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(54) DETECTION OF IMPLANTED INJECTION PORT

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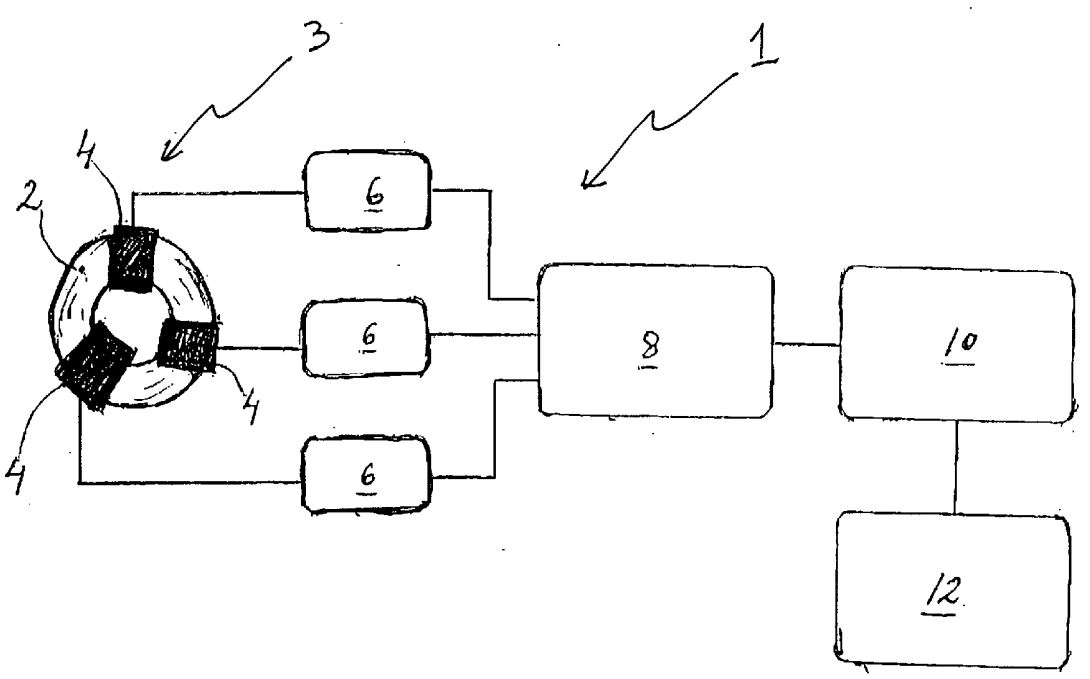
(57) ABSTRACT

An apparatus is disclosed for detecting an injection port subcutaneously implanted in a patient's body to enable accurate positioning of an injection needle outside the patient's body to enable the injection needle to be injected directly into the injection port. Also disclosed is a method for detecting the injection port whereby an injection needle can be positioned to be injected directly into the injection port. The apparatus includes a magnetic device that is subcutaneously implanted in the patient adjacent to the injection port to emit a local magnetic field through the patient's skin adjacent to the injection port. A magnetic detector movable externally along the patient's body is capable of detecting the local magnetic field emitted by the magnetic device. This allows the injection port to be located for the insertion of the injection needle directly into the injection port. Alternatively, the apparatus can include a magnetic detector subcutaneously implanted in the patient by the injection port and an exterior magnetic device movable along the patient's skin to emit a magnetic field that is detected by the implanted magnetic detector. Preferably, the magnetic detector includes a semiconductor circuit that is comprised of at least one Hall element. The magnetic device may be a solenoid or a permanent magnet. The injection port can be used to control a restriction device implant designed for treating reflux disease, urinary incontinence, impotence, anal incontinence or obesity.



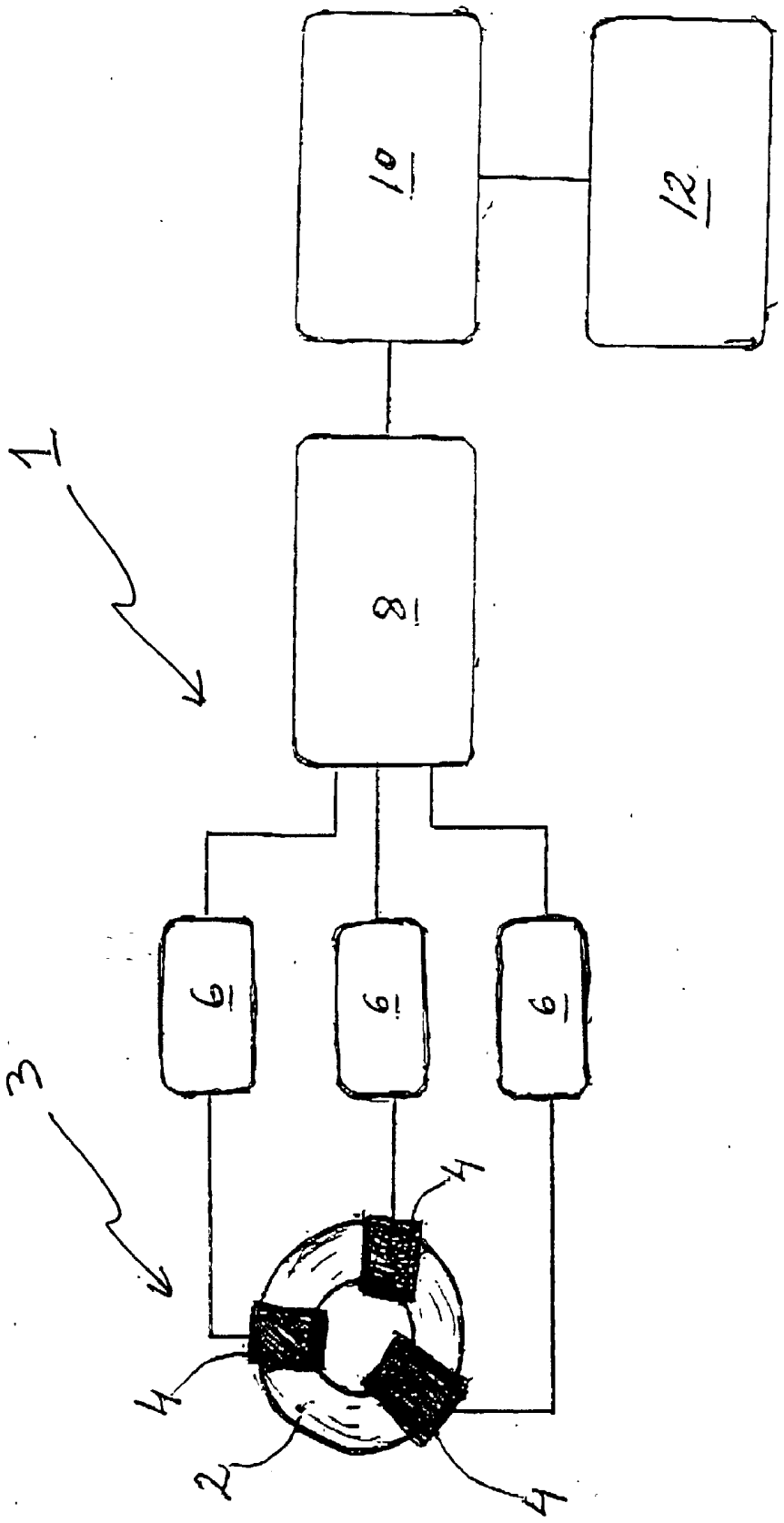


FIG. 1

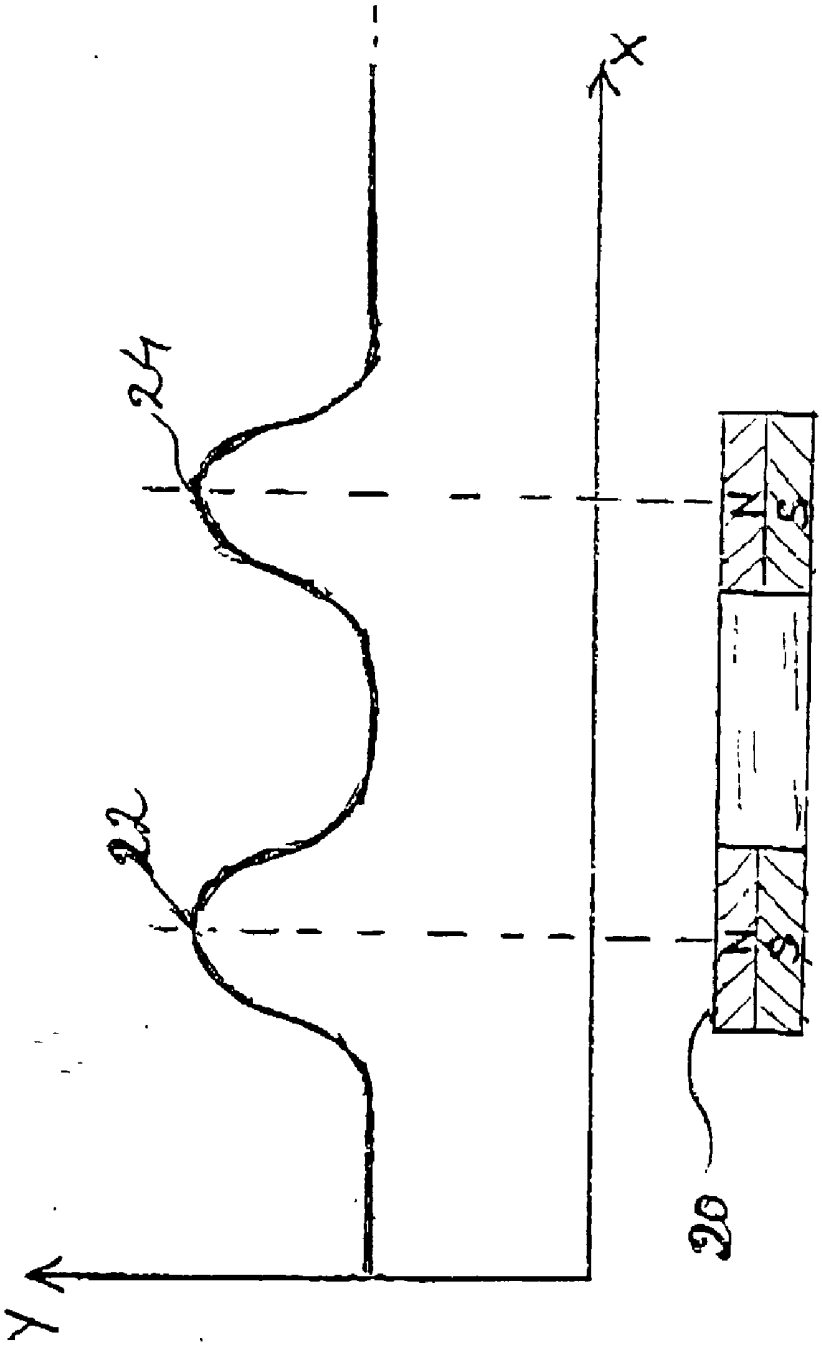


FIG. 2

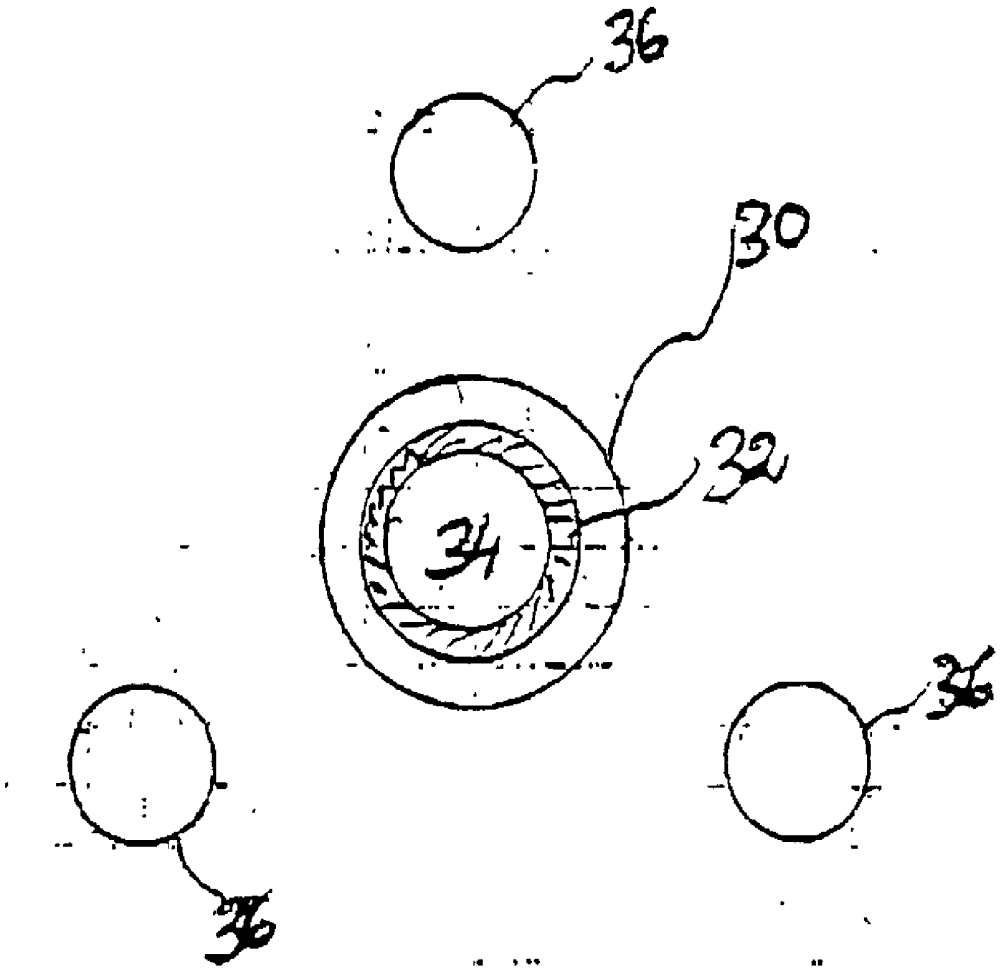


FIG. 3

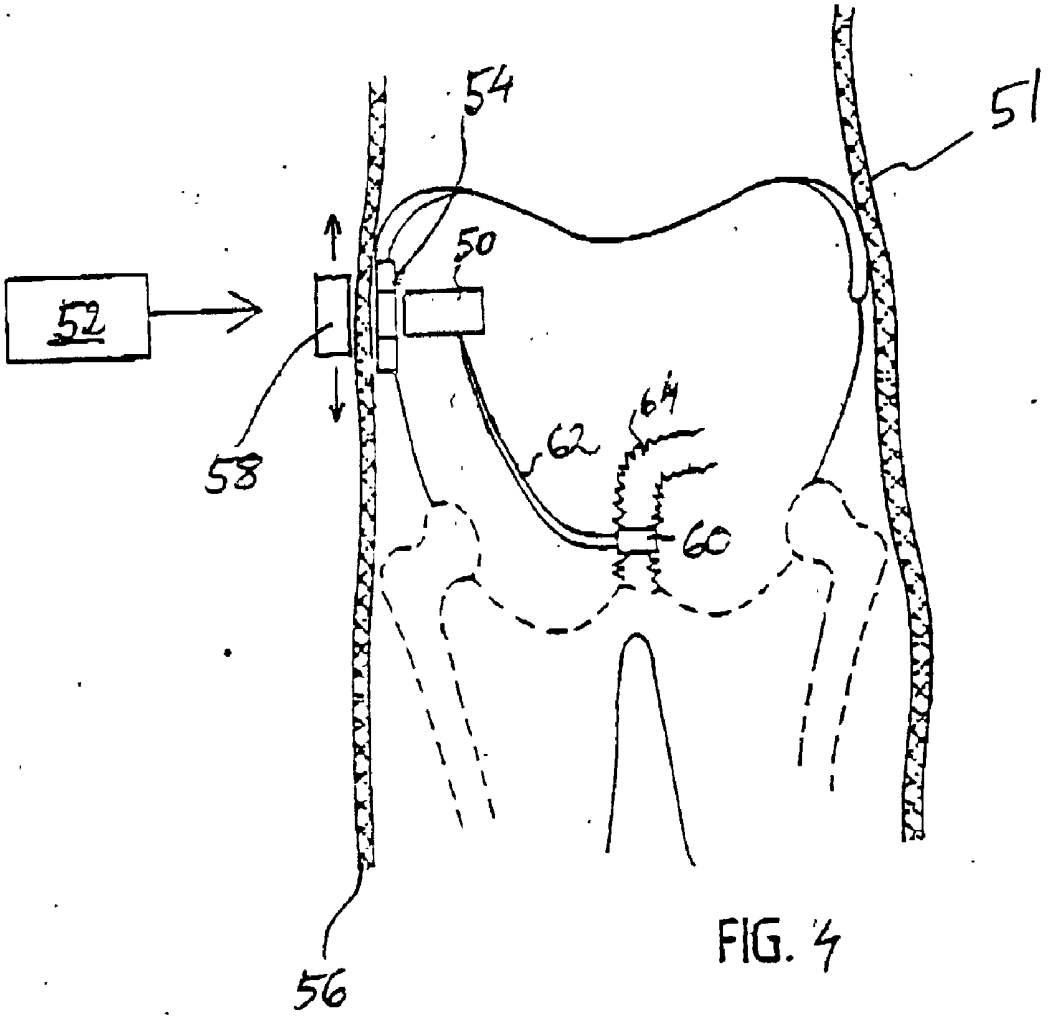


FIG. 4

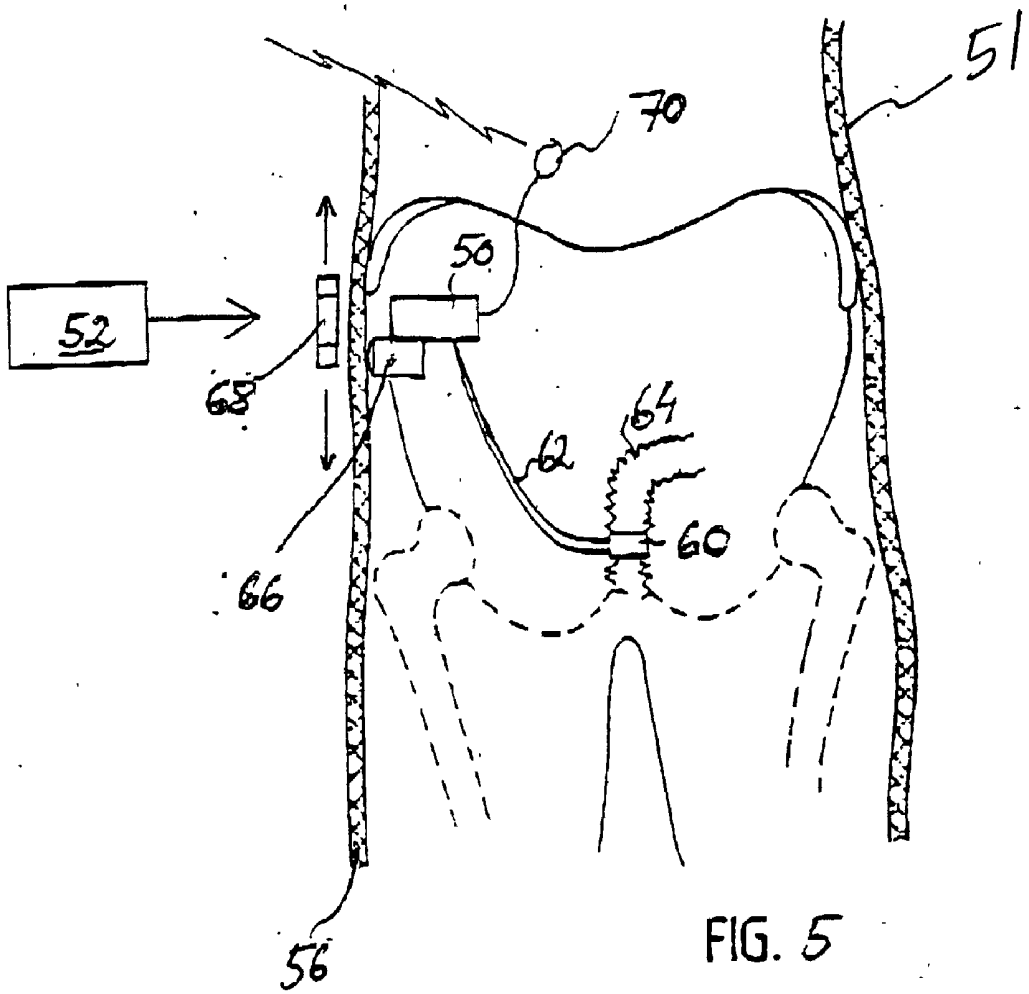


FIG. 5

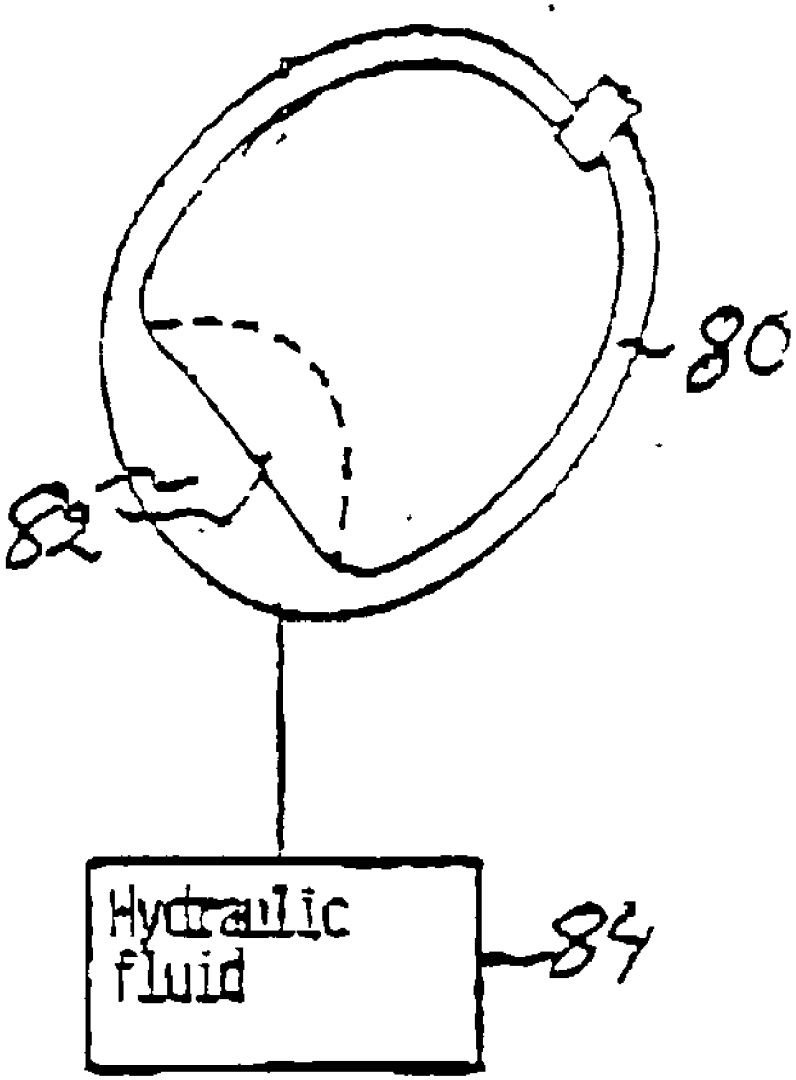


FIG. 6

DETECTION OF IMPLANTED INJECTION PORT

FIELD OF THE INVENTION

[0001] The present invention relates to an apparatus and methods for detecting an injection port subcutaneously implanted in a patient. The present invention also relates to surgical methods for treating a patient having a disease by using the apparatus.

BACKGROUND

[0002] It is important to locate the position of an injection port connected to a hydraulically operable surgical implant in a patient to be able to accurately inject a needle of a syringe through the membrane of the injection port (or simply for the purpose of locating the exact position of the injection port, or alternatively locating the membrane of the injection port), for supplying hydraulic fluid to or withdrawing hydraulic fluid from the implant.

[0003] In the prior art, for the specific purpose of locating an injection port, a technique has been used to detect the injection port by using magnetism induced by a solenoid. More particularly, a rotating solenoid is rotated in different positions to locate the injection port. This technique has clear disadvantages such as the very large size of the apparatus used and the relatively insensitive way of locating the magnetic field.

SUMMARY OF THE INVENTION

[0004] An object of the present invention is to provide an inexpensive apparatus and methods for accurately detecting an injection port subcutaneously implanted in a patient to enable an injection needle to penetrate the patient's skin directly into the injection port. Another object of the present invention is to provide surgical methods for treating diseases by using the apparatus.

[0005] In accordance with a first aspect of the present invention, there is provided an apparatus for detecting an injection port subcutaneously implanted in a patient comprised of a magnetic device designed to be subcutaneously implanted in the patient at the injection port for emitting a local magnetic field extending through the injection port and a portion of the patient's skin adjacent to the injection port, and a magnetic detector movable externally along the patient's body and capable of detecting the local magnetic field emitted by the magnetic device when the magnetic detector is positioned in front of the implanted injection port, the magnetic detector including a semiconductor circuit. Thus, the accurate position on the patient's skin in front of the injection port, which is hidden behind the skin, can be established using the apparatus of the present invention. With an injection needle placed in this position, it is an easy task to properly insert the injection needle through the patient's skin directly into the injection port.

[0006] Alternatively, the apparatus is comprised of a magnetic detector designed to be subcutaneously implanted in the patient at the injection port, the magnetic detector including a semiconductor circuit, an exterior magnetic device movable along the patient's skin and adapted to emit a local magnetic field through the patient's skin, the magnetic detector being capable of detecting the local magnetic field when the movable magnetic device is moved to a position in front of the implanted injection port, whereby an injection needle placed in this position is able to be inserted through the patient's skin directly into the injection port.

[0007] Thus, according to the present invention a new and easy way of detecting the position of an injection port subcutaneously implanted in a patient is provided, which enables accurate positioning of a needle or the like outside the patient's body for safe and accurate injection (contact with the membrane) in the injection port, by using magnetism and a semiconductor circuit. The injection port is arranged in connection (via a conduit) to an implant, for example a food intake restriction apparatus, implanted inside the human body. The method according to the present invention provides a very sensitive way of locating the magnetic field which is a necessity in obese people.

[0008] Alternatively, where the magnetic detector is to be implanted in the patient, a sender capable of sending information about the magnetic detector detecting the local magnetic field may be implanted in the patient.

[0009] Preferably, the magnetic detector includes a semiconductor circuit. According to a preferred embodiment of the present invention, the semiconductor circuit of the magnetic detector is comprised of at least one Hall-element. By using one or more Hall-elements, which is a special type of semiconductor known in the art, it is easy to locate the central axis of the emitted magnetic field. The magnetic detector suitably is comprised of several Hall-elements which are grouped around a central point in a triangular or square configuration. One important feature is that the Hall-elements are able to detect even a weak magnetic field emitted from the magnetic device. The described detection technique is simple, inexpensive and very accurate, and could be used for several different implants in combination with injection ports.

[0010] The magnetic device may be a solenoid or a permanent magnet, which is sending out a magnetic field. If the magnetic device is placed outside the body, the magnetic detector placed inside the body should preferably also be capable of sending information about the position of the magnetic device, directly or indirectly correlated to the intensity of magnetism to outside the body.

[0011] Conveniently, the location of the injection port, subcutaneously implanted in a patient, may be visualised on a screen, by sound or by diodes.

[0012] In accordance with a second aspect of the present invention, there is provided a method for detecting an injection port subcutaneously implanted in a patient, the method comprising the steps of: implanting a magnetic device subcutaneously in the patient at the injection port so that the magnetic device emits a local magnetic field extending through the injection port and the adjacent skin portion of the patient; and moving an exterior magnetic detector along the patient's skin to a position in which the local magnetic field emitted by the implanted magnetic device is detected by the magnetic detector. Then, an injection needle can be placed in the position where the local magnetic field has been detected to efficiently insert the needle through the patient's skin directly into the injection port.

[0013] Alternatively, the method may comprise the steps of: implanting a magnetic detector subcutaneously in the patient at the injection port; moving an exterior magnetic

device along the patient's skin while it emits a local magnetic field extending through the adjacent skin portion; and using the implanted magnetic detector to detect the local magnetic field when the magnetic device is moved to a position in which the local magnetic field extends through the implanted magnetic detector and injection port.

[0014] This alternative method may further comprise implanting a sender and using the sender to send information to outside the patient's body confirming when the implanted magnetic detector detects the local magnetic field emitted by the exterior magnetic device.

[0015] In accordance with a third aspect of the present invention, there is provided a surgical method for treating a patient having a disease, comprising the steps of: insufflating the patient's abdomen with gas; implanting a hydraulically operable implant designed for treating reflux disease, urinary incontinence, impotence, anal incontinence or obesity in the abdomen by using surgical instruments through the trocars; subcutaneously implanting an injection port for supplying hydraulic fluid for the operation of the implant and a magnetic device at the injection port for emitting a local magnetic field through the injection port and the adjacent skin portion of the patient; post-operatively moving an exterior magnetic detector along the patient's body to a position in which the local magnetic field emitted by the implanted magnetic device is detected by the magnetic detector; bringing an injection needle to the position in which the local magnetic field is detected; and moving the injection needle to penetrate the patient's skin into the injection port for supplying hydraulic fluid to or withdrawing hydraulic fluid from the injection port.

[0016] Alternatively, the surgical method may comprise subcutaneously implanting a magnetic detector at the injection port and post-operatively moving an exterior magnetic device emitting a local magnetic field along the patient's body to a position in which the local magnetic field emitted by the exterior magnetic device is detected by the implanted magnetic detector.

[0017] The above described apparatuses and methods may also be designed for treating reflux disease, urinary incontinence, anal incontinence, obesity and impotence.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] **FIG. 1** shows a connection diagram for a magnetic detector according to one aspect of the present invention.

[0019] **FIG. 2** schematically illustrates in a diagram the position relative to the magnet as a function of the sensor (i.e. detector) according to the present invention.

[0020] **FIG. 3** illustrates an embodiment according to the present invention using several Hall-elements as the magnetic detecting device.

[0021] **FIG. 4** is a schematic view of an embodiment where a magnetic device is subcutaneously implanted in the patient, and a magnetic detector movable externally along the patient's body.

[0022] **FIG. 5** is a schematic view of an embodiment where a magnetic detector is subcutaneously implanted in the patient and an exterior magnetic device is movable along the patient's skin.

[0023] **FIG. 6** is a schematic view of a band with a cavity defining a restriction opening for use in accordance with the invention, designed for treating reflux disease, urinary incontinence, anal incontinence or obesity.

DETAILED DESCRIPTION OF THE INVENTION

[0024] **FIG. 1** shows a connection circuit **1** for a magnetic detector **3** according to the present invention. A magnetic device implanted inside a human body is a ring-magnet **2**, which can be a solenoid or a permanent magnet. Located outside the body is magnetic detector **3**, which is comprised of three linear magnetic field sensors **4** (such as Hall-elements or the like) grouped in a triangular configuration. Sensors **4** are connected to signal-conditioning amplifiers **6**, which, in turn, is connected to an A/D-converter **8**. A microprocessor **10** is then connected to A/D-converter **8**. To visually display the sensor output signals of sensors **4**, a display-device **12** is then connected to microprocessor **10**.

[0025] The graph shown in **FIG. 2** illustrates in principle how the information obtained by detector **3** can be presented. On the X-axis in the graph is the position of detector **3** relative to magnet **2**. On the Y-axis is the combined output of sensors **4**. Thus, the graph of **FIG. 2** shows the position "X" of detector **3** relative to magnet **2** as a function of the sensor (i.e. detector) output "Y". To illustrate this method of sensing, a ring-magnet **20** is shown relative to the graph of **FIG. 2**. Ring-magnet **20** is shown in cross-section to show the positions of its magnetic northpole N and southpole S, respectively. **FIG. 2** depicts the case where magnetic detector **3** (not shown in **FIG. 2**) has been centered in front of ring-magnet **20** and where all of the sensors **4** produce a maximum output which is shown as peaks **22**, **24** in the graph of **FIG. 2**. Sensors **4** are connected (e.g., by a connection circuit **1** shown in **FIG. 1**) to display device **12**, which may display the graph shown in **FIG. 2**, or alternatively, a numeral result from the measurements taken by sensors **4**.

[0026] **FIG. 3** shows an embodiment of the apparatus of the invention where the magnetic detector suitably comprises several Hall-elements **36** which are grouped around a central point in a triangular or square configuration. In this embodiment, the magnetic device positioned by the implanted injection port **30** is preferably a ring-shaped magnet **32** surrounding the membrane **34** of the injection port **30**. The magnetic detecting device arranged outside the patient's body comprises three symmetrically arranged Hall-elements **36**. When the Hall-elements **36** are placed symmetrically above and around the ring-shaped magnet **32**, i.e., when the ring-shaped magnet **32** is in the center of injection port **30**, information is sent, directly or indirectly correlated to the intensity of magnetism, about the location of the injection port **30**.

[0027] **FIG. 4** shows an embodiment of the apparatus of the present invention for detecting an injection port **50** subcutaneously implanted in a patient **51** suffering from anal incontinence to enable accurate positioning of an injection needle **52** outside the patient's body for safe and accurate injection in the injection port **50**. Injection port **50** is, via a conduit **62**, connected to an implanted artificial sphincter **60** applied to the patient's rectum **64**. The apparatus of the present invention is comprised of a magnetic device **54**

subcutaneously implanted in patient **51** adjacent to injection port **50**. Magnetic device **54** emits a local magnetic field extending through injection port **50** and a portion of patient **51**'s skin **56** adjacent to injection port **50**. The apparatus of the present invention is further comprised of an external, separate magnetic detector **58** that may be manually moved along patient **51** 's body to detect the local magnetic field emitted by implanted magnetic device **54**. Magnetic detector **58** detects the local magnetic field when it is positioned in front of injection port **50**. When this position has been determined, injection needle **52** can be located in the same position to efficiently insert the needle through patient **51**'s skin directly into injection port **50**.

[**0028**] **FIG. 5** shows a modification of the embodiment of **FIG. 4**, and is comprised of a magnetic detector **66** subcutaneously implanted in patient **51** at injection port **50**. An external separate magnetic device **68** may be manually moved along patient **51** 's body while emitting a local magnetic field through patient **51** 's skin **56**. Magnetic detector **66** is capable of detecting the local magnetic field when movable magnetic device **68** is moved to a position in front of implanted injection port **50**. A sender **70** is implanted in patient **51** and sends information about the status of magnetic detector **66**. Thus, when magnetic detector **66** detects the local magnetic field emitted by external magnetic device **68**, sender **70** sends information confirming that magnetic device **68** is in a proper position for accurate positioning of an injection needle **52** outside the patient's body. When this position has been determined, injection needle **52** can be placed in the same position to efficiently insert it in the injection port **50**.

[**0029**] **FIG. 6** shows an example of artificial sphincter **60**, which is comprised of a band **80** formed into a loop around the patient's rectum (not shown in **FIG. 5**). Band **80** has a cavity **82** which can be inflated by supplying hydraulic fluid thereto, via implanted injection port **50**, to close the rectum, and be deflated by withdrawing hydraulic fluid therefrom, to open the rectum. A hydraulic operation device **84** for operating band **80** can be powered with energy from an implanted energy receiving device. This type of band may also be used as an artificial sphincter for treating patient's suffering from heartburn and reflux disease or urinary incontinence combined with the apparatus of the invention. Furthermore, band **80** may be used for forming an adjustable constricted stoma opening in the stomach or esophagus of an obese patient or for restricting the penile exit blood flow of an impotent patient combined with the apparatus of the invention.

What is claimed is:

1. An apparatus for detecting an injection port adapted to be subcutaneously implanted in a patient, comprising a magnetic device designed to be subcutaneously implanted in the patient at the injection port for emitting a local magnetic field extending through the injection port and a portion of the patient's skin adjacent to the injection port, and a magnetic detector movable externally along the patient's body and capable of detecting said local magnetic field emitted by said magnetic device when said magnetic detector is in a position in front of the implanted injection port, said magnetic detector including a semiconductor circuit, whereby an injection needle put in said position is able to run through the patient's skin right into the injection port.

2. An apparatus according to claim 1, wherein said semiconductor circuit of said magnetic detector comprises at least one Hall-element.

3. An apparatus according to claim 2, wherein said magnetic detector comprises several Hall-elements grouped around a central point in a triangular or square configuration.

4. An apparatus according to claim 1, wherein said magnetic device is a solenoid or a permanent magnet.

5. An apparatus according to claim 1, wherein said magnetic device comprises a ring-shaped magnet.

6. An apparatus for detecting an injection port subcutaneously implanted in a patient, comprising a magnetic detector designed to be subcutaneously implanted in the patient at said injection port, said magnetic detector including a semiconductor circuit, an exterior magnetic device movable along the patient's skin and adapted to emit a local magnetic field through the patient's skin, said magnetic detector being capable of detecting said local magnetic field when said movable magnetic device is moved to a position in front of said implanted injection port, whereby an injection needle placed in said position is able to be inserted through the patient's skin directly into the injection port.

7. An apparatus according to claim 6, further comprising a sender adapted to be implanted in the patient and capable of sending information about said magnetic detector detecting said local magnetic field.

8. An apparatus according to claim 6, wherein said magnetic device is a solenoid or a permanent magnet.

9. An apparatus according to claim 6, wherein said semiconductor circuit of said magnetic detector comprises at least one Hall-element.

10. A method for detecting an injection port subcutaneously implanted in a patient, the method comprising the steps of:

implanting a magnetic device subcutaneously in the patient at the injection port so that the magnetic device emits a local magnetic field extending through the injection port and the adjacent skin portion of the patient; and

moving an exterior magnetic detector along the patient's skin to a position in which the local magnetic field emitted by the implanted magnetic device is detected by the magnetic detector.

11. A method for detecting an injection port subcutaneously implanted in a patient, the method comprising the steps of:

implanting a magnetic detector subcutaneously in the patient at the injection port;

moving an exterior magnetic device along the patient's skin while it emits a local magnetic field extending through the adjacent skin portion; and

using the implanted magnetic detector to detect the local magnetic field when the magnetic device is moved to a position in which the local magnetic field extends through the implanted magnetic detector and injection port.

12. A method according to claim 11, further comprising implanting a sender and using the sender to send information to outside the patient's body confirming when the implanted magnetic detector detects the local magnetic field emitted by the exterior magnetic device.

13. A surgical method for treating a patient having a disease, comprising the steps of:

insufflating the patient's abdomen with gas;

placing at least two laparoscopical trocars in the patient's body;

implanting a hydraulically operable implant designed for treating reflux disease, urinary incontinence, impotence, anal incontinence or obesity in the abdomen by using surgical instruments through the trocars;

subcutaneously implanting an injection port for supplying hydraulic fluid for the operation of the implant and a magnetic device at the injection port for emitting a local magnetic field through the injection port and the adjacent skin portion of the patient;

post-operatively moving an exterior magnetic detector along the patient's body to a position in which the local magnetic field emitted by the implanted magnetic device is detected by the magnetic detector;

bringing an injection needle to the position in which the local magnetic field is detected; and

moving the injection needle to penetrate the patient's skin into the injection port for supplying hydraulic fluid to or withdrawing hydraulic fluid from the injection port.

14. A surgical method for treating a patient having a disease of reflux disease, urinary incontinence, impotence, anal incontinence or obesity, comprising the steps of:

insufflating the patient's abdomen with gas;

placing at least two laparoscopical trocars in the patient's body;

implanting in the abdomen using surgical instruments through the trocars a hydraulically operable implant designed for treating the disease;

subcutaneously implanting an injection port for supplying hydraulic fluid for the operation of the implant and a magnetic detector adjacent to the injection port;

post-operatively moving an exterior magnetic device emitting a local magnetic field along the patient's body to a position in which the local magnetic field emitted by the exterior magnetic device is detected by the implanted magnetic detector;

bringing an injection needle to the position in which the local magnetic field is detected; and

moving the injection needle to penetrate the patient's skin into the injection port for supplying hydraulic fluid to or withdrawing hydraulic fluid from the injection port.

* * * * *

专利名称(译)	检测植入注射口		
公开(公告)号	US20040064030A1	公开(公告)日	2004-04-01
申请号	US10/260546	申请日	2002-10-01
[标]申请(专利权)人(译)	福塞尔PETER		
申请(专利权)人(译)	福塞尔PETER		
当前申请(专利权)人(译)	POTENCIA医药股份公司		
[标]发明人	FORSELL PETER		
发明人	FORSELL, PETER		
IPC分类号	A61B5/06 A61B19/00 A61M5/42 A61M39/02 A61B5/05		
CPC分类号	A61B5/06 A61B19/54 A61M2209/045 A61M5/427 A61M39/0208 A61B2019/5454 A61B90/39 A61B2090/3954		
外部链接	Espacenet USPTO		

摘要(译)

公开了一种用于检测皮下植入患者体内的注射端口的装置，以使注射针能够精确定位在患者体外，以使注射针能够直接注射到注射端口中。还公开了一种用于检测注射口的方法，由此注射针可以定位成直接注射到注射口中。该装置包括磁性装置，该磁性装置在邻近注射端口的皮下植入患者体内，以通过邻近注射端口的患者皮肤发射局部磁场。沿着患者身体向外移动的磁检测器能够检测由其发射的局部磁场磁性装置。这允许注射口定位，以便将注射针直接插入注射口。或者，该装置可包括通过注射口皮下植入患者体内的磁性检测器和可沿患者皮肤移动的外部磁性装置，以发射由植入的磁性检测器检测到的磁场。优选地，磁检测器包括半导体电路，该半导体电路包括至少一个霍尔元件。磁性装置可以是螺线管或永磁体。注射端口可用于控制设计用于治疗反流性疾病，尿失禁，阳痿，肛门失禁或肥胖。