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EP 0211166 A **WO 2016/201082 A1**
US 20140243593 A **US 20030105496 A**

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Other: **EPODOC, WPI**

(54) Title of the Invention: **Securing a sensor at the heart**
Abstract Title: **Securing a sensor at the heart**

(57) An apparatus for securing a sensor 18 at the heart 26 is formed based on a modified, branched, pacemaker lead to provide a heart anchor lead where two anchors are coupled to a single main lead 12 rather than there being just a single anchor 14. The proposed heart anchor lead comprises a single main lead 12. A first anchor 14 coupled to the main lead 12 and extending from a branch point 18 and a second anchor 14 coupled to the main lead 12 and extending from the branch point 18. A sensor fixed to the apparatus at a point between the main lead 12 and one or both of the anchors 14. The heart anchor lead can optionally also have a pacemaking function. The sensor may be an accelerometer or a motion sensor. Each anchor may be coupled to the branch point by an electrode.

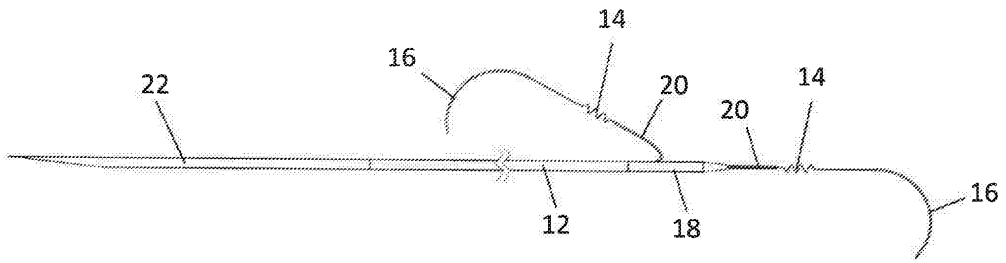

Fig. 1

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14 09 18

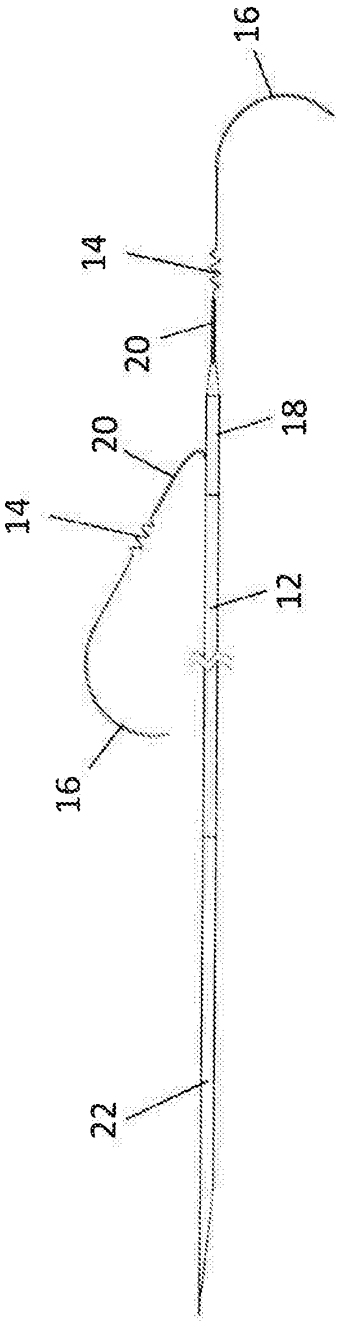

Fig. 1

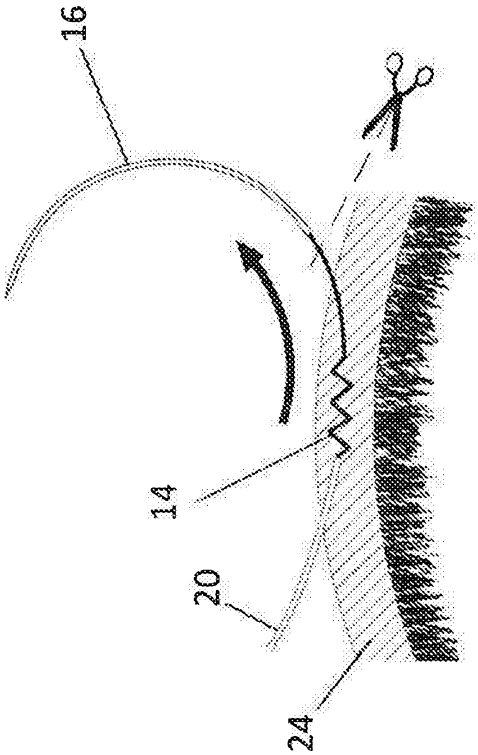

Fig. 2

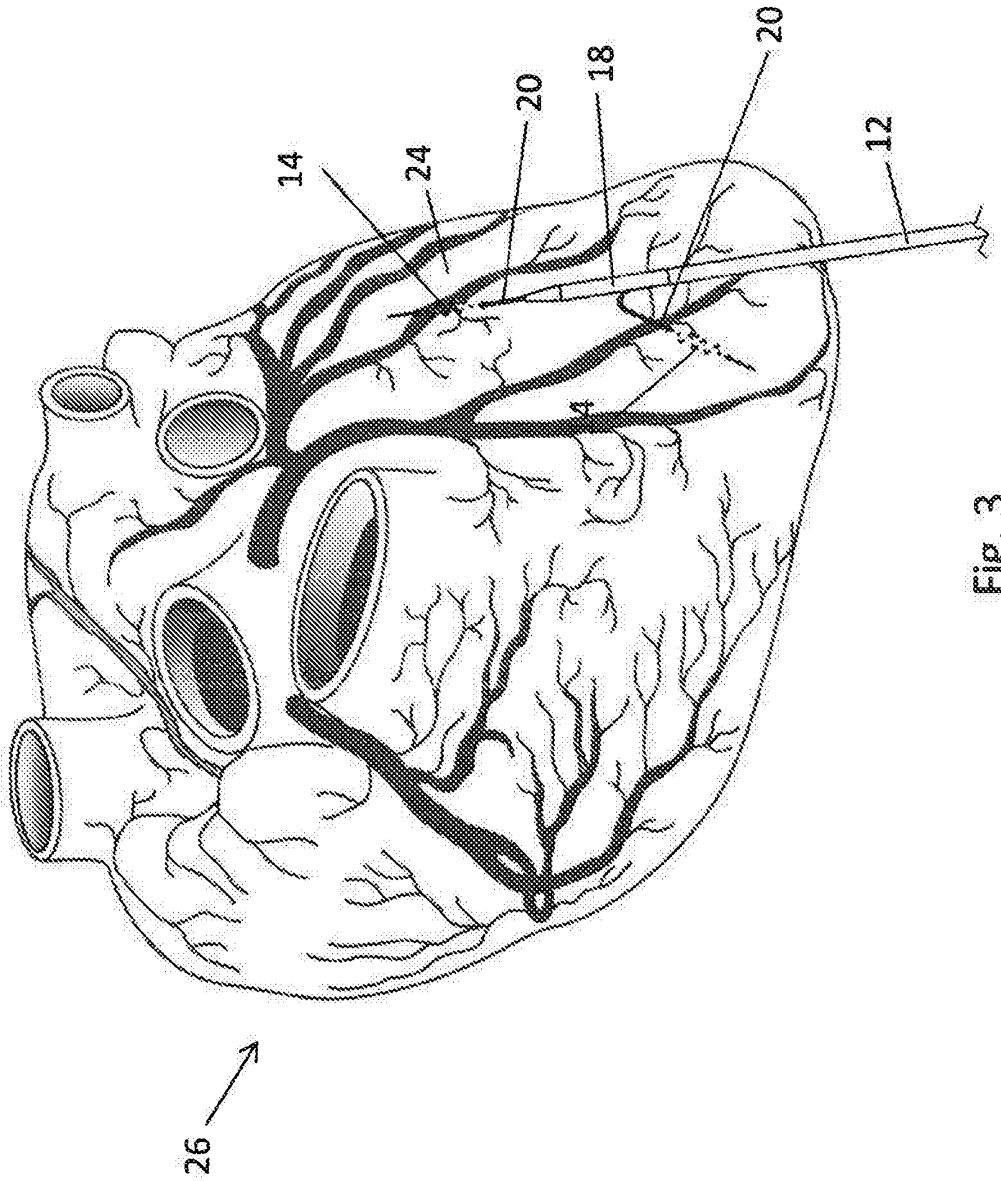

Fig. 3

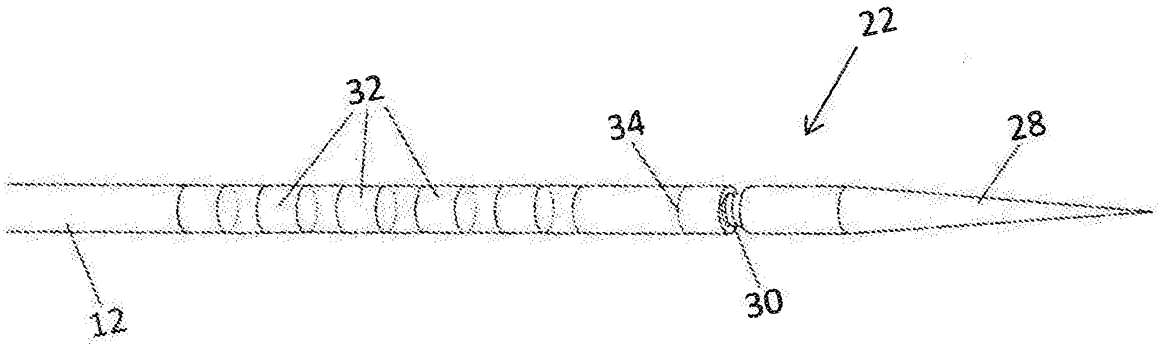

Fig. 4

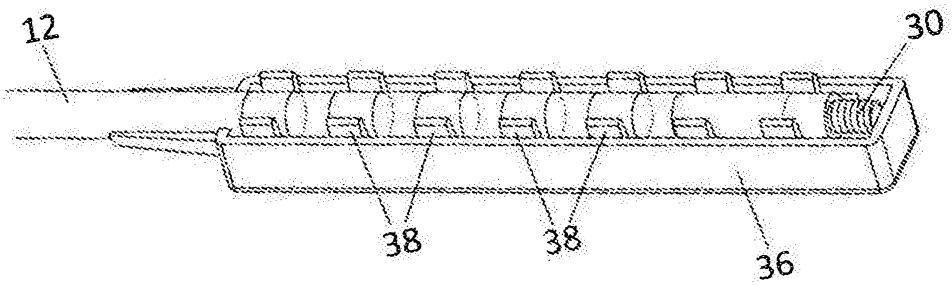

Fig. 5

SECURING A SENSOR AT THE HEART

The present invention relates to an apparatus and a method for securing a sensor at the heart and to a related system for monitoring the heart.

It is often desirable to monitor the functioning of the heart and/or medical devices related to the heart, such as pacemakers and cardiac assist devices. In the prior art various proposals have been made for ways to more effectively monitor a patient in this way. EP 1458290 describes a motion sensor for registering movements of the surface of the heart. The sensor in this case can be a three axis accelerometer. It is designed to be temporarily implanted for monitoring a patient's heart before, during and/or after a surgical operation, for example to monitor for ischemia. US 8282568 describes a system that uses data recorded by an accelerometer positioned on an outer surface of the heart for estimating changes in cardiac pumping capacity in response to an intervention. WO 2014/207225 describes the use of an accelerometer implanted at the heart or at a cardiac assist device such as an implanted pump. As set out in in WO 2014/207225, a motion sensor at the heart, such as an accelerometer, can be used to find information about the function of the cardiac assist device as well as information about the function of the heart.

Sensing the motion of the heart can be used in combination with or in place of conventional monitoring using ECG or other heart monitoring techniques and it is considered to provide advantages in relation to the accuracy of the information that is provided in relation to heart function. When the heart is monitored using a motion sensor such as an accelerometer it is necessary to secure the sensor at the heart. Typically this is done by a surgical procedure to implant the sensor. EP 1458290 suggests that an accelerometer may be temporarily affixed to the heart beneath the epicardium using surgical sutures or via a pacemaker lead.

Pacemaker leads have been known for some time, for example as described in WO 97/25099. Temporary pacemaker leads typically comprise a curved cardiac needle for hooking into the myocardium; an anchor connected to the cardiac needle and arranged to anchor the pacemaker lead in the myocardium; a pacemaker electrode connected to the anchor; a main lead connected to the pacemaker electrode; and a thorax needle at the end of the main lead. The cardiac needle is passed through the myocardium and then anchor is then pulled through the myocardium. The anchor retains the pacemaker electrode in the desired position in the myocardial tissue after the cardiac needle is removed. In WO 97/25099 the anchor is a helix (or 'pigtail') formed in a wire. It is also known to use other shapes within the wire, such as a zig-zag wire. Using a shape formed in a wire allows the anchor to easily connect to the curved needle via a continuation of the wire. The pacemaker electrode includes an exposed conductive material, such as platinum or similar, and this can be an extension of the wire of the anchor. The main lead is an insulated wire

for extending from the pacemaker electrode to the outside of the body where it can be electrically connected to a control apparatus, and the wire of the main lead can be a continuation of the wire of the anchor and the electrode in some cases. The thorax needle can be a straight or a curved needle and it is used for puncturing the chest wall from the inside so that the main lead can be pulled through. The thorax needle is removed after the pacemaker lead has been implanted, in order to allow connection to the control apparatus.

The invention of EP 1458290 provided a significant advance in the field of heart monitoring by allowing for an accelerometer to be directly located on the heart wall by means of a pacemaker type lead. Having an accelerometer small enough to be placed beneath the epicardium in a similar fashion to a pacemaker electrode allows for accurate monitoring of the heart using motion sensing to directly obtain measurements of heart movement. This can be implanted using relatively routine techniques that have been well-established for pacemaker leads.

Viewed from a first aspect, the invention provides an apparatus for securing a sensor at the heart, the apparatus comprising: a heart anchor lead having a single main lead; a first anchor coupled to the main lead and extending from a branch point; a second anchor coupled to the main lead and extending from the branch point; and a sensor fixed to the apparatus at a point between the main lead and one or both of the anchors.

This apparatus may be considered as using a modified, branched, pacemaker lead to provide a heart anchor lead where two anchors are coupled to a single main lead rather than there being just a single anchor. The heart anchor lead can hence take a branched form such as Y-shape or a T-shape. It has been found that with the use of a conventional pacemaker lead as in EP 1458290 then the sensor may twist during movement of the heart and/or during movement of the patient's body. The sensor may also slide or shift along the surface of the heart, for example in cases where the surgeon was unable to fully secure the sensor with the anchor of the pacemaker lead. Since the sensor of EP 1458290 is a motion sensor, such as an accelerometer, then movements of the sensor create inaccuracies and increased noise in the sensor readings. By adding a second anchor then the sensor can be more effectively held with minimal movement relative to the myocardium. This allows for better measurements of the movement of the heart, which in turn allows for better assessment of the function of the heart as well as the function of other sources of movement, such as a cardiac assist device that can generate vibrations and other movements at the heart.

The sensor may be a motion sensor and in example embodiments an accelerometer is used. Accelerometers are readily available with a sufficient level of accuracy and a required small size to be implanted at the heart. This could for example be a three-axis accelerometer for obtaining measurements of three dimensional heart

movements, although other types of accelerometer may also be used. Suitable sensors include MEMS tri-axis accelerometers and gyroscopes, for example.

The proposed apparatus may not have any pacemaker function and thus it may act purely as a heart anchor lead to hold the sensor at the heart. However, it is considered to provide advantages if the apparatus can both secure the sensor to the heart and also allow for one or two pacemaker electrodes to also be fixed to the myocardium. Thus, the heart anchor lead may be seen as a modified pacemaker lead with one or two pacemaker electrodes between the main lead and one or both of the anchors. In this case then one or both of the anchors may be coupled to the branch point by a wire that acts as a pacemaker electrode. This means that the pacemaker electrode is at the distal end of the lead, after the branch point, and where both branches of the lead have pacemaker electrodes then the two electrodes can be implanted into the heart at separate locations by pulling the branched structure of the apparatus open, such as in a Y-shape. Moreover, since pacing requires two electrodes through a bipolar pacemaker, or one pacemaker electrode and a further electrode somewhere else on the body, then by using both branches of the the heart anchor lead to also provide pacemaker electrodes then this provides the benefit of not requiring a second pacemaker lead, or a further electrode placed elsewhere.

The sensor is located between the main lead and one or both anchors. Typically the sensor will be close to the branch point, and it may be located at the branch point. The sensor may thus be located in a similar position between an anchor and the main lead to the pacemaker electrode in a conventional pacemaker lead. The sensor may be housed in a sensor body, which may for example be located at the branch point. In this way the main lead as well as the two anchors may be coupled to the sensor body. Advantageously, the sensor may be encapsulated within the sensor body, for example via a separate encapsulation surrounded by a wall of the body, or by an encapsulation that also forms the sensor body. The encapsulation of the sensor can serve to minimise the risk of exposure of the body to parts of the sensor that may be toxic and/or may react with body fluids, such as by corrosion. The encapsulation may use a material suitable for implantation within the body, such as medical grade silicone, polyethylene or stainless steel. In example embodiments the encapsulation encloses the sensor as well as electrical connections associated with the sensor and/or with the pacemaker electrodes (where present), such as an electrical circuit for connecting the sensor and/or with the pacemaker electrodes (where present) to electrical pathways through the main lead. The sensor body may provide for mechanical as well as electrical connectivity between the main lead, the sensor, and (where present) pacemaker electrodes. The sensor body may be insulating in order to avoid any electrical connection between pacemaker electrodes (where present).

It is preferred to have only relatively short distance between the branch point and the anchors, for example each anchor may be joined to the branch point by a straight wire

of 3-8 mm in length. Where a sensor body is used then the anchors may be joined to the sensor body by a straight wire of 3-8 mm in length. As will be appreciated from the discussion above, these straight wires may optionally include pacemaker electrodes.

The anchors may have a form similar to anchors of known temporary pacemaker leads. Thus, the anchors may be helical, pigtail or zig-zag wires. The anchors may comprise a wire made of an elastic material having a non-straight shape that will deform toward a straight shape when sufficient tension is applied to the anchor. This requirement can be provided by the pigtail or zig-zag wire. The non-straight shape retains the anchor in the myocardium when no large forces are applied. When it is desired to remove the anchor then tension is applied to straighten it out and allow it to be removed.

Whilst two anchors are described it will be understood that similar benefits in terms of the stability of the position of the sensor could be obtained by the use of more than two anchors. Thus, the apparatus may include more than two anchors. Additional anchors would require more steps during implantation of the heart anchor lead, but could allow for the sensor body to be located in some regions on the surface of the heart where there might be difficulties in stable placement with fewer anchors, for example regions with a large curvature and/or regions with a significant range of movement of the heart.

The apparatus may include cardiac needles joined to the first anchor and to the second anchor, such as curved cardiac needles as often used in relation to pacemaker leads. In example embodiments the cardiac needles are arranged to be used to implant the anchors into the tissue of the heart, for example into the myocardium. Thus, the anchors may be implanted in a similar way to implantation of anchors for known pacemaker leads. It will be appreciated that with the use of such cardiac needles then the apparatus would be supplied with the cardiac needles attached to the anchors, but that the cardiac needles may be removed after implantation of the anchors and thus during use to secure the sensor at the heart then the cardiac needles will not be present.

The cardiac needles can have a shape and form similar to cardiac needles used with known pacemaker leads. Thus, the cardiac needles may each be a curved needle with an arc shape of any suitable form for threading through the myocardium. Each cardiac needle may be coupled to the corresponding anchor by a wire or suture. As is known for pacemaker leads the apparatus may be arranged for the cardiac needles to be removed once the anchors are in place. The cardiac needles may for example be surgical stainless steel.

The main lead extends from the branch point, which may be a sensor body as discussed above, to a proximal end of the apparatus. In example embodiments the main lead includes electrical connections for the sensor such as power and data connections. Where the apparatus includes one or two pacemaker electrodes then the main lead may include further electrical connections for the pacemaker electrodes. Thus, in some

examples the main lead provides for a six-way connection. The main lead may be coupled to a thorax needle for piercing the chest wall. The thorax needle can be a straight or a curved needle of a type known for use to pierce the chest wall when a pacemaker is implanted. The thorax needle may for example be surgical stainless steel.

In example embodiments the main lead terminates with a connector for forming an electrical connection with an adaptor. For example, the main lead may comprise a plug or socket part for coupling with a corresponding socket or plug part of the adaptor. The electrical connection between the connector and adaptor should provide for electrical connectivity to suit the number of connections of the main lead. Thus, it may provide for a six-way connection or a higher number of terminals for an apparatus with additional functions. In one example the thorax needle has a removable tip such that the sharp point can be removed from the base of the thorax needle, and in this case the connector may be formed on the base of the thorax needle. Thus, the thorax needle may have a break-off tip or it may include a releasable connection between the base of the thorax needle and the tip, such as a screw fitting or a bayonet fitting. The connector may be formed as conductive rings around the base of the thorax needle, with the adaptor hence including a sequence of conductive terminals for alignment with and electrical connection to the conductive rings.

The main lead may be used for transmission of data and power for the sensor and optionally also for pacing signals sent to the pacemaker electrodes. As noted above there may be one or two pacemaker electrodes, and thus the heart anchor lead has the capability for pacing either via two polarities provided by two electrodes, or pacing via a single active electrode. In the latter case there may be a second pacemaker electrode that is normally inactive but that could be used to provide redundancy in case of failure of the first pacemaker electrode.

Advantageously, the adaptor may be arranged to split the pacemaker signal and the sensor signal. Thus, the adaptor may receive the connector of the main lead as an interface with the pacemaker electrodes and the sensor, with pacemaker signals and sensor signals in two separate input/output leads.

The sensor body may hold the sensor along with a circuit for electrical connections between the main lead, the sensor, and the pacemaker electrodes. The sensor body may be arranged to transmit tensile force from the main lead to the anchors, for example via the straight wires mentioned above, so that the anchors can be withdrawn from the myocardium.

Viewed from a second aspect, the invention provides a heart monitoring system comprising a sensor for monitoring motion of the heart, a heart anchor lead as discussed above for securing the sensor at the heart, and a data processing apparatus for receiving data from the sensor.

Thus, in example embodiments the invention extends to a combination of the heart anchor lead and sensor with a data processing apparatus for receiving data from the sensor. This may take the form of a system whilst in use, where the heart anchor lead and sensor are implanted in the body and the main lead extends out of the body to provide data to the data processing apparatus. In this case the heart anchor lead would have the cardiac needles removed. The system may also take the form of a kit of parts ready to be used with a patient, in which case the heart anchor lead will be in the form prior to implantation and hence may have cardiac needles and/or a thorax needle coupled to the anchors and/or to the main lead, and the data processing apparatus may not yet be coupled to the heart anchor lead. The system may include a connector and adaptor as described above, with the connector being provided at a proximal end of the main lead and the adaptor being in communication with the data processing apparatus.

The data processing apparatus may be a computer or similar device. It may include a power supply for providing power to the sensor via the main lead. In examples where the heart anchor lead also includes a pacemaker electrode then the data processing apparatus may optionally have the function of controlling a pacing signal for the pacemaker electrode. If the data processing apparatus has access to the pacing signal then this may be used to synchronise measurements of heart motion with the heart rhythm. Alternatively there may be a separate controller for pacemaking, in which case the system may include an adaptor as discussed above in which the pacemaking signal is split from the sensor signal. The data processing apparatus may receive an ECG signal from the patient and may be arranged to use the ECG signal to synchronise the measurements of heart motion with the heart rhythm.

The data processing apparatus may thus have access to heart motion data and optionally also pacing data and it may be arranged to provide information to an operator relating to this data. The data processing apparatus may record the data, and it may process the data in order to provide improved information to the operator. For example, the sensor may be motion sensor such as a three axis accelerometer and the data processing apparatus may process the data from the motion sensor in order to provide a representation of the movement of the heart. The data processing apparatus may provide outputs relating to heart rate, the magnitude of movement, and so on. It may provide data about heart function as discussed in EP 1458290, for example. Optionally the data processing apparatus may also identify other features of the motion sensor data, such as movements resulting from activities of the patient and/or motion induced by other devices, for example a cardiac assist device. Thus, it may provide data about function of a cardiac assist device as discussed in WO 2014/207225, for example.

The data processing apparatus may have the primary function of obtaining and processing information about the motion of the heart. This may be the only function of the

data processing apparatus, with control for any pacemaking being carried out through another device. In other examples the data processing apparatus may also control pacing of the heart. In this case then the data received from the sensor, for example data about motion of the heart, may be used in relation to control of the pacing signal. Thus, there may be a feedback mechanism between the pacing signal and the motion of the heart.

The invention also extends to the use of the apparatus of the first aspect, which may include the use of the apparatus within the heart monitoring system of the second aspect. In addition, methods of implantation of the heart anchor lead are encompassed by this invention. Thus, viewed from a further aspect the invention provides a method for securing a sensor at the heart, the method comprising using the heart anchor lead of the first aspect. Optionally this method may include implanting the anchors at the heart and thereby securing the sensor at the heart. The sensor may for example be secured at the left ventricle of the heart. In some examples the apparatus includes a connector as discussed above and the method comprises coupling this connector to an adaptor of a data processing apparatus to form a heart monitoring system as discussed above. The connector may be formed as a part of the base of a thorax needle as discussed above, and thus the method may include passing the thorax needle through the chest wall, removing a tip of the thorax needle, and coupling the connector at the base of the thorax needle to an adaptor.

A yet further aspect involves the use of the sensor for monitoring the heart, wherein the sensor is implanted with the heart anchor lead of the first aspect. This method may include receiving data from the sensor and using it to determine information about heart function and/or about other aspects of the patient's health, optionally including the function of other devices such as a cardiac assist device. The method may include using pacemaker electrodes of the apparatus as discussed above. In this case the method may optionally use data from the sensor in relation to the control of pacing via the pacemaker electrodes.

Certain preferred embodiments of the present invention will now be described in greater detail, by way of example only and with reference to the accompanying drawings, in which:

Figure 1 shows a heart anchor lead for securing a sensor to the heart;

Figure 2 illustrates an anchor of the heart anchor lead being implanted into the myocardium using a curved needle;

Figure 3 shows the heart anchor lead of Figure 1 secured to the heart;

Figure 4 shows detail of a connector at a proximal end of the lead; and

Figure 5 shows the connector of Figure 4 coupled to an adaptor.

The heart anchor lead of Figure 1 is intended for securing a sensor to the heart, and in particular can be used to temporarily secure a motion sensor such as an accelerometer

at the outside surface of the heart. This sensor can be used to obtain measurements that may be used for information about heart function and/or information about related devices, for example as described in EP 1458290 and WO 2014/207225. The sensor is temporarily implanted at the heart to monitor the patient, for example before, during and/or after a surgical operation, and it is removed from the patient after use. Thus, the sensor may be used to monitor the patient's health in relation to a surgical operation, and then it may be removed after the recovery of the patient has progressed sufficiently.

As seen in Figure 1 the heart anchor lead has some similar structural features to a temporary pacemaker lead, such as a pacemaker lead of the type shown in WO 97/25099, but it is modified compared to a conventional pacemaker lead by the use of a single main lead 12 and two anchors 14 with correspondingly two curved cardiac needles 16 for implantation of the anchors. The anchor sections branch from the main lead 12 at a branch point 18 in the form of a sensor body 18. The sensor body 18 encloses the sensor, which in this example is an accelerometer. The sensor is encapsulated in a material suitable for implantation into the body, such as a bio-safe plastic material.

The heart anchor lead can advantageously also function as a pacemaker and thus in each branch a pacemaker electrode 20 is provided at the proximal end of the anchor 14. Implantation of the two anchors 14 will hence both secure the sensor body 18 and also implant the pacemaker electrodes 20, and this can be done using the curved cardiac needles 16 in the same way as for a conventional pacemaker lead as described below with reference to Figure 2. Figure 1 also shows a straight thorax needle 22 for piercing the chest wall so that the main lead 12 can be passed through the chest wall. Again this can be used in a similar fashion to the corresponding parts of a pacemaker lead. A curved thorax needle could also be used.

Figure 2 shows a close up of a section of the myocardium 24 in a location where it is desired to secure the sensor body 18 and implant a pacemaker electrode 20. This Figure shows one branch of the two branches of the heart anchor lead described above in relation to Figure 1. As is known from implantation of pacemaker leads, the curved cardiac needle 16 is threaded through the tissue of the myocardium 24 and in particular it is passed through the outer part of the myocardium 24 without piercing the heart 26. The curved cardiac needle 16 is used to pull the anchor 14 into the myocardium 24 so that the pacemaker electrode 20 is brought into conductive contact with the tissue of myocardium 24. As will be seen from Figure 1 the pacemaker electrode 20 joins the anchor 14 to the sensor body 18, so this also serves to attach the sensor body 18 to the outer surface of the myocardium 24. When the anchor 14 is in place then the cardiac needle 16 can be removed, typically by simply cutting the wire or suture that joins the cardiac needle 16 to the anchor 14. It will be appreciated that the form of the cardiac needle 16 and the form of the anchor 14 could be varied as desired. In Figures 1-3 they are shown as a curved

cardiac needle 16 with an arc shape and an anchor 14 formed as a zig-zag wire with a concertina type fold. The cardiac needle 16 may instead have a curve with varying curvature such as that shown in WO 97/25099. The anchor 14 could take the form of a pigtail or spiral rather than a zig-zag.

Figure 3 shows one configuration for the two anchors 14 after implantation in the myocardium with the sensor body 18 secured in the tissue of the myocardium 24 at the side wall of the heart 26. The sensor body 18 is fixed to the left ventricle. By securing the sensor body 18 and hence the sensor using two anchors 14 then the movement of the sensor is reduced compared to the use of a conventional pacemaker lead with a single anchor 14 as proposed in EP 1458290. The movement of the sensor body 18 relative to the heart 26 is restricted both in terms of unwanted twisting motion along the axis of the main lead 12 and anchor 14 and unwanted sliding of the sensor body 18 across the surface of the heart 26. It will be appreciated that the surgeon can decide the best locations for the two anchors 14, the sensor body 18, and the two pacemaker electrodes 20. The exact placement of the heart anchor lead will depend on the circumstances. However, having multiple anchor points rather than just one anchor point will always improve the stability of the sensor body 18 and hence restrict unwanted motion of the sensor relative to the heart 26. It can also allow for placement of the sensor body 18 in locations on the heart 26 that might be difficult to achieve with only a single anchor 14.

Figure 3 also shows the main lead 12 extending away from the sensor body 18 and the pacemaker electrodes 20. This lead 12 provides electrical connections to a point outside of the body, and as noted above it can be passed through the chest wall using the straight needle 22. The main lead 12 differs from a conventional pacemaker lead in relation to the number of electrical connections since it is necessary to provide for connection of the sensor (e.g. an accelerometer) as well as two pacemaker electrodes 20. Both data and power are transmitted along the main lead 12. Typically it will provide for a six-way connection between the sensor body 18 and the proximal end of the main lead 12, but it will be appreciate that a greater or smaller number of connections could be used depending on the requirements of the sensor and so on. An electrical circuit may be provided at the distal end of the main lead 12 for interconnection of the main lead with the pacemaker electrodes and the sensor. This electrical circuit may be encapsulated along with the sensor and placed within the sensor body 18.

The electrical connections of the main lead 12 can be coupled to an external data processing apparatus such as a computer system (not shown). In one example, as shown in Figures 4 and 5, in order for a suitable electrical coupling to be made outside of the body then the heart anchor lead is arranged with a connector at the base of the straight needle 22 for joining to an adaptor 36 outside of the body. This example uses a simple mechanical coupling to bring electrical terminals 32, 34 at the base of the straight needle

22 into electrical contact with terminals 38 in the adaptor 36. This can allow for a straightforward connection of the sensor body 18 to a data processing apparatus outside of the body without a simple 'snap-fit'. The adaptor 36 may be arranged to split the signals from the sensor from the pacing signals so that a separate controller can be used for pacemaking.

As shown in Figure 4 the thorax needle 22 in this example is a straight needle 22 and it has a removable tip 28. The sharp tip 28 allows the thorax needle 22 to pierce the chest wall. After this it can be removed using a releasable connection 30 between the base of the thorax needle 22 and the tip 28. In this example the releasable connection 30 is shown as a screw thread 30, but it will be appreciated that alternative arrangements may be used, such as a break-off tip 28 or a bayonet fitting. The base of the thorax needle 22 forms an electrical connector with five smaller ring-shaped terminals 32 for data signals including pacemaking signals and the sensor output signals, and one larger ring shaped terminal 34 for carrying a supply voltage. The adaptor 36, which is shown in Figure 5 joined with the base of the thorax needle 22, has sprung clips 38 for mechanical and electrical connection to the ring-shaped terminals 32, 34 on the base of the thorax needle 22. The adaptor 36 further includes wiring (not shown) for connection to an external data processing apparatus for transmission of control signals and power to the heart anchor lead via the main lead 12, and for receiving sensor data from the sensor held within the sensor body 18.

CLAIMS:

1. An apparatus for securing a sensor at the heart, the apparatus comprising: a heart anchor lead having a single main lead; a first anchor coupled to the main lead and extending from a branch point; a second anchor coupled to the main lead and extending from the branch point; and a sensor fixed to the apparatus at a point between the main lead and one or both of the anchors.

2. An apparatus as claimed in claim 1, wherein the sensor is a motion sensor for detecting motion of the heart and in example embodiments an accelerometer is used.

3. An apparatus as claimed in claim 1 or 2, wherein the apparatus can both secure the sensor to the heart and also includes at least one pacemaker electrode.

4. An apparatus as claimed in claim 3, wherein one or both of the anchors is coupled to the branch point by a pacemaker electrode.

5. An apparatus as claimed in any preceding, wherein the sensor is located in a sensor body at the branch point.

6. An apparatus as claimed in claim 5, wherein the main lead as well as the two anchors are coupled to the sensor body.

7. An apparatus as claimed in any preceding claim, wherein each anchor comprises a wire made of an elastic material, the wire having a non-straight shape that will deform toward a straight shape when sufficient tension is applied to the anchor.

8. An apparatus as claimed in any preceding claim, comprising a cardiac needle joined to the first anchor and a cardiac needle joined to the second anchor, wherein the cardiac needles are arranged to be used to implant the anchors into the tissue of the heart.

9. An apparatus as claimed in any preceding claim, wherein the main lead extends from the branch point to a proximal end of the apparatus and the main lead includes electrical connections for the sensor such as power and data connections.

10. An apparatus as claimed in any preceding claim, where the main lead provides for a six-way electrical connection.

11. An apparatus as claimed in any preceding claim, wherein the main lead is coupled to a thorax needle for piercing the chest wall.

12. An apparatus as claimed in any preceding claim, wherein the main lead terminates with a connector for forming an electrical connection with an adaptor.

13. An apparatus as claimed in claim 12, wherein the connector comprises a plug or socket part for coupling with a corresponding socket or plug part of the adaptor, and wherein the electrical connection between the connector and adaptor provide for electrical connectivity to suit the number of connections of the main lead.

14. An apparatus as claimed in claim 12 or 13, wherein the main lead is coupled to a thorax needle for piercing the chest wall and the thorax needle has a base and a removable tip, and wherein the base includes the connector.

15. An apparatus as claimed in claim 14, wherein the connector is formed as conductive rings around the base of the thorax needle and it is arranged to be coupled to an adaptor that includes a sequence of conductive terminals for alignment with and electrical connection to the conductive rings.

16. A heart monitoring system comprising: a heart anchor lead and a sensor as claimed in any preceding claim and a data processing apparatus for receiving data from the sensor.

17. A heart monitoring system as claimed in claim 16, including a connector and adaptor as claimed in any of claims 12 to 15, wherein the connector is provided at a proximal end of the main lead and the adaptor is in communication with the data processing apparatus.

18. A heart monitoring system as claimed in claim 16 or 17, wherein the heart anchor lead includes at least one pacemaker electrode and the data processing apparatus has the function of controlling a pacing signal for the pacemaker electrode.

19. A heart monitoring system as claimed in claim 16, 17 or 18, wherein the data processing apparatus has access to heart motion data and optionally also to pacing data and it is arranged to provide information to an operator relating to this data.

20. A heart monitoring system as claimed in claim 19, wherein the data processing apparatus provides data about heart function.

21. A heart monitoring system as claimed in claim 19 or 20, wherein the data processing apparatus identifies other features of the motion sensor data, including movements resulting from activities of the patient and/or motion induced by other devices, for example a cardiac assist device.

22. A method for securing a sensor at the heart, the method comprising using the apparatus of any of claims 1 to 15 and implanting the anchors at the heart to thereby secure the sensor at the heart.

23. A method as claimed in claim 22, wherein the apparatus includes a connector as claimed in any of claim 12 to 15 and the method comprises coupling this connector to an adaptor of a data processing apparatus to form a heart monitoring system as claimed in any of claims 16 to 20.

24. A method as claimed in claim 23, wherein the connector is formed as a part of the base of a thorax needle as claimed in claim 14 or 15, and the method includes passing the thorax needle through the chest wall, removing the tip of the thorax needle, and coupling the connector at the base of the straight needle to the adaptor.

Amendment to Claims have been filed as follows

CLAIMS:

1. An apparatus for securing a sensor at the heart, the apparatus comprising: a heart anchor lead having a single main lead; a first anchor coupled to the main lead and extending from a branch point; a second anchor coupled to the main lead and extending from the branch point; and a sensor fixed to the apparatus at a point between the main lead and one or both of the anchors; wherein the sensor is a motion sensor for detecting motion of the heart.

2. An apparatus as claimed in claim 1, wherein the motion sensor is an accelerometer.

3. An apparatus as claimed in claim 1 or 2, wherein the apparatus also includes at least one pacemaker electrode.

4. An apparatus as claimed in claim 3, wherein one or both of the anchors is coupled to the branch point by a pacemaker electrode.

5. An apparatus as claimed in any preceding claim, wherein the sensor is located in a sensor body at the branch point.

6. An apparatus as claimed in claim 5, wherein the main lead as well as the two anchors are coupled to the sensor body.

7. An apparatus as claimed in any preceding claim, wherein each anchor comprises a wire made of an elastic material, the wire having a non-straight shape that will deform toward a straight shape when sufficient tension is applied to the anchor.

8. An apparatus as claimed in any preceding claim, comprising a cardiac needle joined to the first anchor and a cardiac needle joined to the second anchor, wherein the cardiac needles are arranged to be used to implant the anchors into the tissue of the heart.

9. An apparatus as claimed in any preceding claim, wherein the main lead extends from the branch point to a proximal end of the apparatus and the main lead includes electrical connections for the sensor such as power and data connections.

10. An apparatus as claimed in any preceding claim, where the main lead provides for a six-way electrical connection.

11. An apparatus as claimed in any preceding claim, wherein the main lead is coupled to a thorax needle for piercing the chest wall.

12. An apparatus as claimed in any preceding claim, wherein the main lead terminates with a connector for forming an electrical connection with an adaptor.

13. An apparatus as claimed in claim 12, wherein the connector comprises a plug or socket part for coupling with a corresponding socket or plug part of the adaptor, and wherein the electrical connection between the connector and adaptor provide for electrical connectivity to suit the number of connections of the main lead.

14. An apparatus as claimed in claim 12 or 13, wherein the main lead is coupled to a thorax needle for piercing the chest wall and the thorax needle has a base and a removable tip, and wherein the base includes the connector.

15. An apparatus as claimed in claim 14, wherein the connector is formed as conductive rings around the base of the thorax needle and it is arranged to be coupled to an adaptor that includes a sequence of conductive terminals for alignment with and electrical connection to the conductive rings.

16. A heart monitoring system comprising: a heart anchor lead and a sensor as claimed in any preceding claim and a data processing apparatus for receiving data from the sensor.

17. A heart monitoring system as claimed in claim 16, including a connector and adaptor as claimed in any of claims 12 to 15, wherein the connector is provided at a proximal end of the main lead and the adaptor is in communication with the data processing apparatus.

18. A heart monitoring system as claimed in claim 16 or 17, wherein the heart anchor lead includes at least one pacemaker electrode and the data processing apparatus has the function of controlling a pacing signal for the pacemaker electrode.

19. A heart monitoring system as claimed in claim 16, 17 or 18, wherein the data processing apparatus has access to heart motion data and optionally also to pacing data and it is arranged to provide information to an operator relating to this data.

20. A heart monitoring system as claimed in claim 19, wherein the data processing apparatus provides data about heart function.

21. A heart monitoring system as claimed in claim 19 or 20, wherein the data processing apparatus identifies other features of the motion sensor data, including movements resulting from activities of the patient and/or motion induced by other devices, for example a cardiac assist device.

Intellectual Property Office

Application No:	GB1709621.5	**Examiner:**	Mr Richard Nicholls
Claims searched:	1-24	**Date of search:**	15 December 2017

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-	US2014/243593 A (ENDOSTIM) see especially figure 1A
A	-	EP0211166 A (OSYPKA) see especially figures 1 and 2
A	-	US2003/105496 A (CARDIAC PACEMAKERS) see especially figure 3

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61N

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI

International Classification:

Subclass	Subgroup	Valid From
A61N	0001/05	01/01/2006
A61B	0017/04	01/01/2006
A61N	0001/362	01/01/2006
A61N	0001/365	01/01/2006