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Inventor(s)	Malakan Rad; Elaheh et al.

Asymmetric Occluder Device

Abstract

An asymmetric occlusion device for occluding an opening in a body tissue where part of the opening is defined by a partial inadequate rim. The asymmetric occlusion device includes a waist portion having a distal end extending to a proximal end. The waist portion is of non-woven material extending around a longitudinal axis opening. The occlusion device further includes a pair of asymmetric occluder disks attached to the waist. The asymmetric distal and proximal occluder disks are formed of shape memory material. The asymmetric occluder disks include a short arm extending from the waist and an extended arm extending from the waist. The extended arm exceeds the length of the first short arm. The density of the first short arm exceeds the density of the second extended arm.

Inventors: **Malakan Rad; Elaheh (Jena, DE), Hijazi; Ziyad Mousa (Jena, DE)**

Applicant: **Occlutech GmbH** (Jena, DE)

Family ID: **51023170**

Assignee: **Occlutech GmbH (Jena, DE)**

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Background/Summary

RELATED APPLICATIONS [0001] This application is a continuation of and claims priority to U.S. patent application Ser. No. 17/454,226, filed Nov. 9, 2021 entitled Asymmetric Occluder Device, which is a continuation of and claims priority to U.S. patent application Ser. No. 16/120,195, filed Aug. 31, 2018 entitled Asymmetric Occluder Device (now U.S. Pat. No. 11,197,660 issued Dec. 14, 2021), which is a continuation of U.S. patent application Ser. No. 14/292,033 filed May 30, 2014 entitled Asymmetric Occluder Device (now U.S. Pat. No. 10,064,612 issued Sep. 4, 2018), which claims benefit of and priority to U.S. Provisional Application No. 61/828,991 filed May 30, 2013 entitled Asymmetric Occluder For Transcatheter Atrial Septal Defect Closure In Patients With Secundum Atrial Septal Defect And Inadequate Rims, all of which are incorporated herein by reference in their entireties.

BIBLIOGRAPHY
[0002] Complete bibliographical citations to the documents cited herein can be found in the Bibliography, immediately preceding the claims.
FIELD OF THE INVENTION
[0003] The present invention is directed to a medical device and particularly to a device for closing or occluding atrial septal defects in patients with secundum atrial septal defect and inadequate rims.
BACKGROUND
[0004] Atrial septal defect (ASD) is one of the most common congenital heart defects, accounting for 7%-10% of all congenital Heart disease in children and 30%-33% of defects diagnosed in adults With congenital heart disease (Kazmouz et al. 2013). Secundum atrial septal defect (ASD) is a congenital heart defect in the septum between the atria of the heart, which allows blood to flow from the left atrium to the right atrium through a hole or defect in the interatrial septum. This defect is typically caused by deficiency of valve tissue of fossa ovalis, excessive or ectopic resorption of septum primum or deficient growth of septum secundum. Forty years ago, Dr. Terry D. King performed the first transcatheter closure of atrial septal defect using double umbrella disks (King et al. 1976). Since then, many devices have been developed to close such defects (King and Mills 2010). During a cardiac catheterization, a thin catheter is inserted into a blood vessel in the groin of a patient and guided to the heart. Through the catheter, a mesh patch or plug is put into place to close to close the interatrial defect. The heart tissue grows around the mesh permanently sealing the defect.
[0005] However, patients With ASD and inadequate rims are not good candidates for the available devices or may pose significant technical challenges seating the device well (Podnar et al. 2001; Amin 2006; Kannan, et al. 2003). An inadequate rim of tissue around the ASD may not allow for proper device anchoring leading to device malposition. The most common site of deficient rim is the retroaortic area (also called the anterior-superior rim) which may be deficient in up to 45% of

patients With ASD (Knirsch et al., 2005; cited in Love, et al., 2012).
[0006] Therefore, currently, many of these patients are referred for traditional surgical closure of their defects (Moore et al. 2013; Gokaslan et al. 2012). However, an inadequate rim is one of the serious challenges for transcatheter closure of ASD, making this treatment modality impossible in many occasions (Li et al. 2012). The purpose of this invention is to modify these defects (defects With deficient or inadequate rims) and to make their defects more feasible for transcatheter closure.

SUMMARY OF THE INVENTION

[0007] The present invention is directed to a heart occluder device comprising two separate, uniquely-shaped members separated by a middle portion or waist wherein each member is shaped into two semi-ovoid designs to form two half-discs by the memory-shaping capability of the Wires forming the members. The waist area is formed between the two semi-ovoid designs.
[0008] The present invention is further directed to an asymmetric occlusion device for occluding an opening in a body tissue wherein the opening is defined by a partial adequate rim and a partial inadequate rim. The asymmetric occlusion device comprises a waist portion having a distal end extending to a proximal end, the waist portion being formed of non-woven material extending around a longitudinal axis opening. The occlusion device further includes a pair of asymmetric occluder disks, comprising an asymmetric distal occluder disk attached to the distal portion of the waist, the asymmetric distal occluder disk being made of shape memory material, and an asymmetric proximal occluder disk attached to the proximal portion of the waist, the asymmetric proximal occluder disk being made of shape memory material. The asymmetric occluder disks are defined by a first short arm extending from the waist wherein the first short arm includes shape memory material, and a second extended arm extending from the waist, wherein the second extended arm exceeds the length of the first short arm and wherein the second long arm includes shape memory material, wherein the density of the first short arm exceeds the density of the second extended arm.
[0009] The present invention is further directed to an asymmetric atrial septum occlusion device for occluding an atrial septum defect, wherein the atrial septum defect is defined by a partial adequate rim and a partial inadequate rim. The occlusion device comprises a waist portion having a distal end extending to a proximal end, the waist portion being formed of non-woven material extending around a longitudinal axis opening, wherein the waist comprises a hub and a channel passing through the hub. The occlusion device further includes a pair of ovoid asymmetric occluder disks, comprising an asymmetric distal occluder disk attached to the distal portion of the waist, the asymmetric distal occluder disk being made of shape memory material, and an asymmetric proximal occluder disk attached to the proximal portion of the waist, the asymmetric proximal occluder disk being made of shape memory material, wherein the distal disk is larger in size than the proximal disk to prevent dislodgement of the occluder device from the body tissue opening, wherein further the asymmetric occluder disks comprise a first short arm extending from the waist wherein the first short arm includes shape memory material, and a second extended arm extending from the waist, wherein the second extended arm exceeds the length of the first short arm and wherein the second long arm includes shape memory material. The density of the first short arm exceeds the density of the second extended arm.
[0010] The design and deployment of this device is easy and very similar to conventional Amplatzer ASD occluder.
[0011] The objects and advantages of the invention will appear more fully from the following detailed description of the preferred embodiment of the invention made in conjunction with the accompanying drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

[0013] FIG. **1** is a schematic representation of a human heart illustrating an atrial septal defect (ASD).

[0014] FIG. **2** is a schematic representation of the heart septum separating the right atrium (RA) from the left atrium (LA) and illustrating an ASD.

[0015] FIG. **3** is a top plan view illustrating the distinctions between the occluder device of the present invention and the prior art occluder device.

[0016] FIG. **4** is a top plan view of the occluder device of the present invention.

[0017] FIG. **5** is a perspective view of the occluder device of the present invention.

[0018] FIG. **6** is a top plan view illustrating the placement of the occluder device on the ASD.

[0019] FIG. **7** is a side plan view illustrating the placement of the occluder device on the ASD.

[0020] FIG. **8** is schematic view illustrating the initial placement of the occluder device through the ASD between the right atrium and the left atrium.

[0021] FIG. **9** is a close up side plan view illustrating the opening of the distal occluder disk in the region of the left atrium.

[0022] FIG. **10** is a close up side plan view illustrating the opening of the waist portion of the occluder disk.

[0023] FIG. **11** is a close up side plan view illustrating the opening of the proximal occluder disk in the region of the right atrium.

[0024] FIG. **12** is a close up side plan view illustrating the removal of the deployment cable and catheter from the occluder device.

[0025] FIG. **13** is a close up side plan view illustrating the attachment of guide wires and a snare for the removal of the occluder device from the ASD.

[0026] FIG. **14** is a side plan view illustrating the removal of the occluder device from the ASD.

DETAILED DESCRIPTION OF THE INVENTION

[0027] The present invention provides a device for occluding an aperture within body tissue wherein the aperture includes an area of adequate rim and an area of inadequate rim.

[0028] FIG. **1** illustrates a human heart **10**, having a right atrium **12**, a left atrium **14**, a right ventricle **16**, and a left ventricle **18**. Shown at **20** is an ASD anatomical anomaly or aperture in the atrial septum **22**. The presence of an ASD **20** could permit blood to travel through septum **22**, such as that schematically illustrated by aperture **20**. A ventricle septal defect (“VSD”) is similar to an ASD, except that an aperture would exist in the septum **24** between the right ventricle **16** and the left ventricle **18**. Unless specifically described otherwise, the term “aperture” will refer to the specific heart defect described above, i.e., the ASD.

[0029] Occluder (or occlusion) devices are known for occluding ASDs. Reference is made to U.S. Patent Publication 2009/0228038 to Amin for one such heart occluder device. However, such devices are typically symmetrical occluders which are able to repair a defect having adequate rim structure completely encircling the defect. By “adequate rim structure,” it is meant that there is a sufficient amount of tissue making up the rim and surrounding tissue of the heart wall to accept an occluder device.

[0030] Unfortunately, there are times when the heart defect does not occur in a more centrally located area of the septum **22**, but rather at the edge of the septum **22** as illustrated in FIG. **2**. In these occurrences, the heart defect rim **25** is defined by a rim **26** of adequate surface structure to accept the heart occluder device and a rim **28** of inadequate surface structure, Where it will be difficult to accept the clamping mechanism of the heart occluder device with enough force to fix the heart occluder to the entire rim **25** structure of the heart defect. This situation requires a

specialized form of heart occluder device as described in the present application.
[0031] As used herein, “distal” refers to the direction away from the delivery catheter and “proximal” refers to the direction nearer the delivery catheter.
[0032] As used herein, “memory” or “shape memory” refers to a property of materials to resume and maintain an intended shape despite being distorted for periods of time, such as during storage or during the process of delivery in viva.
[0033] Reference is now made to FIG. **3**, which illustrates the distinction between a standard, prior-art Amplatzer-type septal occluder **102**, which is typically a self-centering device that consists of two circular retaining discs **104** (one shown in FIG. **3**) made of nitinol wire mesh and linked together by a short connecting waist **106** surrounding a hub **107**. The waist **106** centers the device **102** in the ASD and occludes it with the retaining discs **104** providing equal stability of the rim of the defect (Kasmouz, et al., 2013).
[0034] Unlike the prior art occluder device **102** described above, the septal occluder device **100** of the present invention is distinguished by extended distal and proximal disks **120**, **122** which include an extended arm **110** thereby giving each disk **120**, **122** an ovoid or oval appearance. In addition, the waist **105** separating the disks **120**, **122** is ovoid in shape to accommodate the shape of the disks **120**, **122**. The disks **120**, **122** are further defined by having the hub area **107** offset thus forming a short arm **112** opposing the extended arm **110**. As illustrated by arrows **114** and **116**, the length or radius of the short arm **112** is shorter than the length or radius of the extended arm **110**. As will be illustrated and described in this disclosure, the extended arm **110** in combination with the unique features of the short arm **112** will create a device for adequately occluding an aperture **20** in the heart septum **22** which is characterized by an inadequate rim structure **28**. As illustrated in FIGS. **3**, **4** and **7**, the hub **107** is preferably defined by an extension **108** which includes a channel **109** passing through the extension **108**. The usefulness of the channel **109** will become apparent in the description of the deployment, attachment and removal of the occluder device **100**.
[0035] Referring now to FIGS. **4** and **5**, the occluder device **100** of the present invention comprises two separate uniquely shaped ovoid disks, distal disk **120** and proximal disk **122**, formed of shape memory material, such as wire or other specialized material. The material can be formed of biocompatible metals or polymers, such as bioresorbable polymers, shape memory polymers, shape memory metal alloys, biocompatible metals, bioresorbable metals, or combinations thereof. Specific examples include but are not limited to iron, magnesium, stainless steel, nitinol, or combinations of these and similar materials. A preferred metal for the present invention is a nitinol alloy. Nitinol (an acronym for Nickel Titanium Naval Ordnance Laboratory) is a family of intermetallic materials, which contain a nearly equal mixture of nickel (55 wt. %) and titanium. Other elements can be added to adjust or “tune” the material properties. Nitinol exhibits unique behavior, specifically, a well-defined “shape memory” and super elasticity. In general, any biocompatible material with a memory capability can be used with the present invention. The thermal shape memory and/or superelastic properties of shape memory polymers and alloys permit the occluder **100** to resume and maintain its intended shape in viva despite being distorted during the delivery process.
[0036] In certain embodiments, the memory may also assist in pressing the aperture **20** closed. The diameter or thickness of the wire depends on the size and type of the device, i.e., the larger the device, the larger the diameter of the wire. In general, wire having a diameter between about 0.2 mm and 0.8 mm can be used.
[0037] Each disk **120**, **122** in the occluder device **100** includes a rim **124**, **126**, also made of shaped memory material to create and hold the ovoid shape of each disk **120**, **122** as illustrated. While the ovoid shape is illustrated and is the preferred shape for the device **100** of the present invention, it is within the scope to have other shapes as desired. Ideally, the shape of the disks **120**, **122** is customized to approximate the size and shape of the ASD.
[0038] As illustrated primarily in FIG. **7**, the size and shape of the distal occluder disk **120** is larger

than the proximal occluder disk **122**. Because the flow of blood naturally passes from the left atrium **14** to the right atrium **15**, referred to FIG. **1**, it is preferred but not absolutely necessary to enlarge the size of the distal occluder disk **120** to assist in blocking the flow of fluid and to prevent the occluder disk **100** from dislodging and passing into the right atrium **120** and possibly to the right ventricle **16** or pulmonary artery **202**. For this reason, it is preferred to increase the overall size of the distal disk **120**, in comparison to the proximal disk **122**, to further secure the occluder disk **100** in position over the ASD.

[0039] The disks **120**, **122** are shaped and constructed of a dense mesh of tightly woven wire material, such as nitinol. The form of the distal disk **120** opposes the form of the proximal disk **122** and is connected by a 3-4 mm short ovoid waist **105**, illustrated in FIG. **7**. The shape and relative size of the waist **105** preferably conforms to the shape and the size of the ASD **20**. The disks **120**, **122** are larger than the waist **105**.

[0040] As illustrated in FIGS. **3** and **7**, the waist portion **105** of the occluder device **100** is extended, ovoid and follows the contour of the disks **120**, **122**. The dimensions of the waist are variable, ranging from small to large, and are typically selected based on the size and shape of the ASD. Ideally, the waist **105** is formed to completely fill the ASD **20**. The size of the waist **105** typically ranges between about 1 and 4 mm larger in size than the ASD **20**, preferably between about 2 and 4 mm larger than the ASD. In this manner, the waist **105** can provide a stopper-like plug to the ASD **20** opening.

[0041] In addition to acting as a stopper for the ASD **20**, the waist acts to retain the occluder disks **120**, **122** in place on the ASD **20** for maximum sealing. Further, the waist **105** assists in preventing the inadvertent or accidental displacement of the occluder device **100**.

[0042] The short arm **112** of each disk **120**, **122** is defined by an arcuate portion **126**, **128** in each rim **124**, **125**, and is designed to attach or clamp onto the rim **25** of the aperture **20** defined by the adequate rim **26**.

[0043] Likewise, the extended arm **110** of each disk **120**, **122** is defined by an arcuate portion **130**, **132** in each rim **124**, **125**. This arm is intended to attach or clamp onto the rim **25** of the aperture **20** defined by the inadequate rim **28**.

[0044] To assist in accomplishing this task, the short arm **112** is characterized by increased bulk or thickness density of memory material, illustrated by the dense mesh of memory material **134**, to increase the size, structure, strength and tension of each disk **120**, **122** at the region of the short arm **112**. The added bulk can be accomplished by adding more memory material, such as memory wire, thicker wire, or a combination of both. Without wishing to be restricted to any set dimensions, the preferred thickness of the short arm, illustrated by arrow **136** in FIG. **7**, is approximately twice the thickness of the extended arm **110**, illustrated by arrow **138**. The less dense memory material in extended arm **110** is designated by reference number **135**.

[0045] Referring now to FIG. **7**, the provision of a thicker, stronger, denser material **134** adds tension to the disks **120**, **122** at the short arm **112**. Clamping the disks **120**, **122** onto the septum **22** at the area of the adequate rim **26** will then create a torsional rotation of the extended arms **110** of each disk **120**, **122** along arrows **140**, **142** in order to assist in a more secure attachment of the disks **120**, **122** at the arcuate portion **130**, **132** or precisely at the location of the inadequate rim **28**. The torsional clamping effect will seat the occluder device **100** onto the rim **25** of the aperture **20** in a manner to prevent the device **100** from slipping off the aperture **20** at the area of the inadequate rim **28**. In this manner, the occluding device **100** provides a firm gripping seal on the aperture **20** at the location of the adequate rim surface **26** and an enhanced gripping seal on the aperture **20** at the location of the inadequate rim surface **28**. The “asymmetry” in thickness is therefore helpful in preventing the occluder device **100** from dislodging from the aperture **20**.

[0046] It is also within the scope of the present invention to add a mild magnetic property to occluder device **100** at the short arm **112** of each disk **120**, **122**. The magnetic property is specifically placed on the wire mesh on the interior surfaces **150**, **152** adjacent the adequate rim **26**

area of the septum **20**. Applying a mild magnetic property to each disk **120**, **122** will aid in attracting each disk **120**, **122** to each other for more secure closure over the adequate rim **26**. This in turns adds closure pressure at the extended arm **110** portion of the disk thereby assisting the ends **130**, **132** in a proper sealing closure on the inadequate rim **28**. This effectively seals the aperture **20** without any displacement. Therefore, when both of the disks **120**, **122** are deployed, the magnetic property causes the two disks **120**, **122** to be kept attached to each other at the safe and firm part of the septum **22**. As illustrated in FIG. **7**, the mild magnetic property will be applied bilaterally to the atrial sides of both discs at the location of the short arm covering the adequate and firm rim. Therefore, after deployment, they will gently attach to each other.

[0047] Referring now to the hub **107** located in the center of the waist **105**, the hub **107** is defined by an extension **108**, located on both surfaces of the distal occluder disk **120** and proximal occluder disk **122**. As illustrated in FIGS. **5**, **7** and **13**, the extension **108** includes a channel **109** extending through the extension **108**. The channel **109** in the extension **109** is provided in order to remove the occluder device **100** if necessary. For example, the flow of blood from the left atrium **14** to the right atrium **12** in the heart **10** can dislodge the occluder device **100** if the device **100** is not adequately secure. This is called “embolism.” Typically, the device **100** is dislodged toward the left atrium **14** and subsequently to the left ventricle **18** and aorta (not shown). Additionally, it is possible for the device **100** to be dislodged to the right ventricle **16** and the pulmonary artery **202**. If the occluder device **100** becomes dislodged, causing an embolism, it will be necessary to remove the occluder device **100** from the heart **10**. This can be accomplished by means of the channel **109** in the extension **108** as will be described later.

[0048] The occluder device **100** may also include a scaffold or sealed covering **111**, illustrated in FIG. **7**, over each of the distal and proximal disks **120**, **122**, wherein the covering provides a seal to occlude the ASD **20** wherein the coverings comprise a flexible, biocompatible material capable of promoting tissue growth and/or act as a sealant, including but not limited to polyester fabrics, Teflon-based materials or polyvinyl alcohol.

[0049] The deployment of the occluder device **100** is well-known to the art and similar to standard Amplatzer-type deployment steps. It is typically a percutaneous procedure which does not require major surgery.

[0050] Referring to FIG. **8**, the catheter **33** containing the occluder device **100** attached to the deployment cable **32**, is fed Via a needle stick (not shown) through a large vein in the groin which feeds into the heart **100**. The catheter **33** locates the ASD **20** and is passed through the ASD **20**.

[0051] Referring to FIG. **9**, the catheter **33** is withdrawn which allows the distal disk **120** to open and reform its memory shape in the left atrium **14**. The distal disk **120** is then placed against the ASD **20** to seal off the ASD **20**. The larger size of the distal disk **120**, compared to the size of the proximal disk **122**, assists in the proper placement of the distal disk **120** over the ASD **20**. The radiomarker **300**, housed within the occluder device **100**, assists in the proper placement of the distal disk **120**, by means known to the art. The distal disk **120** is positioned such that the arcuate portion **126** of the rim **124** in the short arm **112** is placed over the adequate rim **26** area of the ASD **20**. As a result of this positioning the arcuate portion **130** of the distal disk is in proper placement over the inadequate rim area **28** of the ASD.

[0052] Referring to FIGS. **6** and **10**, once the distal disk **120** is properly positioned and secured against the rim **25** of the ASD **20**, the catheter **33** is further withdrawn thereby revealing the waist **105** of the occluder **100**. The waist **105** preferably fills and further plugs the entirety of the ASD **20**.

[0053] Referring to FIG. **11**, once both the distal disk **120** and the waist **105** are adequately secured over the ASD **20**, the catheter **33** is further withdrawn revealing the proximal disk **122** in the right atrium **12**. The proximal disk **122** is secured to the ASD **20** in the same position as the distal disk **120**, such that the short arm **112** of the proximal disk **122** aligns with the short arm **112** of the distal disk **120**. As illustrated in FIG. **7**, a significant portion of the septum **22** at the adequate rim **26** area is positioned and essentially clamped between the short arms **112** of the distal and proximal disks

120, **122**. Because of the unique properties of the short arms **112**, i.e., its layer of denser memory material **134**, the short arms **112** of both disks **120**, **122** secure the occluder disk **100** to the ASD **20**. In addition, the secured attachment of the short arms **112** assists in properly securing the extended arms **110** of each disk **120**, **122** to the ASD **20** at the area of inadequate rim structure **28**. Furthermore and as discussed previously, the short arms **112** of the disks **120**, **122** can be provided with magnetic attraction at the interior surfaces **150**, **152** of the short arms **112** to further assist in the clamping action of the short arms **112** of both disks **120**, **122** on the ASD **20** at the area of adequate rim **26**.

[0054] Referring to FIG. **12**, once the position of the occluder disk **100** is verified, the deployment cable **32**, which secures the occluder device **100** to the catheter **33**, is released by means known to the art, and the catheter **33** is removed by means known to the art.

[0055] Properly placed, the occluder device **100** will stay in place for the life of the patient. As the occluder device **100** becomes further embedded into the septum **22** tissue, new tissue will grow over the occluder device **100** further securing the occluder device **100** to the septum **22**.

[0056] The occluder device **100** is connected to a hub **107**, which includes a delivery attachment mechanism for attachment to a deployment cable **32** housed within a delivery catheter sheath or catheter **33**.

[0057] Therefore, one, two or three of the following parameters can help the occluder device **100** seat properly in place without prolapse into the right atrium **12**:

[0058] a. The extra length of the distal and proximal disks **120**, **122** on the side with inadequate rim **28**;

[0059] b. The added thickness or density of the short arms **112** of both the distal and proximal disks **120**, **122**; and

[0060] c. The equal size of the distal and proximal disk members **120**, **122** which provides better support, especially considering the firmer wire mesh and the larger retention disc member on part of the disc member that seats on the part of the septum **22** with the adequate rim **28**.

[0061] In the event, the occluder device **100** must be removed for any reason, such as an inadvertent embolism, the channel **109** within the extension in the hub **108** in the occluder device **100** is useful for this process. The channel **109** within the extension **108** facilitates retrieving the occluder device **100** on both the left atrium **12** and right atrium **14** sides by passing an appropriate guide wire through the channel **109** and snaring the proximal disk **122**.

[0062] Referring to FIG. **13**, the extension **108** of either the distal disk **120** or the proximal disk **122** can receive a guide wire **250** which is threaded to the occluder device **100** Via an appropriate blood vessel. The guide wire **250** is snared by a snare wire **260**, according to methods well known to the art, for retrieval of the occluder device **100**.

[0063] Referring to FIG. **14**, the snare wires **260**, connected to the hubs **107** of both the distal and proximal disks **120**, **122** can then be pulled along the direction of arrows **270** thereby stretching and pulling the occluder device **100** free from the ASD. In this stretched position, the occluder device **100** can be reinserted into a catheter **33** for removal from the heart **10** by means known to the art. Hydrophilic guide wires are preferred for this step.

[0064] Any version of any component or method step of the invention may be used with any other component or method step of the invention. The elements described herein can be used in any combination whether explicitly described or not.

[0065] All combinations of method steps as used herein can be performed in any order, unless otherwise specified or clearly implied to the contrary by the context in which the referenced combination is made.

[0066] As used herein, the singular forms “a,” “an,” and “the” include plural referents unless the content clearly dictates otherwise.

[0067] Numerical ranges as used herein are intended to include every number and subset of numbers contained within that range, whether specifically disclosed or not. Further, these

numerical ranges should be construed as providing support for a claim directed to any number or subset of numbers in that range. For example, a disclosure of from 1 to 10 should be construed as supporting a range of from 2 to 8, from 3 to 7, from 5 to 6, from 1 to 9, from 3.6 to 4.6, from 3.5 to 9.9, and so forth.

[0068] All patents, patent publications, and peer-reviewed publications (i.e., "references") cited herein are expressly incorporated by reference in their entirety to the same extent as if each individual reference were specifically and individually indicated as being incorporated by reference. In case of conflict between the present disclosure and the incorporated references, the present disclosure controls.

[0069] The devices, methods, compounds and compositions of the present invention can comprise, consist of, or consist essentially of the essential elements and limitations described herein, as well as any additional or optional steps, ingredients, components, or limitations described herein or otherwise useful in the art.

[0070] While this invention may be embodied in many forms, what is described in detail herein is a specific preferred embodiment of the invention. The present disclosure is an exemplification of the principles of the invention is not intended to limit the invention to the particular embodiments illustrated. It is to be understood that this invention is not limited to the particular examples, process steps, and materials disclosed herein as such process steps and materials may vary somewhat. It is also understood that the terminology used herein is used for the purpose of describing particular embodiments only and is not intended to be limiting since the scope of the present invention will be limited to only the appended claims and equivalents thereof.

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Claims

1. An asymmetric occlusion device for occluding an opening in a body tissue.
2. A method comprising opening a body tissue with an asymmetric occlusion device.