IMPLANTABLE MEDICAL DEVICE, WITH COVER AND METHOD

[0001] This application incorporates by reference the following United States Patent applications, all of which were filed on filed December 19, 2003: Application Serial No. 10/741,127 titled Subcutaneous Injection Port For Applied Fasteners; Application Serial No. 10/10.741,875 titled Subcutaneous Self Attaching Injection Port With Integral Moveable Retention Members; and Application Serial No. 10/741,868 titled Subcutaneous Self Attaching Injection Port With Integral Fasteners.

TECHNICAL FIELD

[0002] The present invention relates generally to medical implants and appliers therefor, and more particularly to an attachment mechanism for use with a variety of medical implants and appliers for attaching such medical implants to body tissue. The invention will be disclosed in connection with, but not limited to, surgically implantable injection ports and an applier therefor.

BACKGROUND

[0003] Implantable medical devices are typically implanted in a patient to perform a therapeutic function for that patient. Non-limiting examples of such devices include pace makers, vascular access ports, injection ports (such as used with gastric bands) and gastric pacing devices. Such implants need to be attached, typically subcutaneously, in an appropriate place in order to function properly. It is desirable that the procedure to implant such devices be quick, easy and efficient. In many instances it would be beneficial if the surgeon could remove or reposition the device quickly, easily and efficiently.

[0004] The present invention encompasses an attachment mechanism to secure an medical implant device to body tissue quickly and easily. The attachment mechanism may be reversible, allowing the implantable medical device to be detached quickly and easily for repositioning or removal. Although standard, commercially available instruments may be used to actuate the attachment mechanism, the present invention also encompasses an applier for locating an implantable medical device in the desired location and quickly and easily actuating the attachment mechanism to secure the implantable medical device.

Brief Description of the Drawings

[0005] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention, and, together with the general description of the invention given above, and the detailed description of the embodiments given below, serve to explain the principles of the present invention.

[0006] FIG. 1 is a perspective view of an injection port with an attachment mechanism constructed in accordance with the present invention.

[0007] FIG. 2 is a top view of the injection port of FIG. 1.

[0008] FIG. 3 is a bottom view of the injection port of FIG. 1.

[0009] FIG. 4 is a cross sectional view of the injection port of FIG. 1 taken along line 4-4 of FIG. 3.

[0010] FIG. 5 is an exploded perspective view of the injection port of FIG. 1.

[0011] FIG. 6 is perspective view of the bottom of the injection port of FIG. 1, showing the attachment mechanism in the retracted position.

[0012] FIG. 7 is a perspective view of the bottom of the injection port of FIG. 1, similar to FIG. 6, showing the attachment mechanism in the extended/fired position.

[0013] FIG. 8 is a side cutaway view in partial cross-section illustrating a fastener of the attachment mechanism in the retracted position.

[0014] FIG. 9 is a side cutaway view in partial cross-section similar to FIG. 8 illustrating a fastener of the attachment mechanism that is being advanced by the actuator ring toward the extended/fired position.

[0015] FIG. 10 is a side cutaway view in partial cross-section similar to FIG. 8 illustrating a fastener of the attachment mechanism in the extended/fired position.

[0016] FIG. 11 is a side cutaway view in partial cross-section similar to FIG. 8 illustrating a fastener of the attachment mechanism that is being advanced by the actuator ring toward the retracted position.

[0017] FIG. 12 is a top view of the injection port of FIG. 1, with the actuator ring omitted to illustrate the positions of the links when the fasteners are in the retracted position.

[0018] FIG. 13 is a top view of the injection port of FIG. 1, with the actuator ring omitted to illustrate the positions of the links when the fasteners are in the extended/fired position.

[0019] FIG. 14 is an enlarged, fragmentary top view of the visual position indicator and actuator ring detent system of the attachment mechanism of FIG. 1, in the retracted position.

[0020] FIG. 15 is an enlarged, fragmentary top view of the visual position indicator and actuator ring detent system of the attachment mechanism of FIG. 1 in the extended/fired position.

[0021] FIG. 16 is an enlarged, fragmentary, exploded perspective view of the fitting and locking connector of the injection port of FIG. 1.

[0022] FIG. 17 is an enlarged, fragmentary partial cross-section view of the locking connector assembled to the fitting the septum retainer but not locked in place.

[0023] FIG. 18 is an enlarged, fragmentary partial cross-section view similar to FIG. 17 showing the locking connector locked in place.

[0024] FIG. 19 is an enlarged perspective view of the safety cap.

[0025] FIG. 20 is a perspective view of an applier constructed to implant the injection port of FIG. 1.

[0026] FIG. 21 is a exploded, perspective view of the applier of FIG. 20.

[0027] FIG. 22 is a side view of the applier of FIG. 20 with one of the two body halves showing the internal components in the unapplied, non-actuated position.

[0028] FIG. 23 is a side view of the applier of FIG. 20 similar to FIG. 22, showing the internal components in the applied, actuated position.

[0029] FIG. 24 is an enlarged, fragmentary side view of the linear to rotary cam mechanism of the applier of FIG 20.

[0030] FIG. 25 is an enlarged top perspective view of the locator of the applier of FIG. 20.

[0031] FIG. 26 is an enlarged bottom perspective view of the locator and the port actuator of the applier of FIG. 20.

[0032] FIG. 27 is a partially cut away end view of the locator of the applier of FIG. 20.

[0033] FIG. 28 is an enlarged, cross sectional view of the injection port of FIG. 1 retained by the locator of the applier of FIG. 20.

[0034] FIG. 29 is an enlarged, cross-sectional view of the injection port of FIG. 1 disposed in the locator of the applier of FIG. 20 after the applier has been actuated to rotate the applier actuator to the deployed position.

[0035] Reference will now be made in detail to the present preferred embodiment of the invention, an example of which is illustrated in the accompanying drawings.

Detailed Description

[0036] In the following description, like reference characters designate like or corresponding parts throughout the several views. Also, in the following description, it is to be understood that terms such as front, back, inside, outside, and the like are words of convenience and are not to be construed as limiting terms. Terminology used in this

patent is not meant to be limiting insofar as devices described herein, or portions thereof, may be attached or utilized in other orientations. Referring in more detail to the drawings, an embodiment of the invention will now be described.

[0037] Referring to FIGS. 1-5, there is shown an implantable medical device, more specifically an injection port, generally indicated at 2, which embodies an attachment mechanism constructed in accordance with the present invention. Although the attachment mechanism is illustrated in the figures as being embodied with injection port 2, the attachment mechanism may be used with any implantable medical device for which it is suited, including by way of example only pace makers, vascular access ports, injection ports (such as used with gastric bands) and gastric pacing devices.

[0038] Injection port 2 includes septum retainer 4, septum 6 and port body 8. Injection port 2, with the integrally constructed attachment mechanism, also includes one or more fasteners 10, actuator 12 and a plurality of link members 14.

[0039] As seen in FIG. 4, septum 6, which may be made of any biocompatible material such as silicone, is disposed partially within internal cavity 16 of septum retainer 4, adjacent annular flat 18. Septum retainer 4, port body 8, and actuator 12 may be made of any suitable biocompatible material having sufficient stiffness and strength, such as polyetheretherketon (known as PEEK). Fasteners 10 and link members 14 may be made of any suitable biocompatible material, such as stainless steel.

[0040] Port body 8 includes annular rim 20, which engages the upper surface of septum 6 about an annular portion. Port body 8 is retained to septum retainer 4 by a plurality of pins 22 which are disposed through respective holes 24 formed in recesses 24a in port body 8 and which extend inwardly into respective recesses 26 formed about the bottom periphery of septum retainer 4. Pins 22 may be made of any suitable biocompatible material, such as stainless steel.

[0041] The uncompressed height of septum 6 is approximately 5mm around the outer diameter and the uncompressed diameter is approximately 18mm. The exposed diameter for access to reservoir 20 is approximately 14mm. The distance between the lower surface of annular rim 20 and annular flat 18 is approximately 4mm, such that septum 6

is compressed approximately 20% to be adequately self healing to maintain a fluid tight system under pressure and still allow a low profile.

[0042] Plate 28 is disposed in recess 16a formed in the bottom of septum retainer 4, underlying septum 6 and fluid chamber or reservoir 30. As seen in FIG. 4, plate 28 does not contact sidewall 16b. In the embodiment depicted, plate 28 is metallic, such as stainless steel. When a needle is inserted through septum 6 to introduce or withdraw fluid from fluid chamber 30, such as in order to adjust the size of an adjustable gastric band, metallic plate 28 will protect septum retainer 4 from puncture and provide tactile feedback to the surgeon through the needle indicating that the needle has bottomed in reservoir 30. Plate 28 may be secured to septum retainer 4 in any suitable manner. In the embodiment depicted, plate 28 is held in place by retaining lip 4a extending over the periphery of plate 28 as best seen in FIGS 4, 28 and 29. Initially, retaining lip 4a extends upwardly as an annular lip, providing clearance for insertion of plate 28 into the recess at the bottom of septum retainer 4, and retaining lip 4a is then rolled or otherwise deformed to overlie at least a portion of the periphery of plate 28 thereby retaining plate 28. In the embodiment depicted the diameter of recess 16a is smaller than the diameter of sidewall 16b, providing room to form the annular lip and to deform it into retaining lip 4a. Plate 28 could be insert molded, with retaining lip 4a molded as illustrated.

[0043] Septum retainer 4 includes passageway 32, in fluid communication with fluid chamber 30, which is defined by fitting 34 extending from the periphery adjacent the bottom of retainer 4. Tube 36, which in the embodiment depicted, leads to an adjustable gastric band (not shown), is connected to fitting 34, being compressingly urged against annular rib 38 by connector 40, which is disposed about tube 36 and secured to port body 8 as described below. Sleeve 42 is disposed about tube 36, secured to connector 40 by annular ribs 44. Sleeve 42 relieves strain on tube 36, preventing tube 36 from kinking when loaded laterally.

[0044] Actuator 12 is secured to port body 8. Although in the embodiment depicted actuator 12 is illustrated as an annular ring rotatably supported by port body 8, actuator 12 may be any suitable configuration and supported in any suitable manner to permit actuator 12 to function to move fasteners 10 between and including deployed and undeployed positions. As seen in FIG. 5, port body 8 includes a plurality of downwardly

and outwardly extending tabs 46. In the embodiment depicted, there are four equally spaced tabs 46. Actuator 12 includes an equal number of corresponding recesses 48, each having arcuate bottom 50. To assemble actuator 12 to port body 8, recesses 48 are aligned with tabs 46, and pushed down, temporarily deflecting tabs 46 inwardly until tabs 46 reach recesses 48 and move outwardly to dispose lower edges 46a in recesses 48 such that actuator is retained thereby. The lengths of tabs 46 and depth of recesses 48 allow some axial end play between actuator 12 and port body 8, as will be described below.

[0045] Actuator 12 may rotate generally about the central axis of port body 8. In the embodiment depicted, actuator 12 may rotate through an angle of about 40 degrees, although any suitable angle may be used. In the embodiment depicted, when actuator 12 is rotated in the deploying direction, causing fasteners 10 to move to the deployed position, rotation of actuator 12 beyond the fully deployed position is limited by end 48c contacting tab 46.

[0046] A detent system is formed by a pair of spaced apart raised detent ribs 48a, 48b extending inwardly from the wall of each recess 48, and a corresponding raised rib 46b extending outwardly from tab 46. The detent system assists in preventing actuator 12 from rotation and fasteners 10 from moving out of fully retracted or fully extended fired states under vibration or incidental loads, as described below.

[0047] Actuator 12 includes a plurality of spaced apart openings or slots 54, which may be engaged by any suitable instrument to transmit the necessary torque to actuator 12 to extend fasteners 10 to the actuated position. Slots 54 are configured to be engaged by commercially available instruments, rectangular in the embodiment depicted, or by the dedicated applier described below. Port body 6 includes a plurality of recesses 56 disposed about its lower periphery which are configured to cooperate with the dedicated applier as described below.

[0048] Referring also to FIGS. 6 and 7, septum retainer 4 includes a plurality of locating tabs 58 extending outwardly from adjacent the bottom periphery of septum retainer 4. Locating tab 58a may be integral with fitting 34. Tabs 58 and 58a are located in respective complementarily shaped recesses 60 formed in the inner surface of port body 8, aligning septum retainer 4 properly with port body 8.

[0049] FIG. 6 illustrates fasteners 10 in the retracted position. As can be seen, fasteners 10 are disposed in respective recesses or slots 60 formed in port body 8. FIG. 7 illustrates fasteners 10 in the extended, or fired, position, extending from slots 60. Rotation of actuator 12 moves fasteners 10 from the retracted position to the extended position.

[0050] FIGS. 8-11 are a series of figures illustrating the operation of actuator 12 and one of the plurality of fasteners 10, it being understood that the operation on one of fasteners 10 may be the same as for all fasteners 10, which may, in one embodiment, be moved from a deployed position to an undeployed position simultaneously. FIG. 8 illustrates fastener 10 in a fully retracted state, the undeployed position, disposed completely within slot 62 such that sharp tip 64 is not exposed. This prevents tip 64 from accidentally sticking the surgeon or penetrating any object. Actuator 12 is illustrated rotated counter clockwise as far as permitted by recesses 48 and tabs 46. In this position, ribs 46b are disposed clockwise of ribs 48b, as seen in FIG. 14. First ends 14a of link members 14 are rotatably carried by actuator 12, spaced apart at positions corresponding to the positions of fasteners 10. Second ends 14b are disposed within openings 66 of fasteners 10.

[0051] To actuate the attachment mechanism, integral actuator 12 is rotated in a deploying direction, which in one embodiment as depicted is clockwise (any suitable direction configured to actuate the attachment mechanism may be used), and rib 46b passes rib 48b, which may produce an audible signal in addition to a tactile signal to the surgeon. Second end 14b of link member 14 is free to move within slot 66 during actuation, as the force that rotates fastener 10 into the extended position is transmitted to fastener 10 through the interaction between cam surface 68 of fastener 10 and actuating cam surface 70 of actuator 12. As actuator 12 rotates clockwise, actuating cam surface 70 engages and pushes against cam surface 68, rotating fastener 10 about pivot pin 22. The majority of the force from actuating cam surface 70 acts tangentially on cam surface 68, off center relative to pivot pin 22, causing fastener 10 to rotate. During actuation, end 14b of link member 14 remains free to move within slot 66, applying no driving force to rotate fastener 10.

[0052] In FIG. 9, fastener 10 is rotated about half way though its range of rotation, about 90 degrees as a result of the clockwise rotation of actuator 12. As actuator 12 is rotated clockwise, the force between actuator cam surface 70 and cam surface 68 causes actuator 12 to move upward slightly as allowed by the tolerancing of the components. As actuator 12 is rotated further clockwise from the position shown in FIG. 9, actuator cam surface 70 continues to engage and push against cam surface 68, rotating fastener 10 further counterclockwise.

[0053] In FIG. 10, actuator 12 is rotated clockwise to its fullest extent, with rib 46b having been urged past detent rib 48a (see FIG. 15). In this position, fastener 10 has rotated to its fullest extent, almost 180 degrees in the embodiment illustrated, with tip 64 disposed within recess 62. In this position, actuator cam surface 70 is over center, and actuator 12 is resistant to being back driven by an undeploying force imparted to fastener 10 as cam surface 68 acts against actuator cam surface 70 in a direction that tends to push actuator 12 up instead of rotating actuator 12. The distal end portion of fastener 10 is configured essentially as a beam, depicted as having a generally rectangular cross section along its length, tapering to sharp tip 64. With fastener 10 extending approximately 180 degrees in the fully extended state, the deployed position, forces which might act on fasteners 10 tend to act through the pivot axis defined by pivot pin 22, instead of rotating fasteners 10. It is noted that although pin 22 is illustrated as being a separate piece from fastener 10, the two may be integral or even of unitary construction.

[0054] If it is desirable to retract fasteners 10, such as to remove or reposition the implanted device, actuator 12 may be rotated in an undeploying direction, counterclockwise in one embodiment depicted. Starting with the position of actuator 12 shown in FIG. 10, actuator 12 may be rotated counterclockwise, with actuator cam surface 70 sliding against cam surface 68, without rotating fastener 10. In the embodiment depicted, continued counterclockwise rotation of actuator 12 moves cam surface 70 out of contact with cam surface 68, with no substantial rotating force being exerted on fastener 10 until second end 14b of link member reaches a location in slot 66, such as at one end of slot 66, at which link member 14 begins pulling against slot 66 causing fastener 10 to rotate and begin to retract.

[0055] As seen in FIG. 11, actuator 12 has been advanced counterclockwise compared to the position shown in FIG. 10, and fastener 10 is rotated approximately halfway through its range. As can be seen by comparing FIG. 9 to FIG. 11, actuator 12 is in different positions with fastener 10 in the same position, in dependence upon whether the attachment mechanism is being actuated or deactuated (retracted). This results from the lost motion that results when link member 14 is pulling on slot 66 in comparison to actuator cam surface 70 pushing directly on cam surface 68. To retract fasteners 10 fully, actuator 12 is rotated until detent rib 46b snaps past detent rib 48b.

[0056] Referring to FIG. 8, when fasteners 10 reach the fully undeployed position tip 64 may be disposed fully in slot or recess 62. Further undeploying rotation of actuator 12 is prevented by link member 14 which is prevented from further movement by fastener 10.

[0057] Referring to FIGS. 2 and 3, actuator 12 includes openings 52a formed therethrough, which align with corresponding openings 52b formed in port body 8 when actuator is in the undeployed position. Openings 52a and 52b may be used by the surgeon to suture injection port 2 if the integral attachment mechanism is not used.

[0058] Referring to FIGS. 12 and 13, the attachment mechanism is shown without actuator 12. Link members 14 are shown in their actual positions when first ends 14a are supported by actuator 12, in the deployed and in the undeployed states.

[0059] Referring to FIGS. 14 and 15, there is illustrated a top view of the visual position indicator and a portion of the actuator ring detent system of the attachment mechanism as embodied in injection port 2. In FIG. 14, the attachment mechanism is in the retracted, undeployed state or position. In this position, detent rib 46b is clockwise of detent rib 48b, and thus in the undeployed detent position. In FIG. 15, the attachment mechanism is in the actuated or deployed position. In this position, detent rib 46b is counterclockwise of detent rib 48b, and thus in the deployed detent position.

[0060] FIGS. 14 and 15 illustrate a visual indicator of the state of the attachment mechanism. As seen in FIG. 14, indicia may be utilized, such as an unlocked lock icon 72 and a locked lock icon 74 molded integral with actuator ring 12. Any suitable graphic indicator may be used, and may be printed on or otherwise applied in a suitable manner.

Port body 6 may include indicator 76 to provide a reference point for the movable indicia. Arrow 78 may be included to indicate the bidirectional motion of actuator 12.

[0061] FIGS. 16-18 illustrate the locking connection between connector 40 and port body 6. FIG. 16 is an exploded perspective view showing fitting 34 partially surrounded by extension 78. FIG. 17 shows extension 78 in cross-section, with connector 40 generally disposed about fitting 34 and tube 36 aligned in circumferential slot 78c of extension 78. Connector 40 includes a pair of tabs 40a, 40b, extending outwardly therefrom. To assemble, connector 40 is guided along tube 36 and fitting 34, with tabs 40a and 40b aligned with openings 78a and 78b of extension 78. With tabs 40a and 40b aligned with circumferential slot 78c, connector 40 is rotated to lock it in place. During rotation, detent edge 78d creates interference opposing the rotation of tab 40a, but is dimensioned to allow tab 40a to be rotated past, to the locked position seen in FIG. 18.

[0062] FIG. 19 illustrates safety cap 80 which may be removably secured to the bottom of injection port 2 to cover fasteners 10 to protect users from accidental exposure to sharp tips 64 while handling injection port 2. Safety cap 80 includes body 82 with annular rim 84 and raised center 86 defining annular recess 88. Safety cap 80 may be oriented and retained to injection port through any suitable configuration. As depicted, body 82 includes a plurality of arcuate retention tabs 90 extending upwardly from raised center 86. Arcuate retention tabs 90 are shaped complementarily to corresponding arcuate slots 92, best seen in FIGS. 3, 6 and 7, and may have ribs as shown. Safety cap 80 is secured to injection port 2 by inserting arcuate retention tabs 90 into arcuate slots 92, which are sized to retain tabs 90. Fasteners 10 are thus aligned with annular recess 88, which is sized to allow fasteners 10 to be extended without contacting safety cap 80. As depicted, since arcuate retention tabs 90 and arcuate slots 92 are respectively the same size and equally spaced, safety cap 80 is not indexed to a particular position, and may be secured to injection port 2 in four different positions. Safety cap 80 includes pull tab 94 with raised a plurality of ribs 96 to provide a better gripping surface. Although pull tab 94 may be oriented in any suitable orientation, in the embodiment, the relative position between pull tab 94 and arcuate retention tabs 90 locates pull tab at 45 degrees to the direction of connector 40. Tabs 90 and slots 92 may be of any suitable shape.

[0063] As mentioned previously, the attachment mechanism may be actuated by engaging slots 54 with commercially available instruments or by a dedicated applier. FIG. 20 illustrates applier, generally indicated at 100, which is configured to position, actuate, deactuate, remove or reposition injection port 2. It is noted that the practice of aspects of the present invention as applied to an applier is not limited to the specific applier embodiment depicted herein.

[0064] As shown in FIG. 20, applier 100 includes body 102, locator 104, actuator 106 and safety switch 108. As will be described below, injection port 2 may be assembled to locator 104, with extension 78 and tab 96 disposed in alignment slots 110 and 112. Locator 104 is angled relative to body 102, allowing for easier and better visualization of injection port 2 during implantation. In the embodiment depicted, the angle is 20 degrees and the shaft portion of body 102 is 10 cm.

[0065] Referring to FIG. 21, body 102 includes first and second halves 102a and 102b assembled to each other to contain the internal components. Except for locating pins 202, pivot pins 114 and ship laps, body halves 102a and 102b are substantially similar to each other. Locating pins 202, illustrated as extending from body half 102a, fit into respective complementarily shaped openings (not illustrated) on body half 102b. The engagement of the plurality of locating pins 202 in the openings is sufficient to hold body halves 102a and 102b together. Pins 202 may alternatively extend from body half 102b with the openings carried by body half 102a. Any suitable configuration may be used to assemble and secure body halves 102a and 102b together.

[0066] Actuator 106 includes first and second halves 106a and 106b. Locating pins 204, illustrated as extending from actuator half 106a, fit into respective complementarily shaped openings (not illustrated) on actuator half 106b. Pins 204 may alternatively extend from actuator half 106b with the openings carried by actuator half 106a. Any suitable configuration may be used to assemble and secure actuator halves 106a and 106b together. Body half 102b includes pivot pin 114b which rotatably supports actuator 106 at one end, extending through pivot holes 116a and 116b into opening 114a. Body half 102a includes pivot pin 118b (see FIG. 22) which rotatably supports safety switch 108. Body halves 102a and 102b, locator 104, actuator halves 106a and 106b,

and safety switch 108 may be made of any biocompatible material such as polycarbonate.

[0067] Referring to FIGS. 21-24, applier 100 includes cam 120, drive shaft 122 with flexible shaft 124, drive shaft pin 126, cam return spring 128, safety biasing spring 130, and actuator 132. Actuator 132 is configured to effect the deployment or undeployment of the attachment mechanism of the medical implant. Cam 120 includes shaft 134 and cam collar 136. The upper end of shaft 134 has a "T" configuration terminating in cross member 138. Cam collar 136 defines a hollow interior and a pair of spaced apart, complementarily shaped cam tracks 140a and 140b formed on opposite sides of cam collar 136. Upper end 122a of drive shaft 122 is disposed partially within the hollow interior defined by cam collar 136, captured therein by drive shaft pin 126. Drive shaft pin 126 is sized such that each end is located within a respective cam track 140a, 140b. The length of the hollow interior allows upper end 122a to reciprocate therein, with cam tracks 140a and 140b imparting rotation to drive shaft 122 through drive shaft pin 126 during reciprocation. Cam 120, drive shaft 122 and actuator 132 may be made of any suitable material having sufficient stiffness and strength. In the embodiment depicted, cam 120 and actuator 132 are made of a liquid crystal polymer such as Vectra^{tm} LCP, and drive shaft 122 is made of a PPE+PS such as Noryl^{tm}. Drive shaft pin 126 and cam return spring 128 may be made of any suitable material, such as stainless steel.

[0068] Cam 120 is retained between body portions 102a and 102b, and in one embodiment, such as that depicted can reciprocate. Cam collar 136 has spaced apart, generally flat outer surfaces 142a and 142b tracks through which 140a and 140b are formed. These surfaces 140a and 140b are disposed between guide walls 144a and 144b formed in body portions 102a and 102b. Cam collar 136 also includes oppositely facing channels 146a and 146b (see FIG. 23), which are guided for axial reciprocation by guides 148a and 148b (not illustrated) formed in body portions 102a and 102b, respectively. The upper end of shaft 134 and cross member 138 are disposed sandwiched between actuator halves 106a and 106b. Each actuator half 106a, 106b, includes a cam track 150 defined by a pair of spaced apart walls 150a and 150b extending from the interior surfaces of actuator halves 106a and 106b. Cam track 150 is configured to receive and guide cross member 138 as actuator 106 is rotated about pin 114, forcing cam 120 to advance linearly downwardly into body 102.

[0069] Drive shaft 122 includes annular collar 152 which is received in slots 154a and 154b (not illustrated) formed in body halves 102a and 102b, respectively. Slots 154a and 154b rotatably support drive shaft 122. Drive shaft 122 and cam 120 are generally aligned and collinear with each other, defining the axis of the shaft portion of body 102. As cam 120 is advanced downwardly, drive shaft pin 126 follows cam tracks 140a and 140b, causing drive shaft 122 to rotate, thus converting linear motion to rotary motion. Cam return spring 128 provides a nominal return force against cam collar 136.

[0070] Flexible shaft 124 is supported by a plurality of ribs 156, formed in each body half 102a, 102b, which support the bend in flexible shaft 124 that permits the rotary motion to be transferred to actuator 132 which is disposed at an angle relative to the shaft of body 102. Flexible shaft 124 may be made of any suitable biocompatible material, such as stainless steel. In an embodiment depicted, flexible shaft 124 has a stranded construction, with a center core having multiple layers of wire wrapped thereabout. Ends 124a and 124b of flexible shaft 124 may be attached to end 122b and actuator 132, respectively, in any suitable manner which sufficiently limits rotational end play to prevent or minimize lost rotational motion. In an embodiment depicted, end 124a was overmolded into end 122b, and end 124b was press fit into actuator 132. Alternatively, end 124a could be press fit into end 122b, and end 124b overmolded into actuator 132, both could be press fit, or both could be overmolded (with a corresponding change to the configuration of locator 104 to allow assembly.

[0071] Referring to FIGS. 21-25, actuator 132 includes disc shaped member 158 and shaft 160 extending upwardly therefrom. The upper end of shaft 160 includes a pair of outwardly extending tabs 162a and 162b. Locator 104 includes hub 164 defining bore 166 therethrough. Bore 166 is shaped to receive and rotatably support shaft 160, and includes two outwardly extending arcuate recesses 168a and 168b configured to provide assembly clearance for tabs 162a and 162b, allowing hub 164 to be inserted into bore 166. The lengths of shaft 160 and hub 164 are sized such that tabs 162a and 162b are located above upper surface 164a of hub 164, allowing rotation of actuator 132 while retaining it axially relative to hub 164. Stops 170 and 170b extend upwardly from upper surface 164a, limiting the rotation of actuator 132. Bore 166 defines a central axis of locator 104 about which actuator 132 is rotated. The central axis of locator 104 is

disposed at an angle to the axis of the shaft portion of body 102, as previously mentioned.

[0072] Hub 164 includes a pair of oppositely extending tabs 172a and 172b which retain port actuator 104 to body 102 and prevent rotation. Body halves 102a and 102b include respective recesses 174a (see FIG. 21) and 174b (not illustrated) shaped complementarily to tabs 172a and 172b.

[0073] Referring also to FIGS. 26 and 27, disc shaped member 158 of actuator 132 is seen disposed within locator 104. Actuator 132 includes a pair of spaced apart posts 176a and 176b, extending from adjacent periphery 158a of member 158. Posts 176a and 176b are shaped complementarily with openings 54. In the embodiment depicted, the distal ends of posts 176a and 167b are tapered to assist in guiding posts 176a and 176b into openings 54. Any suitable configuration may be utilized to create releasable contact between actuator 132 and actuator 12 capable of actuating actuator 12.

[0074] Disc shaped member 158 also includes a pair of spaced apart cams 178a and 178b which extend outwardly and upwardly from periphery 158a of member 158. FIG. 27 illustrates cam 178a at a cross-section taken near the bottom surface of member 158. Cams 178a and 178b include ramps 180a and 180b which start at periphery 158a and lead out to surfaces 182a and 182b, respectively. Each surface 182a, 182b is arcuate, shown in the embodiment depicted as generally having a constant radius.

[0075] In the embodiment depicted, locator 104 includes a pair of spaced apart cantilever arms 184a and 184b, each having rib 186a and 186b, respectively. For clarity, FIG. 27 illustrates arm 184a in cross-section taken through rib 186a, at the same level as for cam 178a. At their distal ends, arms 184a and 184b include respective inwardly extending flanges 188a and 188b. Flanges 188a and 188b are shaped complementarily to recesses 56 on port body 6, configured to engage ledges 56a when injection port 2 is retained by locator 104.

[0076] In the embodiment depicted, in the non-actuated state, posts 176a and 176b are generally aligned with arms 184a and 184b, respectively, although posts 176a and 176b may be at any position that corresponds to position of the actuating feature of actuator 12, which in the embodiment depicted is openings 54. As actuator 106 is depressed,

actuator 132 rotates (counterclockwise in the embodiment depicted when viewed from the bottom), advancing cams 178a and 178b such that ramps 180a and 180b contact ribs 186a and 186b, respectively, deflecting arms 184a and 184b outwardly. When surfaces 182a and 182b engage ribs 186a and 186b, arms 184a and 184b are deflected a distance sufficient to move flanges 188a and 188b to a position where they no longer extend into recesses 56 or contact ledges 56a, thus releasing injection port 2 from locator 104.

[0077] FIG. 28 illustrates injection port 2 disposed in and retained by locator 104, with extension housing 78 and tab 96 disposed in slots 110 and 112, respectively (see FIG. 20, not seen in FIG 28). As depicted, posts 176a and 176b extend into openings 54 of actuator 12, and flanges 188a and 188b extending into recesses 56 proximal ledges 56a. Safety cap 80 is connected to injection port 12 when injection port 12 is inserted into locator 104, covering fasteners 10 (not seen in FIG 28).

[0078] Referring also to FIGS. 20 and 22, to insert injection port 2 into locator 104, actuator 106 is oriented in the undeployed position so that actuator 132 is in the undeployed position. Actuator 12 is oriented in the undeployed position, and inserted into locator 104, with extension housing 78 and tab 96 disposed in slots 110 and 112, respectively.

[0079] Actuator 106 may, as illustrated in FIG. 20, include a visual indicator to indicate whether actuator 106 is fully in the undeployed state, such as unlocked lock icon 190, and indicia to indicate whether actuator 106 is in the deployed state, such as locked lock icon 192. Such visual indication may be include by any suitable manner, such as by molding integral with actuator 106, applying as a adhesive film or such, or printing directly on actuator 106. With the indicator illustrated, unlocked lock icon 190 is visible adjacent the upper edge of body 102, although other configurations of indication may be utilized, such as a window or such formed in body 102 to reveal the indicia.

[0080] To use, locator 104 and a portion of 102, if necessary, is inserted through an incision by the surgeon and located in the desired position adjacent the body tissue to which the medical implant (which in the embodiment depicted is an injection port 2) is to be attached. The angle between locator 104 and body 102 allows the surgeon to visualize the site directly. With injection port 2 in position, the one or more fasteners 10 are moved from the undeployed position to the deployed position in an annular path to

engage the tissue. Fasteners 10 allow injection port 2 to be secured to the tissue with a retention strength equal to or greater than when secured with sutures. Safety switch 108 is rotated about pivot pin 118, withdrawing lockout tab 194 from lower opening 196, allowing actuator 106 to be rotated about pivot pin 114. This action causes cam track 150 to move cross member 138 downward, causing cam collar 136 to rotate drive shaft 122, thereby rotating actuator 132 relative to locator 104.

[0081] Rotation of actuator 132 actuates actuator 12 by rotating it. The engagement between extension 78 and tab 96 and slots 110 and 112, respectively, prevent port body 8 from rotating, allowing relative motion between actuator 12 and port body 8.

[0082] Once actuator 106 reaches the deployed position, lockout tab 194 is urged into upper opening 198, retaining actuator 106 in the deployed position. In the embodiment depicted, spring 130 biases lockout tab 194 sufficiently to produce sound as lockout tab 194 snaps into upper opening 198, providing an audible signal that actuator 106, and therefore actuator 12 and fasteners 10 are deployed fully. As illustrated in FIG. 29, with actuator 106 in the deployed position, actuator 12 has been rotated and fasteners 10 are in the deployed position having penetrated the body tissue, such as the rectus sheath. Cams 178a and 178b have been rotated to a position where surfaces 182a and 182b are adjacent ribs 186a and 186b, with arms 184a and 184b deflected outwardly such that flanges 188a and 188b are not disposed in recesses 56 and not engaging ledges 56a. With injection port 2 secured to the body tissue, and released from locator 104, the surgeon may withdraw locator 104, leaving injection port 2 in place. If a visual indicator of the state of the attachment mechanism is included with the implant, the surgeon can tell whether the attachment mechanism is fully deployed.

[0083] The attachment mechanism embodied in injection port 2 is configured to be reversible so that the medical implant, injection port 2, may be moved, such as to reposition it or remove it from the patient. To do so, with actuator 106 in the deployed position, locator 104 is placed over injection port 2, locating extension 78 and tab 96 in slots 110 and 112 so that posts 176a and 176b are engaged with recesses 54. Safety switch 108 is rotated to withdraw lockout tab 194 from upper opening 198, while the surgeon pulls up on extension 200 of actuator 106. Although cam return spring 128 urges cam collar 136 upwardly, extension 200 allows an additional return force to be

applied. As cross member 138 is pulled up by cam track 150, actuator 132 rotates actuator 12, moving fasteners 10 from the deployed position to the undeployed position simultaneously, while cams 178a and 178b disengage from ribs 186a and 186b, allowing flanges 188a and 188b to engage recess 56 and ledge 56a so as to retain injection port 2 in locator 104. When actuator 106 has been moved to the undeployed position, lockout tab 194 snaps into lower opening 196, generating an audible signal that actuator 106 is undeployed fully, and injection port 2 is detached from the body tissue and may be relocated or removed.

[0084] In summary, numerous benefits have been described which result from employing the concepts of the invention. The foregoing description of one or more embodiments of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Modifications or variations are possible in light of the above teachings. The one or more embodiments were chosen and described in order to illustrate the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the claims submitted herewith.

What is claimed is:

1. A surgically implantable device:

(a) a medical implant for performing a therapeutic function;

(b) an attachment mechanism comprising at least one fastener integral to said implant for attaching said implant to a body, said at least one fastener having a deployed position, wherein said at least one fastener extends from a distal end of said implant, and an undeployed position, wherein said fastener is proximal to said distal end of said implant; and

(c) a safety member covering said at least one fastener and removably attached to said distal end of said implant.

2. The device of claim 1, wherein said safety member is configured not to contact any of said at least one fastener while said safety member is attached to said implant.

3. The device of claim 1, wherein said distal end and said safety member, when attached to said implant, define an internal cavity, said internal cavity being configured to allow said at least one fastener to move between said undeployed position and said deployed position.

4. The device of claim 3, wherein said safety member comprises an annular recess which defines said internal cavity in conjunction with said distal end.

5. The device of claim 1, wherein said safety member comprises at least one tab extending therefrom, and said distal end comprises an associated recess for each of said at least one tab.

6. The device of claim 5, wherein said associated recess comprises a respective recess for each of said at least one tab.

7. A method of surgically implanting/positioning a medical implant for performing a therapeutic function, said method comprising the steps of:

(a) providing an applier for attaching said medical implant to body tissue, said medical implant having a deployed and an undeployed state;

(b) attaching said medical implant to said applier, said medical implant comprising at least one fastener integral to said implant for attaching said implant to a body, said at least one fastener having a deployed position, wherein said at least one fastener extends from a distal end of said implant, and an undeployed position, wherein said fastener is proximal to said distal end of said implant, said medical implant having a safety member removably

attached to said distal end of said implant, said safety member covering said at least one fastener;

(c) removing said safety member from said medical implant;

(d) locating said medical implant at a first location; and

(e) moving said at least one fastener from said undeployed position to said deployed position, thereby attaching said medical implant to said body tissue at said first location.

8. The method of claim 7, further comprising the step of moving said at least one fastener from said deployed position to said undeployed position, thereby detaching said medical implant from said body tissue.

9. The method of claim 8, further comprising the steps of:

(a) disposing said medical implant at a second location adjacent body tissue; and

(b) moving said at least one fastener from said undeployed position to said deployed position, thereby attaching medical implant to said body tissue at said second location.