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(54) METHOD FOR IMPLANTING FLEXIBLE INJECTION PORT

(76) Inventors: **How-Lun Chen**, Cincinnati, OH (US); **Sean P. Conlon**, Loveland, OH (US); **Dale R. Schulze**, Lebanon, OH (US)

Correspondence Address:
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003 (US)

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(57) **ABSTRACT**

In accordance with the present invention, there is provided a method for subcutaneously implanting an injection port for use with an implantable medical device. The method involves providing an injection port comprising an elongated flexible substantially non-rigid body having first and second ends and a wall therebetween, the wall is such that it will self seal after being punctured, the body further including and a fluid reservoir surrounded by the wall and a flexible elongated tubular catheter attached to the body which is in fluid communication with the reservoir. Thereafter, the method involves creating an incision within the patient, accessing the subcutaneous fat layer of the patient through the incision, creating a space in the subcutaneous fat layer and implanting the injection port within the subcutaneous fat layer such that the port can be found externally by palpitation.

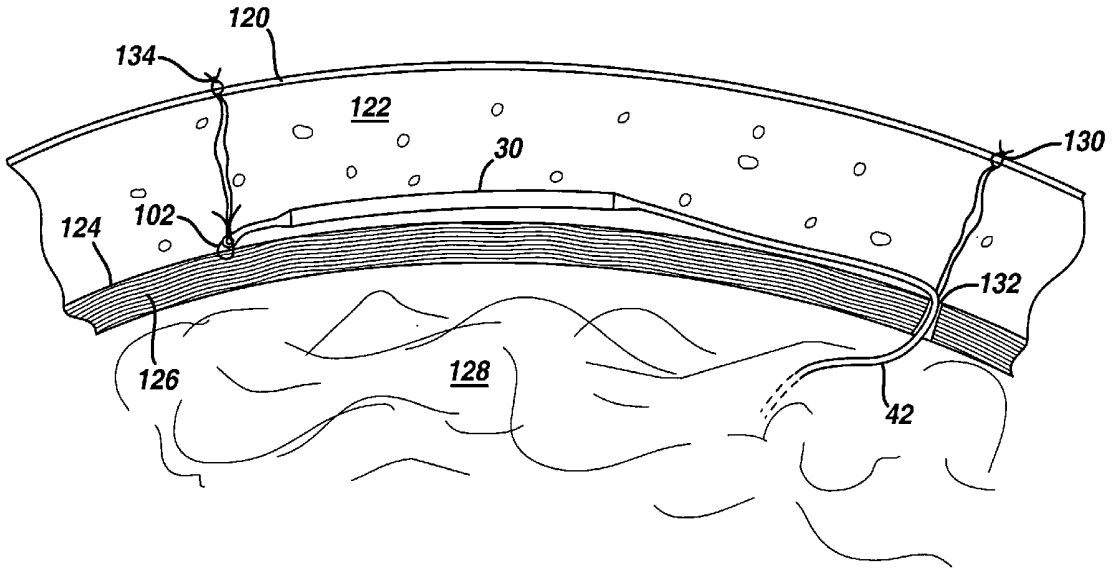


FIG. 1 PRIOR ART

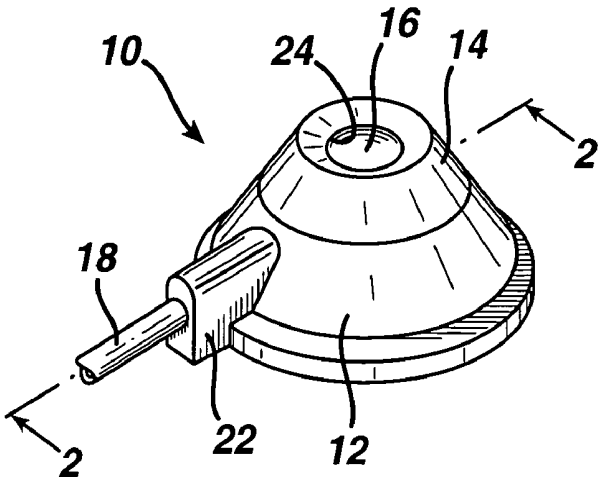
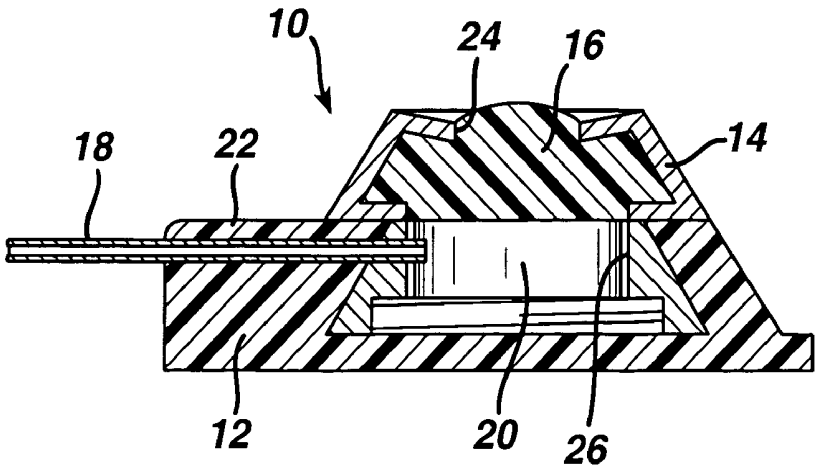


FIG. 2 PRIOR ART



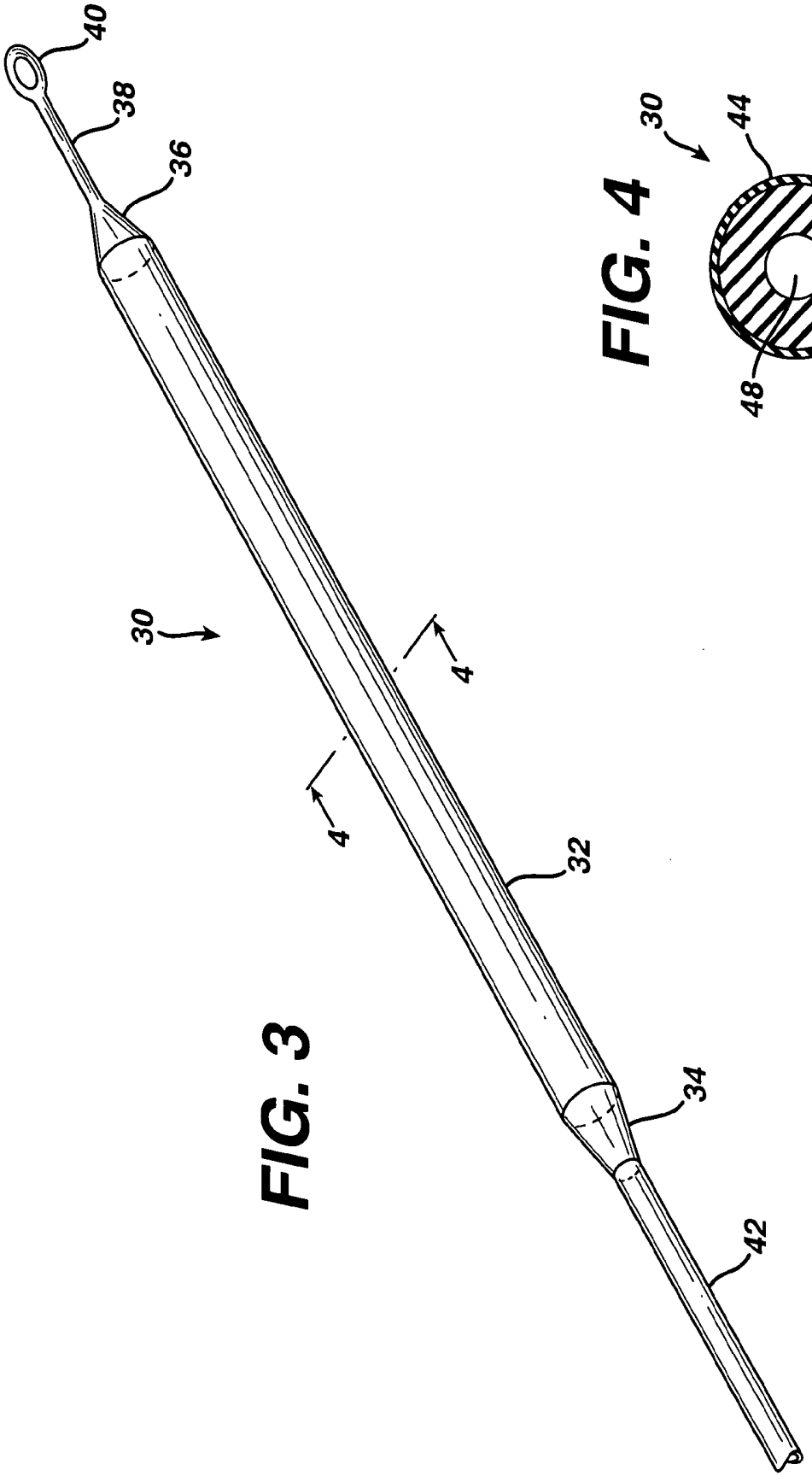


FIG. 3

FIG. 4

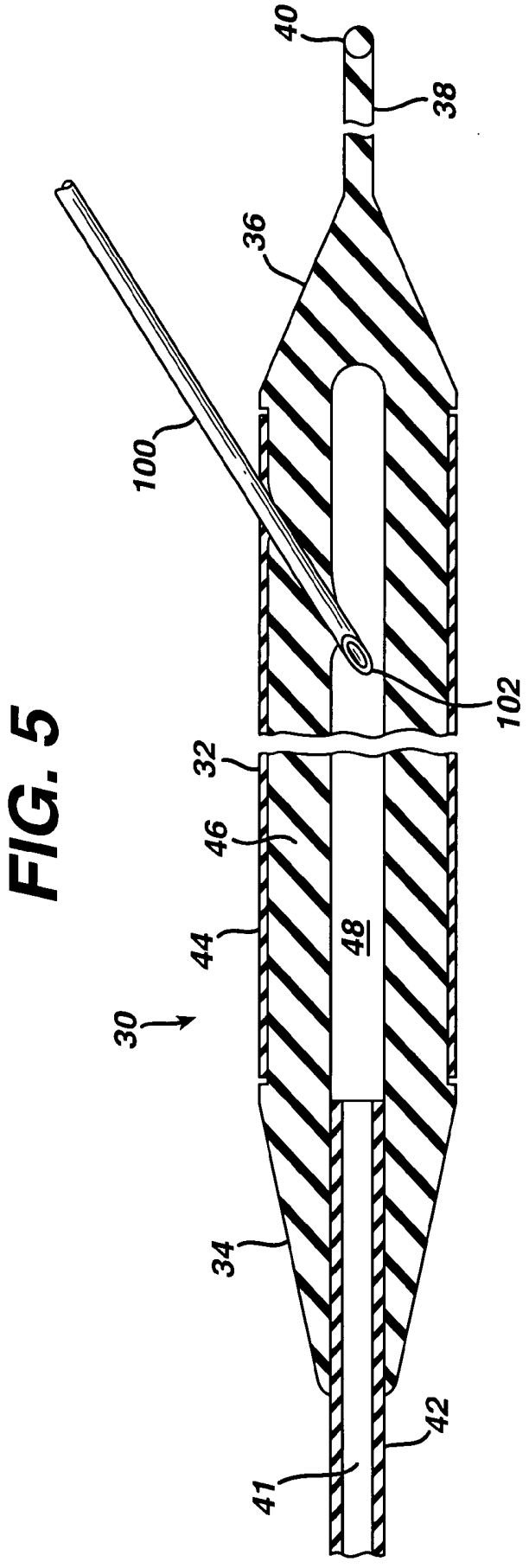


FIG. 5

FIG. 6

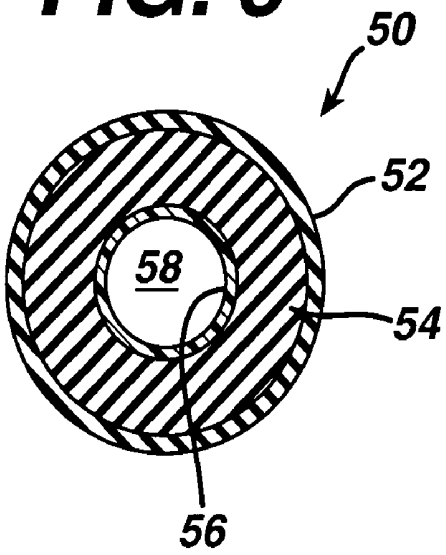
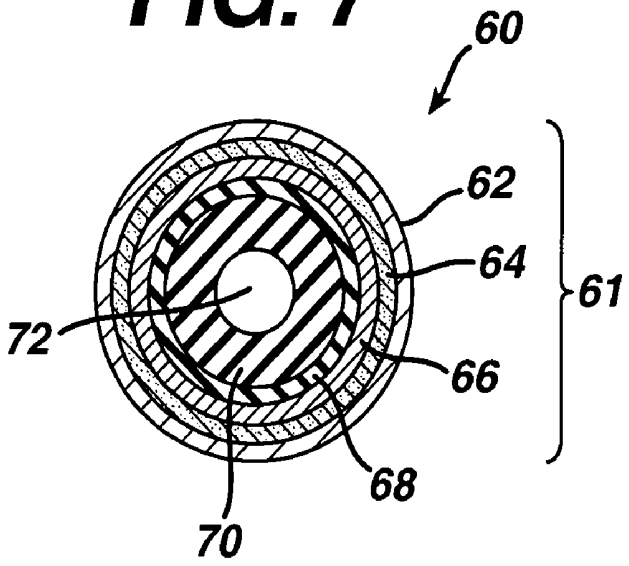


FIG. 7



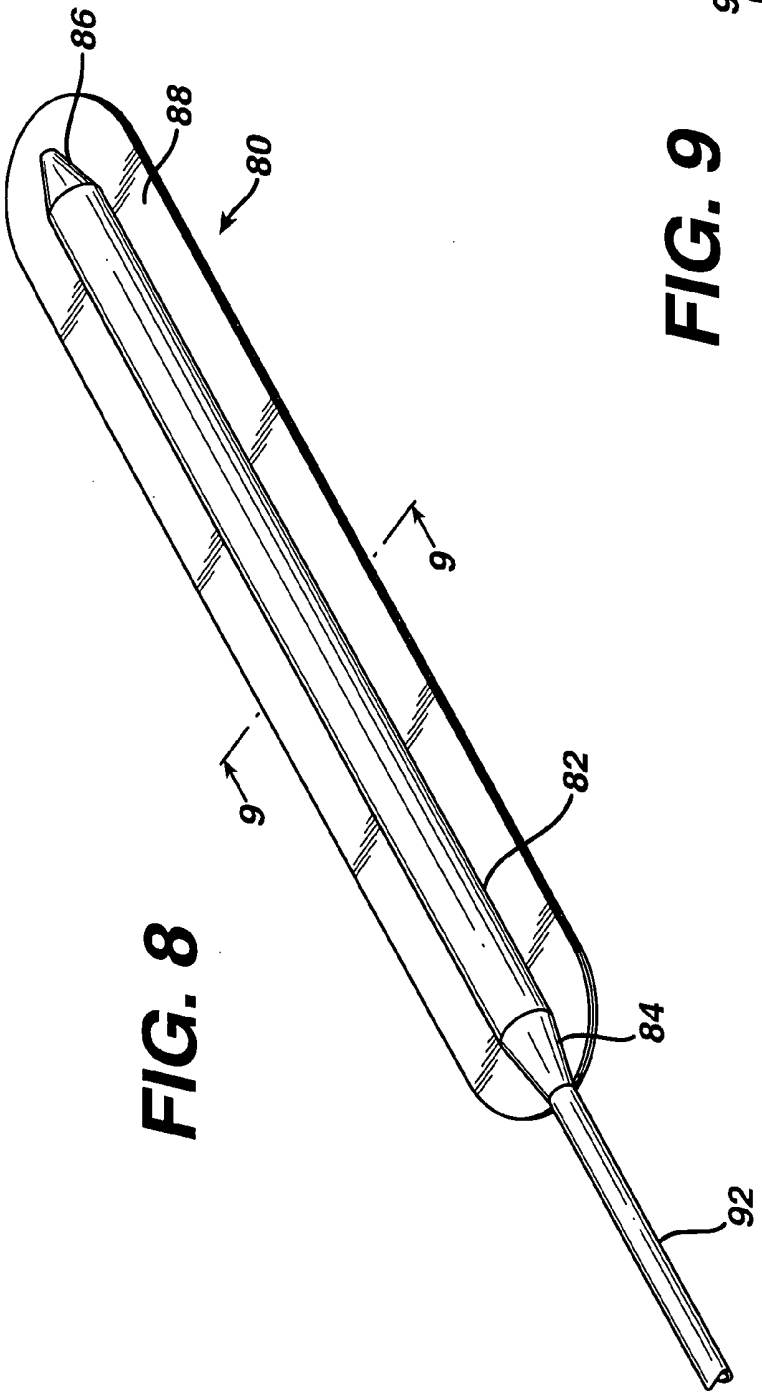


FIG. 8

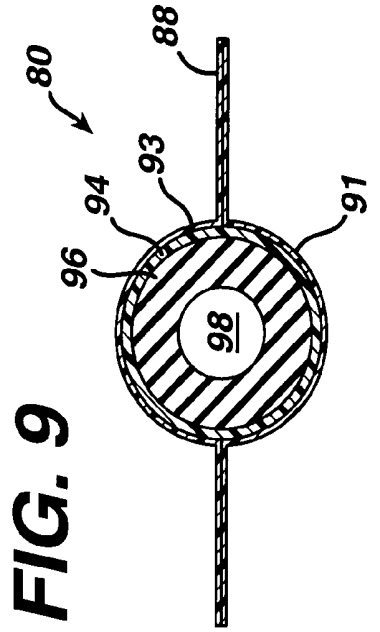


FIG. 9

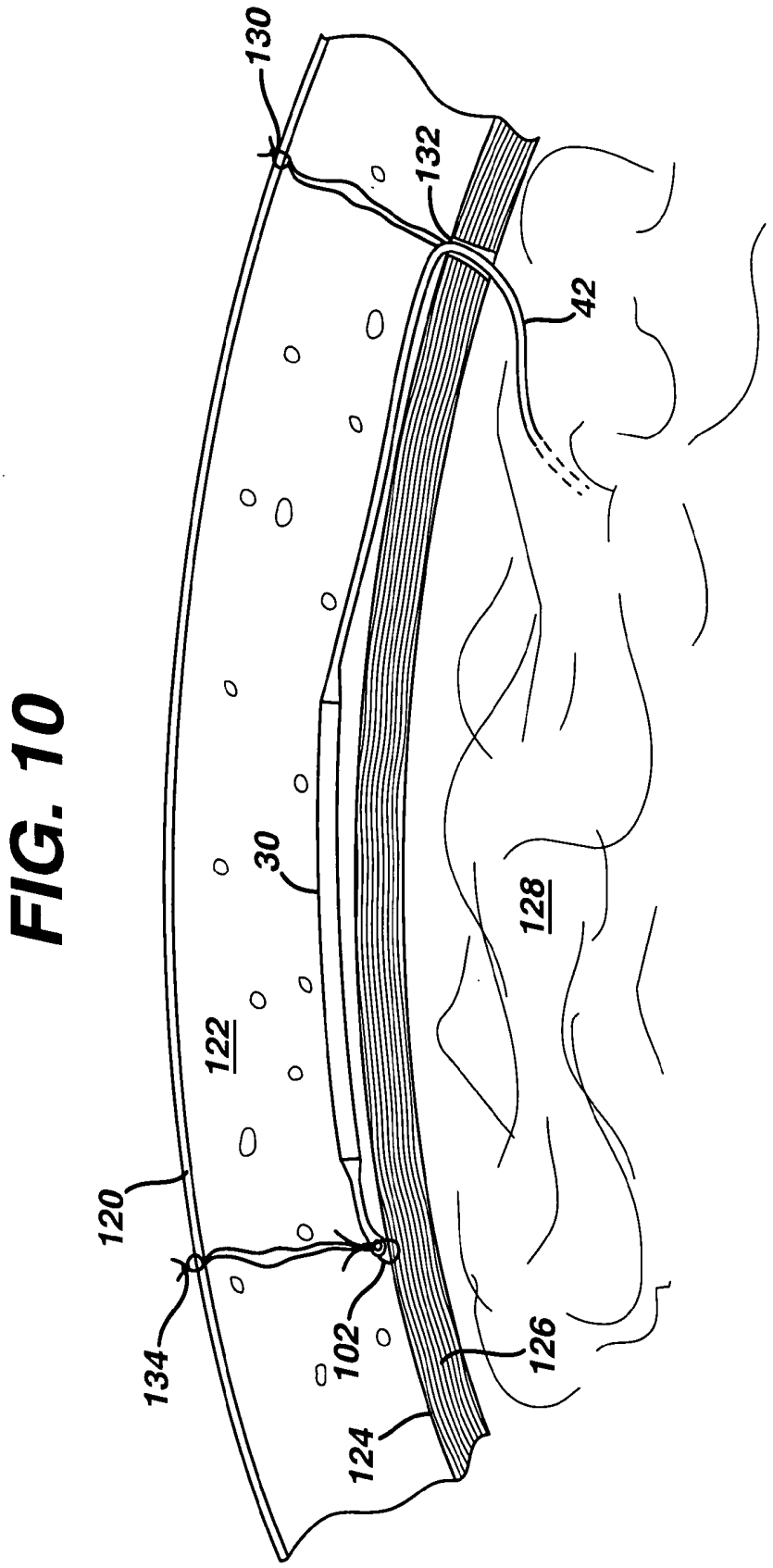


FIG. 10

FIG. 11

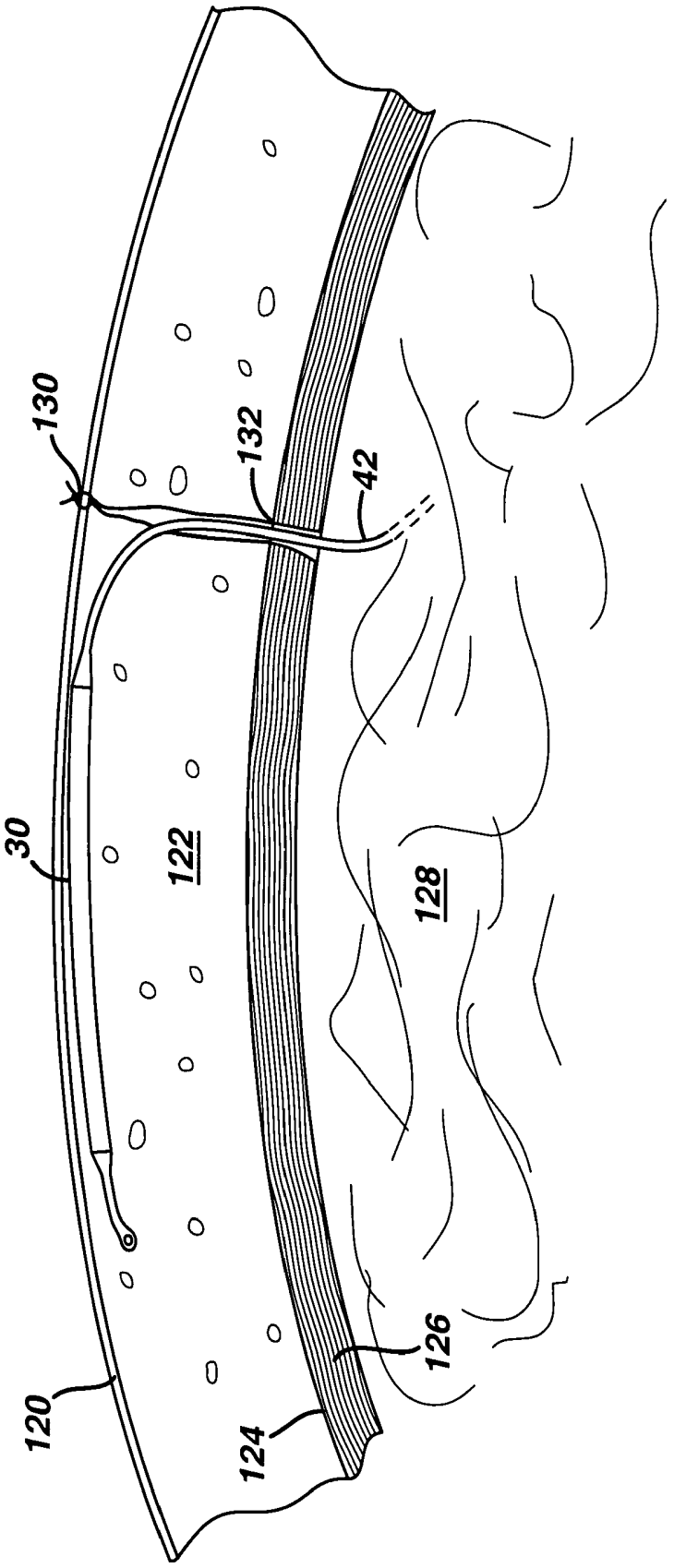
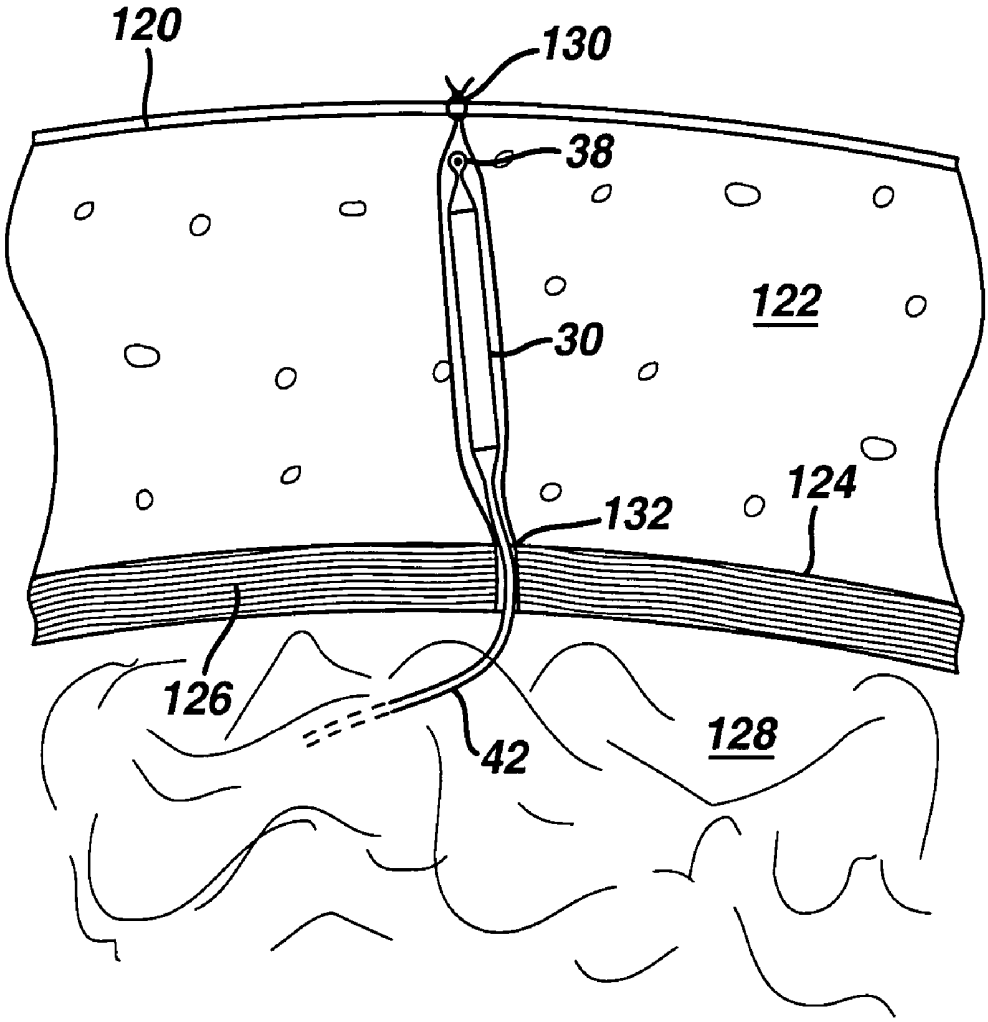


FIG. 12



METHOD FOR IMPLANTING FLEXIBLE INJECTION PORT

FIELD OF THE INVENTION

[0001] This invention relates generally to the field of medicine, and more specifically to medical devices that are surgically implanted in a patient, and is particularly relevant to implantable injection or infusion ports such as used for chemotherapy and adjustable gastric band procedures.

BACKGROUND

[0002] Surgeons routinely implant subcutaneous injection ports in patients requiring long term, periodic fluid injections such as for chemotherapy and gastric band adjustments. The injection port connects to a flexible tube catheter to transport the fluid to the affected area (subclavian vein, etc.) or the gastric band. Current injection ports comprise a rigid metal or plastic housing, which is about 25 mm in diameter and 15 mm tall. A thick, silicone septum captured within the rigid housing covers an inner chamber that fluidly communicates with the catheter. The surgeon uses a hypodermic needle to inject fluid into the chamber through the silicone septum.

[0003] Typically the surgeon fastens the injection port with suture to fascia and beneath the fat and skin layers, primarily to prevent the port from flipping over, but also to prevent the injection port from migrating in the body. Since the septum is accessible from only one side of the injection port, flipping over requires interventional surgery to right the port for subsequent injections.

[0004] For some patients, the surgeon may place the injection port in the lower abdomen, thus burying the port beneath a fat layer that may be several centimeters thick. Usually a surgeon can locate the port with palpation alone. However, if there is a very thick, intervening fat layer, such as on extremely obese, gastric band patients, the surgeon must also use fluoroscopy, ultrasound, or other means to locate the port. Furthermore, the surgeon must inject the needle in a direction approximately perpendicular to the injection port, and hit the target area of the septum, which is only about 12-15 mm in diameter. For some patients, the surgeon may place the injection port on the sternum or upper right chest, just beneath the skin layers. Although easy to locate with palpation, some patients regard the protruding port as uncomfortable or cosmetically objectionable.

[0005] What is needed, therefore, is a subcutaneously implantable injection port that is made of relatively soft and flexible materials, and ideally, that looks and feels more (than current injection ports) like a large, natural blood vessel. What is also needed is a subcutaneously implantable injection port that is penetrable with a hypodermic needle, independent of the orientation of the injection port in bodily tissue, and that is self-sealing when the needle is removed. What is further needed is a subcutaneously implantable injection port that a surgeon may position in the body more quickly and with less dissection than is required for conventional injection ports.

SUMMARY OF THE INVENTION

[0006] In accordance with the present invention, there is provided a method for subcutaneously implanting an injection port for use with an implantable medical device. The method involves providing an injection port comprising an elongated flexible substantially non-rigid body having first and second ends and a wall therebetween, the wall is such that it will self seal after being punctured, the body further including and a fluid reservoir surrounded by the wall and a flexible elongated tubular catheter attached to the body which is in fluid communication with the reservoir. Thereafter, the method involves creating an incision within the patient, accessing the subcutaneous fat layer of the patient through the incision, creating a space in the subcutaneous fat layer and implanting the injection port within the subcutaneous fat layer such that the port can be found externally by palpitation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] We present the specific, novel features of this invention in the appended claims. The reader may best understand, however, the organization and methods of operation of this invention by referring to the detailed description and the following drawings:

[0008] **FIG. 1** is an isometric view of an injection port of the prior art;

[0009] **FIG. 2** is a cross sectional view of the injection port of the prior art shown in **FIG. 1**;

[0010] **FIG. 3** is an isometric view of a first embodiment of a flexible injection port **30**;

[0011] **FIG. 4** is a sectional view of flexible injection port **30** shown in **FIG. 3**;

[0012] **FIG. 5** is an enlarged, longitudinal sectional view of flexible injection port **30** penetrated by a hypodermic needle **100**;

[0013] **FIG. 6** is a cross sectional view of a second embodiment of a flexible injection port **50**;

[0014] **FIG. 7** is a cross sectional view of a third embodiment of a flexible injection port **60**;

[0015] **FIG. 8** is an isometric view of a fourth embodiment of a flexible injection port **80**;

[0016] **FIG. 9** is a cross sectional view of flexible injection port **80**;

[0017] **FIG. 10** shows injection port **30** subcutaneously implanted near a fascia layer **124** in a patient;

[0018] **FIG. 11** shows injection port **30** subcutaneously implanted near a skin layer **120** in a patient; and

[0019] **FIG. 12** shows injection port **30** subcutaneously implanted in a fat layer **122** in a patient.

DETAILED DESCRIPTION OF THE INVENTION

[0020] Referring now to the drawings, **FIGS. 1 and 2** show an injection port **10** of the prior art. Injection port **10** generally has a truncated, conical configuration, and comprises a body portion **12**, a housing **14**, a seal element **16**, and a catheter element **18**. The body portion **12** is made of a flexible, rubberized material with a cavity **20** formed inside. A catheter support **22** integrally forms in body portion **12**. Housing **14** is made of a corrosion resistant

metal, and has a reduced, upwardly facing entry passage **24**. Seal element **16** is made of a rubberized material, which is easily penetrable by a hypodermic needle or the like, and provides a penetrable seal for passage **24**. Housing **14** and seal element **16** define an open cavity **20** in injection port **10** for receiving and containing a fluid. Catheter element **18** extends through catheter support **22** of body portion **12** and through housing **14** so that catheter element **18** extends into cavity **20** for providing communication between cavity **20** and the exterior of injection port **10** for dispensing fluid from the cavity **20** into the body of a patient.

[**0021**] A surgeon implants injection port **10** subcutaneously in a patient. To introduce a fluid such as a medication or a saline solution, the surgeon inserts a hypodermic needle or the like into the patient so that the tip of the needle passes through seal element **16** and into cavity **20**. Due to the relatively small size of passage **24**, each time the surgeon introduces a fluid into the patient, the surgeon must insert the needle through seal element **16** and the same localized area of the skin and tissue of the patient. Accordingly, seal element **16** may become significantly damaged and eventually develop a leak. Also, the localized skin area and underlying tissue may not heal in the desired manner. Further, because housing **14** is made of metal, it can cause barbing of the needle tip, causing increased trauma to the patient upon withdrawal of the needle. Still further, because of the truncated conical configuration of injection port **10** and the metallic construction of housing **14**, injection port **10** can cause substantial discomfort to a patient, particularly if the area of the patient adjacent the injection port is accidentally bumped or bruised. In addition, because of the truncated conical configuration of injection port **10**, it can cause a relatively unattractive mound on the body of a patient. Still further, since fluid can only be introduced in cavity **20** through passage **24**, a surgeon must insert a needle into injection port **10** in substantially perpendicular relation to the skin so that often the adjacent area of tissue or skin of the patient cannot effectively support the needle.

[**0022**] When using injection port **10** of the prior art in a laparoscopic procedure such as implantation of a gastric band, it is necessary for the surgeon to assemble injection port **10** to catheter element **18** during the laparoscopic procedure. This is because injection port **10** is too large to pass through a standard size (12 mm diameter) laparoscopic port, which is used for access to the stomach inside the abdominal cavity. The surgeon must introduce the gastric band and the catheter into the abdominal cavity without the injection port attached to the free end of the catheter. Once the surgeon has secured the gastric band around the stomach, the surgeon externalizes the free end of the catheter through the abdominal muscle and fascia layers, subcutaneous fat layer, and the skin to assemble the injection port to the free end of the catheter. Then the surgeon implants the injection port subcutaneously at the desired location on the patient's abdomen or chest. The surgeon must take extra time to assemble the injection port to the catheter. Also, the surgeon must skillfully connect the injection port to the catheter during less than ideal conditions. Consequently, there is the potential complication of an undiscovered leak developing at the connection of the catheter to the port.

[**0023**] **FIG. 3** is an isometric view of a first embodiment of the present invention showing a flexible injection port or body **30**, that generally comprises a first end **34**, a second end **36**, and a cylindrical injection portion **32** extending there between. A surgeon may use a hypodermic needle or the like to penetrate injection portion **32** and introduce a fluid such as a medication or saline solution into flexible injection port **30**. Injection portion **32** self-seals when the surgeon removes the hypodermic needle. Injection portion **32** may have a length, but is not limited to, approximately 5-20 cm. Injection portion **32** may have a diameter, but is not limited to, approximately 5-12 mm. A catheter **42** attaches to first end **34** and distributes fluid injected into flexible injection port **30** to another portion of the patient's body. Catheter **42** is made from a silicone rubber or other biocompatible polymer such as known in the art for application to conventional injection ports, such as shown in **FIGS. 1 and 2**. A tether **38** having an eye loop **40** extends from second end **36**. A surgeon may use a conventional surgical grasping instrument to grasp tether **38**, or a surgical suture tied to eye loop **40**, or a combination of both grasper and suture, to facilitate placement of flexible injection port **30** in the body.

[**0024**] Although flexible injection port **30** is shown in **FIG. 3** to be essentially straight, it is possible to construct it with a curved or non-straight shape in order to facilitate placement in the body, or to conform to the body anatomy at the implant location. Since flexible injection port **30** is made of relatively soft and flexible materials, the surgeon may temporarily straighten it, for example, when introducing it into the body through a laparoscopic port.

[**0025**] **FIG. 4** is a cross sectional view of flexible injection port **30**, taken at line **44** of injection portion **32** as shown in **FIG. 3**. At this location and anywhere along the length of injection portion **32**, flexible injection port **30** includes an outer tube **44** may exerts a radial, compressive force on an inner tube **46**. Flexible injection port **30** includes a fluid reservoir **48** that extends the entire length of injection portion **32** and fluidly communicates with catheter **42**. The total wall thickness is approximately in the range of 2-4 mm.

[**0026**] **FIG. 5** is a longitudinal sectional view of flexible injection port **30**, showing a hypodermic needle **100** penetrating through injection portion **32** so that distal tip **102** of hypodermic needle **100** is inside of fluid reservoir **48**. First end **34**, second end **36**, tether **38**, eye loop **40**, and inner tube **46** are integrally molded from an elastomer such as, for example, silicone rubber, latex rubber, or polyurethane rubber. The molded elastomer may have a durometer approximately in the range of 40-60, but is not limited to that range. Catheter **42** may be bonded inside of first end **34** using any one of a number of bonding agents and techniques well known in the art, in order to fluidly communicate with reservoir **48**. Outer tube **44** may be made of a PTFE shrink-wrap material, or a similar, biocompatible shrink-wrap. During the manufacturing process, outer tube **44** may be loosely assembled in the pre-shrunken configuration over inner tube **46**. Then the application of heat causes outer tube **44** to conform very tightly around inner tube **46**. Outer tube **44** therefore applies a significant compressive force on the softer, inner tube **46** to enhance the ability of inner tube **46** to close the puncture created by hypodermic needle **100**.

[**0027**] **FIG. 6** is a cross sectional view of a second embodiment of the present invention showing a flexible injection port **50**, which is externally similar to the first embodiment shown in **FIG. 3**. Flexible injection port **50** includes an outer tube **52**, an inner tube **54**, and an inner

lining **56**. Outer tube **52** and inner tube **54** are the same as outer tube **44** and inner tube **46**, respectively, of the first embodiment in **FIG. 4**. Inner lining **56** may be an extruded plastic, thin wall tube, such as polyethylene or PTFE, tightly assembled inside of inner tube **54** to provide internal support to inner tube **54**. By supporting inner tube **54** in this way, a greater compressive force may be applied by outer tube **52** onto inner tube **54**, to further enhance the self-sealing capability. The material of inner lining **56** may be selected to have a higher needle penetration resistance than inner tube **54**. This difference in penetration resistance provides the surgeon with tactile feedback that the needle tip has penetrated into fluid reservoir **58**. Inner lining **56** may also be constructed of a metallic mesh and be similar in many respects to a vascular stent. Again, the total wall thickness is approximately in the range of 2-4 mm.

[**0028**] **FIG. 7** is a cross sectional view of a third embodiment of the present invention showing a flexible injection port **60**, which also is externally similar to the first embodiment shown in **FIG. 3**. Flexible injection port **60** comprises a plurality of layers **61**, which for this third embodiment includes a first layer **62**, a second layer **64**, a third layer **66**, a fourth layer **68**, and a fifth layer **70**, which surrounds a fluid reservoir **72**. Once penetrated by a needle that is inserted at an acute angle, the punctures created through the layers are not aligned to allow leakage once the needle is removed. Each of layers **61** may be made of the same or a different material than any of the other of layers **61**, or may have the same or a different thickness than any of the other of layers **61**. Each of layers **61** may have a specific property or functional contribution. For example, first layer **62** may be made of a material that is permeable to tissue fluids in order to slowly release a medication contained in second layer **64**. Fifth layer **70** may be made of silicone rubber having a durometer in the range of 20-30. Fourth layer **68** may be made of a heat shrinkable PTFE material, which applies a radially compressive force on fifth layer **70** to enhance self-sealing. Third layer **66** may be made of a material such as a metallic foil that acts as a diffusion barrier to prevent the loss of fluid from fluid reservoir **72**. Fourth layer **66** may be made of a high durometer silicone rubber. Many other materials are possible, in a multiplicity of combinations, so that injection port **60** may have characteristics especially suited for its particular application. Diffusion of body fluids into and out of the soft port wall may also be reduced by any one of various material treatment techniques, including, for example, vapor deposition of titanium or another metal on a surface of the soft port, and coating with Paralene polymer. Other coatings are also known in the art for micro bacterial protection. Again, the total wall thickness is in the range of 2-4 mm.

[**0029**] **FIG. 8** is a fourth embodiment of the present invention, a flexible injection port **80**, comprising a first end **84** that attaches to a catheter **92**, a second end **86** and an injection portion **82**. Flexible injection port **80** further comprises a webbing **88** attached to and covering at least injection portion **82**, and made of a thin, flexible, implantable material such as a polyester or polypropylene mesh, expanded PTFE, or the like. Webbing **88** provides broad margins for stapling or suturing to an underlying tissue such as fascia, as well as a large area for tissue in-growth, to enhance long-term stability and to substantially prevent migration of flexible injection port **80**. **FIG. 9** is a cross sectional view of flexible injection port **80**, taken at line **9-9** of **FIG. 8**. Flexible injection port **80** comprises an outer tube **94** made of a heat shrinkable, PTFE material, and an inner tube **96** made of a silicone rubber having a durometer of approximately 20-40. Webbing **88** includes a pair of webbing layers, **91** and **93**, that may be bonded thermally or chemically tightly over at least injection portion **82** in the mid-plane of flexible injection port **80**.

[**0030**] A surgeon may implant the present invention, as described for the preceding embodiments and equivalents, in a number of locations in a patient's body. **FIGS. 10, 11**, and **12** show examples of flexible injection port **30** subcutaneously implanted in the abdomen of a patient, although it is possible to implant flexible injection port **30** beneath the skin in other portions of the body.

[**0031**] **FIG. 10** depicts a first example of flexible injection port **30** subcutaneously implanted in a patient's body. Flexible injection port **30** lies adjacent to a fascia layer **124** covering an abdominal wall **126**. Catheter **42** passes from the abdominal cavity **128** through an abdominal opening **132**, which the surgeon used together with a first incision **130** for laparoscopic access earlier in the surgical procedure. The surgeon optionally may make a second incision **134** offset from first incision **130**, and use conventional, surgical grasping and retracting instruments to pull flexible injection port **30** beneath a fat layer **122** and adjacent to fascia layer **124**. However, the surgeon may determine that it is not necessary to make a second incision **134**, and instead use first incision **130** to push flexible injection port **30** into position. In either situation, the surgeon dissects as little tissue as practical in order to save surgery time and to minimize the size of enclosed cavities that may collect tissue fluids and become sites for infection. The surgeon optionally may anchor flexible injection port **30** to fascia layer **124** with a stay suture **102**. Once the surgeon has placed flexible injection port **30** in the desired location, the surgeon closes first incision **130** and second incision **134** using conventional sutures or staples.

[**0032**] **FIG. 11** shows a second example of flexible injection port **30** subcutaneously implanted in a patient's body. Flexible injection port **30** lies immediately beneath skin layer **120** and above fat layer **122**. Catheter **42** passes through first incision **130** and abdominal opening **132** (the original laparoscopic port site) into abdominal cavity **128**. The surgeon may use finger or instrument dissection through first incision **130** to create a space under skin layer **120** for flexible injection port **30**. The surgeon closes first incision **130** using conventional sutures or staples. Normally it would not be necessary to close abdominal opening **132** through fascia layer **124** and abdominal wall **126**, but the surgeon may do so in order to promote healing and to prevent slippage of catheter **42** through abdominal opening **132**. The surgeon may prefer placement of flexible injection port **30** just beneath skin layer **120** for severely obese patients in which fat layer **122** is over 5-10 cm thick, so that the surgeon may easily use palpation to locate flexible injection port **30** for later injections of fluid. Also, conventional intravenous (IV) needles and techniques may be used for injecting the fluid into flexible injection port **30**, which is situated beneath the skin much like a natural blood vessel. This may allow nurses and other clinicians who are trained in administering IV's to assist the surgeon with fluid injections. Furthermore, if the clinician uses a conventional IV needle, the "flashback" of fluid into the IV needle syringe tip provides the

clinician with visual feedback that the tip of the needle is properly penetrated into the reservoir of flexible injection port **30**. In fact, addition of a colorant to the fluid injected further enhances this visual feedback. Non-toxic colorants that may be added to the saline solution or medication are well known in the art.

[**0033**] **FIG. 12** shows a third example of flexible injection port **30** subcutaneously implanted in a patient's body. For this example, the surgeon does minimal or no dissection of tissue at the laparoscopic port site. Catheter **42** passes from the abdominal cavity **128** through fascia layer **124** and abdominal wall **126**. The surgeon positions flexible injection port **30** vertically in fat layer **122** and beneath skin layer **120**. Optionally, the surgeon may suture abdominal opening **132** to prevent slippage of flexible injection port **30** into abdominal cavity **128**. The surgeon also may use a surgical scissors to trim off tether **38** from flexible injection port **30**, just prior to closing first incision **130** with conventional sutures or staples.

[**0034**] The present invention, a flexible injection port, as described in the preceding embodiments and their equivalents, has numerous advantages over the prior art injection ports. The flexible injection port may not require attachment to fascia, thus reducing the duration of the surgical procedure. The flexible injection port may require a smaller incision size and less tissue dissection for implantation, so that the patient has less pain, less scarring, a faster recovery, and less possibility of infection. Due to the integral construction of the flexible injection port and the catheter, the step of connecting the catheter to the injection port during the surgical procedure is not necessary, thus potentially reducing the number of surgical complications due to fluid leakage at the connection. Because the flexible injection port may be implanted in the fat layer near the skin surface, the surgeon or a trained clinician may use palpation to locate the injection port, and standard IV techniques to administer fluid, yet the implant is still cosmetically acceptable to the patient. In addition, shorter injection needles may be used to reduce patient anxiety during fluid administration. The flexible injection port may have no metallic parts, resulting in a flexible and lightweight implant for greater patient comfort and compatibility with magnetic resonance and fluoroscopic x-ray imaging. Finally, the injection portion of the flexible injection port is accessible with a hypodermic needle for most of the possible orientations of the flexible injection port within the subcutaneous fat layer of the patient.

[**0035**] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. For example, the injection port may me coated with an anit-microbial coating such as triclosan. For example, as would be apparent to those skilled in the art, the disclosures herein have equal application in robotic-assisted surgery. In addition, it should be understood that every structure described above has a function and such structure can be referred to as a means for performing that function. Accordingly, it is intended that the invention be limited only by the spirit and scope of the appended claims.

What is claimed:

1. A method for subcutaneously implanting, within a body, an injection port for use with an implantable medical device comprising:

a. providing an injection port comprising an elongated flexible substantially non-rigid body having first and second ends and a wall therebetween, said wall is such that it will self seal after being punctured, said body further including and a fluid reservoir surrounded by said wall and a flexible elongated tubular catheter attached to said body which is in fluid communication with said reservoir; and

b. creating an incision for laparoscopic access to the abdominal cavity of a patient;

c. accessing the subcutaneous fat layer of the patient through said incision;

d. creating a space in the subcutaneous fat layer;

e. positioning said flexible injection port inside of said space in subcutaneous fat layer; and

f. closing said incision.

2. The method of claim **13**, further comprising the step of attaching said flexible injection port to the fascia layer of the abdominal wall.

3. A method for subcutaneously implanting, within a body, an injection port for use with an implantable medical device comprising:

a. providing an injection port comprising an elongated flexible substantially non-rigid body having first and second ends and a wall therebetween, said wall is such that it will self seal after being punctured, said body further including and a fluid reservoir surrounded by said wall and a flexible elongated tubular catheter attached to said body which is in fluid communication with said reservoir; and

b. creating an incision within the patient;

c. accessing the subcutaneous fat layer of the patient through said incision;

d. creating a space in the subcutaneous fat layer and implanting said injection port within said subcutaneous fat layer such that said port can be found externally by palpitation; and

e. closing said incision.

* * * * *

专利名称(译)	植入柔性注射口的方法		
公开(公告)号	US20050131383A1	公开(公告)日	2005-06-16
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IPC分类号	A61M37/00 A61B17/00 A61M5/00 A61M25/00 A61M31/00 A61M39/00 A61M39/02 A61M39/04		
CPC分类号	A61M39/0208 A61M2039/022 A61M2039/0072		
外部链接	Espacenet USPTO		

摘要(译)

根据本发明，提供了一种用于皮下植入注射口的方法，该注射口用于可植入医疗装置。该方法包括提供注射端口，该注射端口包括细长的柔性的基本上非刚性的主体，该主体具有第一和第二端以及在它们之间的壁，该壁在被刺穿后将自密封，该主体还包括由该主体包围的流体贮存器。壁和连接到身体的柔性细长管状导管，其与贮存器流体连通。此后，该方法包括在患者体内形成切口，通过切口进入患者的皮下脂肪层，在皮下脂肪层中形成空间并将注射端口植入皮下脂肪层内，使得可以在外部找到端口通过心悸。