



(51) International Patent Classification:
A61F 2/04 (2006.01)

(21) International Application Number:
PCT/IL2015/051051

(22) International Filing Date:
27 October 2015 (27.10.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/069,164 27 October 2014 (27.10.2014) US

(71) Applicant: LITHIBLOCK LTD. [IL/IL]; c/o Mr. Shmuel Ben Muvhar, 71940 Peduel (IL).

(72) Inventor: BEN MUVHAR, Shmuel; Peduel, 7194000 (IL).

(74) Agents: EHRLICH, Gal et al.; G.E. Ehrlich (1995) LTD., 11 Menachem Begin Road, 5268104 Ramat Gan (IL).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,

BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

(54) Title: GALLBLADDER IMPLANT AND SYSTEMS AND METHODS FOR THE DELIVERY THEREOF

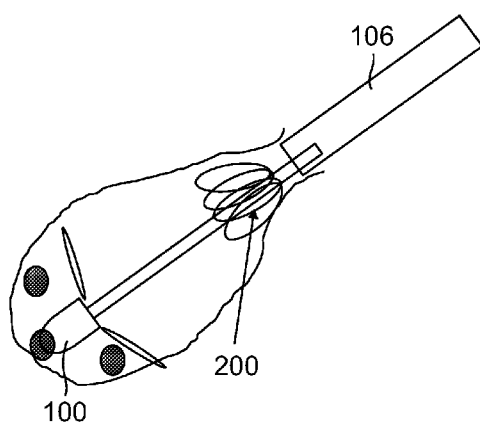


FIG. 2C

(57) Abstract: A filter device for implantation in a gallbladder, comprising: a filter portion configured to filter gallstones of a certain minimum size to prevent them from exiting the gallbladder through an opening of the gallbladder; a blocking portion configured to push gallstones of a certain minimum size away from an opening of the gallbladder where the blocking portion is located distally from the filter portion with respect to the opening of the gallbladder; and, where the blocking portion and the filter portion do not attach to, or apply expansive radial force on, a wall of the gallbladder.

GALLBLADDER IMPLANTS AND SYSTEMS AND METHODS FOR THE DELIVERY THEREOF

5 RELATED APPLICATION/S

This application claims the benefit of priority under PCT Article 8 of U.S. Provisional Patent Application No. 62/069,164 filed October 27, 2014, this application is also related to pending U.S. Pat. App. Ser. No. 13/260,382, filed on September 26, 2011, the contents of which are incorporated by reference herein in their entireties.

10 FIELD AND BACKGROUND OF THE INVENTION

The present invention relates generally to treating medical conditions involving ducts and/or body lumens, for example by preventing occlusion of portions of the biliary tree during treatment device deployment.

"Stones" in the gallbladder and bile ducts are found in the entire population, some of them being asymptomatic, and some – symptomatic. In the U.S., 10 - 15% of the adult population (more than 20 million people) suffer from bile duct stones (about 20 % of the population above 65 years of age suffer from gallstones), with more than two million new cases diagnosed annually, and more than 1,800,000 cholecystectomy procedures performed annually. Patients with gallstones are classified according to three groups: symptomatic, asymptomatic and those suffering from complications caused by the gallstones, such as cholecystitis, pancreatitis or obstructive jaundice.

SUMMARY OF THE INVENTION

There is provided in accordance with an exemplary embodiment of the invention, a filter device for implantation in a gallbladder, comprising: a filter portion configured to filter gallstones of a certain minimum size to prevent them from exiting the gallbladder through an opening of the gallbladder; a blocking portion configured to push gallstones of a certain minimum size away from an opening of the gall bladder where the blocking portion is located distally from the filter portion with respect to the opening of the gallbladder; and, where the blocking portion and the filter portion do not attach to, or apply expansive radial force on, a wall of the gallbladder.

In an embodiment of the invention, the blocking portion and the filter portion are the same.

In an embodiment of the invention, the device further comprises comprising an anchoring portion extending from the filter portion towards the opening of the gallbladder and configured to reduce movement of the filter device in the gallbladder.

5 In an embodiment of the invention, the device further comprises a stopper extending in the longitudinal axis of the filter device away from the opening of the gallbladder, where the stopper and the anchoring portion when taken together prevent migration of the anchoring portion away from the opening of the gall bladder.

In an embodiment of the invention, at least the filter portion is mesh.

In an embodiment of the invention, at least the filter portion is a coil.

10 In an embodiment of the invention, at least the filter portion is a perforated or porous sheet.

In an embodiment of the invention, the filter device is comprised of a single filament.

15 In an embodiment of the invention, the device is made from at least one of a metal, a shape memory alloy and a polymer.

In an embodiment of the invention, the device is adapted for eluting a pharmaceutical after implantation.

In an embodiment of the invention, the device is at least one of bioabsorbable and biodegradable.

20 In an embodiment of the invention, at least one of the blocking portion and filter portion are configured to prevent bio-film growth.

In an embodiment of the invention, at least one of the blocking portion, anchoring portion and filter portion are configured to prevent bio-film growth.

25 In an embodiment of the invention, the filter portion is configured to filter gallstones 5 mm or greater in diameter.

In an embodiment of the invention, the filter portion is configured with wires no more than 4mm apart.

There is further provided in accordance with an exemplary embodiment of the invention, a system for delivery of a filter device for implantation in a gallbladder, 30 comprising: a filter device including a blocking portion configured to push gall stones of a certain minimum size away from an opening of the gallbladder; and, a catheter configured for transit of the filter device therethrough to the gallbladder.

There is further provided in accordance with an exemplary embodiment of the invention, a method for implanting a filter device in a gallbladder, comprising: navigating the filter device to the gallbladder for implantation, the filter device including at least a blocking portion; entering the gall bladder at a gallbladder opening with the blocking portion; manually or automatically expanding the blocking portion in the gallbladder; pushing any gallstones in the gallbladder towards a distal end of the gallbladder and away from the gallbladder opening, thereby clearing a space within the gallbladder for proper and/or full expansion of the filter device; introducing a filter portion of the filter device to the gallbladder; and, manually or automatically expanding the filter portion in the gallbladder.

In an embodiment of the invention, the blocking portion and the filter portion are the same element, and blocking and filtering are performed simultaneously by the same element.

In an embodiment of the invention, the method further comprises deploying an anchoring portion after entering with the blocking portion and after introducing the filter portion.

In an embodiment of the invention, the method further comprises preventing the anchoring portion from moving away from the gall bladder opening using a stopper in conjunction with the anchoring portion.

In an embodiment of the invention, the method further comprises withdrawing the blocking portion after the filter portion has been expanded.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the

drawings in detail, it is stressed that the particulars shown are by way of example, and not necessarily to scale, and are for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

5 In the drawings:

FIGs. 1A-1E are side views of a schematic deployment sequence of a blocking device, in accordance with an exemplary embodiment of the invention;

FIGs. 2A-2C are side views of a schematic deployment sequence of a filtering device after the blocking sequence shown in FIGs. 1A-1E has been performed, in accordance with an exemplary embodiment of the invention;

FIGs. 3A-3C are side views of two tier filtering devices, in accordance with exemplary embodiments of the invention;

FIGs. 4A-4C are top views of the filtering portion of filtering devices, in accordance with exemplary embodiments of the invention;

15 FIGs. 5A and 5B are perspective views of a filtering device, in accordance with an exemplary embodiment of the invention;

FIG. 6 is a top view of a filtering device in situ, in accordance with an exemplary embodiment of the invention; and

20 FIG. 7 is a flowchart of a method of deploying a filtering device in a gall bladder, in accordance with an exemplary embodiment of the invention.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention relates generally to treating medical conditions involving ducts and/or body lumens, for example by preventing occlusion of portions of the biliary tree during treatment device deployment.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Generally, systems, devices and methods for deploying filtering devices in a gallbladder are described. In some embodiments of the invention, a blocking device

and/or a blocking portion of a device are used to push gall stones away from the opening to the gallbladder in order to make space for proper deployment of a gall stone filtering device. In some embodiments of the invention, the blocking device and the filter device are components of a system. In some embodiments of the invention, the blocking device is separate from the filtering device. In some embodiments of the invention, the blocking is performed by a filtering portion of the filtering device. In some embodiments of the invention, the filtering device is two-tiered. Optionally, one tier is configured to block and/or filter. Optionally, one tier is configured to anchor the device. In some embodiments of the invention, the device is provided with a stopper.

In an embodiment of the invention, the devices described herein spare the patient from suffering and/or surgery, and are intended to prevent the complications of cholecystectomy and anesthesia, operative mortality, postoperative infections (wound infection and other infections), and/or delayed impacts of gallbladder absence (impaired absorption, abdominal pain, etc.) by relieving and/or preventing the symptoms of cholecystitis, pancreatitis or obstructive jaundice, and/or preventing and/or delaying the need for cholecystectomy in patients with gallstones. In some embodiments of the invention, temporary relief, for example of pain induced by gallstones, is provided.

It should be understood that exemplary filter devices described herein are intended to prevent gallstones from passing from the gall bladder into the cystic duct while still allowing for normal bile flow and/or bodily fluids and/or secretions through the biliary tree and into the duodenum. In some exemplary embodiments of the invention, filtering is achieved without exerting potentially harmful levels of expansive radial force on the walls of the cystic duct and/or gall bladder. In some embodiments of the invention, no radial force is applied on the walls of the cystic duct and/or gallbladder.

FIGs. 1A-1E are side views of a schematic deployment sequence of a blocking device 100, in accordance with an exemplary embodiment of the invention. For efficiency, description of device embodiments of the invention (FIGs. 1A-1E and FIGs. 2A-2C) are described in conjunction with the methods of their deployment, in conjunction with FIG. 7.

FIG. 7 is a flowchart 700 depicting a method of implanting a filter device 200 in the gallbladder 104, in accordance with an embodiment of the invention. In an

embodiment of the invention, implantation may be performed without general anesthesia and is considered to be minimally invasive. In an embodiment of the invention, the filter device 200 and/or the blocking device 100 are inserted and/or navigated (702) into the GI tract via the mouth, through to the esophagus, through to the stomach and then into the duodenum. Navigation and/or insertion are accomplished using an endoscope and/or a guiding wire and/or an elongated tool, such as a catheter 106, as chosen by the attending medical professional performing the procedure, in an embodiment of the invention.

The filter device 200 is advanced the Sphincter of Oddi/papila into the common bile duct, in an exemplary embodiment of the invention. A sphincterotomy of the Sphincter of Oddi is performed, if required and/or desired, similarly to the method commonly used in endoscopy and ERCP. The filter device 200 is implanted at a desired implantation site by navigating the filter device 200 from the common bile duct through to the cystic duct and/or the gallbladder 104. Contrast material is used in order to image the gallbladder 104 and/or the cystic duct and/or the gastro-intestinal tract, in some exemplary embodiments of the invention. Optionally, other commonly available imaging techniques are used for the implantation, for example X-ray and/or ultrasound.

In an exemplary embodiment of the invention, the filter device 200 and/or the blocking device 100 are inserted and/or navigated (702) into the patient in a contracted form. In some embodiments of the invention, the blocking device 100 precedes the filter device 200 such that during implanting, the blocking device 100 enters (704) the gallbladder 104 first (shown in FIGs. 1A-1B), radially expands (706) in the gallbladder 104 (shown in FIGs. 1C-1D) and pushes (708) any gallstones 102 in the gallbladder 104 down to or at least towards a distal end of the gallbladder 104 and away from the gallbladder opening (shown in FIGs. 1D-1E), thereby clearing a space within the gallbladder for proper and/or full expansion of the filter device.

In an embodiment of the invention, the filter device 200 is then introduced (710) to the gallbladder 104 (now that the area in the gallbladder 104 near the opening has been cleared or substantially cleared of gallstones 102) so that the filter device 200 can properly expand (712) to provide filtering. Introduction of the filter device 200 and expansion in a cleared area is schematically shown in FIGs. 2A-2C. In some

embodiments of the invention, the filter device 200 expands (712) to its intended size and shape upon arrival at the desired site of implantation.

In some embodiments of the invention, the filter device 200 is also provided with blocking capability and functionally operates to both block (to clear out gall stones
5 to make room for filter expansion) and filter. Exemplary devices for performing both functions in the same device are shown and described with respect to FIGs. 3A-3C and FIGs. 4A-4C, below. In some embodiments of the invention, the blocking device 100 also functions as a filter, in addition to and/or alternatively to the filtering device 200.

In some embodiments of the invention, the filter device 200 expands (712) as a
10 consequence of its own spring-like behavior, for example upon deployment from a catheter 106 which was used to pass the filter device 200 to the cystic duct and/or gallbladder 104, the device 200 springs into designed shape and size once the catheter 106 is no longer holding the filter device 200 in a contracted state. Optionally, the filter device 200 expands (712) as a result of its shape memory characteristic. In some
15 embodiments of the invention, an expansion balloon is used to expand the filter device 200. Due to the special anatomic structure of the cystic duct in the gallbladder region, more than one balloon and/or one balloon inflation may be used, for example, using a flexible balloon for initial inflation and a rigid and/or a semi- rigid balloon for filter device fixation.

20 Optionally, the blocking device 100 is withdrawn after the filter device 200 has been deployed, for example through an opening in the filter device configured for passage of the blocking device 100 therethrough.

Besides the implantation method described above, any other technique leading to the Sphincter of Oddi and/or the gallbladder 104, such as laparoscopy or open
25 surgery, may be used.

In an embodiment of the invention, the filter device 200 and/or the blocking device 100 can be removed or are designed to be bio-absorbed at any time.

In some embodiments of the invention, medical imaging is used for guiding the navigation of the biliary tree and/or implantation of the blocking device 100 and/or filter
30 device 200 at the correct implantation site. Optionally, a scope is used to provide imaging. Optionally, x-ray is used to provide imaging. Optionally, ultrasound is used to provide imaging.

FIGs. 3A-3C are side views of two tier filtering devices 300, 320, 340, respectively, in accordance with exemplary embodiments of the invention. In an embodiment of the invention, the two tier filtering devices 300, 320, 340 are provided with a combination filter/blocker portion 302, 322, 342, respectively and an anchoring
5 portion 304, 324, 344, respectively.

In an embodiment of the invention, the filter/blocker portion 302, 322, 342 is configured to enter the gall bladder 104 prior to the second tier, or anchoring portion 304, 324, 344, which when the filter/blocker portion 302, 322, 342 expands pushes any gallstones away from the opening of the gall bladder 104, both to prevent gall stones
10 from entering the biliary tree and also to ensure proper deployment/expansion of the anchoring portion 304, 324, 344.

In an embodiment of the invention, the anchoring portion does not exert radial force on the wall of the gallbladder 104 and/or does not anchor by attaching itself or latching onto a wall of the gallbladder 104. In some embodiments of the invention, the anchor portion 304, 324, 344 works in combination with a stopper 306, 326, 346 which
15 when taken together stretch substantially the length of the gallbladder 104, preventing the devices 302, 320, 340 from moving axially in the gallbladder (that is, preventing the device from migrating away from the opening to gallbladder).

FIGs. 4A-4C are top views of the filter/blocking portions 302, 322, 342 of filtering devices 300, 320, 340, in accordance with exemplary embodiments of the invention. In some embodiments of the invention, at least the filter/blocking portion 302, 322, 342 is configured so that there is spacing between the wires sufficient for blocking gallstones of a specified minimum size, but are also far enough apart to avoid growth of bacterial films, and other bio-film growth, between the wires which could
20 block the natural flow of material from the gallbladder into the biliary tree.

In some embodiments of the invention, the filter/blocking portion is configured to block gallstones approximately 5mm or more in diameter. In some embodiments of the invention, spaces between wires form an opening no greater than 4mm x 4mm.

In some embodiments of the invention, the filter portion and/or blocking portion
30 and/or anchoring portion are mesh, spiral/coiled and/or a perforated sheet. In some embodiments of the invention, the device is shaped to allow for slight movement within the implantation site in order to prevent or delay bio-film growth via device motion.

Optionally, the device is moved by movement of the gallbladder and/or the surroundings of the implantation site itself. In an embodiment of the invention, the device moves and/or flexes to cause any accumulation of bio-film to break, crack and/or at the very least create openings through the bio-film such that natural secretions of the gall bladder continue to flow.

The device material is selected to be biocompatible and/or bio-absorbable, in an exemplary embodiment of the invention. Optionally, the device is constructed of a polymer material. In some embodiments of the invention, the device is at least partly metal. Optionally, the device is at least a shape memory alloy such as nickel titanium, also known as Nitinol®. In some embodiments of the invention, at least a portion of the device is coated, for example with Teflon® or other similarly inert or highly non-reactive coating. Optionally, at least a portion of the device and/or the coating is adapted to elute a substance, for example a pharmaceutical. Optionally, an anti-bio-film agent, like an antibiotic, is eluted from and/or covers at least a portion of the device.

In some embodiments of the invention, the entire device is constructed of a single filament. In an embodiment of the invention, the blocking portion (if separate, such as in the case of the device shown in FIGs. 1A-1E) and/or the filter portion and/or anchoring portion are separately formed elements which are connected together. In some embodiments of the invention, at least two of the portions are connected by at least a single filament. Optionally, at least two of the sections are connected by a plurality of filaments.

Optionally, the anchoring portion 304, 324, 344 could have a configuration shown in any of FIGs. 4A-4C. Optionally, a separate blocking or filter portion could have a configuration shown in any of FIGs. 4A-4C.

FIGs. 5A and 5B are perspective views of a filtering device 500, in accordance with an exemplary embodiment of the invention. FIG. 5B shows an exemplary filtering device 500 configured with a filter/blocking portion 502 and a stopper 504. FIG. 5A is a perspective view of a cross-sectioned gallbladder 104 with the filtering device 500 implanted within the gallbladder 104. In an embodiment of the invention, filtering device 500 is deployed after a blocking device 100 has been deployed. Optionally, the blocking device 100 is removed after the filtering device 500 has been placed in the gallbladder 104. In some embodiments of the invention, the filter/blocking portion 502

is located near an opening 506 to the gallbladder 104 to prevent gallstones 102 of a certain minimum size from leaving the gallbladder 104. In some embodiments of the invention, the stopper 504 is configured to avoid puncturing a wall of the gallbladder, for example by having a rounded shape. In some embodiments of the invention, the stopper 504 (including the length of filament leading to the stopper) and the filter/blocking portion 502 operate in conjunction (by substantially stretching the length of the gallbladder) to reduce the chance of movement of the filter/blocking portion 502 from migrating away from the opening 506.

FIG. 6 is a top view of a filtering device 600 *in situ*, in accordance with an exemplary embodiment of the invention. In an embodiment of the invention, the device 600 is blocking/filtering gall stones 602 of a specified minimum size and preventing them from leaving the gallbladder.

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean "including but not limited to".

The term "consisting of" means "including and limited to".

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range. Further, described ranges are intended to include

numbers outside any range described within statistical error and/or inherent measurement equipment limitations.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases “ranging/ranges between” a first indicate number and a second indicate number and “ranging/ranges from” a first indicate number “to” a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween.

As used herein the term "method" refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

As used herein, the term “treating” includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

WHAT IS CLAIMED IS:

1. A filter device for implantation in a gallbladder, comprising:
 - a filter portion configured to filter gallstones of a certain minimum size to prevent them from exiting the gallbladder through an opening of the gallbladder;
 - a blocking portion configured to push gallstones of a certain minimum size away from an opening of the gall bladder where the blocking portion is located distally from the filter portion with respect to the opening of the gallbladder; and,
 - where the blocking portion and the filter portion do not attach to, or apply expansive radial force on, a wall of the gallbladder.
2. A filter device according to claim 1, where the blocking portion and the filter portion are the same.
3. A filter device according to claim 2, further comprising an anchoring portion extending from the filter portion towards the opening of the gallbladder and configured to reduce movement of the filter device in the gallbladder.
4. A filter device according to claim 3, further comprising a stopper extending in the longitudinal axis of the filter device away from the opening of the gallbladder, where the stopper and the anchoring portion when taken together prevent migration of the anchoring portion away from the opening of the gall bladder.
5. A filter device according to claim 1, where at least the filter portion is mesh.
6. A filter device according to claim 1, where at least the filter portion is a coil.
7. A filter device according to claim 1, where at least the filter portion is a perforated or porous sheet.
8. A filter device according to claim 1, where the filter device is comprised of a single filament.

9. A filter device according to claim 1, wherein the device is made from at least one of a metal, a shape memory alloy and a polymer.
10. A filter device according to claim 1, wherein the device is adapted for eluting a pharmaceutical after implantation.
11. A filter device according to claim 1, wherein the device is at least one of bioabsorbable and biodegradable.
12. A filter device according to claim 1, wherein at least one of the blocking portion and filter portion are configured to prevent bio-film growth.
13. A filter portion according to claim 3, wherein at least one of the blocking portion, anchoring portion and filter portion are configured to prevent bio-film growth.
14. A filter portion according to claim 1, where the filter portion is configured to filter gallstones 5 mm or greater in diameter.
15. A filter portion according to claim 1, where the filter portion is configured with wires no more than 4mm apart.
16. A system for delivery of a filter device for implantation in a gallbladder, comprising:
 - a filter device including a blocking portion configured to push gall stones of a certain minimum size away from an opening of the gallbladder; and,
 - a catheter configured for transit of the filter device therethrough to the gallbladder.
17. A method for implanting a filter device in a gallbladder, comprising:
 - navigating the filter device to the gallbladder for implantation, the filter device including at least a blocking portion;
 - entering the gall bladder at a gallbladder opening with the blocking portion;

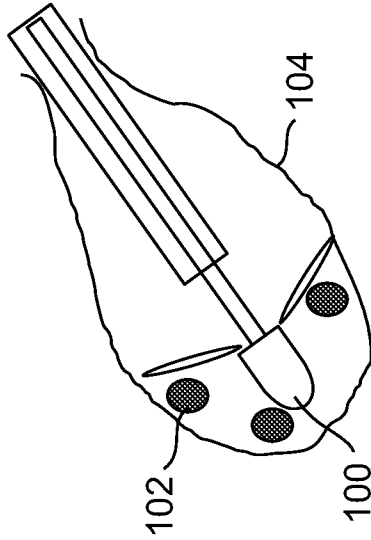
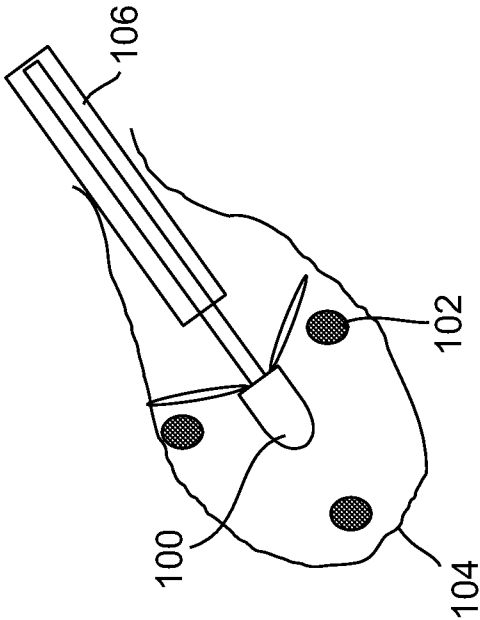
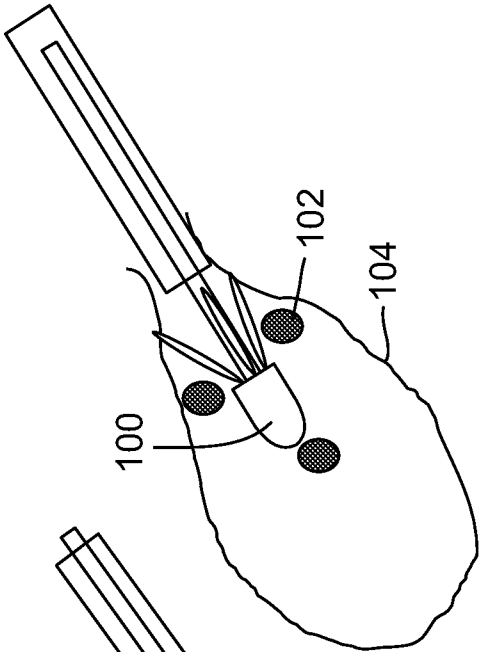
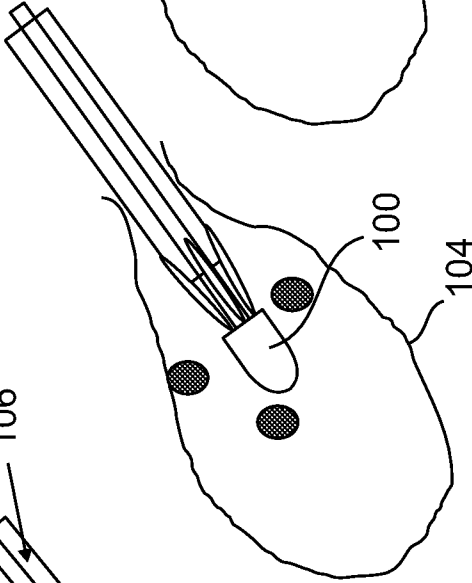
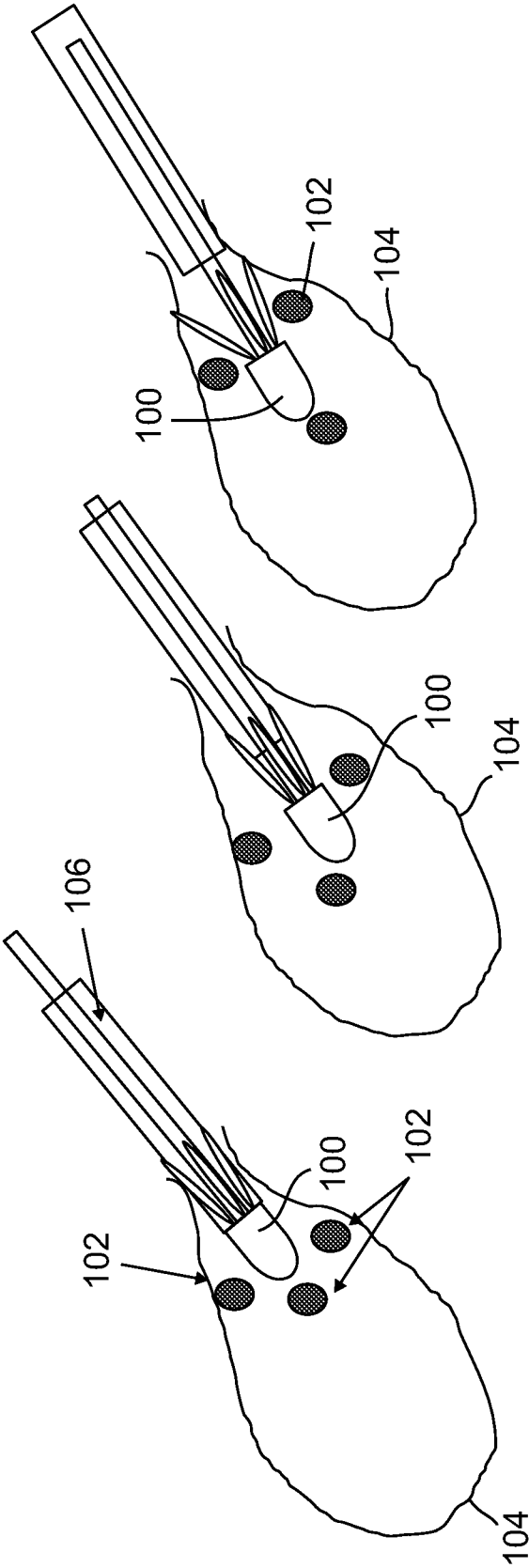
manually or automatically expanding the blocking portion in the gallbladder;
pushing any gallstones in the gallbladder towards a distal end of the gallbladder and away from the gallbladder opening, thereby clearing a space within the gallbladder for proper and/or full expansion of the filter device;
introducing a filter portion of the filter device to the gallbladder; and,
manually or automatically expanding the filter portion in the gallbladder.

18. A method according to claim 17, where the blocking portion and the filter portion are the same element, and blocking and filtering are performed simultaneously by the same element.

19. A method according to claim 17, further comprising deploying an anchoring portion after entering with the blocking portion and after introducing the filter portion.

20. A method according to claim 19, further comprising preventing the anchoring portion from moving away from the gall bladder opening using a stopper in conjunction with the anchoring portion.

21. A method according to claim 17, further comprising withdrawing the blocking portion after the filter portion has been expanded.



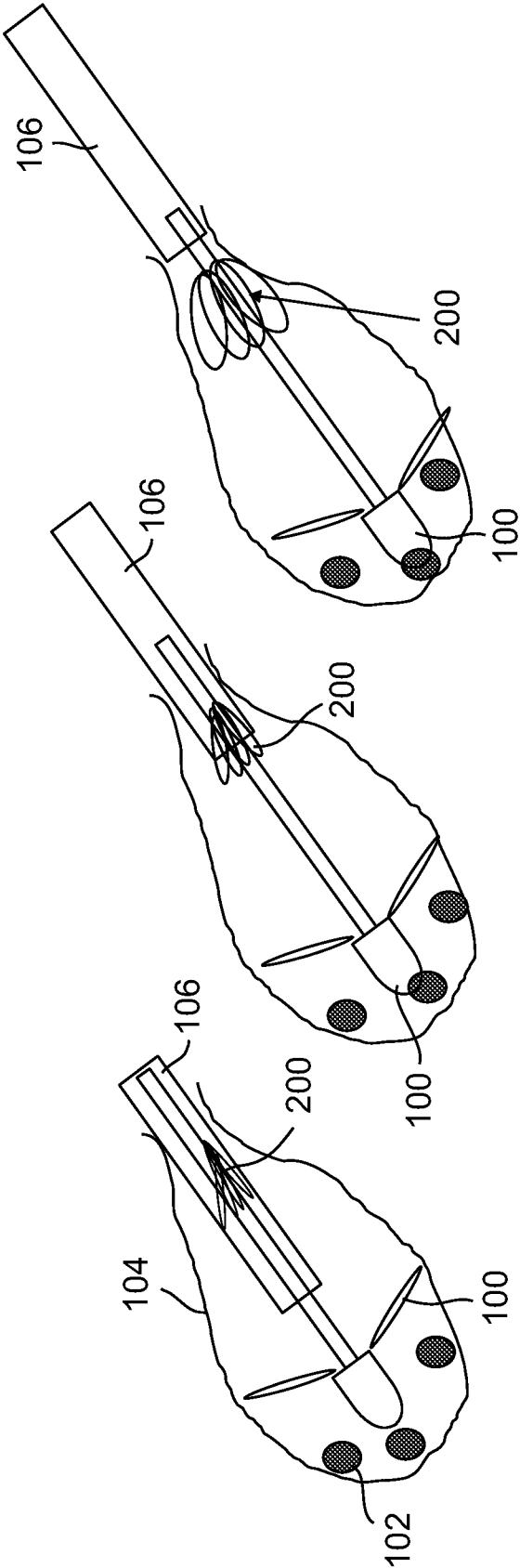


FIG. 2A

FIG. 2B

FIG. 2C

3/6

FIG. 3A

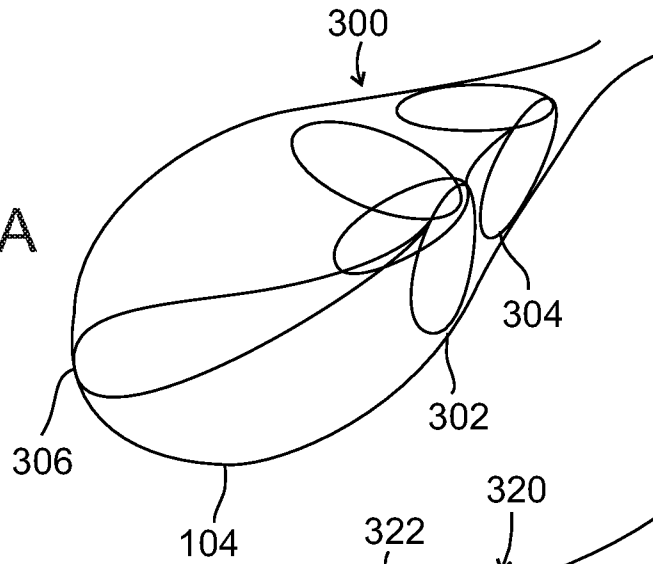


FIG. 3B

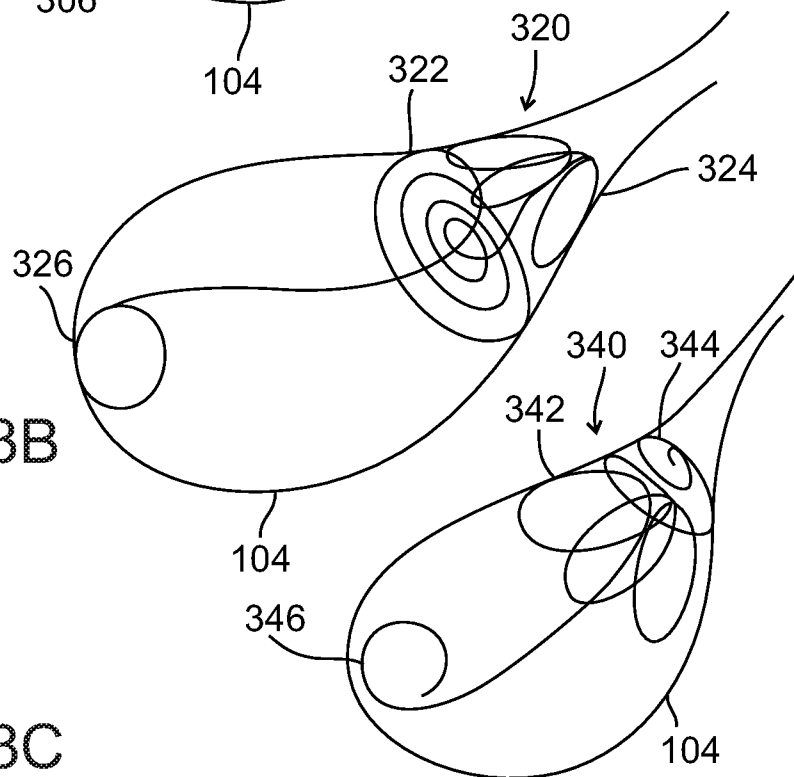


FIG. 3C

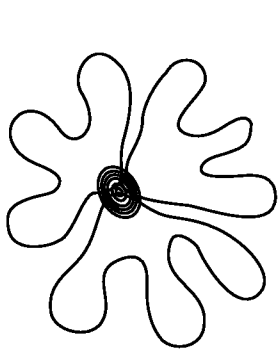


FIG. 4A

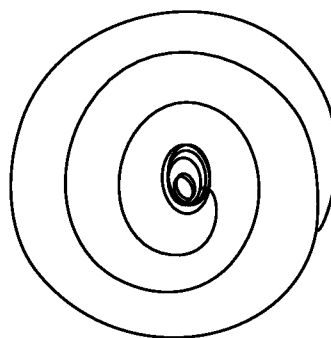


FIG. 4B

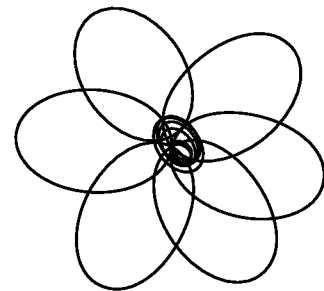


FIG. 4C

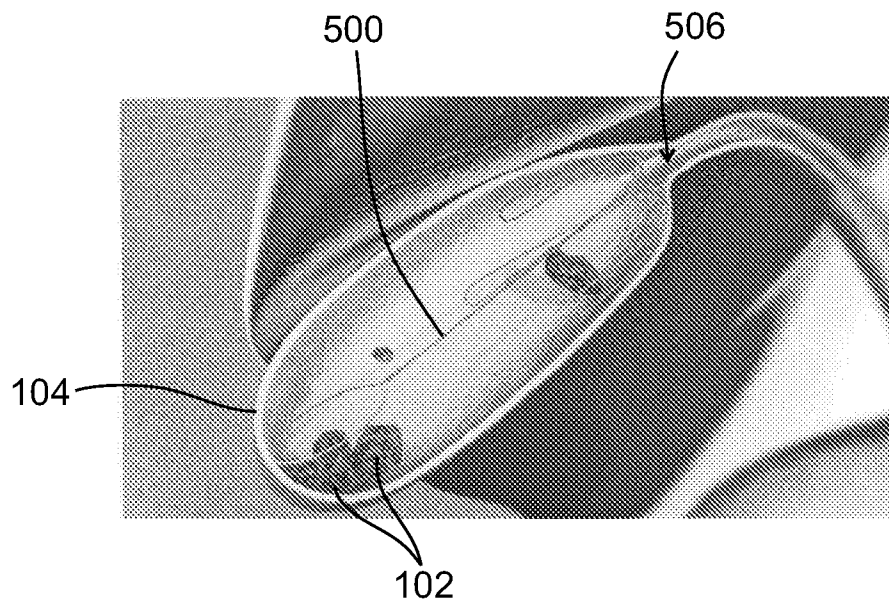


FIG. 5A

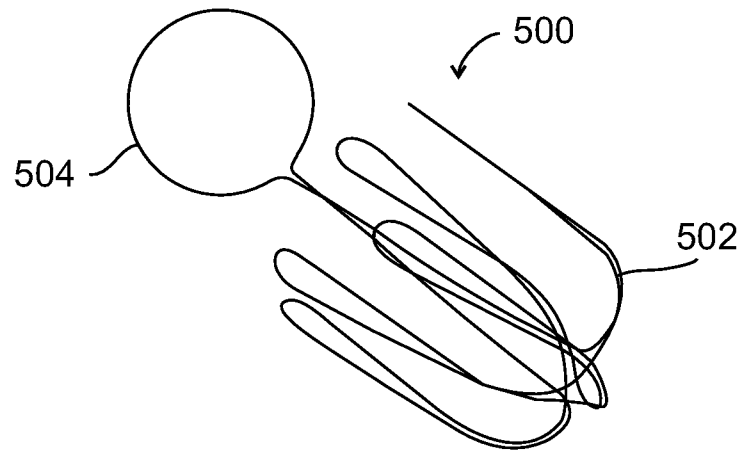
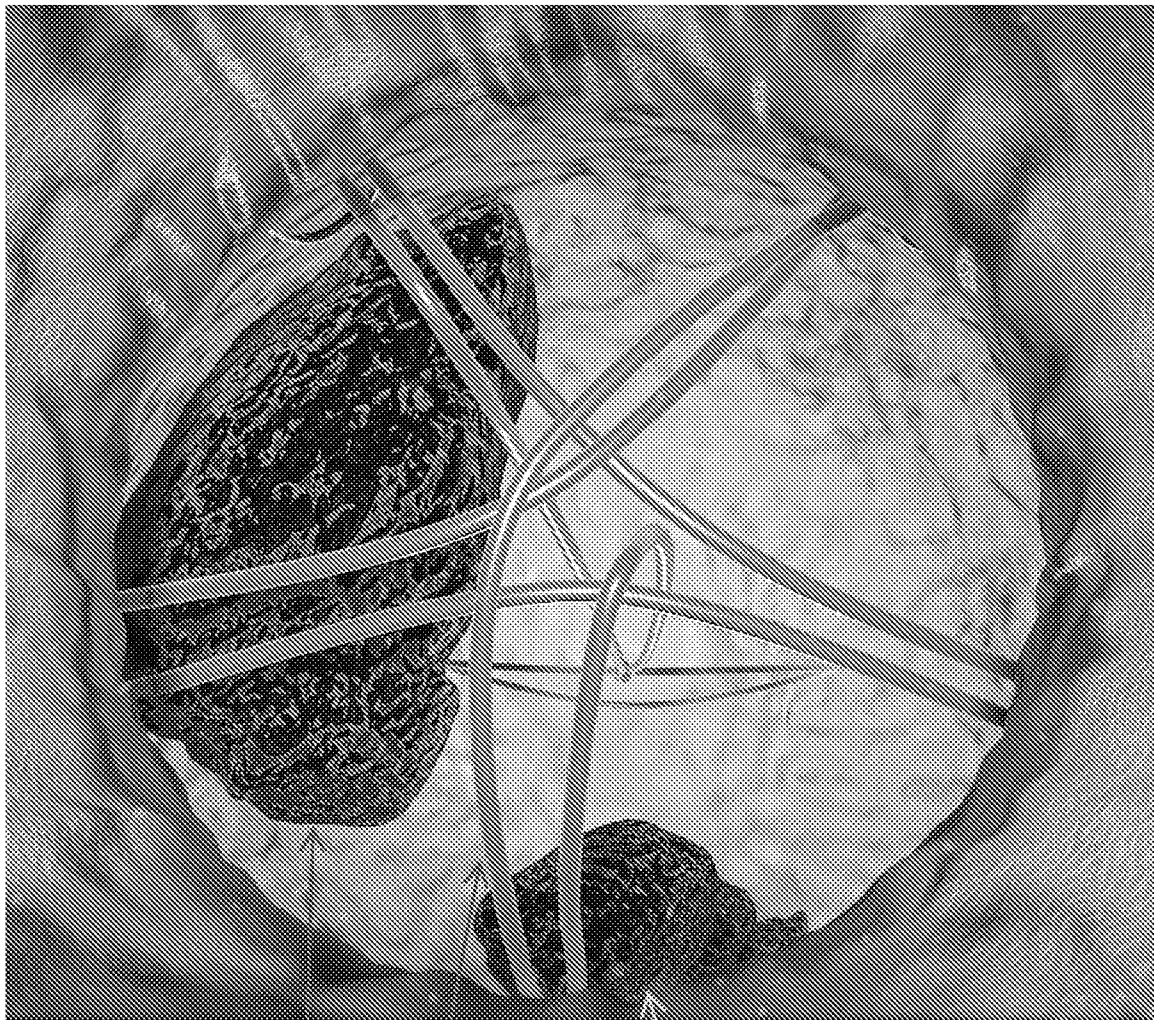


FIG. 5B



502

500

502

FIG. 6

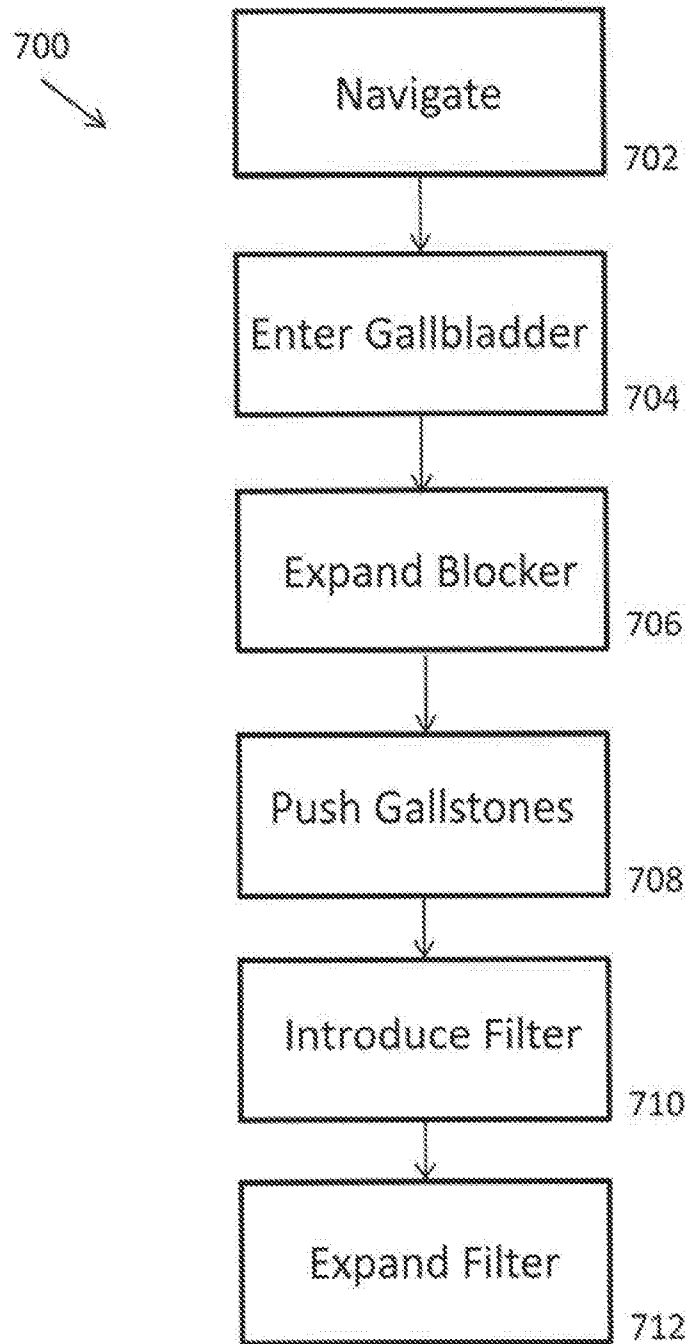


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2015/051051

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/04
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2010/109467 A1 (BEN MUVHAR SHMUEL [IL]) 30 September 2010 (2010-09-30)	16
A	page 18, line 19 - page 19, line 32; figures 3a-3g	1-15
A	----- CN 203 424 992 U (CHEN QI) 12 February 2014 (2014-02-12) the whole document	1-16
A	----- WO 2011/143137 A2 (UNIV LELAND STANFORD JUNIOR [US]; CALLAGHAN MATTHEW JOHN [US]; CHAO KE) 17 November 2011 (2011-11-17) paragraphs [0142] - [0146]; figures 10a-10d	1-16



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

27 January 2016

Date of mailing of the international search report

03/02/2016

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Espuch, Antonio

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2015/051051

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-21
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 67.IV PCT - Method for treatment of the human or animal body by surgery.
The feature "navigating the filter device to the gallbladder" in claim 17 implies surgery.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IL2015/051051

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2010109467	A1	30-09-2010	EP 2410943 A1 01-02-2012
			JP 2012521258 A 13-09-2012
			US 2012022550 A1 26-01-2012
			WO 2010109467 A1 30-09-2010

CN 203424992	U	12-02-2014	NONE

WO 2011143137	A2	17-11-2011	CN 103068326 A 24-04-2013
			EP 2568892 A2 20-03-2013
			JP 2013537434 A 03-10-2013
			US 2013144322 A1 06-06-2013
			WO 2011143137 A2 17-11-2011
