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(54) **IMPLANT SENSORS**

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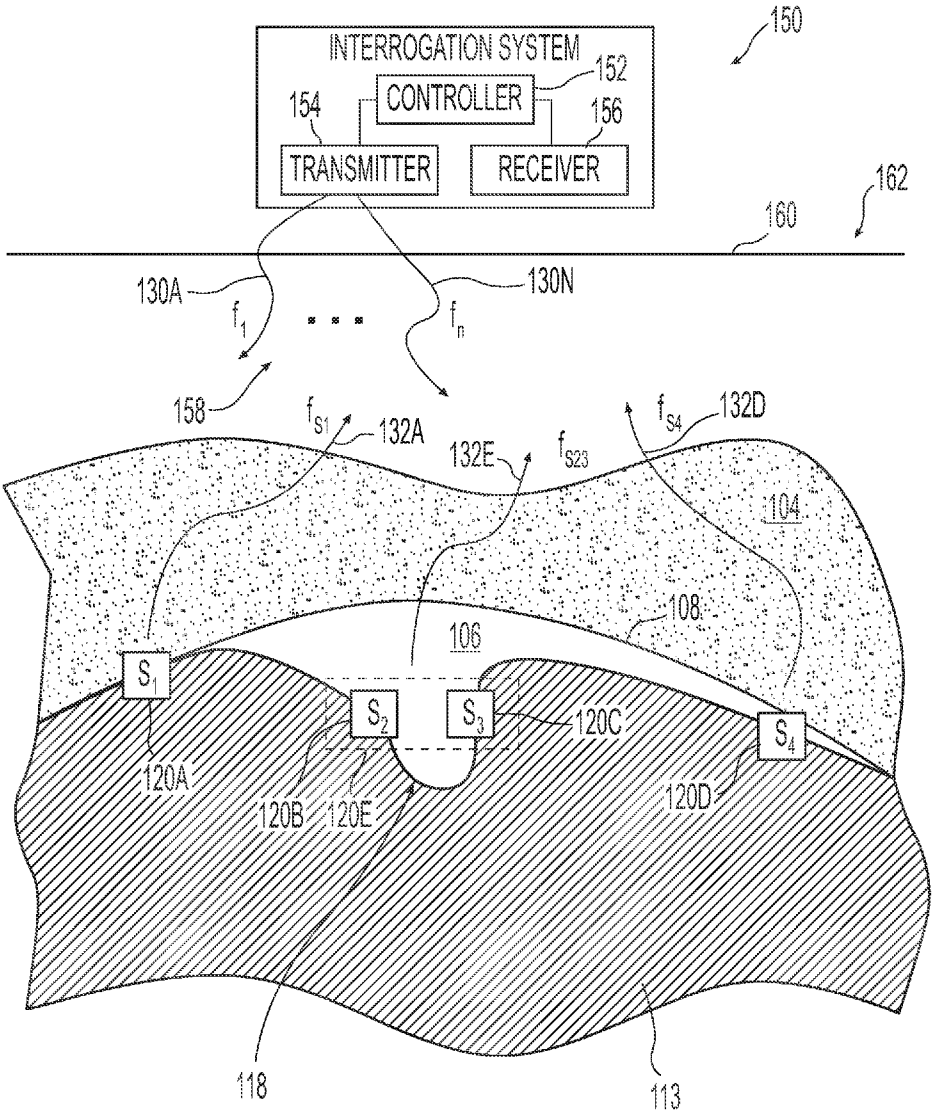
(57) **ABSTRACT**

Exemplary orthopedic implants are disclosed. The orthopedic implants may include one or more sensors. Exemplary sensors include sensors to monitor bone growth, changes to the implant over time, and proper placement of the implant. The orthopedic implants may include a woven material. Sensor arrangements to detect a state of an item are disclosed. Exemplary states include folded, unfolded, and inflated. Exemplary items include an orthopedic implant and a parachute.



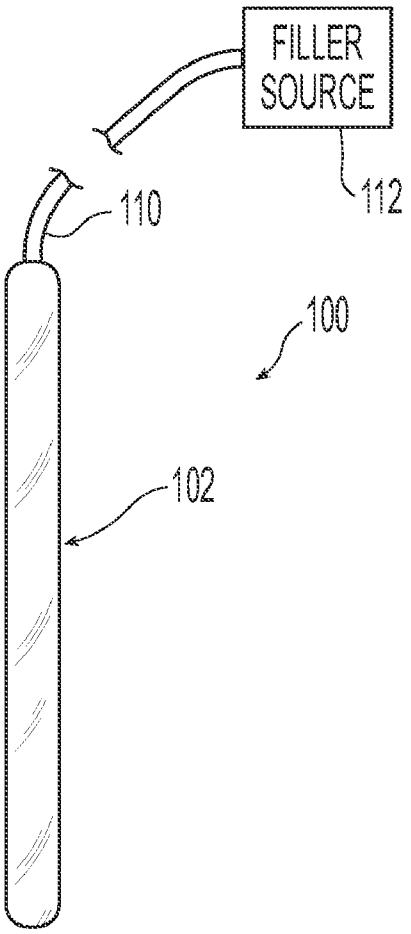


Fig. 1

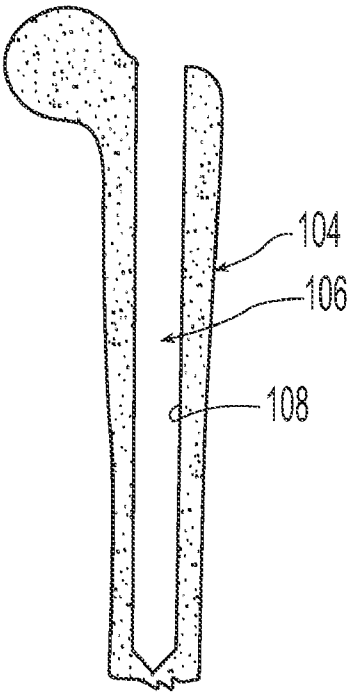


Fig. 2

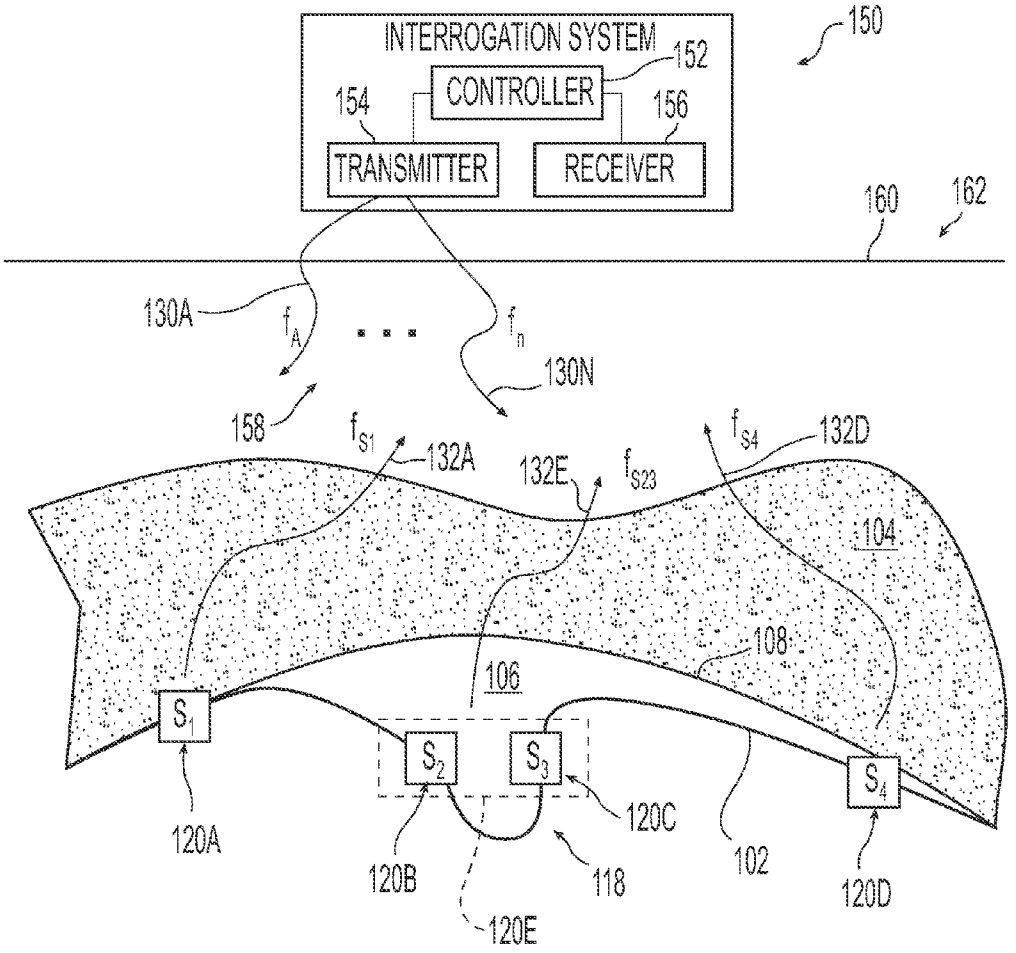

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Fig. 3

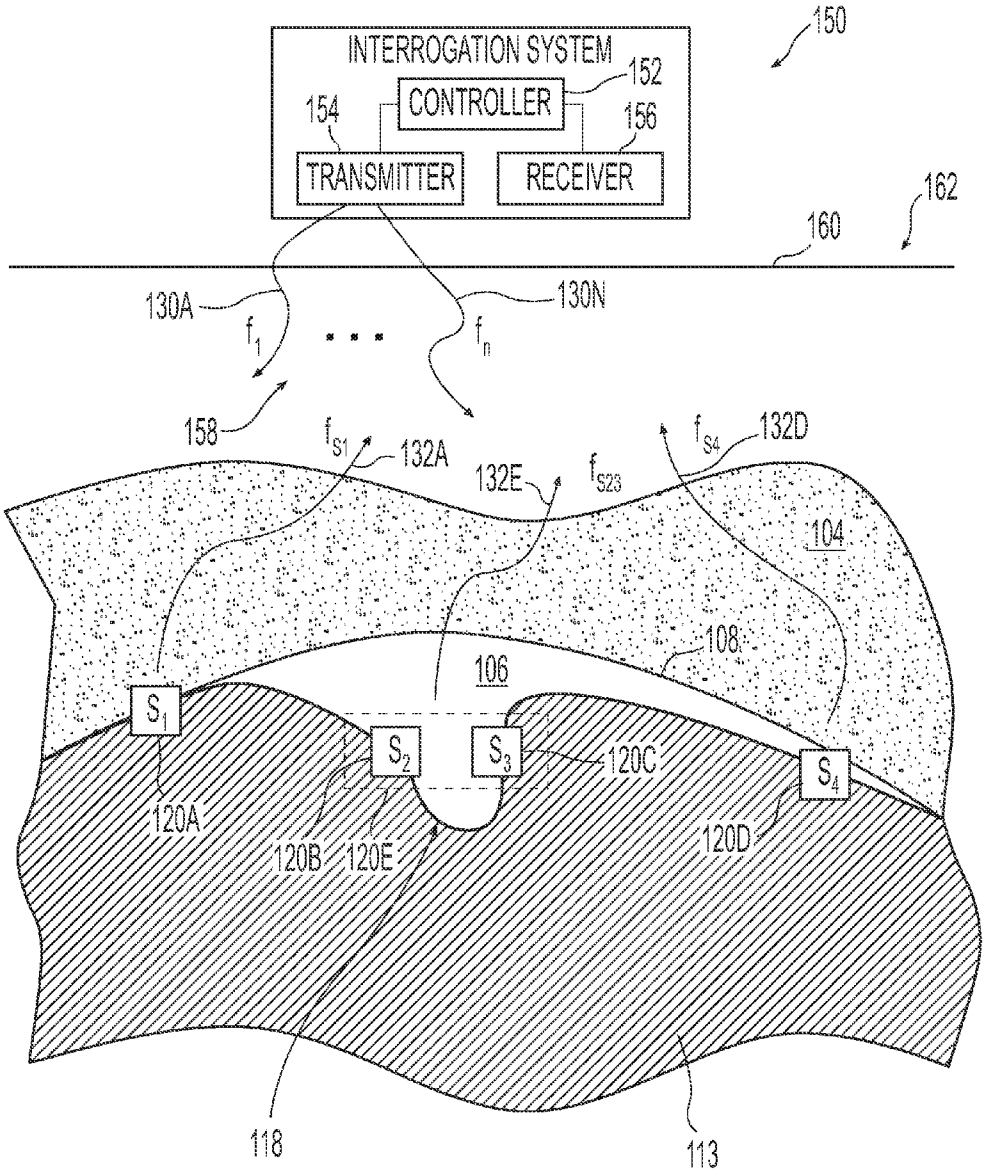
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Fig. 4

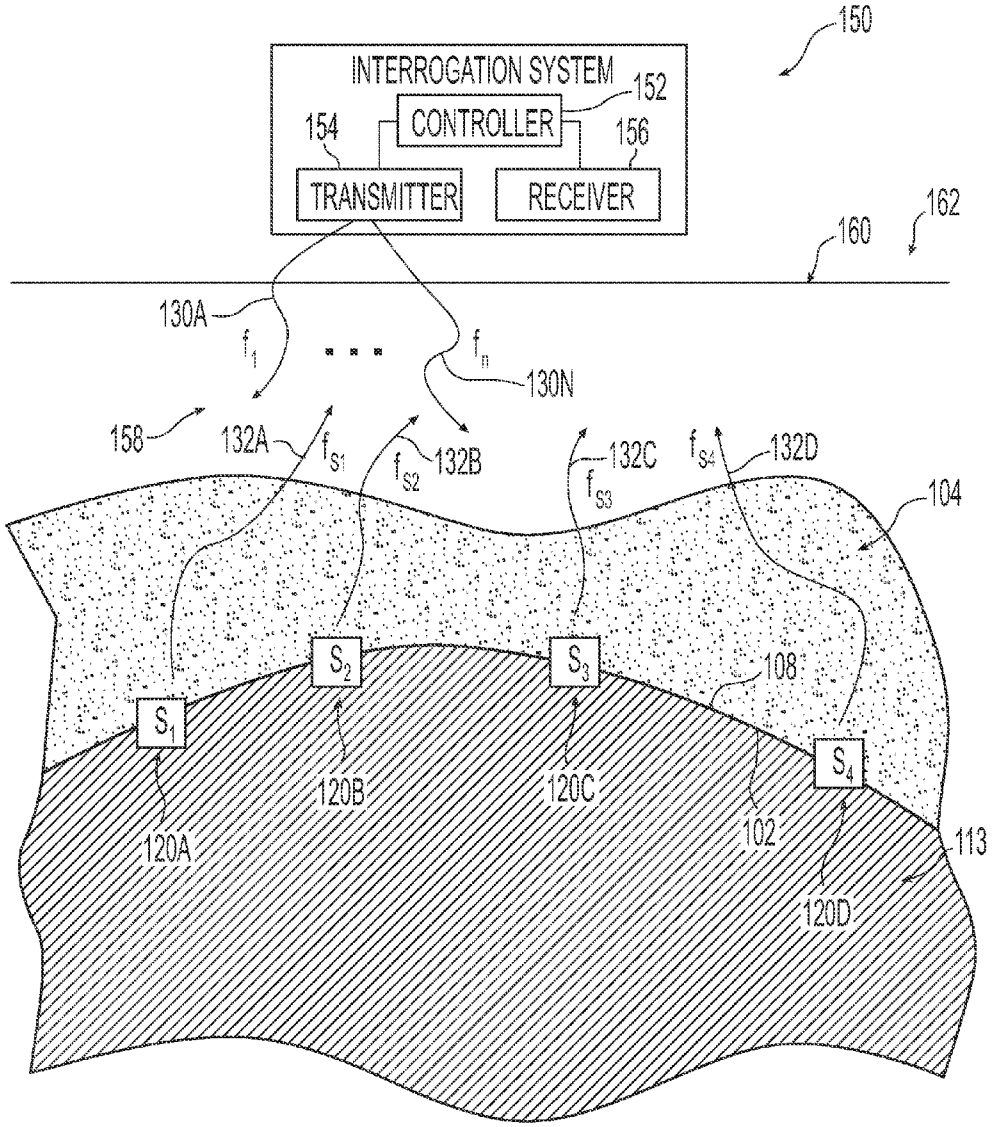
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Fig. 5

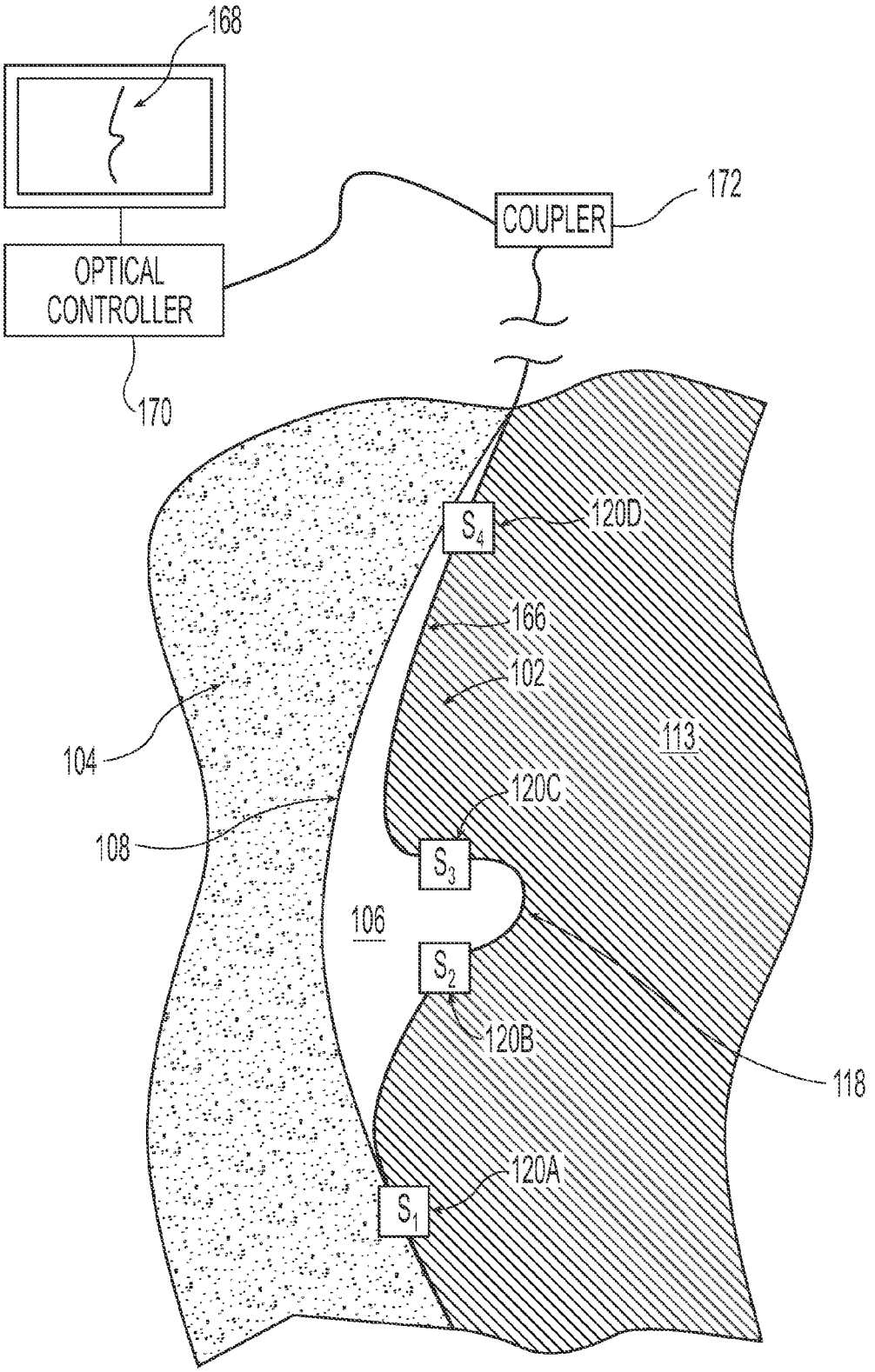
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Fig. 6

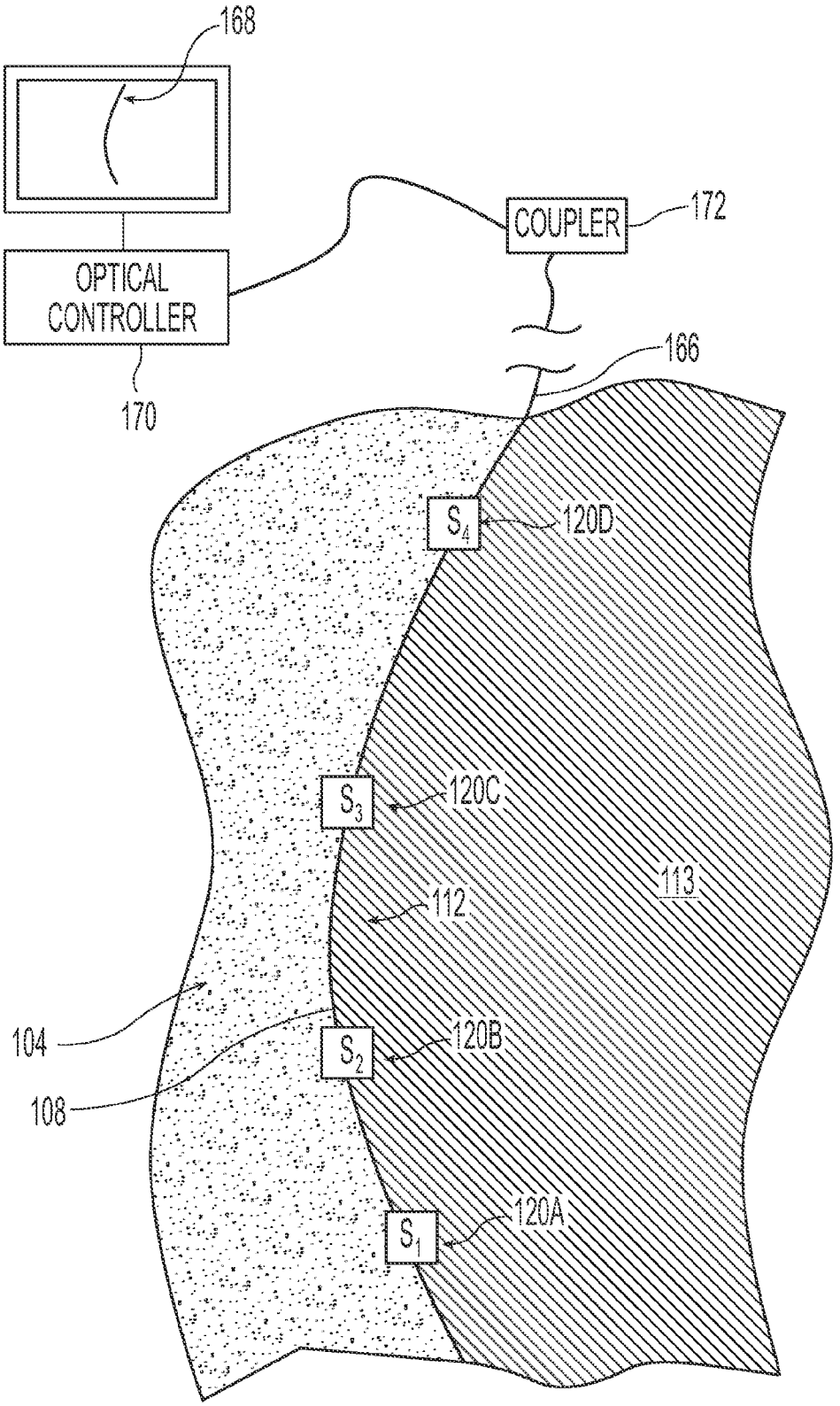
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Fig. 7

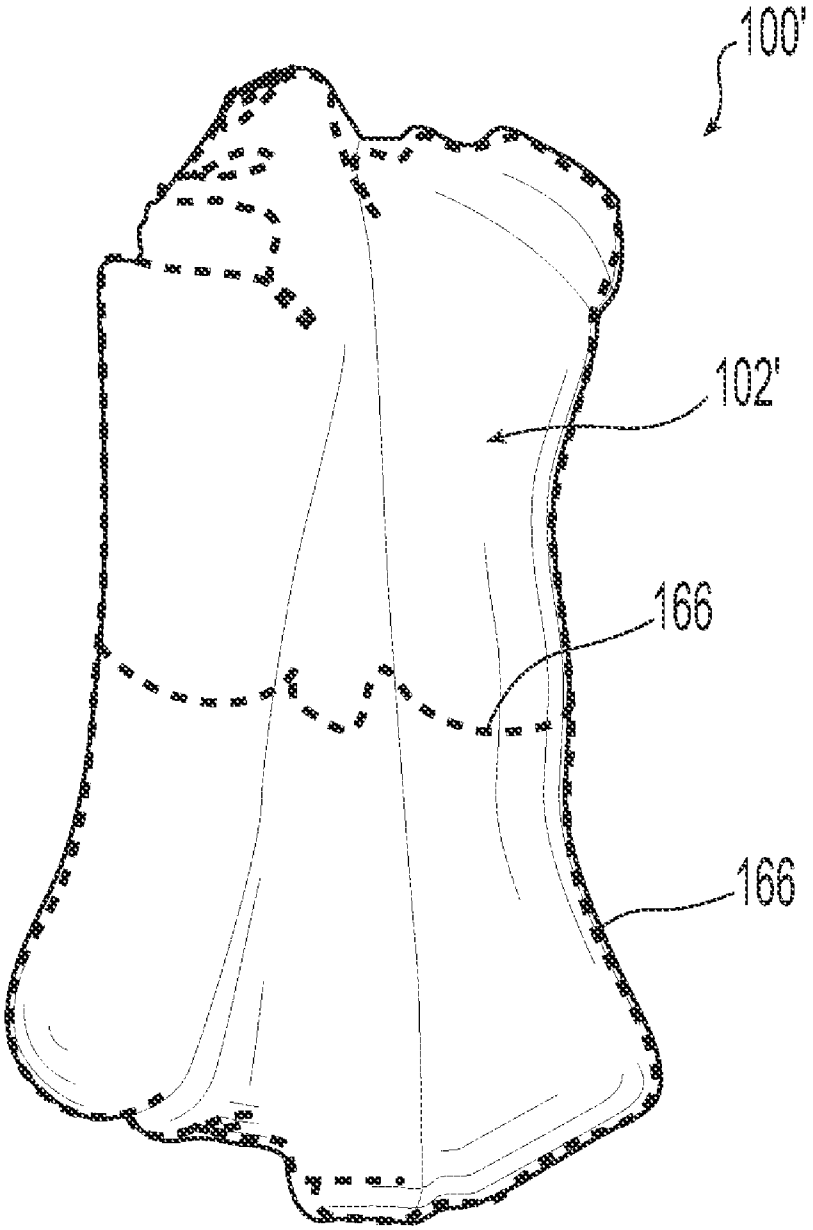

Fig. 8

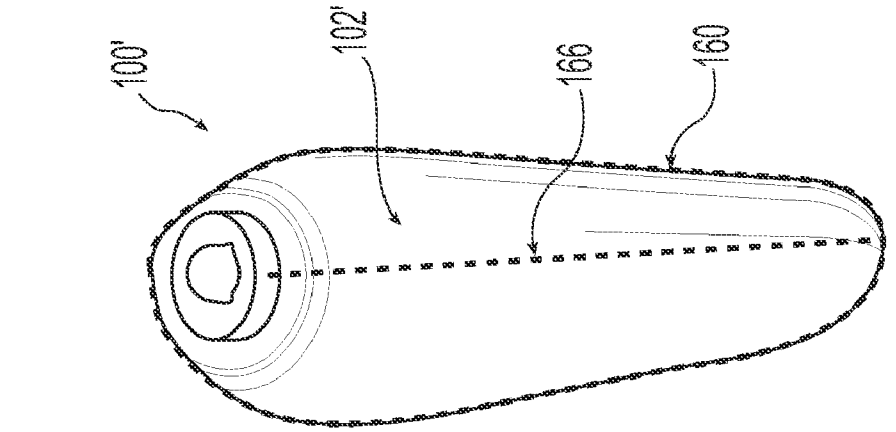

Fig. 9B

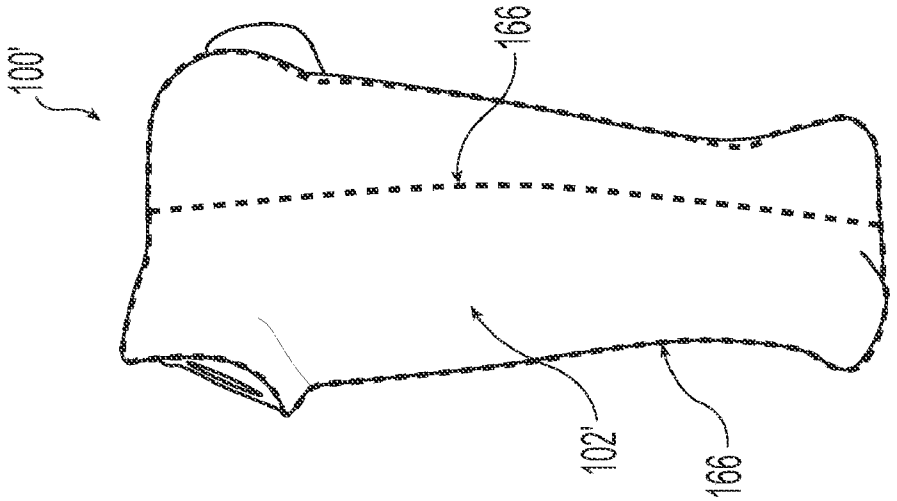

Fig. 9A

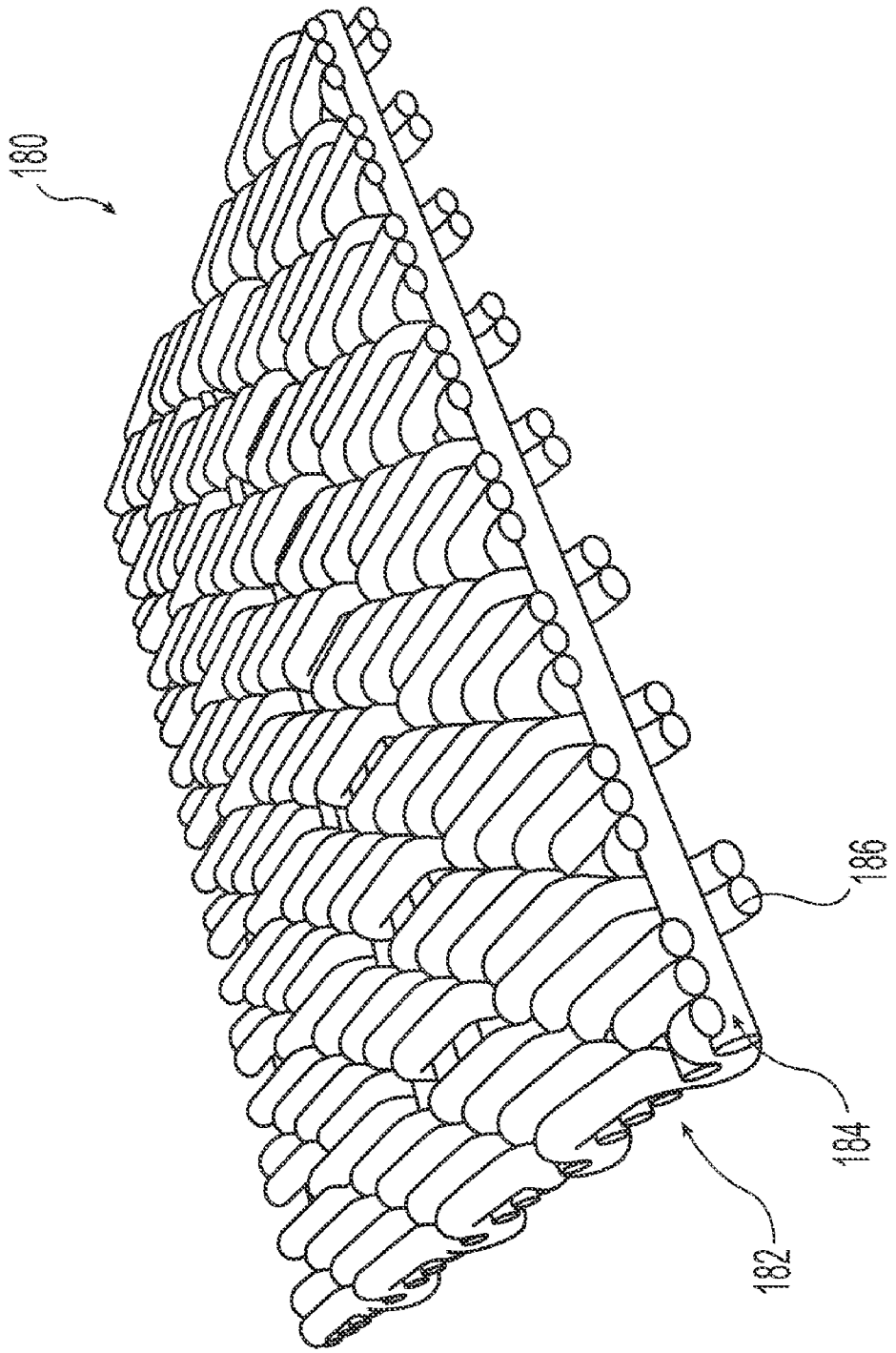

Fig. 10

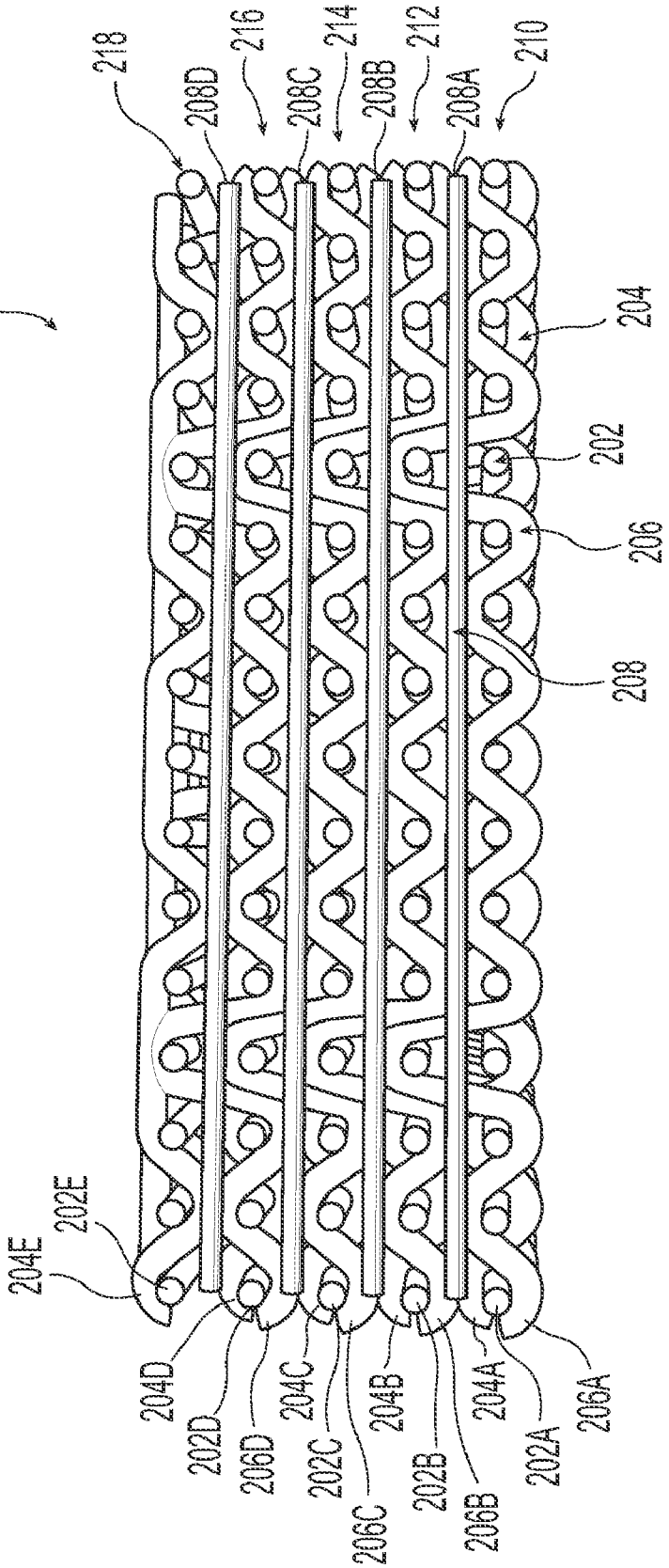
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Fig. 11

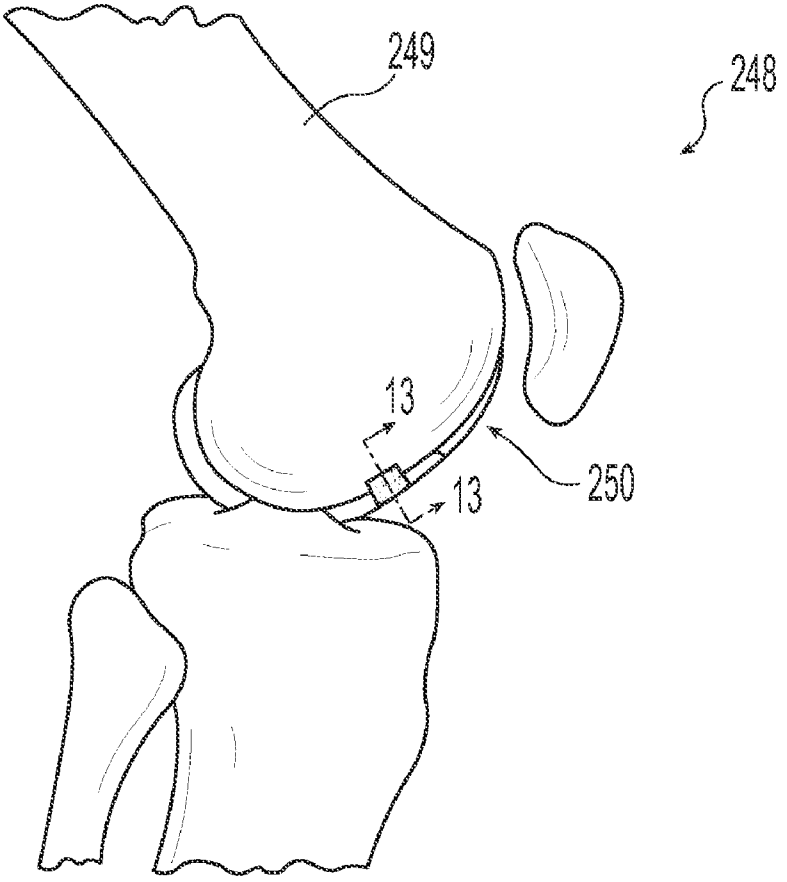
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Fig. 12

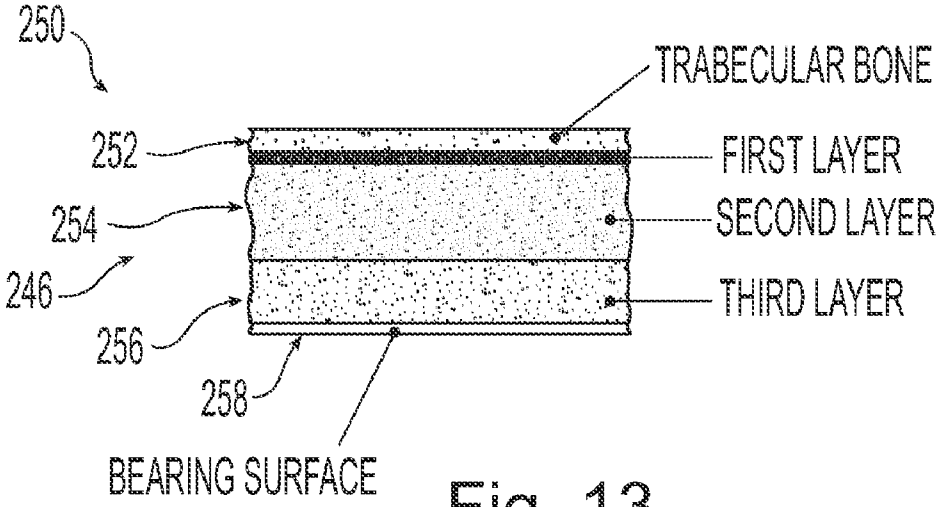
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Fig. 13

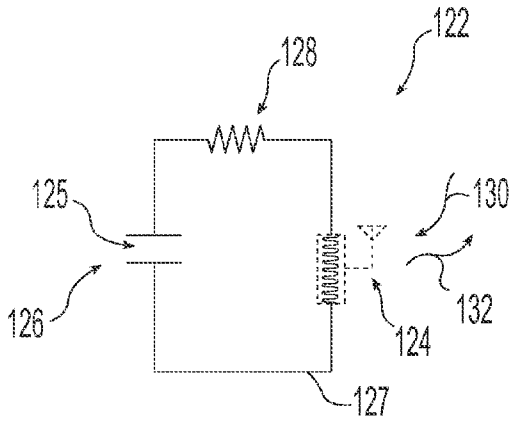

Fig. 14

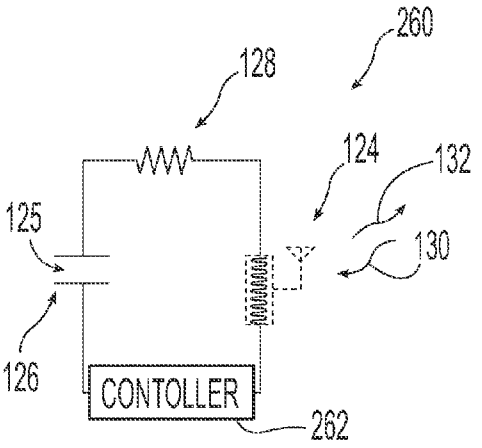

Fig. 15

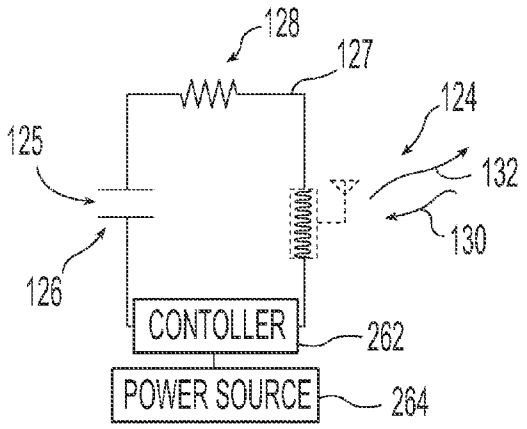

Fig. 16

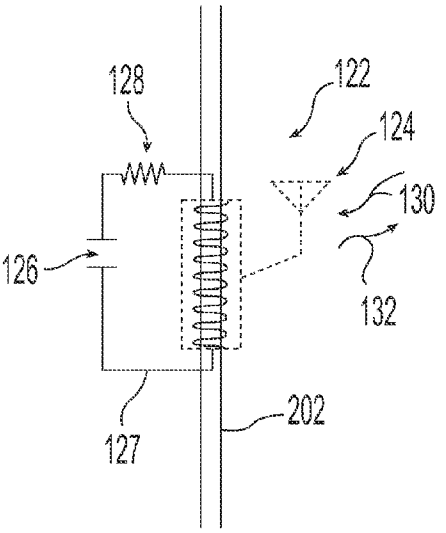

Fig. 17

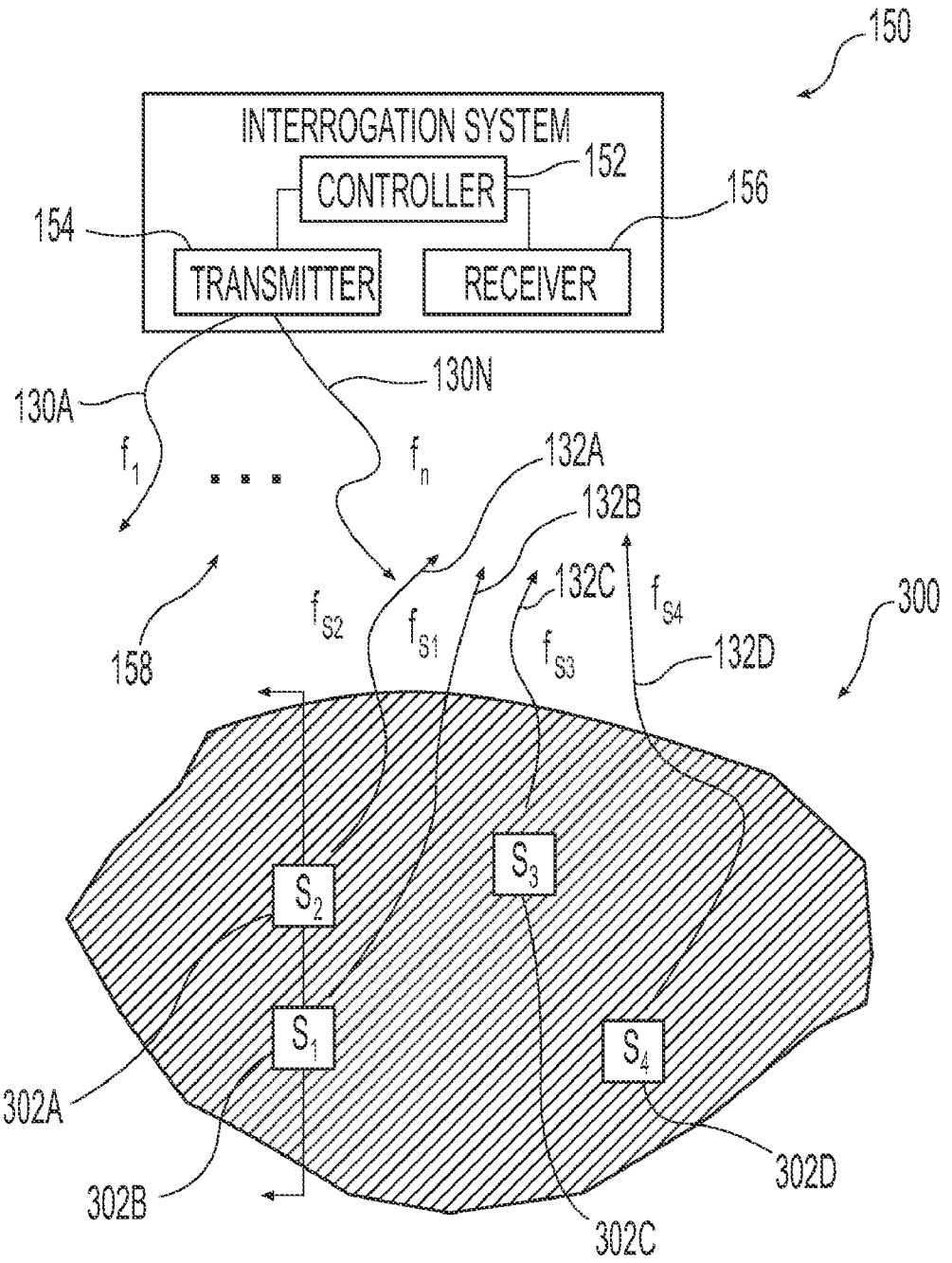
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Fig. 18

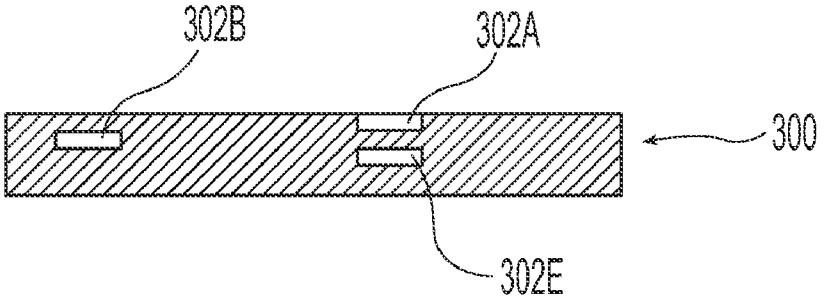

Fig. 19

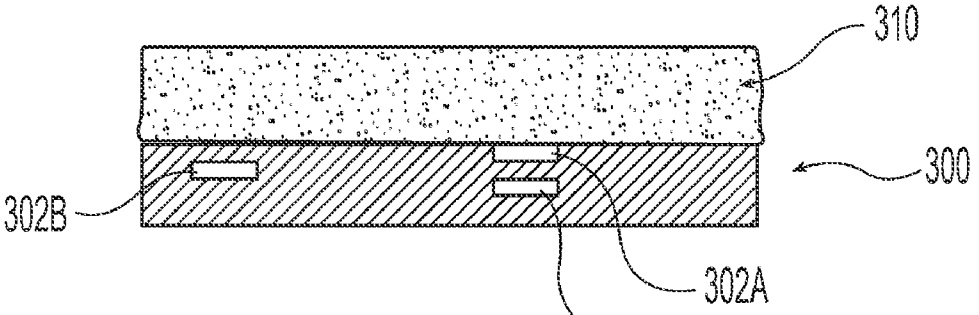

Fig. 20

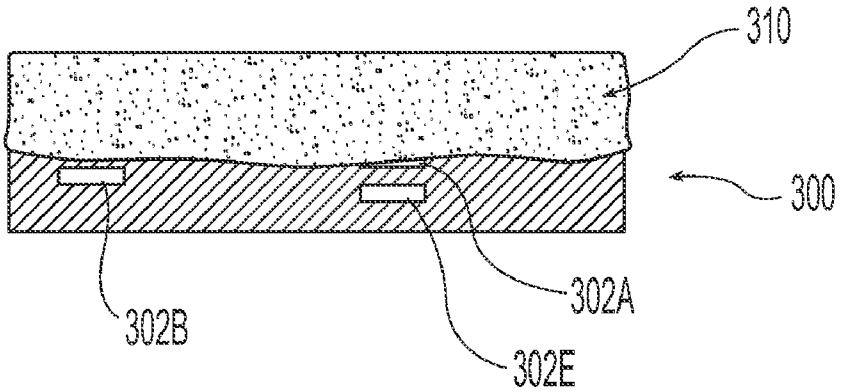

Fig. 21

IMPLANT SENSORS

RELATED APPLICATION

[0001] This application is a continuation of U.S. patent application Ser. No. 12/131,188, filed Jun. 2, 2008, titled IMPLANT SENSORS, docket ZIM0565, the disclosure of which is expressly incorporated by reference herein.

BACKGROUND AND SUMMARY OF THE INVENTION

[0002] The present invention relates generally to orthopedic implants and more particularly to orthopedic implants including one or more sensors,

[0003] Orthopedic implants are known. Further, it is known to implement inflatable orthopedic implants and to implement orthopedic implants including a woven portion.

[0004] The present invention relates to the use of one or more sensors with an orthopedic implant. The orthopedic implant may include one or more sensors for use during a surgical installation of the orthopedic implant. The orthopedic implant may include one or more sensors for use following a surgical installation of the orthopedic implant. The one or more sensors may include a passive sensor. The one or more sensors may include an active sensor.

[0005] In an exemplary embodiment of the present disclosure, an orthopedic implant for placement in a cavity formed in a bone is provided. The cavity having a predetermined shape. The orthopedic implant comprising a flexible body having an opening. The flexible body having an inflated state wherein said body has an outer shape generally corresponding to said predetermined shape formed in said bone and a non-inflated shape wherein said outer shape has a smaller envelope than said inflated state. The implant further comprising a plurality of sensors supported by said flexible body, said plurality of sensors providing an indication of whether said flexible body is in said inflated state or said non-inflated state; and a fitter. The filler being positioned in said flexible body and causing said flexible body to transition from said non-inflated state to said inflated state.

[0006] In another exemplary embodiment of the present disclosure, an orthopedic implant for placement in a cavity having a predetermined shape formed in a bone is provided. The orthopedic implant comprising a flexible body having an inflated shape generally corresponding to said predetermined shape formed in said bone; means for sensing said shape of said flexible body; and a filler. The filler being positioned in said flexible body.

[0007] In a further exemplary embodiment of the present disclosure, a method of implanting an orthopedic implant in a cavity having a predetermined shape formed in a bone is provided. The method comprising the steps of providing a flexible body which is inflatable to a first state having an outer shape generally corresponding to said predetermined shape formed in said bone; positioning said flexible body in said cavity having said predetermined shape formed in said bone; inflating said flexible body; and sensing whether said flexible body is inflated to said first state.

[0008] In yet another exemplary embodiment of the present disclosure, a system for monitoring wear of orthopedic implant for placement proximate a bearing surface when installed. in a body is provided. The system comprising an orthopedic implant body; a plurality of sensors supported by said orthopedic implant body and arranged to be positioned proximate said bearing surface, each sensor corresponding to a location on said orthopedic implant; and an interrogation system to interrogate said plurality of sensors subsequent to installation in said body. Each sensor of said plurality of sensors providing a first indication in response to an interrogation signal in an absence of wear of said orthopedic implant at said location corresponding to said sensor and a second indication in response to said interrogation signal in a presence of wear of said orthopedic implant at said location corresponding to said sensor.

[0009] In a yet further exemplary embodiment of the present disclosure, a method of monitoring wear of an orthopedic implant placed proximate a bearing surface when installed in a body is provided. The method comprising the steps of providing a body of said orthopedic implant; providing a plurality of sensors supported by said orthopedic implant body and arranged to be positioned proximate said bearing surface, each sensor corresponding to a location on said orthopedic implant; and interrogating said plurality of sensors to determine if said orthopedic implant has experienced wear.

[0010] In still a further exemplary embodiment of the present disclosure, a woven material for use within the body is provided. The woven material comprising a first woven layer having a first plurality of weft fibers and a first plurality of in layer warp fibers, said first layer having a first stiffness; a second woven layer having a second plurality of weft fibers and a second plurality of in layer warp fibers, said second layer having a second stiffness generally less than said first stiffness; a third woven layer having a third plurality of weft fibers and a third plurality of in layer warp fibers, said third layer having a third stiffness generally less than said. second stiffness; a first plurality of out of layer warp fibers which couple together said first layer and said second layer; and a second plurality of out of layer warp fibers which couple together said second layer and said third layer,

[0011] In still another exemplary embodiment of the present disclosure, an orthopedic implant for positioning proximate a bone in a body is provided. The orthopedic implant comprising a first body portion including a three-dimensional woven material having a plurality of layers; and a second body portion coupled to said three-dimensional woven material. The three-dimensional woven material includes a first woven layer having a first plurality of weft fibers and a first plurality of in layer warp fibers. The first layer having a first stiffness. The orthopedic implant further comprising a second woven layer having a second plurality of well fibers and a second plurality of in layer warp fibers. The second layer having a second stiffness generally less than said first stiffness. The orthopedic implant further comprising a third woven layer having a third plurality of weft fibers and a third plurality of in layer warp fibers. The third layer having a third stiffness generally less than said second stiffness. The orthopedic implant further comprising a first plurality of out of layer warp fibers which couple together said first layer and said second layer and a second plurality of out of layer warp fibers which couple together said second layer and said third layer.

[0012] In still a further exemplary embodiment of the present disclosure, an orthopedic implant for positioning proximate a bone in a body is provided. The orthopedic implant comprising a body portion including a three-dimensional woven material having a plurality of layers; and a plurality of sensors supported by said three-dimensional

woven material. The plurality of sensors positioned proximate said bone and configured to provide an indication of a. presence of bone in-growth into said three-dimensional woven material.

[0013] In still yet a further exemplary embodiment of the present disclosure, an orthopedic implant for positioning proximate a bone in a body. The orthopedic implant comprising a body portion including a three-dimensional woven material having a plurality of layers; and sensing means supported by said three-dimensional woven material, said sensing means being passive.

[0014] In still yet another exemplary embodiment of the present disclosure, a method of measuring bone in-growth into an orthopedic implant placed proximate a bone when installed in a body is provided. The method comprising the steps of providing a body of said orthopedic implant, said body including a woven material; providing a sensor supported by said woven material and arranged to be positioned proximate said bone; and interrogating said sensor to determine if said bone has grown into said woven material, said sensor providing a first indication if bone in-growth is present.

[0015] In another exemplary embodiment of the present disclosure, a method of measuring strain experienced by an orthopedic implant placed proximate a bone when installed in a body is provided. The method comprising the steps of providing a body of said orthopedic implant, said body including a woven material; providing a sensor supported by said woven material and arranged to be positioned proximate said bone; and interrogating said sensor to determine an amount of strain experienced by said orthopedic implant.

[0016] In still another exemplary embodiment of the present disclosure, an assembly is provided. The assembly comprising a flexible body having a folded state and an unfolded state; and a plurality of sensors supported by said flexible body. The plurality of sensors providing an indication of whether said flexible body is in said folded state or said unfolded state.

[0017] In yet another exemplary embodiment of the present disclosure, an assembly is provided. The assembly comprising a flexible body having a folded state and an unfolded state; and means for sensing whether said flexible body is in said folded state or said unfolded state.

[0018] Additional features and advantages of the present invention will become apparent to those skilled in the art upon consideration of the following detailed description of illustrative embodiments exemplifying the best mode of carrying out the invention as presently perceived.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The detailed description of the drawings particularly refers to the accompanying figures in which:

[0020] FIG. **1** illustrates an inflatable orthopedic implant connected to a filler source;

[0021] FIG. **2** illustrates a bone having a cavity bored therein;

[0022] FIG. **3** illustrates a portion of the inflatable implant of FIG. **1** inserted into the cavity of FIG. **2**, the inflatable implant having a fold and including a plurality of sensors supported by the inflatable implant which may be interrogated by an external device;

[0023] FIG. **4** illustrates the inflatable implant of FIG. **3** with a filler material placed therein;

[0024] FIG. **5**, illustrates the inflatable implant of FIG. **4** having additional filler material placed therein, the inflatable implant being fully inflated;

[0025] FIG. **6** illustrates a portion of the inflatable implant of FIG. **1** inserted into the cavity of FIG. **2**, the inflatable implant having a fold and including a plurality of optical sensors supported by the inflatable implant;

[0026] FIG. **7**, illustrates the inflatable implant of FIG. **6** having additional filler material placed therein, the inflatable implant being fully inflated;

[0027] FIG. **8** is an exemplary embodiment of an inflatable implant for a hip stem having optical sensors, the inflatable implant being in a non-inflated state;

[0028] FIG. **9**A is a front view of the inflatable implant of FIG. **8** fully inflated;

[0029] FIG. **9**B is a side view of the inflatable implant of FIG. **8** fully inflated;

[0030] FIG. **10** is a representation of a single layer woven material having a plurality of weft fibers and a plurality of warp fibers, each warp fiber floating over a plurality of weft fibers;

[0031] FIG. **11** is a representation of a multi-layer three-dimensional woven material including a plurality of weft fibers, a plurality of in layer warp fibers, a plurality of out of layer warp fibers, and a plurality of straight warp fibers;

[0032] FIG. **12** is a representation of the bones of a knee joint and an orthopedic implant coupled to a femur bone;

[0033] FIG. **13** is a representative cross-section of the orthopedic implant of FIG. **12**;

[0034] FIG. **14** is a representation of a resonant circuit which may be supported by an orthopedic implant as a sensor;

[0035] FIG. **15** is a representation of a circuit which may be supported by an orthopedic implant as a sensor;

[0036] FIG. **16** is a representation of the circuit of FIG. **15** including a power source;

[0037] FIG. **17** is a representation of the resonant circuit of FIG. **14** wherein an antenna of the resonant circuit is wrapped around a fiber of a woven material of an orthopedic implant;

[0038] FIG. **18** is a representation of an end view of an orthopedic implant having a plurality of sensors, each sensor corresponding to a location;

[0039] FIG. **19** is a sectional view of FIG. **18** illustrating sensors at various depths;

[0040] FIG. **20** is the sectional view of FIG. **19** illustrating sensors at various depths and a bone positioned proximate an upper surface of the orthopedic implant; and

[0041] FIG. **21** is a representation of the sectional view of FIG. **20** showing the wear of the orthopedic implant.

DETAILED DESCRIPTION OF THE DRAWINGS

[0042] The embodiments of the invention described herein are not intended to be exhaustive or to limit the invention to the precise forms disclosed. Rather, the embodiments selected for description have been chosen to enable one skilled in the art to practice the invention.

[0043] The present disclosure includes multiple uses of sensors in combination with orthopedic implants. Many types of orthopedic implants are known. Exemplary implants include implants to replace a portion of a hip joint and implants to replace portions of a knee joint. As used herein the term orthopedic implant is defined as a device for installation in a living body to provide structural support to at least a portion of the living body.

[0044] Exemplary orthopedic implants for a hip joint, specifically hip stems and acetabular cups are provided in U.S. patent application Ser. No. 11/687,862, filed Mar. 19, 2007, assigned to the assignee of the present application. Exemplary surgical techniques to install hip stems and acetabular cups are described in U.S. Pat. No. 6,676,706, issued Jan. 13, 2004; U.S. Pat. No. 6,860,903, issued Mar. 1, 2005; U.S. Pat.

No. 6,953,480, issued Oct. 11, 2005; U.S. Pat. No. 6,991,656, issued Jan. 31, 2006; abandoned U.S. patent application Ser. No. 10/929,736, filed Aug. 30, 2004; U.S. patent application Ser. No. 10/952,301, filed Sep. 28, 2004; U.S. patent application Ser. No. 11/235,286, filed Sep. 26, 2005; and U.S. patent application Ser. No. 11/105,080, filed Apr. 13, 2005, all titled METHOD AND APPARATUS FOR PERFORMING A MINIMALLY INVASIVE TOTAL HIP ARTHROPLASTY, all assigned to the assignee of the present application, the disclosures of which are hereby expressly incorporated herein by reference.

[0045] One type of orthopedic implant is an inflatable orthopedic implant **100**. Referring to FIG. **1**, inflatable orthopedic implant **100** includes a flexible body **102**. Flexible body **102** is sized to be placed in a cavity **106** formed in a bone **104**. Cavity **106** is generally created during a surgical procedure by boring and/or other operations to remove bone material from bone **104**. Cavity **106** has a predetermined shape **108**.

[0046] Flexible body **102** has an uninflated state and an inflated state. In the uninflated stated, flexible body **102** has an outer envelope smaller than the envelope of flexible body **102** in the inflated state. Flexible body **102** is inflated by introducing a filler material **113** (see FIG. **4**) from a filler source **112** through a conduit **110** into an interior of flexible body **102**. In one embodiment, the filler material **113** being under pressure to force it through conduit **110** and into flexible body **102**. In one embodiment, the filler material **113** is an expandable material which is placed in flexible body **102** and subsequently expands to cause flexible body **102** to inflate. An exemplary filler material **113** is bone cement. The envelope of flexible body **102** in the inflated state generally corresponds to the shape **108** of cavity **106** in bone **104** An exemplary inflatable orthopedic implant **100'** having a flexible body **102'** shaped for use as a portion of a hip stem is provided in FIGS. **8**, **9**A, and **9**B. Additional details regarding exemplary inflatable implants are provided in U.S. Pat. No. 6,425,923, issued Jul. 30, 2002, titled CONTOURABLE POLYMER FILLED IMPLANT, assigned to the assignee of the present disclosure, the disclosure of which is expressly incorporated by reference herein.

[0047] Referring to FIG. **3**, a representation of a portion of flexible body **102** placed in cavity **106** of bone **104** is shown. Flexible body **102** includes a fold **118** and is in the uninflated state because its shape does not generally correspond to shape **108** of cavity **106**. Referring to FIG. **4**, flexible body **102** has been filled with filler material **113**. However, fold **118** is still present. Referring to FIG. **5**, additional filler material **113** has been added causing the expansion of flexible body **102** and the removal of fold **118**. In FIG. **5**, the shape of flexible body **102** generally matches shape **108** of cavity **106**. In one embodiment, flexible body **102** has a shape other than the shape of cavity **106** when in the inflated state.

[0048] As shown in FIGS. **3-5**, flexible body **102** further supports a plurality of sensors **120**A-D which are used to determine whether flexible body is in the fully inflated state of FIG. **5**, or a non-inflated state, such as in FIGS. **3** and **4**. Although four sensors **120**A-D are represented, flexible body **102** may include any number of sensors. Sensors **120** are included to detect the presence of fold **118** in flexible body **102**. In one embodiment, sensors **120** are passive sensors which receive an excitation energy from an external source. In one embodiment, sensors **120** are active sensors having a power source coupled thereto.

[0049] In one embodiment, sensors **120** are resonant circuits **122** which emit a signal of a respective frequency in response to receiving an excitation or interrogation signal of given frequency. The operation of resonant circuits **122** are well known. Referring to FIG. **14**, a representation of a resonant circuit **122** is shown. Resonant circuit **122** includes an antenna **124** which receives an interrogation signal **130** having a first frequency and emits in response thereto a response signal **132** having a second frequency. In one embodiment, the second frequency of the response signal **132** is the same as the first frequency of the excitation signal. Resonant circuit **122** includes a capacitive element **126** and a resistive element **128**. In one embodiment, capacitive element **126** is comprised of multiple layers surrounding a fiber of a woven material, Resistive element **128** is shown to represent the parasitic resistance in the circuit. However, in one embodiment, a resistive element, such as a resistor, may be included to limit the frequency range of circuit **122** or shift the frequency of the response signal **132**. Also, in one embodiment resistive element **128** may function as a sensor. The expected second frequency (such as equal to the first frequency) may be altered by changes in the amount of resistance in the circuit or the duration of the response signal may be altered. Changes in resistance may indicate a change in the tissue in contact with circuit **122** or a strain or other force experienced by circuit **122**.

[0050] Returning to FIG. **4**, an interrogation system **150** is represented. Interrogation system **150** includes a controller **152**, a transmitter **154**, and a receiver **156**. Controller **152** includes a frequency sweep generator and causes transmitter **154** to emit a plurality of discrete interrogation signals **130**A-**130**N across a frequency spectrum **158** (f_A to f_N). These interrogation signals **130** pass through the skin or tissue **160** of a living body **162**.

[0051] Each of sensors **120**A-D is tuned to a respective interrogation frequency included in frequency spectrum **158**. Each of sensors **120**A-D provides a respective response signal **132** at a discrete frequency in response to receiving the respective interrogation signal. These response signals **132** pass through the skin or tissue **160** of a living body **162**. In one embodiment, the frequency of interrogation signals and response signals are generally around about 120 kHz. In one embodiment, the frequency of interrogation signals and response signals are generally in a range of about 120 kHz to less than 1 GHz. In one embodiment, the frequency of interrogation signals and response signals are generally in a range of about 120 kHz to less than 400 MHz.

[0052] Turning to FIG. **5**, flexible body **102** is in the inflated state and its shape generally matches shape **108** of cavity **106**. In the inflated state, sensors **120**A-D are spaced apart such that each responds to interrogation device **150** separately. In response to an interrogation signal **130**A at a first frequency, sensor **120**A emits a response signal **132**A at generally the first frequency. In response to an interrogation signal **130**B at a second frequency, sensor **120**B emits a response signal **132**B at generally the second frequency. In response to an interrogation signal **130**C at a third frequency, sensor **120**C emits a response signal **132**C at generally the third frequency. In response to an interrogation signal **130**D at a fourth frequency, sensor **120**D emits a response signal **132**D at generally the fourth frequency. If all four of the response signal **132**A, response signal **132**B, response signal **132**C, and response signal **132**D are received by receiver **156** in response to the first frequency (interrogation signal **130**A), the second frequency (interrogation signal **130**A), the third frequency (interrogation signal **130**A), and the fourth frequency (interrogation signal **130**A), respectively, controller **152** determines that fold **118** is not present and at least that portion of flexible body **102** is fully inflated. An active element may be used to change the response frequency or modulate the response signal, such as to include identification data. With a

SAW ("a passive element" like an echo chamber) modulated signal, such as one including identification data, may be created without an active control element.

[0053] Returning to FIG. **4**, if fold **118** in flexible body **102** is still present then sensors **120**B and **120**C do not behave as described above. The two inductors (antennas) of sensors **120**B and **120**C begin to affect one another (mutual inductance). The resonant response of the individual sensors **120**B and **120**C begins to decline, and the response of the combined circuit begins to increase. When the two (or more) sensors are very close (due to their closer proximity because of fold **118** in flexible body **102**), the sensors act as a single sensor. As shown in FIG. **4**, sensors **120**B and **120**C act as a single sensor and provide a response signal **132**E at a fifth frequency instead of the two response signals, response signals **132**B and **132**C, at the second frequency and the third frequency. As such, if the fifth frequency (response signal **132**E) is received by receiver **156** or if one or both of the second frequency (response signal **132**B) and the third frequency (response signal **132**C) are not received by receiver **156**, then controller **152** determines that fold **118** is present in flexible body **102** and at least that portion of flexible body **102** is not fully inflated. Further, if controller **152** determines that the received signal at the second frequency (response signal **132**B) and the third frequency (response signal **132**C) are not at an amplitude above a threshold (due to the mutual inductance) then controller **152** may determine that fold **118** is present.

[0054] in one embodiment, inflatable implant **100** is inserted into cavity **106** formed in bone **104**. Filler material **113** is provided to an interior of flexible body **102**. As filler material is being provided to the interior of flexible body **102** or at discrete stop times during the filling of flexible body **102** with filler material **113**, interrogation system **150** interrogates resonant circuits **122** to determine if flexible body **102** is fully inflated. As discussed above, if all of the respective resonant circuits are providing their unique response signal **132** than flexible body **102** is fully inflated. In one embodiment, the location of each resonant circuit **122** is mapped to its location on flexible body **102**. As such, by knowing which resonant circuits **122** are not providing their unique response signal **132**, an operator or a software application may determine the portion of flexible body **102** which is not fully inflated.

[0055] Although flexible body **102** is described herein in connection with orthopedic implants, flexible body may be any component which may include a fold. Another exemplary flexible body is a parachute. When flexible body **102** is a parachute, sensors **120** may be used to provide an indication whether the parachute is properly folded or not based on the relative position of sensors **120**.

[0056] In one embodiment, sensors **120**A-D are optical sensors. In one embodiment, sensors **120**A-D are diffraction gratings provided at discrete locations along an optical fiber **166** which is coupled to or forms a part of flexible body **102**. As is known, the shape **168** of optical fiber **166** may be determined by an optical controller **170** based on the analysis of light interaction with the diffraction gratings. This shape sensing technology is available from Luna innovations located at 1 Riverside Circle, Suite 400, Roanoke, Va. 24016. Additional details regarding an exemplary optical system including diffraction gratings and the methods to determine a shape of the optical system are disclosed in U.S. Published patent application Ser. No. 11/535,438, filed Sep. 26, 2006, titled FIBER OPTIC POSITION AND SHAPE SENSING DEVICE AND METHOD RELATING THERETO, assigned to Luna Innovations incorporated, the disclosure of which is expressly incorporated by reference herein.

[0057] As shown in FIG. **6**, the shape **168** of optical fiber **166** includes fold **118** of flexible body **102**. The fold is shown on the display which provides an indication of the shape of the optical fiber **166**. As such, an operator or a software application may determine that flexible body **102** is not fully inflated based on the shape of the optical fiber. Referring to FIG. **7**, the shape **168** of optical fiber **166** does not include fold **118** of flexible body **102**. The fold is not shown on the display which provides an indication of the shape of the optical fiber **166**. As such, an operator or a software application may determine that flexible body **102** is fully inflated based on the shape of the optical fiber.

[0058] in one embodiment, inflatable implant **100** is inserted into cavity **106** formed in bone **104**. Optical controller **170** is coupled to the one Or more optical fibers through a coupler **172** to provide one or more interrogation optical signal that interacts with the diffraction gratings in optical fiber **166** and to receive one or more response optical signals back from optical fiber **166** which are used to determine the shape **168** of optical fiber **166**. Filler material **113** is provided to an interior of flexible body **102**. As filler material is being provided to the interior of flexible body **102** or at discrete stop times during the filling of flexible body **102** with filler material **113**, the shape **168** of the one or more optical fibers **166** is determined. The shape **168** of the optical fiber **166** provides the shape of flexible body **102** and thus an indication of whether flexible body **102** is fully inflated or not. Once flexible body **102** is frilly inflated, optical controller **168** is uncoupled from the installed implant **100**.

[0059] Referring to FIG. **8**, an exemplary embodiment of an inflatable implant **100'** including a flexible body **102'** in a non-inflated state is shown. The positions of one or more optical fibers **166** are illustrated by dashed lines. Referring to FIGS. **9**A and **9**B, the same embodiment of flexible body **102'** is shown in a frilly inflated state. Again, the positions of the one or more optical fibers **166** are illustrated by dashed lines. It is this layout of optical fibers **166** that an operator or software application would recognize as an indication that flexible body **102** is in the fully inflated state.

[0060] Returning to FIGS. **8**, **9**A, and **9**B, in one embodiment the optical fibers **166** are replaced with one or more fibers which are marginally conductive. The resistively of the fibers are monitored. In one embodiment, the conductivity of the fibers is at a first value when implant **100** is fully inflated. In one embodiment, the first value is a minimum value.

[0061] In one embodiment, flexible body **102'** is made of a woven material **180**. Referring to FIG. **10**, woven material **180** includes a single layer fabric **182** including a plurality of well fibers **184** and a plurality of warp fibers **186**. Optical fibers **166** may replace one of weft fibers **182** and warp fibers **184** and form part of woven material **180**. As illustrated warp fibers **186** are floated over four weft fiber **184** to reduce the amount of bending of optical fibers **166**. The warp fibers **186** which correspond to optical fibers **166** may be floated over more or less weft fibers **184**. In one embodiment, the warp fibers **186** which correspond to optical fibers **166** are floated over at least two of the weft fibers **184**.

[0062] Woven material **180** may be made from any type of bio-compatible material which results in a flexible body having a non-inflated state and an inflated state. Exemplary materials include polymers, such as thermoplastics and hydrophilic hydrogels; bio-degradable materials; acrylics; natural fibers; metals; glass fibers; carbon fibers; ceramics; and other suitable materials. Exemplary polymers include propylene, polyester, high density polyethylene (HDPE), low density-polyethylene (LDPE), ultra-high molecular weight polyethylene (UHMWPE), polycarbonate urethane, polyetherether-

ketones (PEEK). Exemplary hydrophilic hydrogel include polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), and polyethylene glycol (PEG). Exemplary bio-degradable materials include Polylactic Acid (PLA), poly-L-lactide (PLLA) and polyglycolic acid (PGA). Exemplary acrylics include polymethyl methacrylate (PMMA). Exemplary natural fibers include elasin, keratin, silk, hydroxyl apatite (HA), collagen, and chitosan. Exemplary metals include stainless steel, titanium, titanium alloys, cobalt, nickel titanium alloy (nitinol), and tantalum. Exemplary ceramics include zirconia, alumina, and silica.

[0063] Further, inflatable implant **100'** may be made from a three-dimensional woven material **200**. Referring to FIG. **11**, three-dimensional woven material **200** is shown. In one embodiment, three-dimensional woven material **200** includes fibers which make a generally rigid. body for use as an orthopedic implant. In one embodiment, three-dimensional woven material **200** includes fibers which make a generally flexible body **102** for an inflatable orthopedic implant **100**.

[0064] Referring to FIG. **11**, a portion of a three-dimensional woven material **200** is shown. Three-dimensional woven material **200** includes a plurality of well fibers **202** (extending out of the page), a plurality of in layer warp fibers **204**, and a plurality of out of layer warp fibers **206**. In the illustrated embodiment, three-dimensional woven material **200** also includes a. plurality of straight warp fibers **208**.

[0065] In the illustrated embodiment, three-dimensional woven material **200** includes five layers **210**, **212**, **214**, **216**, and **218**. Each of the layers **210**, **212**, **214**, **216**, and **218** is coupled to the adjacent layers through the out of layer warp fibers **206**. Although five layers are shown, three-dimensional woven material **200** may include between two and five layers or more than five layers. Further, although out of layer warp fibers **206** are shown coupling two adjacent layers together, the out of layer warp fibers **206** may couple more than two layers together.

[0066] Each of weft fibers **202**, in layer warp fibers **204**, out of layer warp fibers **206**, and straight warp fibers **208** may be made of one or more materials. In the case of multiple materials, the respective fiber may be a braided fiber. Exemplary materials include polymers, such as thermoplastics and hydrophilic hydrogels; bio-degradable materials; acrylics; natural fibers; metals; glass fibers; carbon fibers; ceramics; and other suitable materials. Exemplary polymers include propylene, polyester, high density polyethylene (HDPE), low density polyethylene (LDPE), ultra-high molecular weight polyethylene (UHMWPE), polycarbonate urethane, polyetheretherketones (PEEK). Exemplary hydrophilic hydrogel include polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), and polyethylene glycol (PEG). Exemplary bio-degradable materials include Polylactic Acid (PLA), poly-L-lactide (PLLA) and polyglycolic acid (PGA). Exemplary acrylics include polymethyl methacrylate (PMMA). Exemplary natural fibers include elasin, keratin, silk, hydroxyl apatite (HA), collagen, and chitosan. Exemplary metals include stainless steel, titanium, titanium alloys, cobalt, nickel titanium alloy (nitinol), and tantalum. Exemplary ceramics include zirconia, alumina, and silica.

[0067] In one embodiment, three-dimensional woven material **200** is a gradient woven material. A gradient woven material is defined as a material which includes a first layer of a first stiffness, a second layer of a second stiffness, and one or more layers between the first layer and the second layer having a stiffness between the first stiffness and the second stiffness. In one embodiment, the first layer is a first end layer of the a woven material and the second layer is a second end layer of the woven material. In one embodiment, the gradient woven material includes at least one of the end layers of the overall woven material. In one embodiment, the gradient woven material is interposed between additional layers of a woven material.

[0068] The first layer, the second layer, and the interposed layers may include a single material or multiple materials. Further, the out of layer warp fiber **206** may have a stiffness generally the same as the layer it is woven in or a stiffness generally the same as the layer which it couples to the layer it is woven in.

[0069] An exemplary gradient material will be presented with reference to FIG. **11**. In general layers made of metallic fibers are stiffer than layers made of ceramic fibers, layers made of ceramic fibers are stiffer than layers made of thermoplastic fibers, layers made of thermoplastic fibers are stiffer than layers made of hydrophilic hydrogels.

[0070] Layer **210** of three-dimensional woven material **200** includes a plurality of weft fibers **202**A, a plurality of in layer warp fibers **204**A, and a plurality of out of layer warp fibers **206**A. The plurality of weft fibers **202**A, and the plurality of in layer warp fibers **204**A are metallic fibers and provide layer **210** with generally a first stiffness.

[0071] Layer **212** of three-dimensional woven material **200** includes a plurality of weft fibers **202**B, a plurality of in layer warp fibers **204**B, and a plurality of out of layer warp fibers **206**B. The plurality of weft fibers **202**B and the plurality of in layer warp fibers **204**B are approximately fifty percent metallic fibers and approximately fifty percent thermoplastic fibers and provide layer **212** with generally a second stiffness, lower than the first stiffness of layer **210**. In one embodiment, all of the weft fibers **202**B are one of metallic fibers and thermoplastic fibers and all of the in layer warp fibers are the other of metallic fibers and thermoplastic fibers. In one embodiment, at least one of weft fibers **202**B and in layer warp fibers **204**B are a blend of metallic fibers and thermoplastic fibers. The plurality of out of layer warp fibers **206**A of layer **210** may either be metallic fibers (similar to layer **210**) or a blend of metallic and thermoplastic fibers (similar to layer **212**).

[0072] Layer **214** of three-dimensional woven material **200** includes a plurality of weft fibers **202**C, a plurality of in layer warp fibers **204**C, and a plurality of out of layer warp fibers **206**C. The plurality of weft fibers **202**C and the plurality of in layer warp fibers **204**C are generally thermoplastic fibers and provide layer **212** with generally a third stiffness, lower than the second stiffness of layer **212**. The plurality of out of layer warp fibers **206**B of layer **212** may either be thermoplastic fibers (similar to layer **214**) or a blend of metallic and thermoplastic fibers (similar to layer **212**).

[0073] Layer **216** of three-dimensional woven material **200** includes a plurality of weft fibers **202**D, a plurality of in layer warp fibers **204**D, and a plurality of out of layer warp fibers **206**D. The plurality of weft fibers **202**D and the plurality of in layer warp fibers **204**D are approximately fifty percent hydrophilic hydrogel fibers and approximately fifty percent thermoplastic fibers and provide layer **216** with generally a fourth stiffness, lower than the third stiffness of layer **214**. In one embodiment, all of the weft fibers **202**D are one of hydrophilic hydrogel fibers and thermoplastic fibers and all of the in layer warp fibers are the other of hydrophilic hydrogel fibers and thermoplastic fibers. In one embodiment, at least one of weft fibers **202**D and in layer warp fibers **204**D are a blend of hydrophilic hydrogel fibers and. thermoplastic fibers. The plurality of out of layer warp fibers **206**C of layer **214** may either be thermoplastic fibers (similar to layer **214**) or a blend of hydrophilic hydrogel fibers and thermoplastic fibers (similar to layer **216**).

[0074] Layer **218** of three-dimensional woven material **200** includes a plurality of weft fibers **202**E and a plurality of in layer warp fibers **204**E. The plurality of weft fibers **202**E and the plurality of in layer warp fibers **204**E are generally hydrophilic hydrogel fibers and provide layer **218** with generally a fifth stiffness, lower than the fourth stiffness of layer **216**. The plurality of out of layer warp fibers **206**D of layer **216** may either be hydrophilic hydrogel fibers (similar to layer **218**) or a blend of hydrophilic hydrogel fibers and thermoplastic fibers (similar to layer **216**).

[0075] Straight warp fibers **208**A are provided generally between layers **210** and **212**. Straight warp fibers **208**A may be made from fibers having the same materials as layer **210** or the same materials as layer **212**. In a similar fashion straight warp fibers **208**B are provided generally between layers **212** and **214**; straight warp fibers **208**C are provided generally between layers **214** and **216**; and straight warp fibers **208**D are provided generally between layers **216** and **218**.

[0076] Any given straight warp fiber **208**, weft fiber **202**, in layer warp fiber **204**, and out layer warp fiber **206**, may be replaced with one or more sensors, such as an optical fiber **166** including optical sensors. Further, any given straight warp fiber **208**, weft fiber **202**, in layer warp fiber **204**, and out layer warp fiber **206**, may support on or more sensors. Exemplary supported sensors include resonant circuits with digital identifiers (see FIG. **15**) and resonant circuits **122**.

[0077] In one embodiment, a three-dimensional woven material **246** forms a portion of an orthopedic implant **250**. Implant **250** is coupled to a femur bone **249** of a knee joint **248**. Woven material **246** includes a first layer **252** positioned adjacent bone **249**, a second layer **254**, and a third layer **256**. Third layer **256** may act as a bearing surface **258**. In one embodiment, third layer **256** is coated with a resin, epoxy, or a biological gel to form bearing surface **258**. In one embodiment, the polymer fibers of the third layer **256** form the bearing surface **258**. In one embodiment, first layer **252** includes metallic fibers, third layer **256** includes polymer fibers, and second layer **254** is a transitional layer, such as thermoplastic fibers and/or ceramic fibers. In one embodiment, at least one of first layer **252**, second layer **254**, and third layer **256** support one or more sensors. An exemplary sensor supported by first layer **252** would be a bone in-growth sensor.

[0078] Exemplary bone in-growth sensors include resonant circuits **122**. Turning to FIG. **14**, to measure bone-in growth, a region **125** between the capacitive plates of capacitor **126** is aligned with a region of expected bone in-growth. As bone grows into region **125**, the dielectric constant of capacitor **125** changes which alters the frequency of the response signal **132** provided by resonant circuit **122**. It should be noted that capacitor **126** does not need to be two plates separated by a dielectric. In one embodiment, a first portion of capacitor **126** may be positioned side-by-side to, but separated from, a second portion of capacitor **126**. Changes in the dielectric material adjacent the first portion and the second portion would cause a change in the capacitance of capacitor **126**.

[0079] Although capacitor **126** is described as the mechanism to measure bone in-growth, either resistor **128** or inductor **124** may be used instead. Changes to the inductor would result in a change in the inductance of the circuit which would have an effect on the response signal. Changes to the resistance would result to changes in the response signal, such as how tong circuit **122** rings (dampen out quickly").

[0080] A resonant circuit with a digital identifier **260** (see FIG. **15**) may also be used as a bone in-growth sensor. Resonant circuit **260** may also monitor the dielectric constant of capacitor **126**. However, unlike resonant circuit **122**, resonant circuit can send a signal with a unique identifier identifying itself and an indication of the dielectric constant of capacitor **126**. The unique identifier and the message packet for signal **132** are controlled by a controller or processor **262** powered by the received signal **130**. In one embodiment, controller **262** is a passive device like a surface acoustic wave (SAW) device which burst back a modulated signal, unique identifier. In this case all resonant circuits may be tuned to the same excitation frequency and the SAW device of each circuit would burst back a modulated signal at a particular frequency. The SAW device includes a converter to generate DC energy to power the logic of the controller and then provide response signal. The response can be sent out with the same antenna (between excitation signals) or a different antenna. In one embodiment, a resonant circuit includes a controller which includes an active device, like a mixed-signal application specific integrated circuits (ASIC). The inclusion of a mixed signal ASIC results in a semi-passive device.

[0081] Another resonant circuit is shown in FIG. **16** which includes a local power source **264** for controller **262** which either supplements the power from the received signal or provides power for intermittent readings of strain or bone in-growth. An exemplary power source is a battery. Another exemplary local power source includes a piezoelectric member. It is believed that another potential local power may be a plurality of zinc oxide nanowires discussed in more detail in "Piezoelectric Nanogenerators Based on Zinc oxide Nanowire Arrays," Science, Apr. 14, 2006. In one embodiment, the local power source may scavenge energy from the received. excitation signal.

[0082] An exemplary sensor supported by one of first layer **252**, second layer **254**, and. third layer **256** is a strain sensor. Exemplary strain sensors include resonant circuits **122**. Referring to FIG. **17**, a resonant circuit **122** is shown wherein the antenna **124** is wrapped around a weft fiber **202**. As weft fiber **202** is compressed or stretched along its length, the frequency response of resonant circuit **122** is altered. In one embodiment, a resistive element of circuit **122** is wrapped around a welt fiber **202** and changes in the resistance of circuit **122** provides an indication of the strain on the fiber. In one embodiment, a capacitive element of circuit **122** is wrapped around a weft fiber **202** and changes in the capacitance of circuit **122** provides an indication of the strain on the fiber.

[0083] Referring to FIGS. **18-21**, an end view of a portion of an orthopedic implant **300** is shown. Implant **300** may be a part of a knee joint **248**, like implant **250**. Over time it is possible for implant **300** to experience wear due to the forces exerted thereon. Orthopedic implant **300** may be made of a woven material and/or other materials.

[0084] Implant **300** includes a plurality of sensors **302**A-E (sensor **302**E shown in FIG. **19**) which provide an indication of wear of the orthopedic implant **300**. In one embodiment sensors **302**A-E are resonant circuits **122**. In one embodiment, sensors **302**A-E are RFID tags **260**. The location of each sensor is mapped to a location on the implant. As such, once interrogated each sensor then provides an indication of wear at that location. As shown in FIG. **19**, sensor **302**E is at a deeper depth than sensors **302**A and **302**B.

[0085] In one embodiment, sensors **302**&-E are resonant circuits **122** and are interrogated by interrogation system **150**. Each resonant circuit **122** provides a response signal **132** in response to its respective interrogation signal **130**. If all sensors provide a response signal **132** than implant **300** has not experienced any appreciable wear. This is shown in FIG. **20** wherein a bone **310** is resting upon implant **300**.

[0086] Referring to FIG. **21** bone **310** (or other items) has over time worn portions of implant **300**. As illustrated in FIG.

21, bone 310 has destroyed sensor 302A. Upon the next interrogation sensor 302A will not respond. An operator or software application based on a knowledge of the location of sensors 302A is able to determine that implant 300 is worn in the area of sensor 302A. However, since sensor 302E still provides a signal in response to the interrogation, it is known that the wear of implant 300 has not reached the depth of sensor 302E.

[0087] Although the invention has been described in detail with reference to certain preferred embodiments, variations and modifications exist within the spirit and scope of the invention as described and defined in the following claims.

1. An orthopedic implant for placement in a cavity formed in a bone, said cavity having a predetermined shape, said orthopedic implant comprising:
- a flexible body having an opening, said flexible body having an inflated state wherein said body has an outer shape generally corresponding to said predetermined shape formed in said bone and a non-inflated shape wherein said outer shape has a smaller envelope than said inflated state;
- a plurality of sensors supported by said flexible body, said plurality of sensors providing an indication of whether said flexible body is in said inflated state or said non-inflated state; and
- a filler, said filler being positioned in said flexible body and causing said flexible body to transition from said non-inflated state to said inflated state, wherein said plurality of sensors include a plurality of optical sensors.

2. The orthopedic implant of claim 1, wherein said plurality of sensors include a plurality of optical sensors.

3. The orthopedic implant of claim 2, wherein said plurality of optical sensors are in optical communication with an external detector through an optical fiber.

4. The orthopedic implant of claim 3, wherein said plurality of optical sensors are a plurality of diffraction gratings disposed in said optical fiber, said optical fiber having a first shape indicating said presence of said fold wherein said plurality of diffraction gratings are in a first plurality of locations and a second shape indicating said absence of said fold wherein said plurality of diffraction gratings are in a second plurality of locations.

5. A system for monitoring wear of orthopedic implant for placement proximate a bearing surface when installed in a body, said system comprising:
- an orthopedic implant body;
- a plurality of sensors supported by said orthopedic implant body and arranged to be positioned proximate said bearing surface, each sensor corresponding to a location on said orthopedic implant; and
- an interrogation system to interrogate said plurality of sensors subsequent to installation in said body, each sensor of said plurality of sensors providing a first indication in response to an interrogation signal in an absence of wear of said orthopedic implant at said location corresponding to said sensor and a second indication in response to said interrogation signal in a presence of wear of said orthopedic implant at said location corresponding to said sensor.

6. The system of claim 5, wherein said first indication is a response signal and said second indication is the lack of said response signal.

7. The system of claim 6, wherein each sensor includes a controller and said response signal includes a unique identifier.

8. The system of claim 6, wherein each sensor is a resonant circuit and said response signal is at a unique frequency.

9. The system of claim 6, wherein said body includes a three-dimensional woven component.

10. The system of claim 9, wherein said three-dimensional woven component includes a plurality of materials which form a gradient woven material.

11. A method of monitoring wear of an orthopedic implant placed proximate a bearing surface when installed in a body, said method comprising the steps of
- providing a body of said orthopedic implant;
- providing a plurality of sensors supported by said orthopedic implant body and arranged to be positioned proximate said bearing surface, each sensor corresponding to a location on said orthopedic implant; and
- interrogating said plurality of sensors to determine if said orthopedic implant has experienced wear.

12. The method of 11, wherein each sensor of said plurality of sensors provides a first indication in response to an interrogation signal in said absence of wear of said orthopedic implant at said location corresponding to said sensor and a second indication in response to said interrogation signal in said presence of wear of said orthopedic implant at said location corresponding to said sensor.

13. The method of claim 12, wherein said step of interrogating said plurality of sensors to determine if said orthopedic implant has experienced wear includes the steps of:
- positioning an external interrogation system proximate to said orthopedic implant; and
- for a respective sensor
  - passing said interrogation signal through said body;
  - receiving from said respective sensor one of said first indication and said second indication.

14. An orthopedic implant for positioning proximate a bone in a body, said orthopedic implant comprising:
- a first body portion including a three-dimensional woven material having a plurality of layers; and
- a second body portion coupled to said three-dimensional woven material, wherein said three-dimensional woven material includes a first woven layer having a first plurality of weft fibers and a first plurality of in layer warp fibers, said first layer having a first stiffness; a second woven layer having a second plurality of weft fibers and a second plurality of in layer warp fibers, said second layer having a second stiffness generally less than said first stiffness; a third woven layer having a third plurality of weft fibers and a third plurality of in layer warp fibers, said third layer having a third stiffness generally less than said second stiffness; a first plurality of out of layer warp fibers which couple together said first layer and said second layer; and a second plurality of out of layer warp fibers which couple together said second layer and said third layer.

15. The orthopedic implant of claim 14, further comprising a plurality of sensors supported by said three-dimensional woven material, said plurality of sensors positioned proximate said bone and configured to provide an indication of a presence of bone in-growth into said three-dimensional woven material.

16. The orthopedic implant of claim 14, further comprising a plurality of sensors supported by said three-dimensional woven material, said plurality of sensors positioned proximate said bone and configured to provide an indication of a strain experience by said three-dimensional woven material.

17. An orthopedic implant for positioning proximate a bone in a body, said orthopedic implant comprising:
- a body portion including a three-dimensional woven material having a plurality of layers; and
- a plurality of sensors supported by said three-dimensional woven material, said plurality of sensors positioned proximate said bone and configured to provide an indication of a presence of bone in-growth into said three-dimensional woven material.

18. The orthopedic implant of claim **17**, wherein said plurality of sensors each include a capacitive element having a first dielectric value, said presence of said bone in-growth into said three-dimensional woven material changing said first dielectric value.

19. The orthopedic implant of claim **18**, wherein said capacitive element is operatively coupled to an antenna which broadcasts a signal having a frequency based at least in part on said first dielectric value, said antenna broadcasting at a first frequency in said absence of bone in-growth into said three-dimensional woven material and at a second frequency in said presence of bone in-growth into said three-dimensional woven material.

20. An orthopedic implant for positioning proximate a bone in a body, said orthopedic implant comprising:
- a body portion including a three-dimensional woven material having a plurality of layers; and
- sensing means supported by said three-dimensional woven material, said sensing means being passive.

21. A method of measuring bone in-growth into an orthopedic implant placed proximate a bone when installed in a body, said method comprising the steps of:
- providing a body of said orthopedic implant, said body including a woven material;
- providing a sensor supported by said woven material and arranged to be positioned proximate said bone; and
- interrogating said sensor to determine if said bone has grown into said woven material, said sensor providing a first indication if bone in-growth is present.

22. The method of claim **21**, wherein said sensor in response to interrogation provides a signal of a first frequency in said absence of said presence of bone in-growth and a signal of a second, different frequency in said presence of bone in-growth, said second, different frequency being said first indication.

23. A method of measuring strain experienced by an orthopedic implant placed proximate a bone when installed in a body, said method comprising the steps of:
- providing a body of said orthopedic implant, said body including a woven material;
- providing a sensor supported by said woven material and arranged to be positioned proximate said bone; and
- interrogating said sensor to determine an amount of strain experienced by said orthopedic implant.

24. The method of claim **23**, wherein said sensor in response to interrogation provides a signal of a first frequency in said absence of strain and a signal of a second, different frequency in said presence of strain, said second, different frequency being said first indication,

25. An assembly, comprising:
- a flexible body having a folded state and an unfolded state; and
- a plurality of sensors supported by said flexible body, said plurality of sensors providing an indication of whether said flexible body is in said folded state or said unfolded state.

26. The assembly of claim **25**, wherein said flexible body is a portion of an orthopedic implant.

27. The assembly of claim **25**, wherein said fold is detected base(on a relative position of a first sensor, to a second sensor.

28. The assembly of claim **27**, wherein said first sensor and said second sensor are passive sensors interrogated by an external device.

29. The assembly of claim **28**, wherein said first sensor and said second sensor are each resonant circuits which provide said indication based on a separation between said first sensor and said second sensor.

30. The assembly of claim **29**, wherein when said first sensor and said second sensor are spaced a first distance apart said first sensor resonates in response to a first frequency from said external device and said second sensor resonates in response to a second frequency from said external device and when said first sensor and said second sensor are spaced less than said first distance apart said first sensor and said second sensor resonate together in response to a third frequency from said external device.

31. The assembly of claim **30**, wherein said external device interrogates said plurality of sensors through a frequency range including said first frequency, said second frequency, and said third frequency.

32. An assembly, comprising:
- a flexible body having a folded state and an unfolded state; and
- means for sensing whether said flexible body is in said folded state or said unfolded state.

33. The assembly of claim **32**, wherein said means for sensing said shape of said flexible body is a passive sensing means.

34. The assembly of claim **32**, wherein said means for sensing said shape of said flexible body is an active sensing means.

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