



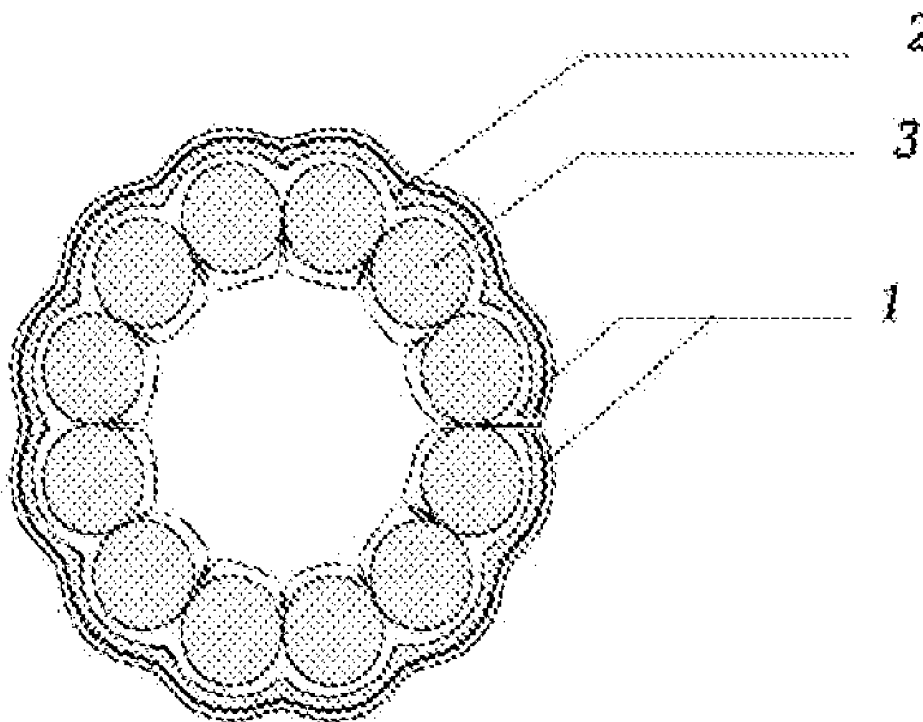
US 20150164508A1

(19) **United States**(12) **Patent Application Publication**
Hernandez et al.(10) **Pub. No.: US 2015/0164508 A1**(43) **Pub. Date: Jun. 18, 2015**(54) **MODULAR MAGNETIC ANASTOMOSIS
DEVICE****Publication Classification**(75) Inventors: **Juan Hernandez**, Strasbourg (FR);
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Kennedy Wall**, Palo Alto, CA (US)(51) **Int. Cl.**
A61B 17/11 (2006.01)(73) Assignee: **IRCAD**, Strasbourg Cedex (FR)(52) **U.S. Cl.**
CPC **A61B 17/1114** (2013.01); **A61B 17/11**
(2013.01); **A61B 2017/00876** (2013.01)(21) Appl. No.: **14/237,521**(22) PCT Filed: **Jul. 11, 2012**(57) **ABSTRACT**(86) PCT No.: **PCT/US12/46272**

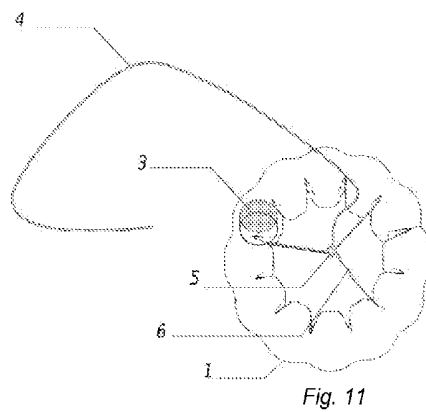
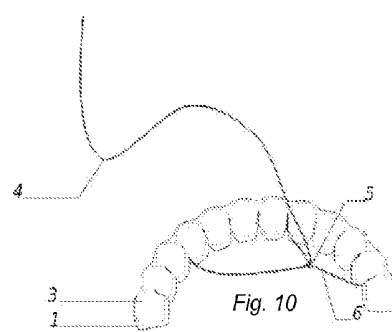
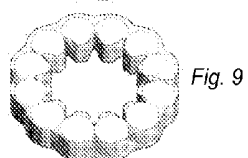
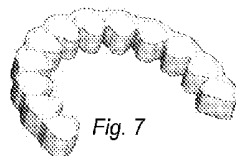
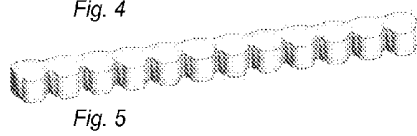
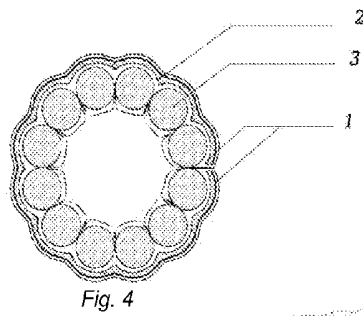
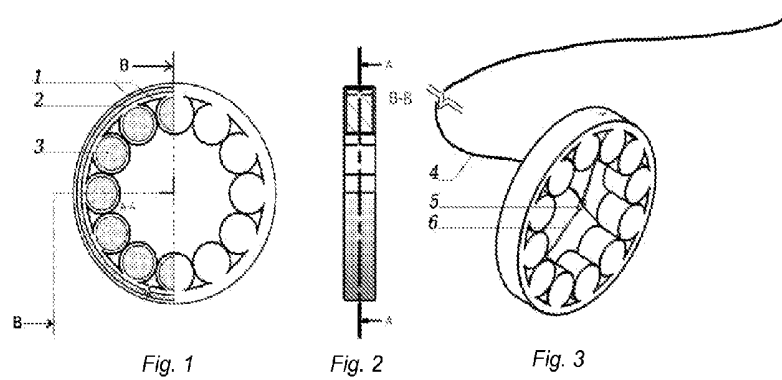
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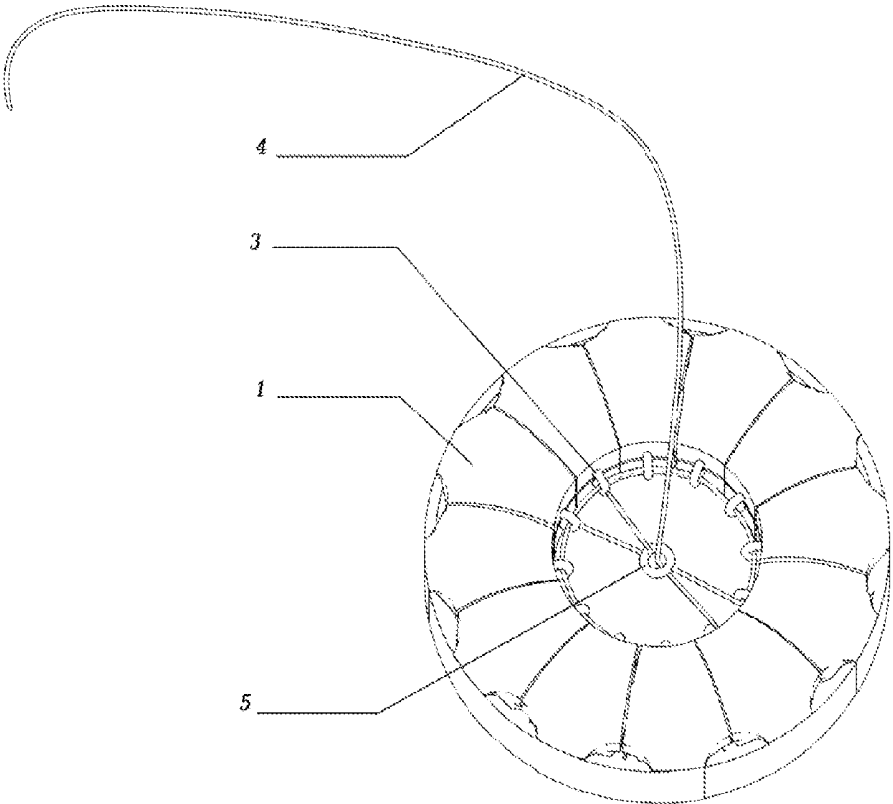
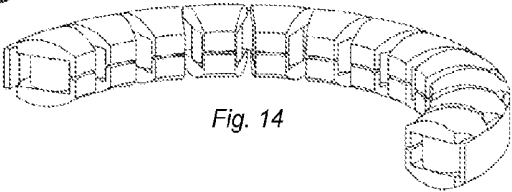
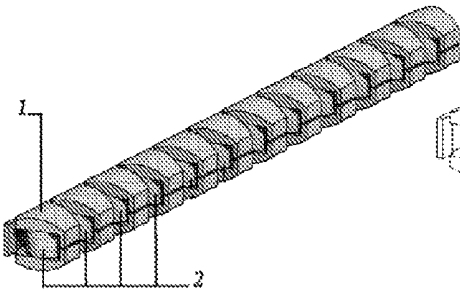
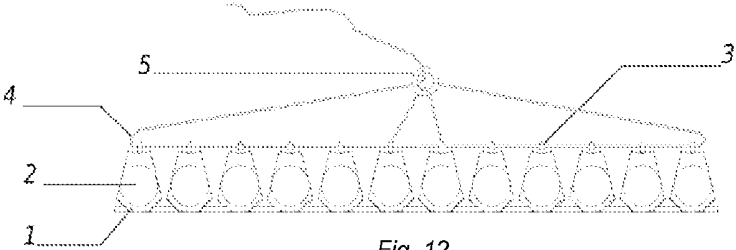
(2), (4) Date: **Jun. 23, 2014****Related U.S. Application Data**(60) Provisional application No. 61/506,710, filed on Jul.
12, 2011.

The present disclosure provides modular magnetic anastomosis devices that can be implemented in digestive surgery or in any circumstance of anastomosis between adjacent organs or two hollow viscera. The device is minimally invasive and easily and quickly delivered using laparoscopic or endoscopic procedures.



Modular Magnetic Anastomosis Device : Example 1





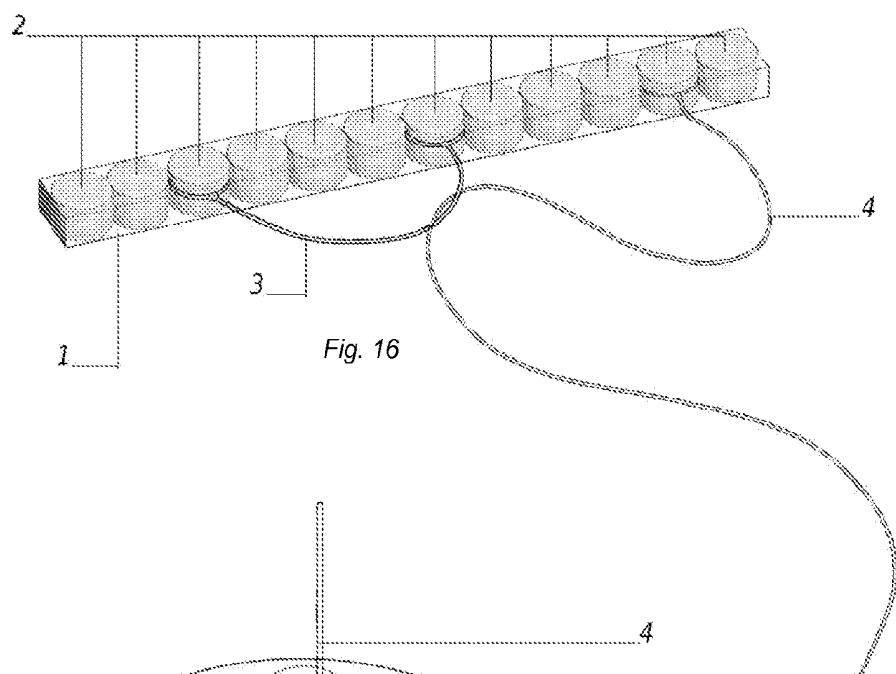


Fig. 16

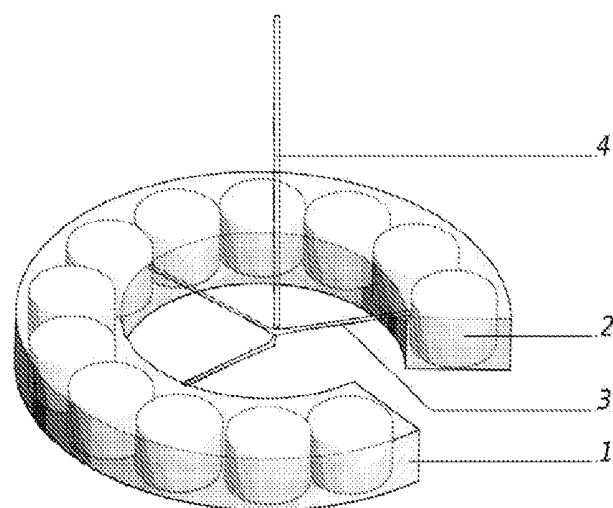


Fig. 17

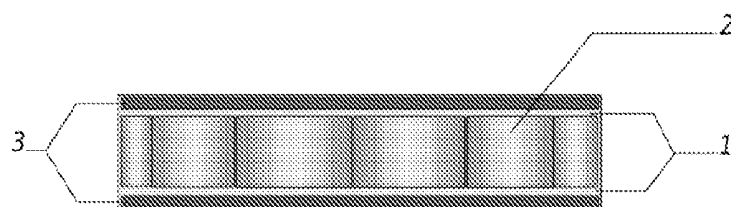


Fig. 18

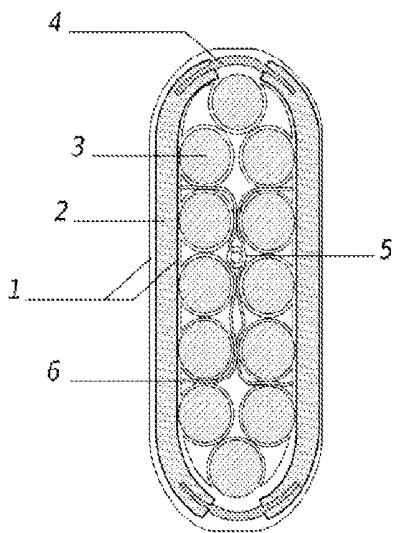


Fig. 19

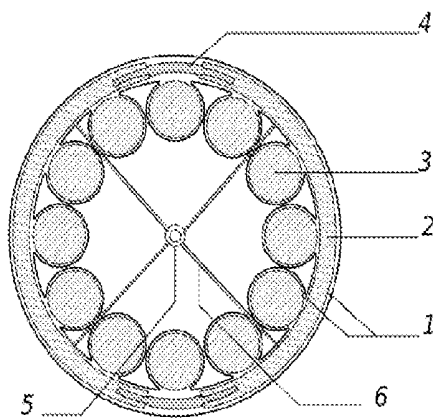


Fig. 20

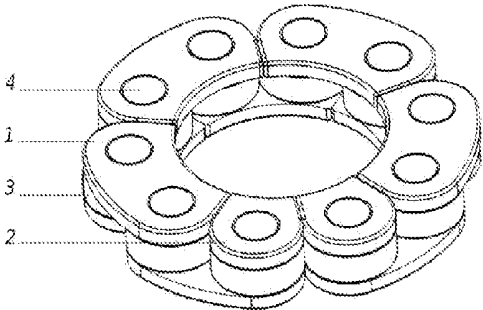


Fig. 21



Fig. 22

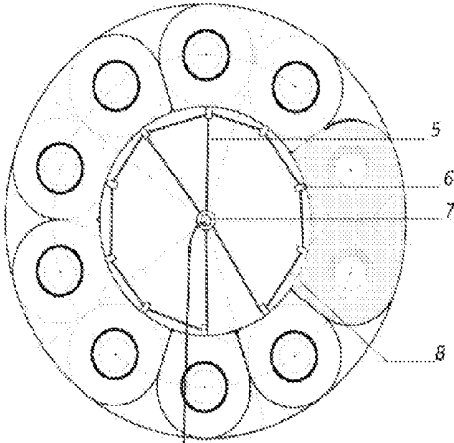


Fig. 23

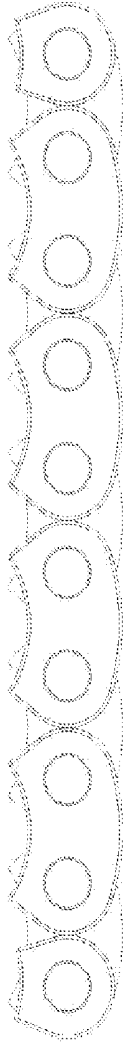


Fig. 24

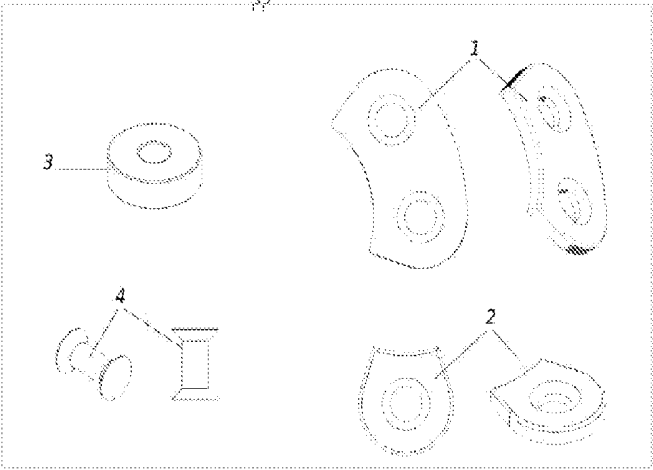


Fig. 25

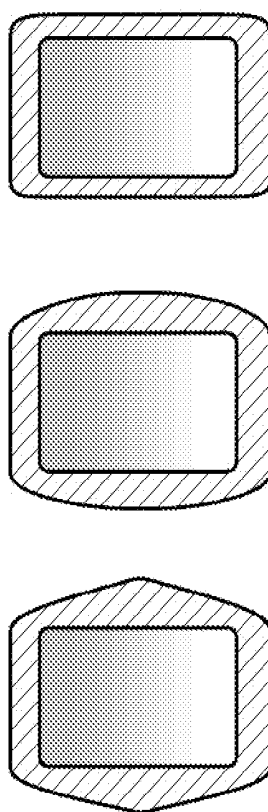


Fig. 26

MODULAR MAGNETIC ANASTOMOSIS DEVICE

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. provisional application Ser. No. 61/506,710, filed Jul. 12, 2011, which is incorporated herein by reference in its entirety.

BACKGROUND

[0002] The present invention relates to a modular magnetic anastomosis device for a gastro-intestinal procedure or circumstance where anastomosis between two hollow organs is required in a minimally invasive surgery procedure.

SUMMARY

[0003] The present invention extends this concept by means of implementing a modular magnetic anastomosis device that can be implemented in digestive surgery or in any circumstance of anastomosis between adjacent organs or two hollow viscera.

[0004] In one embodiment the modular magnetic assembly possesses the non-deployed configuration and can be placed in a small sized channel and can be used in laparoscopy and endoscopy known to the person skilled in the art. The modular magnetic assembly takes the deployed form at its implementation position.

[0005] In another embodiment the modular assembly anastomosis device is flexible and the modular aspect of the device allows it to be available in different sizes by addition of magnetic elements and adapts to the anatomical shape of the structure in which it is to be implemented.

[0006] In one embodiment the anastomosis device is linear.

[0007] In another embodiment the anastomosis device can be U-shaped in its deployed configuration.

[0008] Alternatively the anastomosis device can be S-shaped in its deployed configuration.

[0009] In another embodiment the device has a circular deployed configuration.

[0010] According to one embodiment the modular magnetic anastomosis device is a set of magnetic components, the two sets form the device used for forming an anastomosis between two bodily walls.

[0011] In another embodiment the modular magnetic set is enveloped in a jacket of resilient material.

[0012] Alternatively the modular magnetic component is enveloped in a jacket of biodegradable material.

[0013] In an alternative embodiment the magnets are embedded in a biodegradable material.

[0014] In one embodiment self assembly in a connected chain of magnetic components in this modular device is based on an even number of magnetic dipoles with alternate North-South/South-North orientation.

[0015] In another embodiment alternate geometrical flexible materials are connected to the magnet and allow for mechanical articulation of the magnets.

Incorporation by Reference

[0016] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present invention and together with the description serve to explain the principles of the invention. In the drawings:

[0018] FIG. 1 depicts how each set is formed of a chain of magnets (3), a neck comprised of flexible material (2), the resilient material (2) allows to the chain of the magnets to adopt a round structure after deployment and a jacket made of resilient material with a low friction coefficient allowing the easy movement of the device during an operation (1).

[0019] FIG. 2 is a cross sectional view of the magnet chain of example 1.

[0020] FIG. 3 illustrates the deployed form of the magnet with wire guides.

[0021] FIG. 4 shows a variant of the magnet set.

[0022] FIG. 5 to FIG. 9 illustrate the transition from the non-deployed linear form to the deployed circular structure of the device.

[0023] FIG. 10 is the transition of the non deployed form of the magnet with the wire guide.

[0024] FIG. 11 is the magnet in deployed form with the wire guides.

[0025] FIG. 12 is a representation of the encapsulated shell attached to a flexible band of example 2.

[0026] FIG. 13 illustrates detailed cross-representation of the assembled shell of the device of example 2.

[0027] FIG. 14 depicts a cross-sectional view of the magnet assembly for the device of example 2.

[0028] FIG. 15 illustrates the deployed structure of the magnet assembly.

[0029] FIG. 16 illustrates the structure of a set of the modular magnet assembly for a device of example 3.

[0030] FIG. 17 is a presentation of simple magnets and external jacket.

[0031] FIG. 18 is a profile view of the set of the magnets of example 3.

[0032] FIG. 19 illustrates the non-deployed form of the magnet assembly of example 4.

[0033] FIG. 20 describes the deployed form of example 4.

[0034] FIG. 21 illustrates the ring shaped modular magnetic anastomosis device in the deployed configuration of example 5.

[0035] FIG. 22 shows a profile view of the device.

[0036] FIG. 23 is a cross-sectional view of the magnet assemblies.

[0037] FIG. 24 illustrates the linear non deployed configuration.

[0038] FIG. 25 describes different components of the magnet.

[0039] FIG. 26 presents different geometrical structure of magnet and resilient material jacket.

DETAILED DESCRIPTION

[0040] In creating the anastomosis in the digestive tract several methods have been developed with different techniques and instrumentation, such as manual and mechanical sutures using staplers, biological glue or through compression.

[0041] The circular stapler (EEA) allows to perform complex procedures such as colic resections or gastric bypasses via a minimally invasive approach (laparoscopic). However, the rigid structure of circular stapler does not allow anasto-

mosis beyond the rectum. Also, using the circular stapler during a gastric bypass needs an enlarged incision through one of the operating trocars.

[0042] Anastomosis through compression is a concept initially described by Denan in 1826 and was later popularized by Murphy in 1892 with the “Murphy Button”. It is a surgical procedure that needs introduction of two metallic rings, screwed one against the other in order to generate a constant compression force on intercalated tissues. This procedure induces secondary health issues after the anastomosis through the ischemia→necrosis→cicatrizizing cycle.

[0043] Covidien recently has developed Valtrac™, a set of biofragmentable rings (Covidien, Norwalk, Conn.) which are composed of two rings made of absorbable material, this device eliminates manual or mechanic suture while maintaining a comparable dehiscence and stenosis rate.

[0044] Experimentations with magnetic anastomosis in surgery date back to the 1980s by a Dutch group which also used magnetic rings to perform muco-mucosal anastomosis while the serous membrane (serosa) had to be sutured by hand. The latency between the positioning of magnets and the realization of the anastomosis took 7 to 12 days. This prolonged time to obtain anastomosis ended the later development of the device.

[0045] A device, called MAGNAMOSIS™, is composed of 2 magnetic rings, auto-oriented, producing a compression force with a progressive internal-external gradient. This device has been developed by the research group of Prof Harrison from the University of San Francisco (California).

[0046] Detailed embodiments of the present invention are disclosed herein. The present invention comprises a modular magnetic device that is minimally invasive, easily and quickly delivered and is accurately positioned via laparoscopy or endoscopy, without the use of the staples.

[0047] According to one embodiment constructed with the teaching of the present invention, a magnetic anastomosis device used for forming an anastomosis between two bodily walls includes a first magnet assembly and a second magnet assembly configured to be magnetically coupled to compress the two bodily walls therebetween to form the anastomosis. The magnet assembly of the present invention is a modular magnetic structure with variable geometry. The articulated flexible modular device is composed of a network of magnetic elements placed and maintained in place by a flexible material made of resilient, biocompatible material and shape memory material or a material coated with a biocompatible material, known to a person skilled in the art. Suitable resilient materials include metal (e.g. stainless steel), alloys (e.g. nickel titanium) or polymers (e.g. polyethylene, polytetrafluoroethylene (PTFE) including Teflon®, polyvinyl chloride (PVC), and composites.

[0048] It will be recognized by those skilled in the art that the elongate modular magnet assemblies of the present invention are capable of being delivered with the same small delivery configuration as prior art, but also provide the advantage of reducing the probability of the anastomosis being closed over time and eliminating the need to intervene the patient for a second procedure to place a stent in the anastomosis to prevent closure thereof. Moreover, those skilled in the art will recognize the centering and alignment advantages of having two magnets disposed within each of the respective magnet assemblies.

[0049] Accordingly, it will be recognized by those skilled in the art that the modular magnetic assembly with a smaller

delivery configuration may be easily located within the body for accurate delivery using laparoscopic trocars through single skin incision. The catheter made of non-ferromagnetic material can deliver the two sets of magnets. The placing step preferably includes introducing the first set of modular anastomosis device into one of the viscera and positioning the set of magnet assemblies with the wire guide that help the device acquire the deployed configuration. After delivery of first set of the magnets to the location to be deployed by retracting the wire guide, the delivery portion of the catheter can then be positioned and deliver the second set of the magnet assembly to the second deployment position and the wire guide can be retracted.

[0050] The excising step includes introducing a cutting instrument into one of the viscera and manipulating the cutting instrument.

[0051] The two sets of magnet assemblies can be maneuvered to mate one another; once mated, the ischemic necrosis process can begin on the walls of the two viscera being treated.

[0052] Alternatively, the set of the magnets may also be implanted non-surgically using endoscopy where one or more catheters are introduced into the stomach cavity via the patient's mouth and esophagus and colon.

[0053] It will be recognized by those skilled in the art that the modular magnet assemblies can pass through the body naturally or can be removed by means such as laparoscopic removal, endoscopic removal or other procedure.

[0054] Accordingly, it will be recognized by those skilled in the art that the modular magnetic assembly in its non-deployed form can be linear. This particularity allows the use of a small sized channel for implementation of the modular magnetic device. The modular magnetic assembly possesses the advantage to be deployed in an open structure, thus permitting adaptation of the anastomosis device to anatomical features. The modular magnet assembly in the deployed configuration can take different shapes; such as circular, elongated, U shape and S shape

[0055] The concept of magnet self assembly in a connected chain of magnetic components in this modular device is based on an even number of magnetic dipoles with alternate North-South/South-North orientation. This alternate orientation of the magnets confers stability of the magnets and global magnetic inertia in the magnetic chain. However, despite the magnetic inertia of one part of the modular anastomosis device, in presence of each other the set of the magnets auto-orient and form the anastomosis set.

[0056] Although, only one set of magnetic assembly will be described, two magnet assemblies are intended for use as a magnetic anastomosis device.

EXAMPLE 1

[0057] Set of magnets enveloped in a resilient material with a hole for introduction of the wire guide, which will enter into the passageway created in the flexible material of the neck and will allow passage from non-deployed to deployed configuration. FIG. 1 to FIG. 11 describe this example.

[0058] As illustrated in FIG. 1, each set is formed of chain of magnets (3), a neck comprised of flexible material (2), the resilient material (1) allows the chain of the magnet adopt a round structure after deployment and a jacket made of resilient material with a low friction coefficient allowing the easy movement of the device during an operation (1). The

variant in FIG. 4 has the same structural feature with a more flexible jacket enveloping the magnets.

[0059] FIG. 5 to FIG. 9 show the transition from a non-deployed linear to one of deployed circular form.

[0060] The illustrations in FIGS. 10 and 11 describe the passage of the non-deployed to circular deployed form of the wire guide assembly of the magnet after delivery to the organ where it is to be implemented. The wire-guide (4) and (6) positions the magnetic chain and brings the terminal parts of the magnetic chain into proximity and aids, by mutual attraction of the magnets, in the closure of the ring; the deployed form and (5) is the central crossing ring for the wire guide.

EXAMPLE 2

[0061] FIG. 12 to FIG. 15 illustrate the modular magnetic assembly as a chain formed from separate encapsulated magnets. Every magnet (2) is separately enveloped in a shell of a resilient or biocompatible material (1) and affixed to a flexible band that can adopt its deployed shape after being deployed in the organ to where it is to be implemented. A passageway created between shells (3) allows the attachment of wire guide (4). FIG. 12 to FIG. 14 presents the organization of such a modular magnetic assembly. FIG. 15 is a representation where the wire guides enter the central ring (5) and close the device to its deployed form.

[0062] FIG. 14 and FIG. 15, illustrate the biconvex structure of the magnet set. The biconvex structure refines the quality of the magnetic compression anastomosis.

EXAMPLE 3

[0063] FIGS. 16, 17, 18 describe the device of Example 3. In one embodiment of this invention the magnet network is embedded in layers of resilient material (3). This laminated structure is compromised of a silicon layer (1) around the magnet (2) and a rubber layer covering the silicon. In its delivery form the magnet assembly is in a linear structure. In addition of this organization, the chain of the magnet can be enveloped in a jacket of resilient and biocompatible material.

[0064] FIGS. 16 and 17 illustrate the structure of one set of the magnets.

[0065] FIG. 17 is a presentation of simple magnets and external jacket.

[0066] FIG. 18 is a profile view of the set of the magnets, where (2) is the magnet, (1) the silicon layer and (3) the biocompatible polymer.

EXAMPLE 4

[0067] FIG. 19 and FIG. 20 describe the non-deployed and deployed form of the magnet assembly representing another example of this invention compromises a set of magnets encapsulated in a resilient or biocompatible material which may also be a shape memory material allowing the delivery of magnets in a flattened configuration. A spring of resilient or biocompatible material (4) is on either side of the device in the non-deployed configuration. When it is delivered the magnet assembly will automatically assume its deployed configuration.

[0068] The biodegradable resilient material (1) envelopes magnets (3) and the shape memory material (2). The central circular ring (5) holds the wire guides (6).

EXAMPLE 5

[0069] FIG. 21 to FIG. 25 describe different elements of the modular magnetic assembly of example 5.

[0070] According to this example in accordance with the teachings of the present invention the modular magnet assembly is composed of a chain of ring-shaped magnetic elements (3) linked to each other by a network of articulate mechanic elements (1 and 2). The ring-shaped magnets are enveloped with a network of sheets that allows the device to pass from a non-deployed structure to the deployed structure. Alternate and specific geometry of the sheets is designed for the ease of the articulation between magnets in the chain.

[0071] The individual magnets and the sheets are linked together through a centralized axis (4).

[0072] FIG. 21 illustrates the ring shaped modular magnetic anastomosis device in the deployed configuration.

[0073] FIG. 22 shows a profile view of the device.

[0074] FIG. 23 is a cross-sectional view of the magnet assemblies; illustrate the passageway formed with the ring structure (6) for the wire guide (8). The central ring (7) is used for the wire guide (5).

[0075] FIG. 24 illustrates the linear non deployed configuration.

[0076] FIG. 25 describes different components of the magnet, flexible structured sheets in the various geometries (1 and 2); the central magnet (3) and the component forming the central axis linking the sheets and the magnetized rings.

What is claimed is:

1. A modular magnet assembly, comprising:

a) a first set of modular magnets b) a second set of modular magnets; wherein the first and second sets of modular magnets are configured for placement on a first and a second bodily wall; respectively, within such a distance that the first set of modular magnets and the second set of modular magnets are magnetically attracted to one another through a defined tissue area.

2. The modular magnet assembly of claim 1 wherein each set comprises at least 2 magnets.

3. The modular magnets assembly of claim 1, wherein the dipole for the magnets is in an alternating configuration north-south, south-north.

4. The modular magnet assembly of claim 1, comprising a plurality of magnetic members having a delivery configuration.

5. The modular magnet assembly of claim 1, comprising a plurality of magnetic members having a deployed configuration.

6. The modular magnet assembly of claim 5, wherein the deployed configuration is circular.

7. The modular magnet assembly of claim 5, wherein the deployed configuration is elongated.

8. The modular magnet assembly of claim 5, wherein the deployed configuration is a U shape.

9. The modular magnet assembly of claim 5, wherein the deployed configuration is an S shape.

10. The modular magnet assembly of claim 5, wherein the deployed configuration is achieved using a wire guide.

11. The modular magnet assembly of claim 1, wherein each set comprises:

a) a chain of magnets,
b) a neck composed of flexible material with a passageway sized to receive a wire guide,
c) a jacket composed of a resilient material with a hole used as the wire guide.

12. The modular magnet assembly of claim 11, wherein the delivery configuration is elongated.

13. The modular magnet assembly of claim 11, wherein the deployed configuration is one of:

- a) Circular;
- b) U shape;
- c) S shape; and
- d) elongated shape

14. The modular magnet assembly of claim 1, wherein every magnet is separately enveloped in a shell.

15. The modular magnet assembly of claim 14, wherein the shell is a resilient material.

16. The modular magnet assembly of claim 14, wherein the shell is a biocompatible material.

17. The modular magnet assembly of claim 14, wherein the encapsulated shell is affixed to a flexible band.

18. The modular magnet assembly of claim 14, wherein encapsulated shells are joined with a wire guide.

19. The modular magnet assembly of claim 14, wherein the delivery configuration is elongated.

20. The modular magnet assembly of claim 14, wherein the deployed configuration is one of:

- a) Circular.
- b) U shape
- c) S shape
- d) elongated shape

21. The modular magnet assembly of claim 14, wherein the deployed circular configuration is biconvex.

22. The modular magnet assembly of claim 1, wherein the magnet network is embedded in a multilayer structure, said multilayer structure comprises a:

- a) rubber layer
- b) silicon layer
- c) magnets
- d) silicon layer
- e) rubber layer

23. The modular magnet assembly of claim 22, wherein the multilayer structure is enveloped in a jacket of resilient.

24. The modular magnet assembly of claim 22, wherein the multilayer structure is enveloped in a jacket of biocompatible material.

25. The modular magnet assembly of claim 22, wherein the delivery configuration is elongated.

26. The modular magnet assembly of claim 22, comprising a deployed configuration selected from:

- a) circular.
- b) U shape
- c) S shape
- d) elongated shape

27. The modular magnet assembly of claim 1, wherein magnets are enveloped in a jacket with a spring made of resilient and biocompatible material on either side of the jacket.

28. The modular magnet assembly of claim 27, wherein the jacket is a shape memory material.

29. The modular magnet assembly of claim 27, wherein the device delivered automatically assumes a deployed configuration.

30. The modular magnet assembly of claim 27, wherein the jacket has passageway sized to receive the wire guide,

31. The modular magnet assembly of claim 27, wherein the deployed configuration is circular.

32. The modular magnet assembly of claim 1, wherein the magnet is composed of a chain of ring shaped magnetic elements linked to each other by a network of mechanical elements.

33. The modular magnet assembly of claim 32, wherein the magnets are enveloped with a network of sheets.

34. The modular magnet assembly of claim 32, wherein alternate and specific geometry ease the articulation between magnets.

35. The modular magnet assembly of claim 32, wherein magnets and sheets are linked together through a centralized axis.

36. The modular magnet assembly of claim 1, wherein the magnets are delivered to the organ using laparoscopic trocars.

37. The modular magnet assembly of claim 1, wherein the magnets are delivered to the organ using endoscopy.

38. The modular magnet assembly of claim 1, wherein the two sets of magnet assembly when in proximity the magnets are in configuration (North-South-North-South)/(South-North-South-North).

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| 专利名称(译) | 模块化磁吻合装置 | | |
| 公开(公告)号 | US20150164508A1 | 公开(公告)日 | 2015-06-18 |
| 申请号 | US14/237521 | 申请日 | 2012-07-11 |
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| 当前申请(专利权)人(译) | IRCAD | | |
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| 发明人 | HERNANDEZ, JUAN DIANA, MICHELE WALL, JAMES KENNEDY | | |
| IPC分类号 | A61B17/11 | | |
| CPC分类号 | A61B17/1114 A61B17/11 A61B2017/00292 A61B2017/00862 A61B2017/00876 A61B2017/1117 A61B2017/1132 A61B2017/1135 A61B2017/1139 | | |
| 优先权 | 61/506710 2011-07-12 US | | |
| 其他公开文献 | US10568630 | | |
| 外部链接 | Espacenet USPTO | | |

摘要(译)

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