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(56) Documents Cited:
JP 020307480 A
US 6080182 A
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(58) Field of Search:
INT CL[7] **A61B**
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(54) Abstract Title: **Intravascular occlusion device**

(57) An inflatable medical occlusion device 4, particularly for intra cardiac septal defects comprises at least one disc portion 6, 8 attached to a neck portion 12, each of which at least one disc portions comprises a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable support in an inflated configuration.

A delivery system for delivering a device of this type includes a retractable sheath 2; the inflatable medical occlusion device and detachable means for locating the device in a desired location and inflating the inflatable supports via the at least one inflation port.

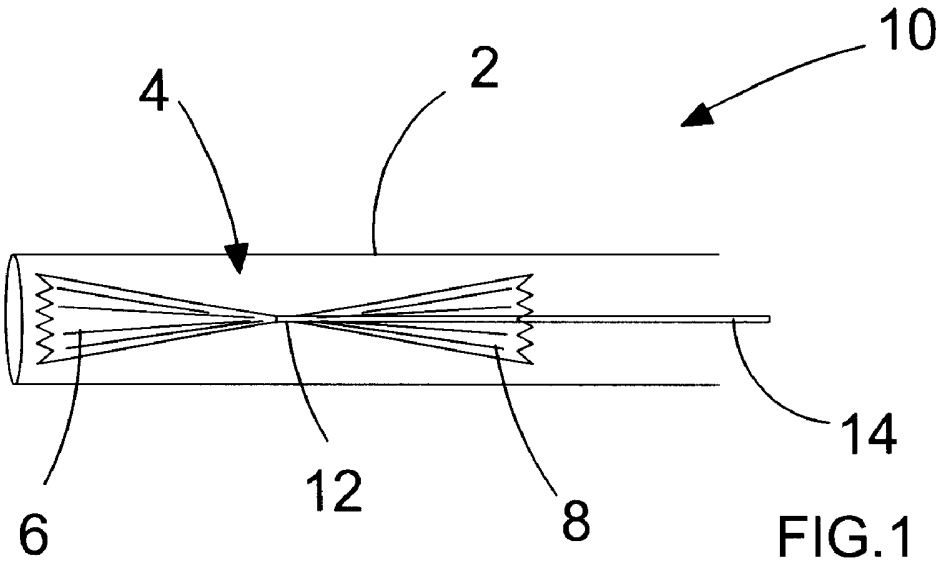

FIG.1

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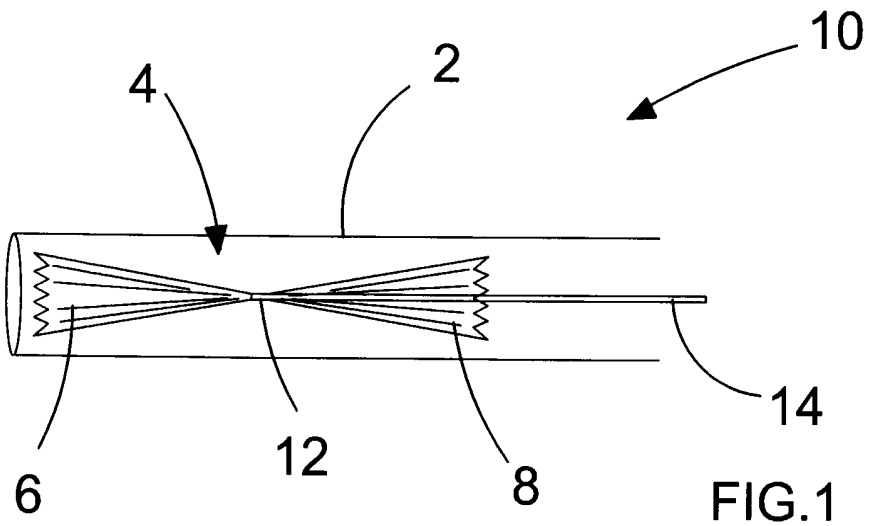

FIG.1

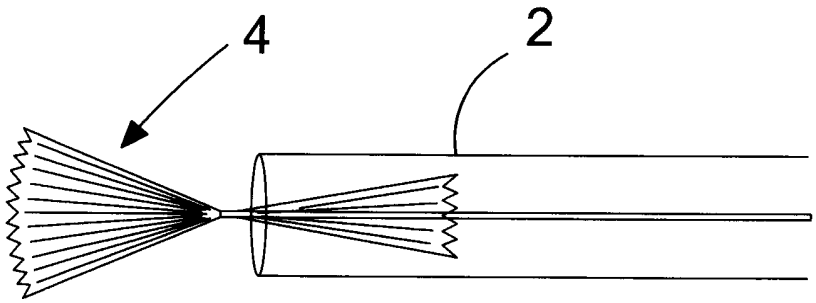

FIG.1a

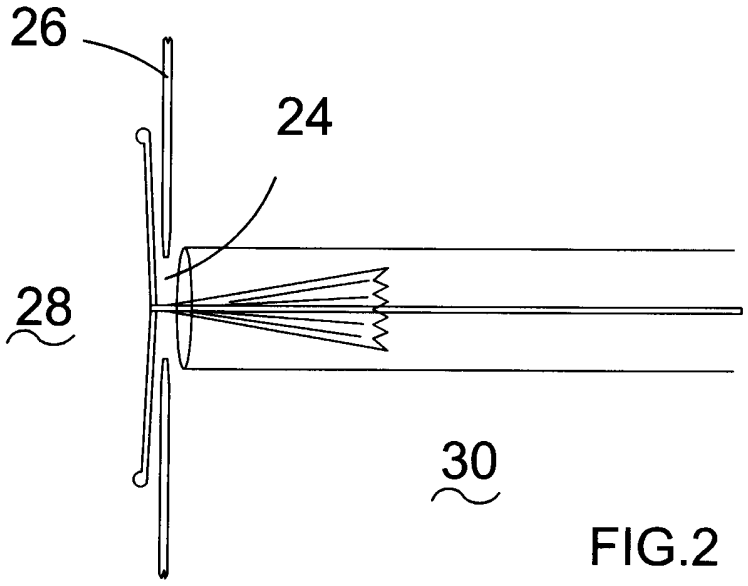

FIG.2

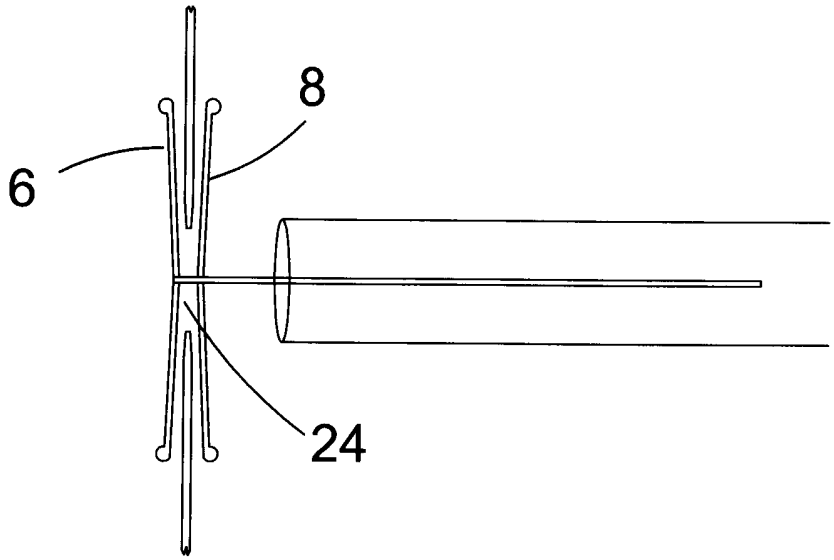

FIG.3

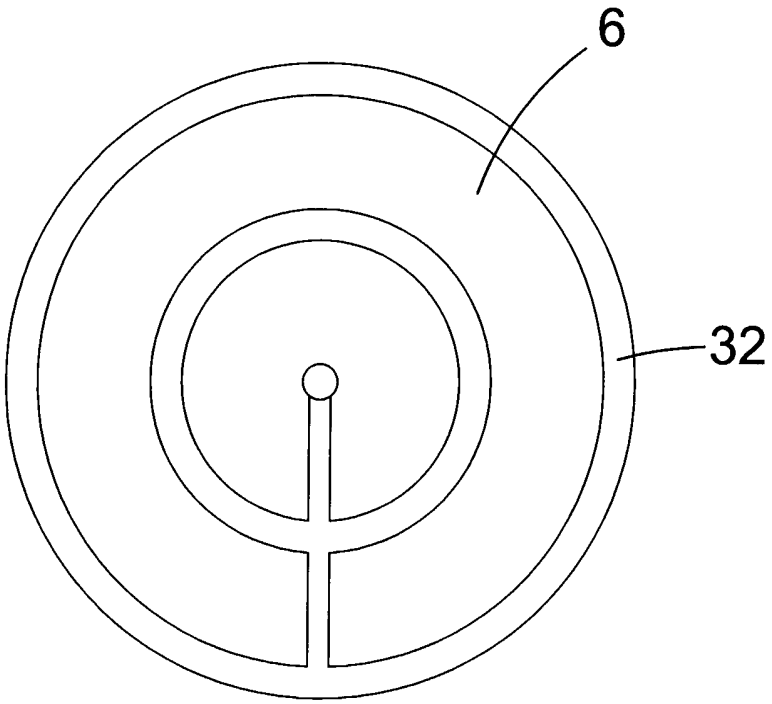

FIG.6

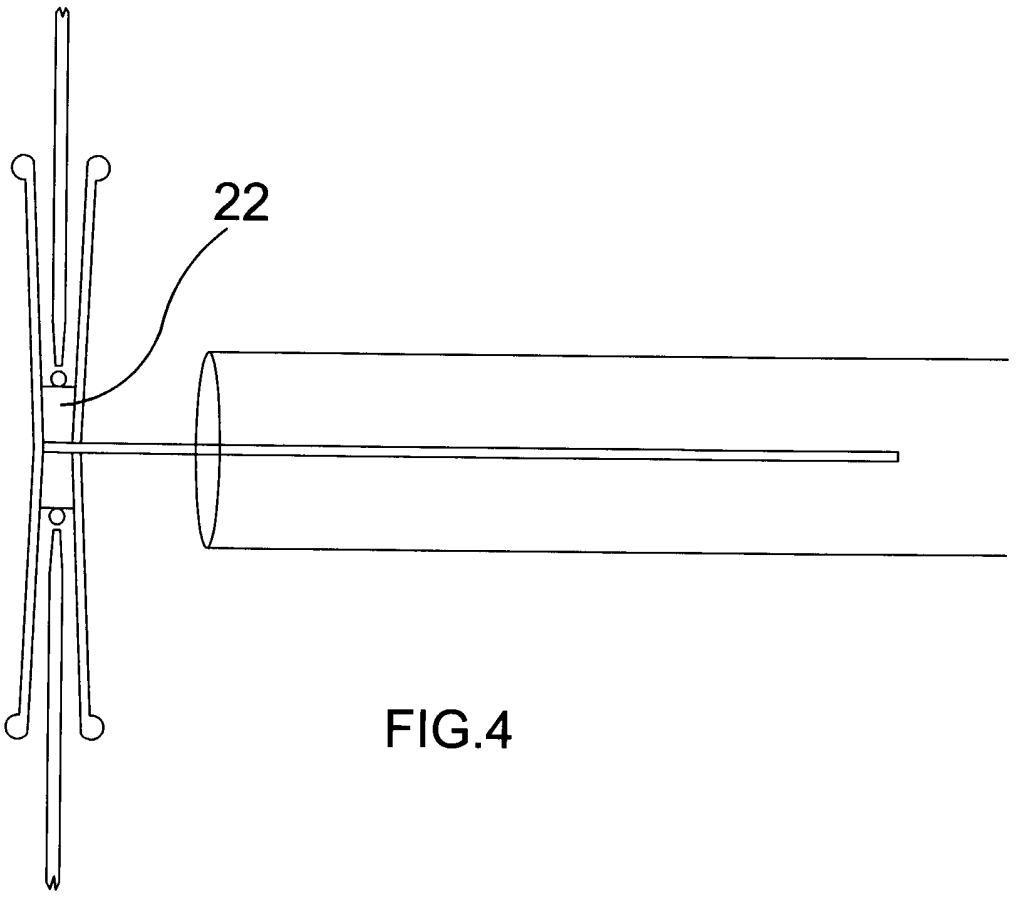

FIG.4

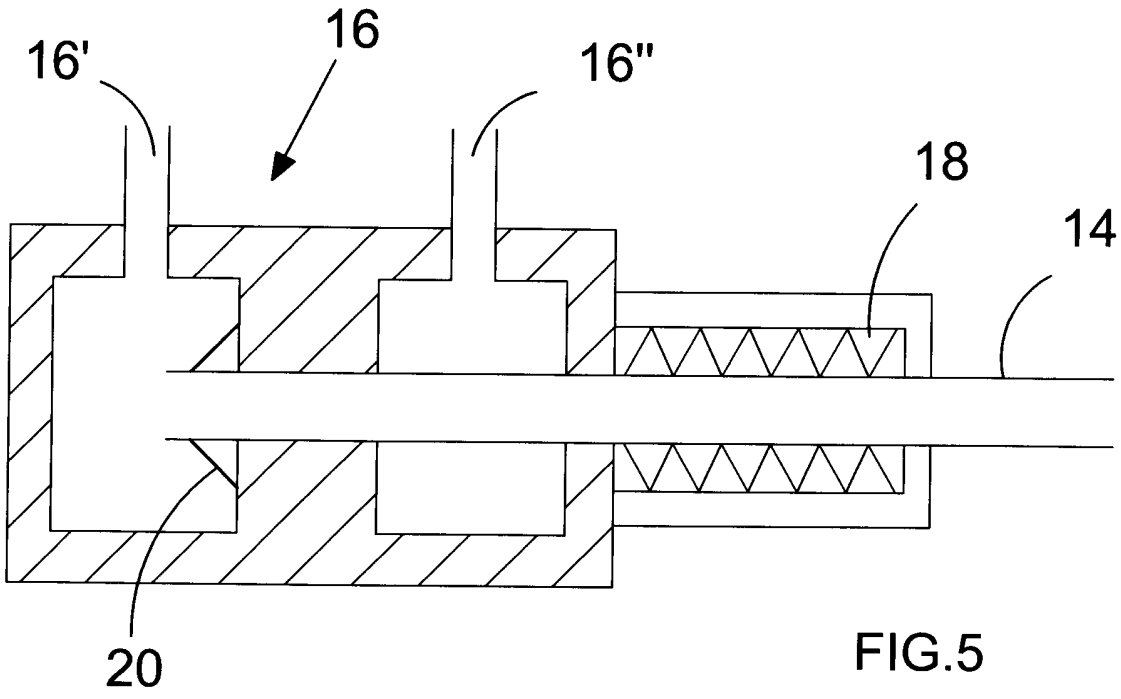

FIG.5

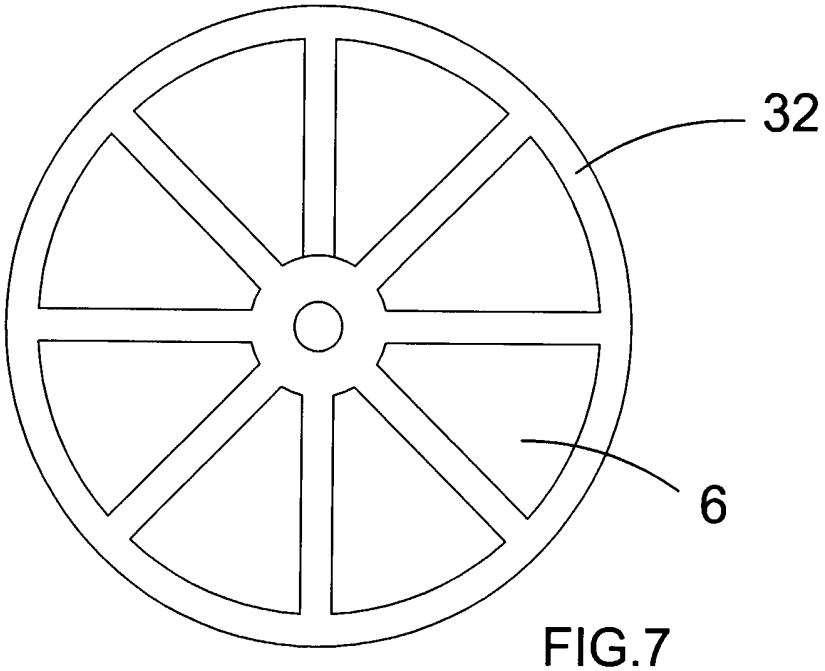

FIG.7

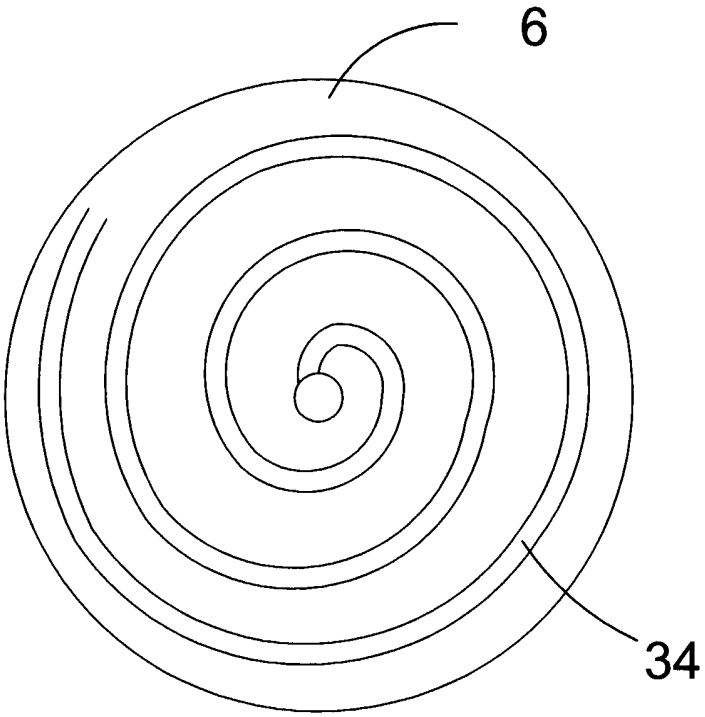

FIG.8

Title: Improved Medical Device

The present invention relates to an improved medical device, in particular to an improved intravascular occlusion device, more particularly an intracardiac septal defect occlusion device. The device is particularly suitable for use in the treatment of congenital heart defects.

It was proposed in US Patent No 4,836,204 to provide a double-balloon septal defect occlusion catheter for use in conjunction with a surgical procedure to temporarily close septal perforations, particularly spontaneous ventricular septal perforations following acute myocardial infarction, without the need for open heart surgery, thus permitting the patient's condition to stabilize and permitting elective surgical closure of the defect at a later date. The balloons described in this US patent are introduced into the desired location, filled with a fluid, for example a resin which hardens inside the balloon, until the balloon substantially fills the defect and becomes lodged therein. It is a disadvantage of the devices proposed in this patent that they are suitable only for use as a temporary closure, subsequently requiring surgical removal. It is a further disadvantage of these devices that in order to avoid problems associated with incomplete filling of the balloon with fluid, and the possibility of subsequent dislodgement, there is a risk that the physician may overfill the balloon and cause it to rupture, thus allowing leakage of the fluid into the patient's bloodstream.

It is also known from WO97/42878 in the name of AGA Medical Corporation to provide an intravascular occlusion device for Atrial Septal Defects (ASD), and Patent Ductus Arteriosus (PDA) treatment. The device is constructed of resilient metal fabric, and is capable of assuming both an expanded configuration and a collapsed configuration. Once expelled out of a delivery catheter the device returns to its expanded configuration in either a generally barbell configuration or a generally bell-shaped configuration.

The devices described in the AGA Medical Corporation patent application have achieved significant success in the treatment of, inter alia, congenital heart defects. It has however been

observed that, in a small but significant number of cases, damage may occur to the structures adjacent to the occlusion device due to abrasion by the metal fabric of the device. The long term, beyond five to ten year, performance of these devices is uncertain and there has been clinical concern about the long term implications of implanting these devices.

Examples of scientific papers in which such observations and concerns have been reported include: Chun et al "Development of aorta-to-right atrial fistula following closure of secundum atrial septal defect using the Amplatzer septal occluder", Catheterization & Cardiovascular Interventions 2003; 58: 246-251; Trepels et al "Cardiac perforation following transcatheter PFO closure." Catheterization & Cardiovascular Interventions 2003; 58: 111-113 and Aggoun et al "Perforation of the aorta after percutaneous closure of an atrial septal defect with an Amplatz prosthesis, presenting with acute severe hemolysis". Archives des Maladies du Coeur et des Vaisseaux 2002; 95: 479-482.

It is an object of the present invention to provide an occlusion device in which the above disadvantages are reduced or substantially obviated.

The present invention provides an inflatable medical occlusion device comprising at least one disc portions attached to a neck portion, each of which at least one disc portions comprises a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable support in an inflated configuration.

The present invention further provides an inflatable medical occlusion device comprising first and second disc portions joined by a neck portion, which first and second disc portions each comprise a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable supports in an inflated configuration.

The first and second inflatable supports may be joined in communication with each other via the

neck portion or they may be isolated from each other. Where the inflatable supports are isolated from each other, then the device may comprise two inflation ports, one associated with each of the first and second inflatable supports.

In a preferred embodiment of the occlusion device according to the invention, the neck portion is provided with a centring mechanism, preferably an inflatable centring ring which is provided with an inflation port.

In a further preferred embodiment of the occlusion device according to the invention, the sealing device for the balloon is biodegradable.

The present invention further provides a delivery system for delivering an inflatable medical occlusion device, which delivery system includes a retractable sheath; an inflatable medical occlusion device comprising at least one disc portion attached to a neck portion, each of which at least one disc portions comprises a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable supports in an inflated configuration; and detachable means for locating the device in a desired location and inflating the inflatable supports via the at least one inflation port.

The present invention further provides a delivery system for delivering an inflatable medical occlusion device, which delivery system includes a retractable sheath; an inflatable medical occlusion device comprising first and second disc portions joined by a neck portion, which first and second disc portions each comprise a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable supports in an inflated configuration; and detachable means for locating the device in a desired location and inflating the inflatable supports via the at least one inflation port.

In a preferred delivery system according to the invention, the detachable means for inflating the inflatable supports via the at least one inflation port includes a valve releasably attached to the inflation port, for example by means of a threaded coupler. The detachable means for inflating the

inflatable supports preferably comprises a hypotube.

The inflatable supports are made of a non-compliant biocompatible material. Suitable materials for the balloon include the materials used for balloon angioplasty catheters, such as those manufactured by Boston Scientific or Medtronic Inc (Vascular Division).

The deformable fabric discs are preferably manufactured from a polyester fabric, for example the proprietary polyester fabric sold under the Trade Mark Dacron by E.I. du Pont de Nemours and Company

Preferred embodiments of an inflatable medical occlusion device and a delivery system for such a device will now be described with reference to the accompanying drawings, in which

Figure 1 is a view of a delivery system ready for insertion;

Figure 1a is a view of a delivery system ready for insertion with the sheath partially retracted and prior to inflation of the inflatable support;

Figure 2 is a view of the delivery system in the desired location, with the sheath partially retracted and after inflation of the inflatable support;

Figure 3 is a view of the medical occlusion device in the desired location after inflation and retraction and detachment of the detachable means;

Figure 4 is a view of an alternative embodiment of a medical occlusion device in the desired location after inflation and retraction and detachment of the detachable means;

Figure 5 is a view in enlarged scale of a part of the medical occlusion device;

Figure 6 is a plan view of the medical occlusion device of Figure 3;

Figure 7 is a plan view of a further alternative embodiment of a medical occlusion device in the desired location after inflation and retraction and detachment of the detachable means and

Figure 8 is a plan view of a further alternative embodiment of a medical occlusion device in the desired location after inflation and retraction and detachment of the detachable means.

As can be seen from Figure 1, a delivery device shown generally at 10 comprises a retractable sheath 2 in which is located a folded medical occlusion device shown generally at 4. The device 4

comprise a first disc portion 6, a second disc portion 8 and a neck portion 12 joining the first disc portion 6 and second disc portion 8. A hypotube 14 is releasably attached to the device, as will be explained in more detail below.

In Figure 1a, the occlusion device 4 is shown with the sheath 2 partially withdrawn.

In Figure 2, the occlusion device 4 is shown in position within an aperture 24 in the atrial septum 26 of the heart of a patient suffering from a congenital heart defect (hole in the heart), which may be either an atrial septal defect (ASD) or a Patent Foramen Ovale (PFO). The first disc portion 6 is located in the left atrium 28 of the patients heart and the second disc portion 8 is located in the right atrium 30, with the neck portion 12 located in the septum 26. The sheath 2 has been partially withdrawn and first disc portion 6 has been inflated. The device 4 is ready for inflation, after further withdrawal of the sheath 2.

In Figure 3, the occlusion device 4 is shown in an inflated condition, with the first disc portion 6 and second disc portion 8 inflated. The aperture 24 is effectively closed.

In Figure 4, an alternative embodiment of an occlusion device is shown, in which the neck portion is provided with a centring ring 22. This centring ring 22 may be made of a similar material to the disc portions and may itself be in the form of an inflatable centring balloon.

In Figure 5, the central portion of the device is shown in more detail, to an enlarged scale. A hypotube 14 is releasably attached to the device by means of a threaded coupler 18. An inflation port housing 16 comprises a first inflation port 16' provided in the wall of the first disc portion 6 and a second inflation port 16" provided in the wall of the second disc portion 8. A seal 20 is provided within the inflation port housing 16.

As can be seen from Figure 6, the first disc portion 6 is provided with an inflatable support 32 in

the form of an annulus mounted at the periphery of the fabric disc, with a single radial spoke connecting the annulus to the inflation port.

The left atrial disc 6 is inflated first in the left atrium, and the device is then pulled back against the rim of the defect. The neck portion 12 which acts as a centring ring and the right atrial disc are then inflated to secure the device across the defect. The device can be retrieved into the delivery catheter by deflation of the balloon support in case of malpositioning of the device across the defect.

In the alternative embodiments shown in Figures 7 and 8 respectively, the first disc portion 6 is provided (Figure 7) with an inflatable support 32 in the form of an annulus mounted at the periphery of the fabric disc, with a plurality of radial spokes connecting the annulus to the inflation port or (Figure 8) with an inflatable support 34 in spiral form and extending across the fabric disc.

In the operation to insert the device 4, the delivery system 10 is introduced via a femoral vein into the right atrium 30 and across the aperture 24 (ASD or PFO) into the left atrium, with the first disc portion 6 located in the left atrium. The sheath 2 is retracted and the inflatable support of the first disc portion 6 inflated by filling the support via the hypotube 14 with saline solution in which a contrast agent is dissolved. The contrast agent is used so that the progress of the inflation of the device 4 can be monitored by radiography and/or ultrasound.

The threaded coupler 18 allows the hypotube 14 to be screwed back in two stages after inflation of the first disc portion 6 via the first inflation port 16'. As the hypotube is screwed back in the first stage, the seal 20 closes and the second disc portion can be inflated via the second inflation port 16". After inflation of both discs, the hypotube can be further withdrawn, thus releasing the device. The location and inflating means is withdrawn together with the sheath 2 along the patient's vein.

In the condition shown in Figure 3, the occlusion device may be left indefinitely in the patient's septum. Since the device is made from a soft material and does not contain any metal or any sharp edges, there is no risk of the device damaging the surrounding septum. As the device stays in the

patient, tissue grows around the device providing a natural closure for the aperture.

As has been stated above, the device may comprise biodegradable seals or valves. If a device including such seals or valves is used, as the natural closure described above forms, the balloon will deflate and the saline solution contained therein will diffuse harmlessly into the patients blood supply.

While the occlusion device according to the invention has been described specifically in relation to the occlusion of an atrial aperture, it will be appreciated that the device is of general applicability in the occlusion of congenital and other defects in vessels.

Claims

1. An inflatable medical occlusion device comprising at least one disc portion attached to a neck portion, each of which at least one disc portions comprises a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable support in an inflated configuration.

2. An inflatable medical occlusion device according to claim 1 which comprises first and second disc portions joined by a neck portion, which first and second disc portions each comprise a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable supports in an inflated configuration.

3. An inflatable medical occlusion device according to claim 2 wherein the first and second inflatable supports are joined in communication with each other via the neck portion.

4. An inflatable medical occlusion device according to claim 2 wherein the first and second inflatable supports are isolated from each other.

5. An inflatable medical occlusion device according to claim 4 wherein the device comprises two inflation ports, one associated with each of the first and second inflatable supports.

6. An inflatable medical occlusion device according to any of claims 1 to 5 wherein the neck portion is provided with a centring mechanism.

7. An inflatable medical occlusion device according to claim 6 wherein the centring mechanism is an inflatable centring ring which is provided with an inflation port.

8. An inflatable medical occlusion device according to any of claims 1 to 7 wherein the sealing device is biodegradable.

9. A delivery system for delivering an inflatable medical occlusion device, which delivery system includes a retractable sheath; an inflatable medical occlusion device comprising at least one disc portion attached to a neck portion, each of which at least one disc portions comprises a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable supports in an inflated configuration; and detachable means for locating the device in a desired location and inflating the inflatable supports via the at least one inflation port.

10. A delivery system for delivering an inflatable medical occlusion device, which delivery system includes a retractable sheath; an inflatable medical occlusion device comprising first and second disc portions joined by a neck portion, which first and second disc portions each comprise a deformable fabric disc mounted on an inflatable support made from a non-compliant biocompatible material and having one or more inflation ports, sealable for sealing the inflatable supports in an inflated configuration; and detachable means for locating the device in a desired location and inflating the inflatable supports via the at least one inflation port.

11. A delivery system substantially as herein described and with reference to the accompanying drawings.

Application No:	GB 0326447.0	**Examiner:**	Dave Cannon
Claims searched:	1-11	**Date of search:**	12 February 2004

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X	1-3 & 8-10	US 5634936	(LINDEN *et al.*). Whole document particularly col.4, l.17-24; col.8, l.47 to col.9, l 21, and col.9 l.66-col.10, l.5; col.10, l.26-36 and figs. 11-13
X	1-5 & 9-10	US 4836204	(LANDYMORE *et al.*). Whole document particularly col 1, l.48-65; col.2, l.11-16 and l.47-53; col.3, l.50-col 4, l.11; and figs. 13 &14.
X	1, 2, 4-5 & 9-10 at least	JP 020307480 A	(TANAKA). See PAJ abstract and figures.
A	1 at least	US 2002/0096183 A1	(STEVENS *et al.*). Whole document particularly figure 2c.
A	1 at least	US 6080182	(SHAW *et al.*). Whole document.
A	1 at least	US 6217548 B1	(TSUGITA *et al.*). Whole document.

Categories

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art
Y	Document indicating lack of inventive step if combined with one or more other documents of same category	P	Document published on or after the declared priority date but before the filing date of this invention
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[W]:

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Worldwide search of patent documents classified in the following areas of the IPC[7]:

A61B

The following online and other databases have been used in the preparation of this search report:

EPODOC, WPI, PAJ