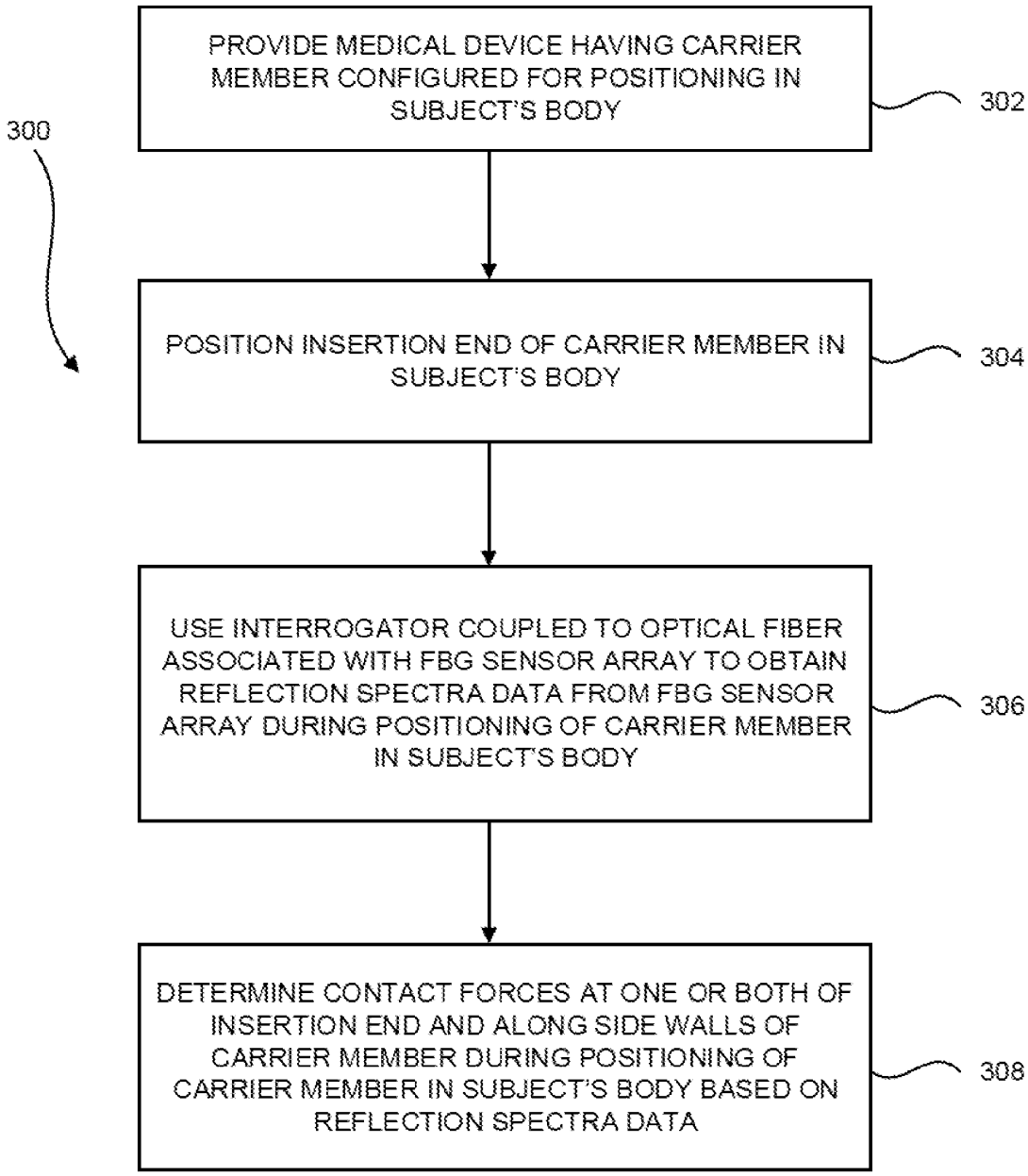

300
PROVIDE MEDICAL DEVICE HAVING CARRIER MEMBER CONFIGURED FOR POSITIONING IN SUBJECT'S BODY
302
POSITION INSERTION END OF CARRIER MEMBER IN SUBJECT'S BODY
304
USE INTERROGATOR COUPLED TO OPTICAL FIBER ASSOCIATED WITH FBG SENSOR ARRAY TO OBTAIN REFLECTION SPECTRA DATA FROM FBG SENSOR ARRAY DURING POSITIONING OF CARRIER MEMBER IN SUBJECT'S BODY
306
DETERMINE CONTACT FORCES AT ONE OR BOTH OF INSERTION END AND ALONG SIDE WALLS OF CARRIER MEMBER DURING POSITIONING OF CARRIER MEMBER IN SUBJECT'S BODY BASED ON REFLECTION SPECTRA DATA
308

Figure 13

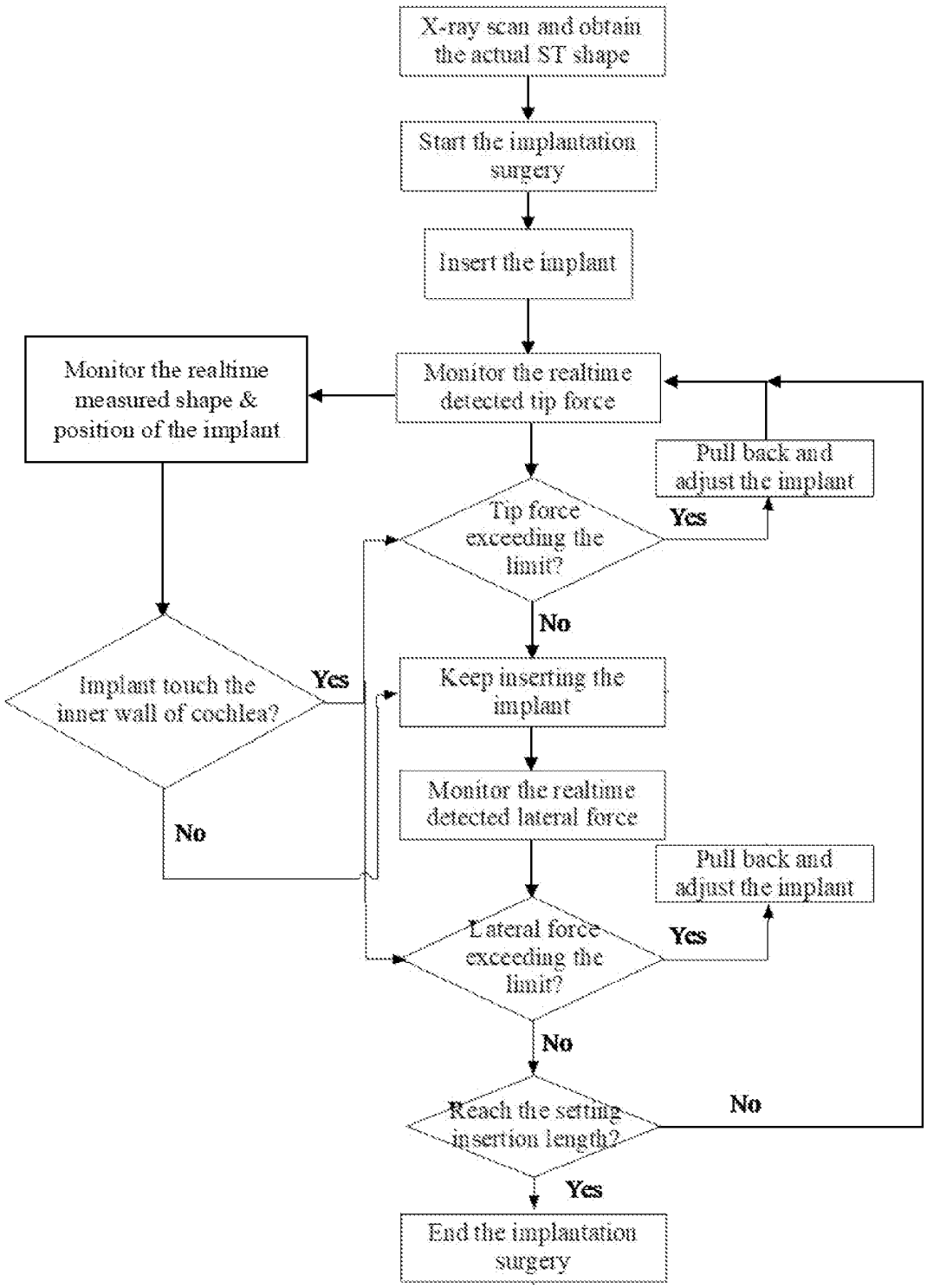

X-ray scan and obtain the actual ST shape
Start the implantation surgery
Insert the implant
Monitor the realtime detected tip force
Monitor the realtime measured shape & position of the implant
Pull back and adjust the implant
Tip force exceeding the limit?
Yes
No
Implant touch the inner wall of cochlea?
Yes
No
Keep inserting the implant
Monitor the realtime detected lateral force
Pull back and adjust the implant
Lateral force exceeding the limit?
Yes
No
Reach the setting insertion length?
No
Yes
End the implantation surgery

Figure 14

MEDICAL DEVICE AND SYSTEM AND METHOD FOR GUIDING POSITIONING OF SAME

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a National Phase filing under 35 U.S.C. § 371 of International Application No. PCT/AU2020/051424, filed Dec. 23, 2020, and published as WO 2021/127738 A1 on Jul. 1, 2021, which claims the benefit of priority from Australian Patent Application No. 2019904938, filed on 24 Dec. 2019, the entire contents of each of the prior applications are incorporated herein by reference in their entirety.

TECHNICAL FIELD

The present invention relates to a medical device having fiber Bragg grating (FBG) sensors for guiding positioning of the medical device in a human or animal subject's body. It also relates to a system and method for guiding positioning of a medical device in a human or animal subject's body, and an optical fiber configured for use with a medical device.

BACKGROUND OF INVENTION

Medical devices can be temporarily or permanently positioned or implanted in human or animal patients. Depending on the relative dimensions and flexibility of the patient's anatomy and the medical device, the configuration of the insertion or implantation path, and a variety of other factors, injury is sometimes caused due to physical contact between the medical device and patient's anatomy. Physical damage may be caused to surrounding tissues of the patient during positioning or implantation which may adversely affect the patient, surgical procedure or medical device performance.

For example, implantation of an electrode array of a cochlear implant may cause physical trauma or damage to the patient. A cochlear implant is a surgically implanted device which resides inside a cochlea and restores hearing in a patient who suffers from severe hearing deficiencies. It is vital to preserve the residual hearing of the patient so that the cochlear implant operates effectively. A series of complications may arise during the surgical procedure in which the electrode array is inserted into the scala tympani of the cochlea. Any possible physical trauma or damage to the cochlea during implantation must be avoided or at least minimised to maximise the benefit of such a surgical procedure for the patient.

Various attempts have been made to provide guidance and assistance to avoid trauma to the cochlea during insertion of the implant. For instance, introducing an automated insertion tool integrated with force sensing and an image guided positioning system for minimally invasive access to the cochlear, (D. Schurzig et al., "A force sensing Automated Insertion Tool for cochlear electrode implantation," in 2010 IEEE International Conference on Robotics and Automation (IEEE, 2010), pp. 3674-3679), development of a steerable EA and optimum path planning strategies to follow during the insertion of the implant (Zhang, Jian et al., (2008). Path Planning and Workspace Determination for Robot-Assisted Insertion of Steerable Electrode Arrays for Cochlear Implant Surgery. Medical image computing and computer-assisted intervention: MICCAI International Conference on Medical Image Computing and Computer-Assisted Intervention. 11. 692-700), and usage of a robot-assisted steerable electrode

prototype to reduce insertion forces and prevent buckling of the electrodes (J. Zhang et al., "Inroads Toward Robot-Assisted Cochlear Implant Surgery Using Steerable Electrode Arrays," Otol. Neurotol. 31(8), 1199-1206 (2010)).

Fiber Bragg grating (FBG) sensors can be an attractive solution for this extremely sensitive surgical procedure. Axial and lateral forces at the electrode array tip, and frictional forces and lateral forces from the proximal section of the array exist during insertion. The experimental configuration of most studies is limited to evaluating only a subset of these forces (Kontorinis, et al., (2011). Impact of the insertion speed of cochlear implant electrodes on the insertion forces. Otology & neurotology, 32(4), 565-570), Rebscher, S. J., et al., (1999). Strategies to improve electrode positioning and safety in cochlear implants. IEEE Transactions on Biomedical Engineering, 46(3), 340-352), which fails to provide detailed information on all these individual force components.

A study has used one FBG sensor in the cochlear implant (Wade S A et al., "Measurement of Forces at the Tip of a Cochlear Implant During Insertion," IEEE Trans. Biomed. Eng., vol 61, no. 4, pp. 1177-1186, April 2014 and Capcelea, E et al., (2013). U.S. patent application Ser. No. 13/231,957.). This FBG has been inscribed in 125 μm single mode fiber (SMF) where the tip force of the cochlear implant ranged from 75-225 mN which is far above the threshold of approximately 20-25 mN that surgeons can perceive. Furthermore, during insertion of the cochlear implant, the FBG based sensors are expected to navigate through critical bending radii due to the curvature of the cochlear, making the widely used 125 μm SMF unsuitable due to its stiffness which increases the risk of trauma. Moreover, a uniaxial sensor as proposed in the aforementioned studies, limits the information that can be retrieved in a complex 3-D geometry such as the cochlea. This extremely sensitive surgical procedure which involves small dimensions and complex navigation makes insertion of the cochlear implant challenging.

Rogge et al filed a patent describing shape sensing using a multi-core optical fiber (U.S. Pat. No. 8,746,076). The proposed method is employed to calculate the bending curvature and bending direction via the FBGs inscribed in all the cores of the optical fiber. However, the optical fiber is designed in a standard approach, where it exhibits a relatively high stiffness and cannot be bent into small diameters, thus limiting use in a tiny space, such as the cochlear scala tympani.

Taylor et al proposed a sensing system for cochlear implant surgery (U.S. Pat. No. 9,345,397). The sensing device measures from an end of the cochlear implant to the anatomic surface at a distance from the end of the cochlear implant, and the sensor is integrated into an Optical Coherence Tomography (OCT) system so that OCT produces images for quantitative distance measurements. Such a system is considered as an extra-cochlear approach and is not compact for use during surgery. Additionally, no information on the contact force can be provided.

It would be desirable to provide a sensing system that can provide force sensing of the cochlear implant during implantation, and preferably, provide real-time feedback to a surgeon. It may also be desirable to provide a medical device configured to provide force sensing for guiding positioning in a patient's body, and which ameliorate and/or overcome one or more problems or inconveniences of the prior art.

A reference herein to a patent document or any other matter identified as prior art, is not to be taken as an admission that the document or other matter was known or

that the information it contains was part of the common general knowledge as at the priority date of any of the claims.

SUMMARY OF INVENTION

In one aspect, the present invention provides a medical device including a carrier member configured for positioning in a subject's body, one or more operative components disposed in the carrier member, an optical fiber at least partly disposed in the carrier member and at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the carrier member. The carrier member includes an insertion end and side walls that contact the subject's body during positioning of the carrier member in the subject's body. The at least one FBG sensor array is configured for measuring contact forces at one or both of the insertion end and along the side walls of the carrier member during positioning of the carrier member in the subject's body.

In some embodiments, the device further includes a plurality of FBG sensor arrays configured for measuring position of one or both of the insertion end and the side walls of the carrier member during positioning of the carrier member in the subject's body.

In some embodiments, the optical fiber is a multi-core optical fiber having a FBG sensor array disposed in each core for providing contact force and/or position measurements at the location of each FBG. The grating pitch of each FBG in the FBG sensor arrays may be different to enable the reflection wavelengths of the FBGs along each core to be detected individually. The FBG separation in each of the FBG sensor arrays may be substantially identical for providing contact force and/or position measurements at the location of each FBG based on variations in the reflection spectra of the FBG sensor arrays in each core.

In some embodiments, the multi-core optical fiber includes a central core located centrally along the optical fiber and a plurality of cores surrounding the central core that are equally spaced from each other. The multi-core optical fiber may include a low-index region associated with each core. The low-index region may have a lower refractive index than the refractive index of the core and a cladding of the optical fiber for reducing bending loss of optical light during positioning of the carrier member in the subject's body. The low-index region may include a trench surrounding the core, where the trench is air-filled or filled with a fluid having the lower refractive index. Alternatively, the low-index region may include one or more holes surrounding the core, where the holes are air-filled or filled with a fluid having the lower refractive index. In another alternative embodiment, the low-index region may include a plurality of elongate members positioned around and colinearly with the core, where the elongate members include a material have the lower refractive index.

In some embodiments, the multi-core optical fiber includes a plurality of holes arranged in a cladding of the optical fiber to induce bending in a desired direction during positioning of the carrier member in the subject's body. The multi-core optical fiber may also include a cladding that is shaped to induce bending in a desired direction during positioning of the carrier member in the subject's body. For example, a cross-section of the cladding may include one or more of the following shapes: circular, rectangular, square, triangular, oval and elliptical.

The one or more operative components may include at least one electrode array or optical array, and the FBG sensor array may be aligned relative to the at least one electrode array or optical array in the carrier member.

In some embodiments, the device is an implantable medical device and the carrier member is configured for implantation in the subject's body. The device may be a cochlear implant device and the one or more operative components may include at least one electrode array or optical array for providing stimulation to the nervous system of the subject.

In another aspect of the present invention, there is provided a multi-core optical fiber configured for use in a medical device for positioning in a subject's body. The multi-core optical fiber includes a fiber Bragg grating (FBG) sensor array disposed in each core configured for providing one or both of contact force and position measurements at the location of each FBG during positioning of the medical device in the subject's body.

In some embodiments, the grating pitch of each FBG in the FBG sensor arrays is different to enable the reflection wavelengths of the FBGs along each core to be detected individually. The FBG separation in each of the FBG sensor arrays may also be substantially identical for providing contact force and/or position measurements at the location of each FBG based on variations in the reflection spectra of the FBG sensor arrays in each core.

In some embodiments, the multi-core optical fiber includes a central core located centrally along the optical fiber and a plurality of cores surrounding the central core that are equally spaced from each other. The multi-core optical fiber may include a low-index region associated with each core. The low-index region may have a lower refractive index than the refractive index of the core and a cladding of the optical fiber for reducing bending loss of optical light during positioning of the medical device in the subject's body. The low-index region may include a trench surrounding the core, where the trench is air-filled or filled with a fluid having the lower refractive index. Alternatively, the low-index region may include one or more holes surrounding the core, where the holes are air-filled or filled with a fluid having the lower refractive index. In another alternative embodiment, the low-index region may include a plurality of elongate members positioned around and colinearly with the core, where the elongate members include a material have the lower refractive index.

In some embodiments, the multi-core optical fiber further includes a cladding having a plurality of holes arranged therein to induce bending of the optical fiber in a desired direction during positioning of the medical device in the subject's body. The multi-core optical fiber may further include a cladding that is shaped to induce bending in a desired direction during positioning of the medical device in the subject's body. For example, a cross-section of the cladding may include one or more of the following shapes: circular, rectangular, square, triangular, oval and elliptical.

In some embodiments, the device is an implantable medical device configured for implantation in the subject's body. The device may be a cochlear implant device.

In another aspect, the present invention provides a system for guiding positioning of a medical device in a subject's body. The system includes a medical device including: a carrier member configured for positioning in the subject's body, the carrier member including an insertion end and side walls that contact the subject's body during positioning of the carrier member in the subject's body; one or more operative components disposed in the carrier member; an optical fiber at least partly disposed in the carrier member; and at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the

carrier member. The system also includes an interrogator coupled to the optical fiber and configured to obtain reflection spectra data from the FBG sensor array during positioning of the carrier member in the subject's body. The system also includes a processor configured to receive the reflection spectra data from the interrogator and to process the reflection spectra data to determine contact forces at one or both of the insertion end and along the side walls of the carrier member during positioning of the carrier member in the subject's body.

In some embodiments, the device further includes a plurality of FBG sensor arrays, and the processor is further configured to process the reflection spectra data to determine position of one or both of the insertion end and the side walls of the carrier member during positioning of the carrier member in the subject's body.

Preferably, the optical fiber is a multi-core optical fiber including a fiber Bragg grating (FBG) sensor array disposed in each core, and the system further includes a coupling device for coupling each core to the interrogator for separately detecting the reflection spectra of the FBG sensor arrays in each core.

In some embodiments, the processor is further configured to receive position data of a target region of the subject's body prior to positioning of the carrier member in the subject's body, and process data corresponding to the position of the carrier member relative to the position data of the target region to determine a depth of positioning of the carrier member in the subject's body. The processor may be further configured to receive an image of the target region of the subject's body prior to positioning of the carrier member in the subject's body, reconstruct an image of the carrier member using the data corresponding to the position of the carrier member, overlay the reconstructed image of the carrier member on the image of the target region of the subject's body, and output data representing an image of the position of the carrier member relative to the target region of the subject's body.

Optionally, the system may further include a display device. The processor may be further configured to display on the display device one or both of: an infographic of the contact forces on the carrier member relative to the depth of positioning of the carrier member, and an image of the position of the carrier member relative to the target region of the subject's body.

Ideally, the processor is further configured to process the data in real-time to provide contact force and/or position information of the carrier member during positioning of the carrier member in the subject's body.

The processor may be further configured to detect when the contact forces on the carrier member exceed a threshold value over which damage to internal tissues of the subject's body is likely to occur. When the threshold value is exceeded, the processor may be configured to output a notification signal of excessive contact forces on the internal tissues of the subject's body. When the threshold value is exceeded, the processor may be further configured to output data representing instructions to perform one or more of the following: stop advancing the carrier member into the subject's body, at least partially withdraw the carrier member from the subject's body, adjust an insertion angle of the carrier member relative to the subject's body, and re-insert the carrier member into the subject's body.

In some embodiments, the device is an implantable medical device and the carrier member is configured for implantation in the subject's body. The medical device may be a cochlear implant device and the one or more operative components may include at least one electrode array or optical array for providing stimulation to the nervous system of the subject. The processor may be further configured to one or both of: process the data to detect when the contact forces on the carrier member are indicative of fold-over of a tip of the at least one electrode array or optical array, and output a notification signal of fold-over of the tip.

In another aspect of the present invention, there is provided a method for guiding positioning of a medical device in a subject's body. The method includes the step of providing a medical device including: a carrier member configured for positioning in the subject's body, the carrier member including an insertion end and side walls that contact the subject's body during positioning of the carrier member in the subject's body; one or more operative components disposed in the carrier member; an optical fiber at least partly disposed in the carrier member; and at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the carrier member. The method also includes the step of positioning the insertion end of the carrier member in the subject's body. The method also includes the step of using an interrogator coupled to the optical fiber to obtain reflection spectra data from the FBG sensor array during positioning of the carrier member in the subject's body. The method also includes the step of determining contact forces at one or both of the insertion end and along the side walls of the carrier member during positioning of the carrier member in the subject's body based on the reflection spectra data from the interrogator.

In some embodiments, the device further includes a plurality of FBG sensor arrays, and the method further includes the step of determining position of one or both of the insertion end and the side walls of the carrier member during positioning of the carrier member into the subject's body based on the reflection spectra data from the interrogator.

Preferably, the optical fiber is a multi-core optical fiber including a fiber Bragg grating (FBG) sensor array disposed in each core, and the method further includes the step of coupling each core to the interrogator by a coupling device for separately detecting the reflection spectra of the FBG sensory arrays in each core.

In some embodiments, the method further include the following steps: receiving, using a processor, position data of a target region of the subject's body prior to positioning of the carrier member in the subject's body; and processing, using the processor, data corresponding to the position of the carrier member relative to the position data of the target region to determine a depth of positioning of the carrier member in the subject's body. The method may also include the following steps: receiving, using the processor, an image of the target region of the subject's body prior to positioning the carrier member in the subject's body; reconstructing, using the processor, an image of the carrier member using the data corresponding to the position of the carrier member; overlaying, using the processor, the reconstructed image of the carrier member on the image of the target region of the subject's body; and outputting, using the processor, data representing an image of the position of the carrier member relative to the target region of the subject's body.

Optionally, the method further includes the step of displaying, using the processor, on a display device one or both of: an infographic chart of the contact forces on the carrier member relative to the depth of positioning in the subject's body; and an image of the position of the carrier member relative to the target region of the subject's body.

Preferably, the method further includes determining in real-time contact force and/or position information of the carrier member during positioning of the carrier member in the subject's body.

In some embodiments, the method further includes the step of determining when the contact forces on the carrier member exceed a threshold value over which damage to internal tissues of the subject's body is likely to occur. When the threshold value is exceeded, the method may further include the step of outputting, using a processor, a notification signal of excessive contact forces on the internal tissues of the subject's body. When the threshold value is exceeded, the method may further include one or more of the following steps: stopping advancing of the carrier member in the subject's body; at least partially withdrawing the carrier member from the subject's body; adjusting an insertion angle of the carrier member relative to the subject's body; and re-inserting the carrier member into the subject's body.

In some embodiments, the device is an implantable medical device and the carrier member is configured for implantation in the subject's body. The medical device may be a cochlear implant device and the one or more operative components include at least one electrode array or optical array for providing stimulation to the nervous system of the subject. The method may further include the steps of determining when the contact forces on the carrier member are indicative of fold-over of a tip of the at least one electrode array or optical array; and outputting, using a processor, a notification signal of fold-over of the tip.

In another aspect, the present invention provides an implantable medical device including: a carrier member configured for implantation into a subject, the carrier member including an insertion end and side walls that contact the subject during implantation; one or more operative components disposed in the carrier member; an optical fiber at least partly disposed in the carrier member; and at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the carrier member, wherein the at least one FBG sensor array is configured for measuring contact forces at one or both of the insertion end and along the side walls of the carrier member during implantation into the subject.

In another aspect of the present invention, there is provided a multi-core optical fiber configured for use in an implantable medical device, the multi-core optical fiber including a fiber Bragg grating (FBG) sensor array disposed in each core configured for providing one or both of contact force and position measurements at the location of each FBG during implantation of the medical device in a subject.

In another aspect of the present invention, there is provided a system for guiding implantation of a medical device into a subject, the system including: an implantable medical device including: a carrier member configured for implantation into the subject, the carrier member including an insertion end and side walls that contact the subject during implantation; one or more operative components disposed in the carrier member; an optical fiber at least partly disposed in the carrier member; and at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the carrier member; an interrogator coupled to the optical fiber and configured to obtain reflection spectra data from the FBG sensor array during implantation of the carrier member into the subject; and a processor configured to receive the reflection spectra data from the interrogator and to process the reflection spectra data to determine contact forces at one or both of the insertion end and along the side walls of the carrier member during implantation into the subject.

In another aspect of the present invention, there is provided a method for guiding implantation of a medical device into a subject, the method including the steps of: providing an implantable medical device including: a carrier member configured for implantation into the subject, the carrier member including an insertion end and side walls that contact the subject during implantation; one or more operative components disposed in the carrier member; an optical fiber at least partly disposed in the carrier member; and at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the carrier member; advancing the insertion end of the carrier member into an implantation region of the subject; using an interrogator coupled to the optical fiber to obtain reflection spectra data from the FBG sensor array during implantation of the carrier member into the subject; and determining contact forces at one or both of the insertion end and along the side walls of the carrier member during implantation based on the reflection spectra data from the interrogator.

BRIEF DESCRIPTION OF DRAWINGS

The invention will now be described in greater detail with reference to the accompanying drawings in which like features are represented by like numerals. It is to be understood that the embodiments shown are examples only and are not to be taken as limiting the scope of the invention as defined in the claims appended hereto.

FIG. **1** is a schematic illustration showing components of a medical device according to some embodiments of the invention.

FIG. **2** is a schematic illustration showing the device of FIG. **1** inserted into a scala tympani channel of a cochlea of a subject according to some embodiments of the invention.

FIG. **3** is a perspective view of a multi-core optical fiber showing a FBG in each core at a distal tip according to some embodiments of the invention.

FIG. **4** is a series of charts showing reflection spectra of a five-FBG array inscribed in a four-core multi-core optical fiber according to some embodiments of the invention.

FIGS. **5**A-C are schematic illustrations showing cross-sections and corresponding index profiles of a multi-core optical fiber according to some embodiments of the invention with traditional step-index profiles (FIG. **5**A), low-index trenches around the core (FIG. **5**B), and air holes around the core (FIG. **5**C).

FIGS. **6**A-B are schematic illustrations showing cross-sections of a multi-core optical fiber according to some embodiments of the invention with air holes in one half of the cladding, showing a circular cross-section of the cladding (FIG. **6**A) and a rectangular cross-section of the cladding (FIG. **6**B).

FIG. **7** is a schematic illustration showing coupling of a medical device having a multi-core optical fiber to a multi-channel interrogator according to some embodiments of the invention.

FIG. **8** is a perspective view of a multi-core optical fiber with a FBG in each core at a distal tip and showing tip force measurement based on the grating inscribed in the four cores according to some embodiments of the invention.

FIG. **9** is a schematic illustration showing a multi-core optical fiber with a FBG in each core along a length of the

optical fiber and the lateral force and position measurement based on the grating according to some embodiments of the invention.

FIG. **10** is a schematic illustration of an experimental arrangement to calibrate the coefficient of the tip force and grating signal according to some embodiments of the invention.

FIG. **11** is a chart showing results of the calibration using the experimental arrangement of FIG. **10**.

FIG. **12** is a schematic illustration showing a system for guiding positioning of a medical device in a subject's body according to some embodiments of the invention.

FIG. **13** is a flow chart illustrating steps of a method for guiding positioning of a medical device in a subject's body according to some embodiments of the invention.

FIG. **14** is a flow chart illustrating steps performed by a processor of a system and/or steps performed in a method, both for guiding implantation of a cochlear implant into a subject's body, according to some embodiments of the invention.

DETAILED DESCRIPTION

Embodiments of the invention are discussed herein by reference to the drawings which are not to scale and are intended merely to assist with explanation of the invention. Reference herein to a subject may refer to a human or an animal subject or patient. Reference herein to the terms "distal" and "proximal" are to be interpreted relative to a surgeon or operator implanting the medical device. Distal refers to a feature being directed away from the surgeon or operator and proximal refers to a feature being directed towards the surgeon or operator.

Embodiments of the invention are generally directed to providing force and/or position sensing for guiding positioning or implantation of a medical device into a subject. As noted, many types of medical devices are temporarily or permanently positioned or implanted into a subject's body. The following detailed description is provided with reference to one type of implantable medical device, namely, a cochlear implant. It will be appreciated, however, that aspects and embodiments of the invention will also have application to other types of medical devices that may cause physical trauma or damage during or subsequent to positioning or implantation in a subject's body. For example, embodiments of the invention may have application to other medical devices which require positioning or implantation, temporarily or permanently, into narrow and/or delicate sections of the patient's anatomy and/or which require complex navigation by a surgeon.

FIG. **1** is a simplified schematic diagram showing components of a medical device **100** according to some embodiments of the invention. The medical device **100** includes a carrier member **110** configured for positioning in a subject's body **400** (see also FIG. **2**). The carrier member **110** includes an insertion end **114** and side walls **116** that contact the subject's body **400** during positioning of the carrier member **110** in the subject's body **400**. The medical device **100** also includes one or more operative components **118** disposed in the carrier member **110** and an optical fiber **140** at least partly disposed in the carrier member **110**. The medical device **100** also includes at least one fiber Bragg grating (FBG) sensor array **130** associated with the optical fiber **140** and is disposed in the carrier member **110**. The at least one FBG sensor array **130** is configured for measuring contact forces at one or both of the insertion end **114** and along the side walls **116** of the carrier member **110** during positioning of the carrier member **110** in the subject's body **400**.

The device **100** may be an implantable medical device and the carrier member **110** may be configured for implantation in the subject's body **400**.

The carrier member **110** may, in use, be coupled with an implant unit **124** through a coupling such as induction coils (not shown). The implant unit **124** may include a sound processor and other components for a cochlear implant. Alternatively, the medical implant **100** may be completely implanted in the subject's body **400** and include the implant unit **124**.

The carrier member **110** may be made of a medical grade material, preferably silicone, which is suitable for positioning or implantation temporarily or permanently into the subject's body **400**. The carrier member **110** includes an insertion end or distal tip **114**, side walls **116** along a length of the carrier member **110** and a proximal end **112** as shown in FIG. **1**. One or more operative components **118** disposed in the carrier member **110** may include an electrode array **118** and stimulation circuitry for stimulating the nervous system of the subject (not shown). The one or more operative components or electrode array **118** may be embedded in the carrier member **110**. The carrier member **110** also includes at least one FBG sensor array **130** disposed therein. Optionally, the FBG sensor array **130** may be embedded in the carrier member **110**. The FBG sensor array **130** and electrode array **118** may be located along the entire length of the carrier member **110** from the distal tip **114** to the proximal end **112** as shown in FIG. **1**. However, in other embodiments, the FBG sensor array **130** and/or electrode array **118** may only be positioned within part of the carrier member **110**. Preferably, the FBG sensor array **130** and/or electrode array **118** are at least positioned or located near the distal tip **114** of the carrier member **110**.

Additionally/alternatively, the one or more operative components **118** may include an optical array and stimulation circuitry for optically stimulating the nervous system of the subject. In some embodiments, the optical array may include one or more of the features described with respect to the electrode array **118**, namely the structure and alignment of the array in the carrier member **110** and relative to the FBG sensor array **130**.

As illustrated in FIG. **1**, the electrode array **118** may include a number of electrodes **120** and electrical wires associated with each electrode **120** (which have been omitted for clarity). Typically, cochlear implant devices **100** may include about 20 electrodes spaced approximately 400 μm apart along a length of the implant **110** and the total effective implant length may be approximately 20 mm. It would be ideal to include more electrodes **120** and a longer insertion length of the cochlear implant **100** for implantation inside the scala tympani (ST) channel **440** of the cochlear **430** to stimulate a wider range of frequencies (see also FIG. **2**). However, insertion of the cochlear implant **100** deep into the ST channel **440** is challenging due to its tiny size and spiral structure. A cochlear implant **100** without any force feedback during implantation could result in trauma to the neural membrane of the cochlea **430**.

The electrode array **118** is preferably in a linear array as shown in FIG. **1**. However, other suitably dimensioned and structured electrode arrays may be used, which optionally, may also be suitable for arrangement with the FBG sensor array **130**. Carrier member **110**, electrodes **120** and implant unit **124**, apart from the differences explained herein, are provided in existing cochlear implants and will therefore not be described in further detail.

An optical fiber **140** extends from the insertion end **114** to the proximal end **112** of the carrier member **110** as shown in FIG. **1**. However, in other embodiments the optical fiber **140** may only be partly disposed in the carrier member **110**. The at least one FBG sensor array **130** is associated with the optical fiber **140**. The FBG sensor array **130** may be disposed in the optical fiber **140** as shown in FIG. **1**. Preferably, the FBG sensor array **130** is embedded in the optical fiber **140**. In some embodiments, the FBG sensor array **130** may be inscribed or written into the optical fiber **140** during manufacture, as will be described in further detail.

The optical fiber **140** extends beyond the carrier member **110**, exiting at the proximal end **112** as illustrated in FIG. **1**. The optical fiber **140** may be coupled to an interrogator **210** through a coupling device **230** (see also FIG. **7**). In some embodiments, the optical fiber **140** is terminated in an implant unit **124** or extends through the implant unit **124** as shown in the broken lines in FIG. **1**. When the optical fiber **140** is terminated in implant unit **124**, an interrogator **210** is coupled (e.g., optically connected by a suitable optical fiber) with a port of the implant unit **124** (not shown). When optical fiber **140** extends through implant unit **124**, the optical fiber **140** is suitably connected to the interrogator **210** (see also FIG. **7**).

In some embodiments, the FBG sensor array **130** and electrode array **118** are co-located in the carrier member **110**. Preferably, the FBG sensor array **130** is aligned relative to the electrode array **118** in the carrier member **110** as shown in FIG. **1**. The FBG sensor array **130** includes a number of fiber Bragg gratings (FBGs) **128** along a length of the array **130** (see also FIG. **3**). The FBG sensor array **130** is preferably in a linear array as shown in FIG. **1**. However, other suitably dimensioned and structured arrays may be used, which optionally, may also be suitable for arrangement with the electrode array **118**.

The FBG sensor array **130** may be arranged in such a way that each FBG **128** lies in between two electrodes **120** as shown in FIGS. **1** and **2**. For electrode arrays **118** in cochlear implants **110**, the typical length of one electrode **120** is approximately 400 μm and its separation is approximately 400 μm. The FBG sensor array **130** can be designed with the same length and spacing as the electrode array **118** as shown in FIG. **1**. However, the FBG sensor array **130** can also be fabricated in other configurations in which one FBG **128** could cross over an electrode **120**. In this example, the FBG sensors **128** will provide less spatial resolution for contact force and/or position measurements. For cochlear implant applications, the recommended length of one FBG **128** is in the range of approximately 0.4 mm to 3 mm, and the separation between two FBGs **128** is also in the range of approximately 0.4 mm to 3 mm. The length of the FBG grating array **130** may be in the range of approximately 10 mm to 40 mm, depending on the length of the electrode array **118**. It should be noted that longer FBG length may lead to a chirped effect on the FBG signal, which is undesirable during detection.

In some embodiments, the carrier member **110** is integrally formed. Alternatively, in other embodiments, carrier member **110** is formed in parts, joined together through welding, adhesive, over-molding or other techniques. Ideally, the electrode array **118** is embedded in the carrier member **110**. The fabrication process may follow a standard fabrication process for conventional cochlear implants, apart from the FBG sensor array **130** which may also be embedded in the carrier member **110** of a cochlear implant **100** along a length of the carrier member **110**.

FIG. **2** depicts a schematic illustration of the medical device **100** of FIG. **1** inserted into a scala tympani channel **440** of a cochlea **430** of a subject according to some embodiments of the invention. As shown, the cochlear implant **100** includes an arrangement of the electrode array **118** and FBG sensor array **130** having alternating electrodes **120** and FBGs **128** positioned from the insertion end or tip **114** and along the carrier member **110** to the proximal end **112**. The electrode array **118** functions to stimulate acoustic frequencies of the nervous system of the subject **400**. The FBG array **130** is configured for measuring contact forces at one or both of the insertion end or tip **114** and along the side walls **116** of the carrier member **110** during positioning or implantation of the carrier member **110** into the subject's body **400**. Ideally, the medical device **100** includes a plurality of FBG sensor arrays **130** configured for measuring position of one or both of the insertion end **114** and the side walls **116** of the carrier member **110** during positioning or implantation of the carrier member **110** into the subject's body **400** (see also FIG. **3**). The contact force and/or position measurements may be provided at a number of locations along the implant **100** to provide information about the location or orientation of the implant **100**, and in some embodiments, to reconstruct the shape of the cochlear implant **100** inside the ST channel **440** (see also FIG. **12**).

FIG. **3** is a perspective view of a multi-core optical fiber **140** showing a FBG **128** in each core at a distal tip **114** thereof according to some embodiments of the invention. The optical fiber **140** includes a central core **142** located centrally along the optical fiber **140** and a plurality of cores **144**,**146** and **148** surrounding the central core **142** that are equally spaced from each other (see also cross-sections of FIGS. **5**A-C). In other embodiments, the multi-core optical fiber **140** may include at least one core parallel to the central core **142**, or alternatively, more than three cores surrounding the central core **142**. Additionally/alternatively, the surrounding cores **144**, **146** and **148** may not be equally spaced from each other but may have an unequal radial spacing relative to the central core **142**.

The multi-core optical fiber **140** illustrated in FIG. **3** includes a FBG sensor array **132**, **134**, **136** and **138** disposed in each core **142**, **144**, **146** and **148**, respectively, for providing force and/or position measurements at the location of each FBG **128**. Reference throughout the figures to $FBG_{n,i}$ (i=1, . . . , K; n=1, 2, 3 . . . , M) denotes the FBG sensor arrays **130** inscribed in the K cores (i=1, . . . , K), and each core **142**, **144**, **146** and **148** has M FBG sensors **128**. The multi-core optical fiber **140** is preferably placed on a cylindrical axis of the carrier member **110** as shown in FIG. **1**.

In some embodiments, the grating pitch of each FBG **128** in the FBG sensor arrays **132**, **134**, **136** and **138** is different to enable the reflection wavelengths of the FBGs **128** along each core **142**, **144**, **146** and **148** to be detected individually. This ensures that the Bragg wavelengths of FBGs **128** along the same core **142**, **144**, **146** and **148** are different and can be detected individually. The grating pitch or reflection wavelength can increase or decrease consecutively along the FBG sensor arrays **132**, **134**, **136** and **138**.

In some embodiments, the FBG separation in each of the FBG sensor arrays **132**, **134**, **136** and **138** is substantially identical for providing contact force and/or position measurements at the location of each FBG **128** based on variations in the reflection spectra **250** of the FBG sensor arrays **130** in each core **142**, **144**, **146** and **148** (see also FIG. **4**). The FBG sensor arrays **132**, **134**, **136** and **138** in the different cores may be substantially identical in one or more

of the following: number of FBGs **128**, FBG length, FBG separation and reflection wavelength. Alternatively, the FBG sensor arrays **132**, **134**, **136** and **138** in the different cores may be substantially identical in one or more of the following: number of FBGs, FBG length and FBG separation, and have different reflection wavelengths. The reflection wavelength of FBGs **128** at different positions may increase or decrease following the sequence of the grating array **130**.

To fabricate the FBG sensor array **130** (e.g., arrays **132**, **134**, **136** and **138**), the FBGs **128** at a certain position can be fabricated using phase mask technique by scanning a UV laser beam (e.g. with wavelengths of 193 nm, 213 nm, 248 nm, 266 nm, 325 nm) and the grating is created in the multi-core optical fiber **140** due to the photosensitivity. Alternatively, the FBGs **128** can also be fabricated using other approaches, namely, using Talbot interferometer where two laser beams interfere constructively or destructively at the fiber position to create grating patterns, and using point-by-point micromachining based on femtosecond laser. Generally, the FBGs **128** in all of the multiple cores **142**, **144**, **146** and **148** can be inscribed simultaneously at the certain position. After completing the inscription, either the optical fiber **140** or the phase mask or femtosecond laser beam moves to the next position to fabricate the next grating. When the FBGs **128** are created at the certain position, multiple FBGs **128** are inscribed simultaneously in all of the cores **142**, **144**, **146** and **148**, and these FBGs **128** typically have the same pitch. However, a slight difference in Bragg wavelength may occur for the FBGs **128** in different cores **142**, **144**, **146** and **148** due to differences in core index. Typically, all of the gratings are apodised to suppress the side lobes in the reflection spectrum **250**, making the detection of the Bragg wavelength more precise. However, uniform gratings are also applicable as long as the main reflective peak dominates in the spectrum. Peak detection is generally precise when the side lobe suppression (SLS) is over 15 dB.

FIG. **4** is a series of charts showing reflection spectra **250** of a five-FBG sensor array **130** inscribed in a four-core multi-core optical fiber **140** according to some embodiments of the invention. The FBG sensor arrays **132**, **134**, **136** and **138** in each of the four cores **142**, **144**, **146** and **148** includes five FBGs **128**. The FBGs **128** at the same position or location along the optical fiber **140** have similar grating pitch, resulting in the same Bragg wavelength. However, FBGs **128** at different positions or locations along the optical fiber **140** have different pitches, either decreasing or increasing with the FBG sequence. This leads to different Bragg wavelengths for all of the FBGs **128** written, inscribed or embedded in the same core, making the Bragg peaks from one core detectable in the reflection spectrum **250**. Preferably, each core **142**, **144**, **146** and **148** of the multi-core optical fiber **140** is connected to a separate channel of an interrogator **210** so that the grating signal from all of the cores do not cross and are separately detectable (see also FIG. **7**).

As previously discussed, the multi-core optical fiber **140** can include a central core **142** located centrally along the optical fiber **140** and include one or more cores surrounding the central core **142**. The surrounding cores can be arranged in various formations in the cladding **150** relative to the central core **142**. FIGS. **5**A-C show some embodiments of a four-core optical fiber **140** where one core **142** is located in the centre of the optical fiber **140** and the other three cores **144**, **146** and **148** are arranged in a triangular formation relative to the central core **142**. The three cores **144**, **146** and **148** may be located at the apexes of an equilateral triangle as shown in FIGS. **5**A-C. The distance between the central core **142** and each outer-core **144**, **146** and **148** is di, and the distance between two of the outer cores **144**, **146** and **148** is d_2, where $d_2=2d_1 \cos 30°$. Typically, d_1 can be one quarter of the diameter of the optical fiber **140**. In other embodiments, the surrounding cores may be arranged in e.g., hexagonal, square, circular or other formations, relative to the central core **142**.

Ideally, the multi-core optical fiber **140** is a low-bending loss optical fiber **140**. The refraction index of the core is slightly higher than the refraction index of the cladding **150** ensuring light guidance along the optical fiber **140**. When inscribing the FBGs **128** in this optical fiber **140**, four gratings can be manufactured simultaneously at the same cross-sectional plane, as shown in FIG. **5**A. Typically, each grating has the same pitch, resulting in the same Bragg wavelength. However, the difference in the refractive index of each core may cause different Bragg wavelengths, which does not affect the interrogation of the grating.

The index profile of the core (n_core) and cladding (n_cladding) can be standard step-index, as shown in FIG. **5**A as long as the index contrast can confine the light well especially in small bending diameters, e.g., <3 mm for use with medical devices **100**, and preferably cochlear implants. FIGS. **5**B-C show alternative designs of the core-cladding index profile where there is a low-index region associated with each core **142**, **144**, **146** and **148**. The low-index region has a lower refractive index than the refractive index of each core **142**, **144**, **146** and **148** and a cladding **150** of the optical fiber **140** for reducing bending loss of optical light, particularly during positioning or implantation of the optical fiber **140** of a medical device **100** in a subject's body **400**.

FIG. **5**B shows a design having a low-index region in the form of a trench **154** (n_trench) around each of the cores **142**, **144**, **146** and **148**, meaning that the index of the trench **154** is lower than both core and cladding indices. The trench **154** may be air-filled or filled with a fluid having a lower refractive index than those of the core and cladding. The trench **154** may be a channel that surrounds each core **142**, **144**, **146** and **148** and extends longitudinally along the entire length of the optical fiber **140**. Alternatively, the trench **154** may only extend along each FBG **128** of the FBG sensor array **130** such that there may be a plurality of short trenches positioned along the optical fiber **140** at the location of each FBG **128**.

FIG. **5**C shows another embodiment in which the low-index region is the form of one or more holes **156** surrounding each core **142**, **144**, **146** and **148**. The holes are air-filled in this embodiment and arranged in a ring structure having six air holes **156** for each core **142**, **144**, **146** and **148**. The average index of the air holes (n_{avg}_air hole) is also lower than those of the core and cladding. In other embodiments, the holes may be filled with a fluid having a lower refractive index than those of the core and cladding **150**. Furthermore, the holes **156** may be arranged in different structures or shapes in the optical fiber **140**. Additionally/alternatively, the low-index region may include a single hole **156** or two or more holes **156** and not be limited to the six air holes **156** as shown in FIG. **5**C. The holes or ring structure **156** may be located at each FBG **128** along the FBG sensor array **130** and the ring structure or similar shape may be located in a cross-sectional plane of the optical fiber **140** as shown in FIG. **5**C. Alternatively, in some embodiments the one or more holes **156** may extend longitudinally either partly or entirely along the optical fiber **140** surrounding each core **142**, **144**, **146** and **148**. In some embodiments, the one or

more holes **156** form elongate channels along the optical fiber **140** that extend partly or entirely through the cladding **150**.

In another embodiment, the low-index region includes a plurality of elongate members positioned around and colinearly with each core **142**, **144**, **146** and **148** (not shown). The elongate members include a material having a lower refractive index than the core and cladding. The elongate members may be shaped as rods positioned in the cladding **150** around each core **142**, **144**, **146** and **148**. The rods may extend longitudinally partly or entirely through the cladding **150**. Since the index of air is 1, lower than silica glass (1.444 at 1550 nm), each air hole **156** of the embodiment of FIG. **5**C can also be replaced by a low-index rod that has a lower index than silica glass (not shown). Among all these designs, the low-index trenches **154** or air-hole rings **156** or low-index rods are introduced to reduce the bending loss, particularly for the extremely small bending diameter (e.g. <3 mm), which is applicable for the limited space in implantation into the scala tympani (ST) channel **440** of the cochlea **430**.

To fabricate the low-bending loss multi-core optical fiber **140**, the core canes can be firstly drawn from a preform manufactured using a modified chemical vapor deposition (MCVD) technique. The silica core cane is doped with germanium to increase its refractive index and enable its photosensitivity for inscribing FBGs. Then, four core canes are chosen to create a stack in a jacketing tube and the arrangement of the four core canes follows the aforementioned designs (e.g., those of FIGS. **5**B-C and the low-index elongate members or rods). All the gaps during the stacking can be filled with different sizes of pure silica rods.

As for the design with low-index trench **154**, the trench **154** can be introduced during the MCVD process. For the design with air holes **156** or low-index rods, the air holes **156** and low-index rods can be introduced during the stacking process. Instead of stacking the cores in a jacket tube, the preform can be made based on a pure silica rod with a large diameter and four inner holes pre-drilled in the shape same as the core arrangement. This kind of silica rod with inner holes is called a multi-bore rod. Then, the core canes can be directly inserted into the inner holes of the multi-bore rod. The diameter of the core canes is slightly smaller than the inner diameter of the holes.

As an embodiment of the design in FIG. **5**C, there are three feasible approaches to fabricate the fiber. 1) Using the stack-and-draw technique: firstly, a jacket tube with inner/outer diameter of e.g., 19 mm, 25 mm is fully filled with silica rods in a diameter of 2 mm, and all these rods are arranged in a hexagonal structure. Then, the four core canes are inserted in a certain position and replace four silica rods, depending on the design shown in FIG. **5**C. Then around each core cane, another six capillaries with a diameter of 2 mm are used to replace six silica rods. The final assembly is drawn to fiber with desirable diameter at a temperature of ~1950° C. 2) Using the stack-and-draw technique: firstly, stack an intermediate preform in a tube with inner/outer diameter of e.g., 6 mm, 12 mm. In this intermediate preform, one core rod in 1 mm diameter and six capillaries in 1 mm diameter are stacked together in a hexagonal structure. Then the intermediate preform is drawn to a core cane with a diameter of 6 mm. One core cane has a similar structure of one core as shown in FIG. **5**C. To form the second preform, four core canes are inserted in another jacket tube with inner/outer diameter of e.g., 19 mm, 25 mm, during which all the gaps can be filled with purse silica rods having various sizes. The final assembly is drawn to fiber with a desirable diameter at a temperature of ~1950° C. 3) Using cane-in-tube approach: firstly, draw the core cane as the same as the former approach. Then, insert the four core canes in a multi-bore rod which has four holes with diameter of ~6 mm. In this approach, there is no gap between the core canes as the previous one. The final assembly is drawn to fiber with desirable diameter at a temperature of ~1950° C.

FIG. **6** illustrates designs of a multi-core optical fiber **140** having a plurality of holes **158** arranged in a cladding **150** of the optical fiber **140** to induce bending in a desired direction during positioning or implantation of the carrier member **110** into a subject's body **400**. Preferably, the plurality of holes **158** are air holes in the cladding **150**. The plurality of holes **158** may also form channels through the cladding **150** in any direction with respect to the optical fiber **140**, such as longitudinally, orthogonally or diagonally (not shown). As shown in FIGS. **6**A-B, the optical fiber **140** may include holes **158** arranged in substantially half of the cross-section of the optical fiber **140**, where two cladding profiles circular (FIG. **6**A) and rectangular (FIG. **6**B), are presented. The introduction of the holes **158** not only further reduces the stiffness of the optical fiber **140**, but also makes the fiber **140** prone to bend in one specific direction. The rectangular cladding also makes the fiber **140** tend to bend in one specific direction. Such direction is designed to follow the normal direction of the scala tympani channel **440** as shown in FIG. **2**. Due to the existence of the holes **158** in one side, the stiffness of the half part with holes **158** is smaller than the other half, therefore, the optical fiber **140** is prone to bend towards the low-stiffness side. This intended bending direction helps to reduce the possibility of trauma during implantation of the optical fiber **140** in a medical implant **100**, preferably, a cochlear implant. The number, size, shape and location of the holes **158** can be used to tailor the flexibility and/or stiffness of the optical fiber **140** in different bending directions.

In some embodiments, the multi-core optical fiber **140** includes a cladding **150** that is shaped to induce bending in a desired direction during positioning or implantation of the carrier member **110** into a subject's body **400**. The cladding **150** can have different cross-sectional shapes or profiles to tailor the stiffness of the fiber **140** in different bending directions. A cross-section of the cladding may include a circular (FIG. **6**A) or rectangular (FIG. **6**B) shape, or alternatively, square, triangular, oval or elliptical shapes. The different cladding shapes advantageously allow the medical device **100** to be inserted into the subject's body **400** with reduced trauma or damage to the internal or surrounding tissues of the subject's body **400**. This is particularly beneficial where the medical device **100** is a cochlear implant for insertion into the narrow diameter and length scala tympani **440** of the cochlea **430** with reduced or minimal trauma.

The multi-core optical fiber **140** is preferably silica glass based. However, other materials can be utilised to fabricate the fiber with aforementioned designs shown in FIGS. **6**A-B. The pure silica glass as cladding **150** can be replaced by pure Poly(methyl methacrylate) (PMMA), and the silica core rod doped with germanium can be replaced by the PMMA doped with diphenyl sulfide (DPS), trans-4-stilbenemthanol (TS), diphenyl disulphide (DPDS) individually or mixed. Instead of using the stack-and-draw technique, the casting method can be used to make the cladding rod with certain holes, e.g., the arrangement with four bores, and the four core canes with dopants are inserted in the four bores. The index of the PMMA typically is approximately 1.5 at the wavelength of

850 nm, and the core index can be increased slightly by controlling the dopant concentration.

Alternatively, the polymer material can also be ZEONEX cyclo olefin polymer (COP), which is commercially available, such as from ZEON Corporation. Two types of the ZEONEX can be used, e.g., E48R and 480R, which have refractive indices of 1.531 and 1.525, respectively. Both materials have similar glass-transition temperature (Tg~139°). With these two ZEONEX materials, the 480R type can be used as the cladding part, and E48R can be the core part. These two materials can be used to fabricate the multi-core optical fiber **140** with design shown in FIG. **5**A, the standard step-index approach. Also, using one of the ZEONEX materials, the multi-core optical fiber **140** with design shown in FIG. **5**C can be fabricated, where the air holes **156** are prepared by casting method.

FIG. **7** is a schematic illustration showing coupling of a medical device **100** having a multi-core optical fiber **140** with a multi-channel interrogator **210** according to some embodiments of the invention. To interrogate the sensing signal from the FBG sensor array **130** disposed in the carrier member **110**, and preferably embedded in the multi-core optical fiber **140**, each core **142**, **144**, **146** and **148** of the multi-core optical fiber **140** can be connected to one single mode fiber (SMF) **232** via a fiber fan-in/out coupler **230**. Fiber fan-in/out **230** is a fiber combiner that combines multiple standard single mode fibers to one specific multi-core fiber **140**. FIG. **7** illustrates a connection between the multi-core optical fiber **140** and the fan-in/out **230**. The common end (i.e., multi-core fiber) is connected to the multi-core optical fiber **140** and all of the multi-cores are aligned precisely. The multiple SMF **232** ends are connected to the channels of the interrogator **210**, one SMF **232** to one channel. As an embodiment of the four-core multi-core fiber **140** mentioned in FIG. **3**, each core **142**, **144**, **146** and **148** can be connected to one channel of the interrogator **210** via the fan-in/out **230**. The common fiber of fan-in/out can be a standard seven-core multi-core fiber **140** or a customized four-core multi-core fiber **140**. When using the standard seven-core multi-core fiber, four cores will be selected and scaled to match the position and separation of the four-core multi-core fiber **140**. In alternative embodiments, the coupling device **230** may include a butt-coupling device that directly couples the optical light to each core of the multi-core optical fiber **140** (not shown).

FIG. **8** is a perspective view of a multi-core optical fiber **140** with a FBG **128** at the insertion end or tip **114** of the medical device **100** and showing tip force measurement based on the grating inscribed in the four cores according to some embodiments of the invention. The first group of FBGs (i.e., FBG_{1i}) is placed at the insertion or distal end **114** of the carrier member **110**. $FBG_{1,1}$, $FBG_{1,2}$, $FBG_{1,3}$, and $FBG_{1,4}$, correspond to the four FBGs written in the outer three cores **144**, **146** and **148**, and the central core **142** (i=4), respectively. When the tip end **114** touches the subject's body **400**, such as internal tissues **410** at the target or implantation region **420** as shown in FIG. **8**, a certain contact force F_{tip} is induced to the optical fiber **140** and therefore, the medical device tip **114**. For cochlear implants **100**, this typically involves the tip end **114** touching the cochlear wall. To simply the model, the FBGs **128** close to the distal end **114** are assumed under compression stress due to the pressure of the tip force F_{tip}. The Bragg wavelength of each FBG **128** shows a wavelength shift, i.e. $\Delta\lambda_{1,1}$, $\Delta\lambda_{1,2}$, $\Delta\lambda_{1,3}$, $\Delta\lambda_{1,4}$, corresponding to the strain on each core **142**, **144**, **146** and **148**. Therefore, the measured tip force can be deduced as

$$F_{tip}=S\cdot E\cdot\bar{\varepsilon},$$

where S is the cross-sectional area of the multi-core optical fiber **140**, E is the Young's modulus of the fiber **140**, and $\bar{\varepsilon}$ is the average strain induced at the distal tip **114**, which can be obtained via:

$$\bar{\varepsilon}=\frac{1}{4}\sum_{i=1}^{4}\eta_{1,i}\cdot\Delta\lambda_{1,i}$$

where $\eta_{1,i}$ is a coefficient between the strain and the Bragg wavelength of each FBG **128**. Those coefficients can be calibrated during the calibration test as discussed below in relation to FIG. **10**.

FIG. **9** is a schematic illustration showing a multi-core optical fiber **140** with a FBG grating along a length of the optical fiber **140** and the lateral force and position measurements based on the grating according to some embodiments of the invention. The measurement of lateral force and the position occurs via the FBGs **128** in the middle part of the medical device **100** as shown in FIG. **9**. Take the $FBG_{n,i}$ at the location n as an example, the four FBGs are $FBG_{n,1}$, $FBG_{n,2}$, $FBG_{n,3}$, $FBG_{n,4}$, where $FBG_{n,4}$ is the one in the central core **142**. When the fiber **140** is subject to the bending and lateral force at the same time, the induced strain on all the FBGs **128** can be a sum of the strain caused by bending and the lateral force. The lateral force ($F_{lateral}$) can be divided to provide the friction force (F_t) and the normal force (F_n). For cochlear implants **100**, friction force is typically induced when the implant **100** slides on the inner wall of cochlea **430** during implantation, and also induced because of the fluid in the cochlea **430**. The force that may cause trauma is the normal force, i.e. F_n, which can be expressed by $F_n=F_n/\tan(\varphi)$. Since the central core **142** is located in the neutral plane, it is less prone to have strain induced by bending. Thus, the strain on the central core **142** can be assumed to come from the friction force with respect to the inner wall and fluid. The friction force can be expressed as: $F_t=S\cdot E\cdot\varepsilon$, where S is the cross-sectional area of the multi-core optical fiber **140**, E is the Young's modulus of the multi-core optical fiber **140** and ε is the total strain at the FBG-n location. The total ε can be expressed by the strain on the FBG **128** inscribed in the central core **142**, i.e. $\varepsilon=\varepsilon_{n,4}$, which can be measured by the centre $FBG_{n,4}$. Therefore, the friction force can be measured via the central core **142** grating, i.e. $F_t=S\cdot E\cdot\eta_{n,4}\cdot\Delta\lambda_{n,4}$, where η_4 is a coefficient between the strain and the Bragg wavelength shift that can be calibrated in experiment (see FIG. **10**).

The strain on the outer cores **144**, **146** and **148** is induced by the bending and the friction, thus the friction effect has to be excluded when determining the bending. The bending-induced Bragg wavelength on the outer cores **144**, **146** and **148** can be expressed by:

$$\Delta\lambda_{n,1}{}^{b}=\Delta\lambda_{n,1}-\Delta\lambda_{n,4}$$

$$\Delta\lambda_{n,2}{}^{b}=\Delta\lambda_{n,2}-\Delta\lambda_{n,4}$$

$$\Delta\lambda_{n,3}{}^{b}=\Delta\lambda_{n,3}-\Delta\lambda_{n,4}$$

Then, the bending induced strain on the outer cores **144**, **146** and **148** can be deduced as:

$$\varepsilon_{n,1}{}^{b}=\eta_{n,1}\Delta\lambda_{n,1}{}^{b}$$

$$\varepsilon_{n,2}{}^{b}=\eta_{n,2}\Delta\lambda_{n,2}{}^{b}$$

$$\varepsilon_{n,3}{}^{b}=\eta_{n,3}\Delta\lambda_{n,3}{}^{b}$$

The bending curvature can be written as: $\kappa_n=\varepsilon_{max}/d$, where ε_{max} is the total bending strain of the fiber **140**, d is the distance between outer core **144**, **146** and **148** and the central core **142**. The total bending strain (ε_{max}) can be calculated by the measured strain on outer cores **144**, **146** and **148**, which is deduced as:

$$\varepsilon_{max} = \mathrm{sgn}\{(\varepsilon_{n,1}^{b} - \varepsilon_u)\cdot \sin\varphi\}\cdot\sqrt{\frac{2}{3}\sum_{i=1}^{3}(\varepsilon_{n,i}^{b} - \varepsilon_u)^2}$$

where,

$$\varepsilon_u = \frac{\varepsilon_{n,1}^{b} + \varepsilon_{n,2}^{b} + \varepsilon_{n,3}^{b}}{3}$$

$$\varphi_n = \arctan\left(\frac{\sqrt{3}\cdot(\varepsilon_{n,1}^{b} - \varepsilon_u)}{\varepsilon_{n,2}^{b} - \varepsilon_{n,3}^{b}}\right)$$

The bending angle φ_n can also be used to obtain the lateral force ($F_{lateral}$) With the information of bending curvature (κ_n) and angle (φ_n), the position or shape of the device **100** can be reconstructed via the known Frenet-Serret formulas. Eventually, the lateral force ($F_{lateral}$) as well as the position of device **100** with FBG sensor array **130** disposed or embedded therein can be obtained.

FIG. **10** is a schematic illustration of an experimental arrangement to calibrate the coefficient of the tip force and grating signal according to some embodiments of the invention. FIG. **11** is a chart showing results of the calibration using the experimental arrangement of FIG. **10**. For cochlear implants, when the cochlear implant **100** with FBG sensor array **130** is subject to contact with the scala tympani channel **440** of the cochlea **430**, the induced force on the fiber **140** can be retrieved by detecting the shift of the Bragg wavelengths of all of the FBGs **128** in the cores **142**, **144**, **146** and **148**. To establish a relationship between the measured force and the Bragg wavelength shift, the coefficient can be determined in a calibration test. FIG. **10** illustrates one embodiment of calibrating the Bragg wavelength of one FBG **128** and the axial contact force. The FBG **128** written in a single mode fiber (SMF) with cladding diameter of 50 μm is embedded in a cylindric silicone, which is the same as the fiber **140** embedded in the silicone carrier **110** of one cochlear implant **100**. The SMF is connected to an interrogator **210** to monitor the Bragg wavelength shift. The FBG **128** is compressed by a vertical translation stage **234** where a miniature force sensor is installed. The FBG **128** is under compression tension when the vertical translation stage **234** moves towards the fiber **140**, resulting in a shift of the Bragg wavelength. As shown in FIG. **11**, the Bragg wavelength shift follows a linear relationship with the applied force, giving a coefficient of ~0.0068 nm/m N. This means that when the force is axially applied to the tip **114** of the cochlear implant **100** with FBG sensor array **130**, 1 mN force can induce a shift of 0.0068 nm in Bragg wavelength. It is worth noting that the compression strain response of one FBG **128** is the same as the tensile strain response except that the sign is different. Therefore, the force response of the FBGs **128** not at the distal end can be calibrated by pulling the FBG sensor array **130**.

FIG. **12** is a schematic illustration showing a system **200** for guiding positioning of a medical device **100** in a subject's body **400** according to some embodiments of the invention. The system **200** includes a medical device **100** including: a carrier member **110** configured for positioning in the subject's body **400**, the carrier member **110** including an insertion end **114** and side walls **116** that contact the subject's body **400** during positioning of the carrier member **110** in the subject's body **400**; one or more operative components **118** disposed in the carrier member **110**; an optical fiber **140** at least partly disposed in the carrier member **110**; and at least one fiber Bragg grating (FBG) sensor array **130** associated with the optical fiber **140** and being disposed in the carrier member **110**. The system **200** also includes an interrogator **210** coupled to the optical fiber **140** and configured to obtain reflection spectra data **250** from the FBG sensor array **130** during positioning of the carrier member **110** in the subject's body **400**. The system **200** also includes a processor **220** configured to receive the reflection spectra data **250** from the interrogator **210** and to process the reflection spectra data **250** to determine contact forces at one or both of the insertion end **114** and along the side walls **116** of the carrier member **110** during positioning of the carrier member **110** in the subject's body **400**.

In some embodiments, the medical device **100** is an implantable medical device and the carrier member **110** is configured for implantation in the subject's body **400**. The system **200** may enable guidance of implantation of the medical device **100** into the subject's body **400**.

In some embodiments, such as shown in FIG. **12**, the system **200** is configured for guiding implantation of a cochlear implant **100** into a scala tympani **440** of a cochlea **430** of a subject. However, the system **200** may be configured for guiding positioning or implantation of various medical devices **100**, as would be appreciated by a person skilled in the art. The medical device **100** and optical fiber **140** of the system **200** may include one or more features in any combination of the embodiments described above and with reference to FIGS. **1** to **11**.

Preferably, the medical device **100** includes the multi-core optical fiber **140** with a plurality of FBG sensor arrays **130** as shown and described with reference to FIG. **3**. The system **200** may further include a coupling device **230** for coupling each core **142**, **144**, **146** and **148** of the multi-core optical fiber **140** to a multi-channel interrogator **210** for separately detecting the reflection spectra **250** of the FBG sensor arrays **132**, **134**, **136** and **138** as shown and described with reference to FIG. **7**. In FIGS. **7** and **12**, the optical fiber **140** is connected to a fan-in/out coupling device **230** that separates the signals from each core into standard SMFs individually. Each SMF **232** is connected to one channel of the interrogator **210**. The interrogator **210** is configured to retrieve the reflected optical spectra **250** of the FBGs **128**, which includes the Bragg wavelength shifts of all the FBGs **128** (e.g., each FBG **128** in the FBG sensor arrays **132**, **134**, **136** and **138**).

Preferably, the interrogator **210** includes a light source **212** and an opto-electrical converter **214** for retrieving the reflected optical spectra **250** as shown in FIG. **7**. The light source **212** generates light for transmission to the FBGs **128** via the FBG sensor array **130** and optical fiber **140**. The opto-electrical converter **214** receives light reflected back from the FBGs **128**, along the same light path. The processor **220** may receive the raw data in terms of the Bragg wavelength shifts of all the FBGs (e.g., each FBG **128** in the FBG sensor arrays **132**, **134**, **136** and **138**) from the interrogator **210**. The processor **220** may include a memory **222** storing one or more algorithms **260** for a mathematical relationship between the wavelength and/or intensity against a measure of the strain (or force) applied to the FBG **128** as shown in

FIG. **12**. Preferably, the algorithms **260** include those shown and described with reference to FIGS. **8** and **9** to calculate the contact force and/or position of the insertion end **114** and/or side walls **116** of the carrier member **110**. The processor **220** may then perform the algorithms **260** described with reference to FIGS. **8** and/or **9** and output data corresponding to the contact force and/or position of the carrier member **110**.

In some embodiments, the processor **220** is configured to receive position data of a target or implantation region **420** of the subject's body **400** prior to positioning or implantation of the device **100**. For cochlear implants **100**, the position data may include the position of a scala tympani **440** of a cochlear **430** of the subject. The processor **220** may be further configured to process data corresponding to the position of the carrier member **110** relative to the position data of the target or implantation region **420** to determine a depth of positioning or implantation of the carrier member **110** in the subject's body **400**. Preferably, the processor **220** is configured to determine angular position of the carrier member **110** in the subject's body **400**. Furthermore, the processor **220** may be configured to determine an angular depth of insertion or implantation of the carrier member **110** in the subject's body **400**. This may assist the surgeon or operator in guiding positioning or implantation of the carrier member **110** based on feedback received from the sensing system **200**.

In some embodiments, the processor **220** is further configured to receive physiological data of the subject prior to positioning of the carrier member **110** in the subject's body **400**. The physiological data may include, for example, pre-operative hearing data of the subject. This is particularly useful where the medical device **100** to be guided for positioning or implantation in the subject's body **400** is a cochlear implant. The processor **220** may be further configured to process the physiological data with the position data of the target or implantation region **420** to determine a desired angle of insertion or implantation of the carrier member **110** into the cochlea **430**. Advantageously, the surgeon or operator may perform steps including rotating or altering a trajectory of the insertion depending on the desired angle of insertion or implantation. This may also depend on the specific operative components **118** of the medical device **100**, such as the electrode array type (e.g., straight or curved) and the stage of implantation or insertion of the device **100** into the subject's body **400**.

The processor **220** may be further configured to receive an image **240** of the target or implantation region **420** of the subject's body **400** prior to positioning or implantation of the device **100** (see also FIG. **2**). The image **240** may include an X-ray image, or imaging from other modalities such as ultrasound or MRI to name a few. An exemplary image **240** is shown in FIG. **12** which depicts a scala tympani **440** of a cochlea **430** of a subject. The carrier member **110** of medical device **100** is shown being inserted or advanced into the scala tympani **440**. The processor **220** may be further configured to reconstruct an image of the carrier member **110** using the data corresponding to the position of the carrier member **110**. The processor **220** may be further configured to overlay the reconstructed image **242** on the image **240** of the target or implantation region **420** of the subject's body **400**, and to output data representing an image **244** of the position of the carrier member **110** relative to the target or implantation region **420** of the subject's body **400** as shown in FIG. **12**.

In some embodiments, the system **200** further includes a display device **224** which is configured to display data processed by the processor **220**. The display device **224** may be a graphical display screen, and may optionally, be a display screen of a computer, tablet or mobile phone or the like, as would be appreciated by a person skilled in the art. The processor **220** may be configured to display on the display device **224** an infographic of the contact forces on the carrier member **110** relative to the depth of positioning or implantation of the carrier member **110** in the subject's body **400**. The infographic may include a chart **246** showing the contact forces relative to the insertion positioning or depth of the carrier member **110**. The processor **220** may be configured to display two charts, a first chart showing the contact force on the insertion end or tip **114** (F_{tip}) relative to the insertion depth, and a second chart showing the contact force on the side walls **116** ($F_{lateral}$) relative to the insertion depth as illustrated in FIG. **12**. In some embodiments, the insertion depth displayed is the angular depth of insertion of the carrier member **110** determined by the processor **220**.

The processor **220** may also be configured to display on the display device **224**, the image **244** of the position of the carrier member **110** relative to the target or implantation region **420** of the subject's body **400**. This is illustrated in FIG. **12** in the images **244** shown below the charts of the tip force and lateral force. The images **244** illustrate the carrier member **110** prior to bending through the scala tympani **440**, where the device **100** is straight, and during/after bending in the scala tympani **440**, where the device **100** has bent and is curved around the scala tympani **440**. Advantageously, since the FBG sensor array **130** may be fabricated in a low-bending loss optical fiber **140**, the sensing signal extracted by the interrogator **210** has neglectable loss in power even though the fiber **140** may be bent to a diameter as small as approximately 3 mm inside the cochlea **430**.

Ideally, the processor **220** is further configured to process the data received from the interrogator **210** in real-time to provide contact force and/or position information of the carrier member **110** during positioning or implantation in the subject's body **400**. During implantation surgery, the display device **224** may be configured to provide the real-time monitoring information of force and/or position of the medical device **100** during positioning or implantation in the subject's body **400**. The tip contact force (F_{tip}) and lateral force ($F_{lateral}$) may be provided in a chart **246** given with respect to the actual insertion depth, preferably the angular insertion depth, of the implant as shown in FIG. **12**. The actual position, preferably the angular position, of the medical device **100** in the subject may be shown on an image **240** of the target or implantation region **420** prior to surgery, such as an X-ray image of the cochlea as shown in FIG. **12**. The real-time force and position information may allow a surgeon or operator to determine whether the medical device **100** has contacted internal tissues **410** of the subject's body **400** (such as the cochlear inner wall **410** for cochlear implants **100** as shown in FIG. **2**) and the location of contact.

In some embodiments, the processor **220** is further configured to detect when the contact forces on the carrier member **110**, namely one or both of the tip contact force (F_{tip}) and lateral force ($F_{lateral}$), exceed a threshold value over which damage to internal tissues **410** of the subject's body **400** is likely to occur. Typically, trauma may occur when the contact force on the cochlear inner wall for cochlear implants exceeds a threshold value of approximately 30 mN. The various threshold values for incurring damage or trauma to internal tissues **410** of the subject's body **400** would be appreciated by a person skilled in the art. When the threshold value is exceeded, the processor **220** is configured to output a notification signal of excessive con-

tact forces on the internal tissues **410** of the subject's body **400**. For example, this may include an alarm signal on the display device **224** indicating that the threshold has been exceeded. The alarm signal may include an indicator light or message to the surgeon or operator. Additionally/alternatively, the processor **220** may be further configured to output data representing instructions to perform a number of steps. The processor **220** may output the instructions on the display device **224**. The instructions may include one or more of: stop advancing the carrier member **110** into the subject's body **400**, at least partially withdraw the carrier member **110** from the subject's body **400**, adjust an insertion angle of the carrier member **110** relative to the subject's body, and re-insert the carrier member **110** into the subject's body **400**. The notification signal and/or instructions outputted by the processor **220** may inform the surgeon or operator of appropriate action to prevent trauma or damage to the internal tissues **410** of the subject's body **400**.

Occasionally, an undesirable effect may occur during implantation of a cochlear implant **100** which is fold-over of the tip **114**. Such occurrence currently can only be detected after surgery using fluoroscopy. The FBGs **128** near the tip **114** of the cochlear implant **100** can provide real-time monitoring of bending of the tip **114** during the insertion process, and therefore can alert the surgeon to prevent excessive bending of the tip **114** (see FIGS. **3** and **12**). In some embodiments, the first FBG **128** inscribed in the optical fiber **140** at the tip **114** is configured to measure contact force at the insertion end or tip **114** in terms of applied force value and direction, and also to monitor bending of the tip **114**. The rest of the FBGs **128** along the length of the FBG sensor array **130** may be configured to measure position along the side walls **116** in order to determine the curvature and orientation of the cochlear implant **100**, and thus enable reconstruction of the shape of the cochlear implant **100** which determine its actual position. For a certain FBG **128** in the middle of the carrier member **110** instead of the distal tip **114**, the lateral force can be retrieved by compensating the curvature effect using the FBG **128** written in a central core **142**. The processor **220** of the system **200** may be further configured to one or both of: process the data to detect when the contact forces on the carrier member **110** are indicative of fold-over of a tip of the electrode array **118**, and to output a notification signal, such as on the display device **224**, of fold-over of the tip.

FIG. **13** is a flow chart illustrating steps performed by a processor **220** in the system **200** of FIG. **12** or steps in a method **300** for guiding positioning of a medical device **100** in a subject's body **400** according to some embodiments of the invention. In these embodiments, the system **200** and method **300** are provided for guiding implantation of a cochlear implant **100** into a subject's body **400**.

Before the surgery, the method **300** includes imaging an implantation region **420** of the subject's body **400**, which includes the scala tympani (ST) channel **440** of the cochlea **430** in this embodiment. The imaging modality may include X-ray scanning, although other modalities including ultrasound and MRI may be employed. The imaging enables the position of the implantation region **420** to be obtained, which is received by a processor **220** as a shape reference.

The next step of the method **300** includes beginning the implantation surgery which involves the surgeon or operator inserting the carrier member **110** of the implant **100** into the cochlea **430**. Preferably, the FBG **128** at the distal tip **114** of the cochlear implant **100** measures the tip force (F_{tip}) and the system **200** determines whether the contact force value exceeds a threshold over which damage or rupture to the cochlear wall **420** is likely to occur. The processor **220** is also configured to determine in real-time the shape/position of the inserted carrier member **110** of the implant **100**, and determine whether the implant **100** contacts the inner wall **420** of the cochlea **430** by comparing with the shape reference (i.e., the image of the implantation region **420** received prior to surgery).

If the tip force exceeds the limit or threshold, the processor **220** outputs a notification signal of excessive contact forces on the cochlear wall **410**. The processor **220** may also output instructions to the surgeon or operator to stop insertion of the carrier member **110** into the subject's body **400**, at least partially withdraw the carrier member **110** from the subject's body **400**, adjust an insertion angle of the carrier member **110** relative to the subject's body **400** and re-insert the carrier member **110** into the subject's body **400**. The surgeon or operator may view the instructions on a display device **224**, together with charts showing the tip force and an image showing the real-time position, to precisely adjust an insertion angle of the carrier member **110** and re-insert the carrier member **110** into the subject's body **400**.

If the tip force does not exceed the limit or threshold, the operator continues to insert the implant **100** into the subject's body **400**. The processor **220** is then configured to monitor the real-time detected lateral force. If the lateral force on the carrier member **110** is exceeded, the operator is instructed to pull back and adjust the implant **100**. Otherwise, the operator continues inserting the implant **100** and the method **300** continues another iteration until a desired length of the implant **100** is inserted. In the meantime, when the system **200** determines that the inserted implant **100** has contacted the inner wall, then the tip force as the lateral force will be assessed and if they are over limit, similar adjustments may be conducted, until the surgery is finished.

FIG. **13** is a flow chart illustrating steps of a method **300** for guiding positioning of a medical device **100** in a subject's body **400** according to some embodiments of the invention. The method **300** includes the step **302** of providing a medical device **100** including: a carrier member **110** configured for positioning in the subject's body **400**, the carrier member **110** including an insertion end **114** and side walls **116** that contact the subject's body **400** during positioning of the carrier member **110** in the subject's body **400**; one or more operative components **118** disposed in the carrier member **110**; an optical fiber **140** at least partly disposed in the carrier member **110**; and at least one fiber Bragg grating (FBG) sensor array **130** associated with the optical fiber **140** and being disposed in the carrier member **110**. The method **300** also includes the step **304** of positioning the insertion end **114** of the carrier member **110** in the subject's body **400**. The method **300** also includes the step **306** of using an interrogator **210** coupled to the optical fiber **140** to obtain reflection spectra data **250** from the FBG sensor array **130** during positioning of the carrier member **110** in the subject's body **400**. The method **300** also includes the step **308** of determining contact forces at one or both of the insertion end **114** and along the side walls **116** of the carrier member **110** during positioning of the carrier member **110** in the subject's body **400** based on the reflection spectra data **250** from the interrogator **210**.

In some embodiments, the medical device **100** is an implantable medical device and the carrier member **110** is configured for implantation in the subject's body **400**. The method **300** may enable guidance of implantation of the medical device **100** into the subject's body **400**. The method **300** may include the step of advancing the insertion end **114** into the subject's body **400**.

In some embodiments, the method **300** may guide implantation of a cochlear implant **100** into a scala tympani **440** of a cochlea **430** of a subject. However, in other embodiments the method **300** may guide positioning or implantation of different medical devices **100**, as would be appreciated by a person skilled in the art. The medical device **100** and optical fiber **140** of the method **300** may include one or more features in any combination of the embodiments described above and with reference to FIGS. **1** to **12**.

The step **304** of positioning an insertion end **114** of the carrier member **110** in the subject's body **400** may be performed by a surgeon or operator during e.g., implantation surgery on a subject. The step **304** may include inserting the insertion end **114** into the subject's body **400** through an orifice and advancing the carrier member **110** into the subject's body **400** until a desired insertion length is reached.

The step **306** of using an interrogator **210** may be performed by a surgeon or operator in which they operate the interrogator **210** to retrieve the reflection spectra data **250**. The step **308** of determining contact forces is preferably performed by a processor **220**, such as described above with reference to the system **200** of FIG. **12**. However, the contact forces can also be determined by the surgeon or operator through calculation of contact forces using the mathematical algorithm described herein with reference to FIG. **8** and reflection spectra data **250** from the interrogator **210**.

Preferably, the medical device **100** includes the multi-core optical fiber **140** with a plurality of FBG sensor arrays **130** as shown and described with reference to FIG. **3**. The method **300** may further include the step of coupling each core **142**, **144**, **146** and **148** of the multi-core optical fiber **140** to the interrogator **210** by a coupling device **230** for separately detecting the reflection spectra **250** of the FBG sensor array **132**, **134**, **136** and **138** in each core. The method **300** may further include the step of determining position of one or both of the insertion end **114** and the side walls **116** of the carrier member **110** during positioning of the carrier member **110** in the subject's body **400** based on the reflection spectra data **250** from the interrogator **210**. Preferably, the step of determining position is performed by a processor **220**, such as described above with reference to the system **200** of FIG. **12**. However, the position can also be determined by the surgeon or operator through calculation of position using the mathematical algorithm described herein with reference to FIG. **9** and reflection spectra data **250** from the interrogator **210**.

In some embodiments, the method **300** further includes the step of receiving, using a processor **220**, such as described with reference to the system **200** of FIG. **12**, position data of a target or implantation region **420** of the subject's body **400** prior to positioning or implantation of the device **100**. The method **300** may also include the step of processing, using the processor **220**, data corresponding to the position of the carrier member **110** relative to the position data of the target or implantation region **420** to determine a depth of positioning or implantation of the carrier member **110** in the subject's body **400**. Preferably, the processor **220** is configured to determine angular position of the carrier member **110** in the subject's body **400**. Furthermore, the processor **220** may be configured to determine an angular depth of insertion or implantation of the carrier member **110** in the subject's body **400**. This may assist the surgeon or operator in guiding positioning or implantation of the carrier member **110** based on feedback received from the sensing system **200**.

In some embodiments, the method **300** further includes receiving, using the processor **220**, physiological data of the subject prior to positioning of the carrier member **110** in the subject's body **400**. The physiological data may include, for example, pre-operative hearing data of the subject. This is particularly useful where the medical device **100** to be guided for positioning or implantation in the subject's body **400** is a cochlear implant. The method **300** may further include, processing, using the processor **220**, the physiological data with the position data of the target or implantation region **420** to determine a desired angle of insertion or implantation of the carrier member **110** into the cochlea **430**. Advantageously, the method **300** may then include steps of rotating or altering a trajectory of the insertion depending on the desired angle of insertion or implantation, which may be performed by the surgeon or operator. This may also depend on the specific operative components **118** of the medical device **100**, such as the electrode array type (e.g., straight or curved) and the stage of implantation or insertion of the device **100** into the subject's body **400**.

The method **300** may also include the following steps performed using processor **220**: receiving an image **240** of the target or implantation region **420** of the subject's body **400** prior to positioning or implantation of the carrier member **110** in the subject's body **400**, reconstructing an image of the carrier member **110** using the data corresponding to the position of the carrier member **110**, overlaying the reconstructed image **242** of the carrier member **110** on the image of the target or implantation region **420** of the subject's body **400** and outputting data representing an image **244** of the position of the carrier member **110** relative to the target or implantation region **420** of the subject's body **400**.

In some embodiments, the method **300** further includes the step of displaying, using the processor **220**, on a display device such as display device **224** of system **200**, one or both of: an infographic **246** of the contact forces on the carrier member **110** relative to the depth of positioning or implantation of the carrier member **110**, and an image **244** of the position of the carrier member **110** relative to the target or implantation region **420** of the subject's body **400**, similar to the images **244** and infographic **246** as illustrated in FIG. **12**.

Ideally, the method **300** further includes determining in real-time contact force and/or position information of the carrier member **110** during positioning or implantation of the carrier member **110** into the subject's body **400**. This may involve processing the data by a processor such as the processor **220** of system **200** to enable real-time information to be provided.

In some embodiments, the method **300** further includes the step of determining when the contact forces on the carrier member **110** exceed a threshold value over which damage to internal tissues **410** of the subject's body **400** is likely to occur. When the threshold value is exceeded, the method **300** may further include the step of outputting, using a processor **220**, a notification signal of excessive contact forces on the internal tissues **410** of the subject's body **400**. The notification signal may be observed by a surgeon or operator during the implantation procedure. When the threshold value is exceeded, the method **300** may further include one or more of the following steps, which are performed by a surgeon or operator during the positioning or implantation surgery: stopping advancing of the carrier member **110** into the subject's body **400**; at least partially withdrawing the carrier member **110** from the subject's body **400**; adjusting an insertion angle of the carrier member **110**

relative to the subject's body **400**; and re-inserting the carrier member **110** into the subject's body **400**.

In some embodiments, the medical device **100** is a cochlear implant device and the one or more operative components **118** include at least one electrode array or optical array **118** for providing stimulation to the nervous system of the subject. In this example, the method **300** may further include the steps of: determining when the contact forces on the carrier member **110** are indicative of fold-over of a tip of the at least one electrode array or optical array **118**, and outputting, using a processor **220**, a notification signal of fold-over of the tip. The surgeon or operator may observe the notification signal in real-time during the implantation surgery and stop advancing and/or withdraw the carrier member **110** from the subject's body **400** to unfold the tip of the electrode array or optical array **118**. The carrier member **110** may then be re-inserted into the subject's body **400** for positioning or implantation.

FIG. **14** is a flow chart illustrating steps performed by a processor **220** of a system **200** and/or steps performed in a method **300**, both for guiding implantation of a cochlear implant **100** into a subject's body **400**, according to some embodiments of the invention. Before the surgery, an implantation region **420** of the subject's body **400** is imaged, which includes the scala tympani (ST) channel **440** of the cochlea **430**. The imaging modality may include X-ray scanning, although other modalities including ultrasound and MRI may be employed. The imaging enables the position of the implantation region **420** to be obtained, which is received by a processor **220** as a reference of the shape of the scala tympani **440**.

Implantation surgery is then started which involves the surgeon or operator inserting the cochlear implant **100** into the cochlea **430** of the subject. The detected force at the tip **114** of the cochlear implant **100** is then monitored in real-time by measuring the tip force (F_{tip}) and determining whether the tip force exceeds a threshold over which damage or rupture to the cochlear wall **420** is likely to occur. The shape and position of the implant **100** is also monitored, preferably simultaneously, in real-time by determining whether the implant **100** contacts the inner wall **420** of the cochlear **430** by comparing the determined implant position with the shape reference (i.e., the image of the implantation region **420** received prior to surgery).

If the tip force exceeds the limit or threshold, the surgeon or operator stops insertion of the implant **100**, at least partially withdraws the implant **100** from the subject's body **400**, adjusts an insertion angle of implant **100** relative to the subject's body **400** and re-inserts the implant **100** into the subject's body **400**. The surgeon or operator may view charts showing the tip force and an image showing the real-time position, to precisely adjust an insertion angle of the carrier member **110** and re-insert the carrier member **110** of the implant **100** into the subject's body **400**.

If the tip force does not exceed the limit or threshold, the surgeon or operator continues to insert or advance the implant **100** into the subject's body **400**. The detected lateral force on side walls **116** of the cochlear implant **100** is then monitored in real-time by measuring the lateral force ($F_{lateral}$) and determining whether the lateral force exceeds a threshold or limit over which damage or rupture to the cochlear wall **420** is likely to occur. If the lateral force is exceeded, the operator or surgeon again withdraws the implant **100**, adjusts an insertion angle and re-inserts the implant **100** into the subject's body **400**. Otherwise, the operator continues inserting the implant **100** until a desired length of the implant **100** is inserted into the subject's body **400**. The surgeon or operator may view charts showing the lateral force and an image showing the real-time position (e.g., such as shown in FIG. **12**), to precisely adjust an insertion angle of the carrier member **110** of the implant **100** and re-insert the carrier member **110** into the subject's body **400**. Finally, if the cochlear implant **100** is determined to contact the inner wall **420** of the cochlea **430**, then the tip force and lateral force are assessed, and if they exceed the thresholds or limit, similar adjustment of the implant **100** is conducted, until the surgery is finished.

The processor **220** of the system **200** or processor used to implement certain steps of the method **300** according to embodiments of the invention may include a micro-processor or controller configured to receive data from components of the system **200** or a computing server, such as through a wireless or hard-wired connection. The processor **220** or controller may be co-located with the interrogator **210**, or may be part of a stand-alone computer. The controller may include a personal computer processor such as a Celeron chip by Intel Corporation located on an ETX form factor PCB (not shown). The controller may contain or store a number of predefined protocols or steps in a non-volatile memory such as a hard drive. Protocols may be programmable by the user to implement a number of steps for the method **300**, or they may be predefined. Additionally/alternatively, the processor **220** may include any other suitable processor device known to a person skilled in the art. The processor **220** and method steps performed by the processor **220** may be implemented through a controller and further in software, firmware and/or hardware in a variety of manners as would be understood by a person skilled in the art.

Embodiments of the invention provide a medical device configured to provide force sensing for guiding positioning into a subject's body, and a sensing system and method for the same. The medical device in some embodiments is a cochlear implant and the system and method guide implantation of the cochlear implant into the scala tympani of the subject. The device, system and method described herein provide force and/or position sensing of the medical device during positioning or implantation into a subject's body. The force and/or position sensing may be enabled by the medical device having one or more FBG sensor arrays with FBGs at various positions in the medical device, including at a tip of the medical device for measuring tip force, direction of force and position, and along a length thereof for measuring lateral forces and shape/position of the medical device during positioning or implantation. Advantageously, embodiments of the invention may provide real-time feedback to the surgeon or operator in terms of tip force, lateral force and shape/position of the medical device during positioning or implantation. This may enable the surgeon or operator to precisely position the medical device in the subject in a way that minimises or reduces trauma or damage to surrounding tissues of the subject during positioning or implantation in a subject.

It is to be understood that various modifications, additions and/or alternatives may be made to the parts previously described without departing from the ambit of the present invention as defined in the claims appended hereto.

Where any or all of the terms "comprise", "comprises", "comprised" or "comprising" are used in this specification (including the claims) they are to be interpreted as specifying the presence of the stated features, integers, steps or components, but not precluding the presence of one or more other features, integers, steps or components or group thereof.

It is to be understood that the following claims are provided by way of example only, and are not intended to limit the scope of what may be claimed in any future application. Features may be added to or omitted from the claims at a later date so as to further define or re-define the invention or inventions.

The invention claimed is:

1. A medical device including:

a carrier member configured for positioning or implantation in a subject's body, the carrier member including an insertion end and side walls that contact the subject's body during positioning or implantation of the carrier member in the subject's body;

one or more operative components disposed in the carrier member;

an optical fiber at least partly disposed in the carrier member, the optical fiber comprising a core comprising a first cyclo olefin polymer having a first refractive index and a cladding comprising a second cyclo olefin polymer having a second refractive index that is less than the first refractive Index; and

at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the carrier member,

wherein the at least one FBG sensor array is configured for measuring contact forces at one or both of the insertion end and along the side walls of the carrier member during positioning or implantation of the carrier member in the subject's body.

2. The device according to claim **1**, further including a plurality of FBG sensor arrays configured for measuring position of one or both of the insertion end and the side walls of the carrier member during positioning of the carrier member in the subject's body.

3. The device according to claim **2**, wherein the optical fiber is a multi-core optical fiber having a FBG sensor array disposed in each core for providing contact force and/or position measurements at the location of each FBG.

4. The device according to claim **3**, wherein the grating pitch of each FBG in the FBG sensor arrays is different to enable reflection wavelengths of the FBGs along each core to be detected individually.

5. The device according to claim **3**, wherein the FBG separation in each of the FBG sensor arrays is substantially identical for providing contact force and/or position measurements at the location of each FBG based on variations in reflection spectra of the FBG sensor arrays in each core.

6. The device according to claim **3**, wherein the multi-core optical fiber includes a low-index region associated with each core, wherein the low-index region has a lower refractive index than the refractive index of the core and a cladding of the optical fiber for reducing bending loss of optical light during positioning of the carrier member in the subject's body.

7. The device according to claim **6**, wherein the low-index region includes one of:

a trench surrounding the core, wherein the trench is air-filled or filled with a fluid having the lower refractive index;

one or more holes surrounding the core, wherein the holes are air-filled or filled with a fluid having the lower refractive index; or

a plurality of elongate members positioned around and colinearly with the core, wherein the elongate members include a material having the lower refractive index.

8. The device according to claim **3**, wherein the multi-core optical fiber includes a plurality of holes arranged in a cladding of the optical fiber to induce bending in a desired direction during positioning of the carrier member in the subject's body.

9. The device according to claim **3**, wherein the multi-core optical fiber includes a cladding that is shaped to induce bending in a desired direction during positioning of the carrier member in the subject's body, and wherein a cross-section of the cladding includes one or more of the following shapes: circular, rectangular, square, triangular, oval and elliptical.

10. The device according to claim **1**, wherein the one or more operative components include at least one electrode array or optical array, and wherein the FBG sensor array is aligned relative to the at least one electrode array or optical array in the carrier member.

11. The device according to claim **1**, wherein the device is an implantable medical device and the carrier member is configured for implantation in the subject's body.

12. The device according to claim **1**, wherein the device is a cochlear implant device and the one or more operative components include at least one electrode array or optical array for providing stimulation to the nervous system of the subject.

13. The device according to claim **1**, wherein the core comprises a first refractive index of 1.531 and the cladding comprises a second refractive index of 1.525.

14. The device according to claim **1** wherein the core comprises an absence of microstructures.

15. A system for guiding positioning or implantation of a medical device in a subject's body, the system including:

a medical device including:

a carrier member configured for positioning or implantation in the subject's body, the carrier member including an insertion end and side walls that contact the subject's body during positioning or implantation of the carrier member in the subject's body;

one or more operative components disposed in the carrier member;

an optical fiber at least partly disposed in the carrier member, the optical fiber comprising a core comprising a first cyclo olefin polymer having a first refractive index and a cladding comprising a second cyclo olefin polymer having a second refractive index that is less than the first refractive index; and

at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the carrier member;

an interrogator coupled to the optical fiber and configured to obtain reflection spectra data from the FBG sensor array during positioning or implantation of the carrier member in the subject's body; and

a processor configured to receive the reflection spectra data from the interrogator and to process the reflection spectra data to determine contact forces at one or both of the insertion end and along the side walls of the carrier member during positioning or implantation of the carrier member in the subject's body.

16. The system according to claim **15**, wherein the device further includes a plurality of FBG sensor arrays, and wherein the processor is further configured to process the reflection spectra data to determine position of one or both of the insertion end and the side walls of the carrier member during positioning of the carrier member in the subject's body.

17. The system according to claim **16**, wherein the optical fiber is a multi-core optical fiber including a fiber Bragg grating (FBG) sensor array disposed in each core, and

wherein the system further includes a coupling device for coupling each core to the interrogator for separately detecting the reflection spectra of the FBG sensor arrays in each core.

18. The system according to claim **16**, wherein the processor is further configured to:

receive position data of a target region of the subject's body prior to positioning of the carrier member in the subject's body; and

process data corresponding to the position of the carrier member relative to the position data of the target region in real-time to provide contact force and/or position information of the carrier member during positioning of the carrier member in the subject's body.

19. The system according to claim **16**, wherein the core comprises a first refractive index of 1.531 and the cladding comprises a second refractive index of 1.525.

20. The system according to claim **15**, wherein the processor is further configured to detect when the contact forces on the carrier member exceed a threshold value over which damage to internal tissues of the subject's body is likely to occur.

21. The system according to claim **20**, wherein when the threshold value is exceeded, the processor is configured to output a notification signal of excessive contact forces on the internal tissues of the subject's body.

22. The system according to claim **15**, wherein the medical device is a cochlear implant device and the one or more operative components include at least one electrode array or optical array for providing stimulation to the nervous system of the subject.

23. The system according to claim **22**, wherein the processor is further configured to one or both of:

process the data to detect when the contact forces on the carrier member are indicative of fold-over of a tip of the at least one electrode array or optical array; and

output a notification signal of fold-over of the tip.

24. A method for guiding positioning or implantation of a medical device in a subject's body, the method including the steps of:

providing a medical device including:

a carrier member configured for positioning or implantation in the subject's body, the carrier member including an insertion end and side walls that contact the subject's body during positioning or implantation of the carrier member in the subject's body;

one or more operative components disposed in the carrier member;

an optical fiber at least partly disposed in the carrier member, the optical fiber comprising a core comprising a first cyclo olefin polymer having a first refractive index and a cladding comprising a second cyclo olefin polymer having a second refractive index that is less than the first refractive index; and

at least one fiber Bragg grating (FBG) sensor array associated with the optical fiber and being disposed in the carrier member;

positioning the insertion end of the carrier member in the subject's body;

using an interrogator coupled to the optical fiber to obtain reflection spectra data from the FBG sensor array during positioning or implantation of the carrier member in the subject's body; and

determining contact forces at one or both of the insertion end and along the side walls of the carrier member during positioning or implantation of the carrier member in the subject's body based on the reflection spectra data from the interrogator.

25. The method according to claim **24**, wherein the core comprises a first refractive index of 1.531 and the cladding comprises a second refractive index of 1.525.

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