(51) International Patent Classification:  
A61B 17/00 (2006.01)

(21) International Application Number:  
PCT/GB2007/004757

(22) International Filing Date:  
12 December 2007 (12.12.2007)

(25) Filing Language:  
English

(26) Publication Language:  
English

(30) Priority Data:  
0625103.7 15 December 2006 (15.12.2006) GB

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(54) Title:  
DEVICE FOR OCCLUDING A SEPTAL DEFECT

(57) Abstract:  
A device for occluding a sepal defect opening that has collapsible and expandable first and second anchor portions and a connection member, extending along an axis between the first and second anchor portions, and connected to the first and second anchor portions at respective connection points. The first and/or second anchor portion defines, in the expanded state, an envelope for occluding a respective side of the septal defect opening, and the connection point is offset from the centre of the envelope and/or the perimeter of the envelope has a non-circular shape. The first and second anchor portions are relatively rotatable about the axis of extension of the connection member.
The invention relates to a device for closing an opening in a human or animal body, particularly, but not necessarily exclusively, for closing a septal defect such as the patent foramen ovale (PFO).

The foramen ovale is a conduit located between the left and right atria of the heart which remains open during foetus gestation to allow oxygenated blood to pass from the placenta to the left hand side of the heart, bypassing the lungs. Soon after birth, once the pulmonary vasculature is functioning, the foramen ovale should close. However, for up to 30% of the population, the foramen ovale remains open. This open foramen ovale septal defect is known as the 'patent foramen ovale' (PFO).

Patients having a PFO septal defect are susceptible to strokes, due to thromboses passing through the septal defect, and migraines, especially those that occur with aura (flashes and glowing visually experienced by the sufferer), thought to be caused by impurities passing though the septal defect and flowing up to the brain.

Traditional treatment for a septal defect is performed using open surgery or thoracoscopic surgical techniques. However, in recent years, percutaneous devices are being used to occlude septal defects.

Commonly available devices for percutaneously occluding septal defects include NMT Medical Inc.'s device, described in PCT publication no. W02006036837, the Amplatzer® device, described in US Patent no. US5944738, and St. Jude Medical, Inc.'s device, described in PCT publication no. W02006028813.
These occluder devices are configured and deployed in a similar manner. Each device is dumbbell-shaped, having proximal and distal umbrella-type anchor portions at respective ends, linked by a connector.

The anchor portions of these devices comprise shape memory alloy so that they can be constrained in a collapsed state within a delivery catheter during deployment to the septal defect.

To deploy these known devices at a septal defect, normally a delivery catheter containing the device is inserted into the vasculature, through the femoral vein and into the right atrium via the inferior vena cava, and then through the septal defect. The distal anchor portion is then opened by pushing the device halfway out of the catheter at the distal side of the defect such that the distal anchor portion is no longer constrained by the catheter. Since it is no longer constrained, the distal anchor portion can expand to its natural shape. The delivery catheter is then fully withdrawn, causing the distal anchor portion to close the distal side of the defect and the proximal anchor portion to be exposed. Since the proximal anchor portion is no longer constrained by the catheter, it is also free to expand to its natural shape, and thus close the proximal side of the septal defect. The connector passes through the septal defect, linking the anchor portions together. The connector may be flexible to allow for variations in the anatomy of the heart. This deployment procedure is executed using fluoroscopy and echocardiography.

The devices are intended to seal the septal defect, preventing emboli from passing therethrough.

However, commonly, the devices do not conform appropriately to the shape of the septum adjacent the defect upon deployment. As a result, these known occluding devices can cause damage to the septum and they may not fully close or seal the septal defect.

Generally, the present invention may provide a device, for occluding a septal defect opening, with first and second anchor portions connected via a connector portion, which device is configured such that, when deployed at the septal defect opening, it can be rotated to change its conformity with the septum adjacent the defect opening.

According to a first aspect, the present invention provides:
a device for occluding a septal defect opening, the device comprising:

first and second anchor portions, each anchor portion being adjustable between a collapsed configuration, for delivery to the septal defect opening, and an expanded configuration, for engagement with the septum at a respective side of the septal defect opening; and

a connection member for extending through the septal defect opening, the connection member extending along an axis between the first and second anchor portions and being connected to the first and second anchor portions at respective connection points,

wherein the first and/or second anchor portion defines, in the expanded state, an envelope for occluding a respective side of the septal defect opening, and the connection point is offset from the centre of the envelope.

Preferably, the first and second anchor portion both define, in the expanded state, respective envelopes for occluding a respective side of the septal defect opening, and the connection point of each anchor portion is offset from the centre of the respective envelope.

The envelope may have a closed-curve shape. For example, it may be circular, elliptical, ovoid, oblong, pear-shaped, kidney-shaped etc.. By having such a shape for the envelope, the anchor portion may take a smooth form, minimising damage to the septum upon rotation.

Preferably, the connection point is located at a distance from the centre of the envelope of 10-90%, 20-50%, or most preferably 30-40% of: the radius of the envelope, if the envelope is circular; or of half the major axis of the envelope, if the envelope is elliptical or ovoid. If the envelope is elliptical, the connection point may be located at or adjacent a focus of the ellipse.

By having this eccentric mounting of the connector to the anchor portion, the distance between the connection point and the perimeter of the envelope will vary around the perimeter of the envelope. Thus, if the respective anchor portion is rotated about the axis of extension of the connection member, and/or a guidewire passing through the connection member, the envelope will change its configuration relative to the septum.

Upon rotation, the dimension of the envelope in a direction generally perpendicular to the
axis of rotation will change. Since the septum is not uniform, the rotation ensures that the most appropriate fit between the anchor portion and the septum may be achieved. Rotation may be performed in order to avoid contact between one of the anchor portions and sensitive tissue adjacent the defect, or to prevent unwanted obstruction of a pathway adjacent to the defect, such as the coronary sinus.

Furthermore, by having the eccentric mounting, the area over which the envelope can pass on rotation is greater than if the same envelope were centrically mounted. This principle means the envelope may take a smaller size to occlude one or more defects. Having a smaller envelope means production of the device may be cheaper, and delivery of the device to a septal defect, e.g. using a catheter, may be easier.

According to a second aspect, the present invention provides:

a device for occluding a septal defect opening, the device comprising:

first and second anchor portions, each anchor portion being adjustable between a collapsed configuration, for delivery to the septal defect opening, and an expanded configuration, for engagement with the septum at a respective side of the septal defect opening; and

an elongate connection member for extending through the septal defect opening,

the connection member extending along an axis between the first and second anchor portions and being connected to the first and second anchor portions at respective connection points,

wherein the first and/or second anchor portion defines, in the expanded state, an envelope, for occluding a respective side of a septal defect opening, that has a perimeter which has a non-circular shape.

Preferably, the first and second anchor portion both define, in the expanded state, respective envelopes.

Since the envelope has a perimeter which is non-circular in shape, the distance between the connection point and the perimeter of the envelope will vary around the perimeter. Thus, if the respective anchor portion is rotated about the axis of extension of the connection member, the envelope will change its configuration relative to the septum (e.g. atrial wall). Upon rotation, the dimension of the envelope in a direction generally perpendicular to the axis of rotation will change. Since the septum may not be uniform in
shape, the rotation ensures that the most appropriate fit between the anchor portion and the septum may be achieved.

Preferably, the non-circular shape of the envelope is a closed-curved shape. By having a curved shape for the envelope, the anchor portion may take a smooth form, minimising damage to the septum upon rotation.

The closed-curve shape for envelope may be elliptical, ovoid, oblong, pear-shaped, kidney-shaped etc.. The first and second anchor portions may have differently shaped envelopes.

The anchor portions of the first and/or second aspect of the present invention are relatively rotatable about the axis of extension of the connection member. Thus, for example, one anchor portion may be rotated relative to the septum/defect whilst the other anchor portion remains stationary relative to the septum/defect. If both anchor portions have envelopes for covering and occluding the septal defect opening, the anchor portions may be relatively rotated to cover different openings (fenestrations) of the defect (or different defects). If the device is located on a guidewire, the axis of extension of the connection member may lie along the longitudinal axis of the guidewire.

So that the anchor portions are relatively rotatable, the connection member may be rotatably mounted to the first anchor portion and may be fixed to the second anchor portion.

The device may be comprised in apparatus, the apparatus including first and second catheters, each having proximal and distal ends, wherein the first and second catheters are relatively rotatable about their longitudinal axes to relatively rotate the first and second anchor portions of the device. Preferably, the distal end of the first catheter is releasably connected to the first anchor portion, and the distal end of the second catheter is releasably connected to the second anchor portion. Particularly when the connection member is fixed to the second anchor portion, the second catheter may be releasably connected to the second anchor portion by engaging the connection member, rather than engaging the second anchor portion directly.
The first catheter may be held in releasable engagement with the first anchor portion by one or more monofilaments. The monofilaments may be tightened to force the first catheter and the first anchor portion together, and loosened to allow the first catheter and the first anchor portion to move apart. The one or more monofilaments may be provided in a loop, which loop extends to a proximal end of the apparatus where it can be cut to completely separate the first catheter and the first anchor portion.

Preferably, the second catheter is arranged to extend through a core cavity in the first catheter. Accordingly, the apparatus may take a compact profile. Furthermore, the arrangement may allow a single guidewire to be used to guide the two catheters to the defect. Still furthermore, the arrangement may facilitate the second catheter extending through the connection member to connect to the second anchor portion.

Preferably, in the device according to the first and/or second aspects of the invention, the connection member is extendable such that the distance between the first and second anchor portions can be varied. This may permit the connection member of the device to extend across defects of differing sizes. Furthermore, it may allow the anchor portions to be rotated without contacting the walls of the septal defect, which could otherwise cause damage as a result of frictional engagement between the anchor portions and the walls.

So that the connection member may be placed in an extended state, preferably it is resiliently flexible. For example, it may comprise one or more leaf springs or a helical spring.

Preferably, the distance between the first and second anchor portions can be increased by extending the second catheter out of the core cavity of the first catheter, via a distal opening of the first catheter.

Preferably, the anchor portions are spring-biased so that they may move from the collapsed state to the expanded state automatically. Preferably, the anchor portions comprise shape memory material such as a shape memory alloy, e.g. nitinol or a type of steel, or shape memory plastics, which causes the anchor portions to move to the expanded state automatically. The shape memory material may be used to form a support, such as a plurality of arms. The arms may extend radially from the connection points of the anchor portions and the connection member. The support, e.g. the plurality
of arms, may support a membrane. The shape of the envelope may correspond to the shape of the perimeter of the membrane. The membrane may be formed of a weave. One or both of the anchor portions may comprise membranes.

The devices of the first or second aspects of the present invention may be entirely or partially biodegradable. For example, the arms and/or the membrane may be biodegradable. Alternatively, the devices may be entirely non-biodegradable.

Preferably, the devices of the first and/or second aspects of the present invention are for occluding the patent foramen ovale PFO. However, the devices are not limited to such use. Additionally, or alternatively, the device may be for occluding e.g. other arterial defects, abdominal and/or ventricular defects.

According to a third aspect, the present invention provides a method of deploying the device of the first or second aspect of the present invention at a septal defect opening, the method comprising the steps of delivering the device to the septal defect opening, and rotating one of the anchor portions, or both of the anchor portions independently or simultaneously.

According to a fourth aspect, the present invention provides a method of treating a septal defect opening, the method comprising the steps of delivering the device of the first or second aspect to the septal defect opening, and rotating one of the anchor portions, or both of the anchor portions independently or simultaneously.

Embodiments of the present invention will now be described by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 shows an oblique view of a device for occluding a septal defect according to a first embodiment of the present invention;

Fig. 2 shows an end view of the device of Fig. 1;

Fig. 3 shows a side view of the device of Fig. 1;

Fig. 4 shows a delivery catheter, with the device of Fig. 1 contained therein, passing through a septal defect;

Fig. 5 shows a control rod connected to the device of Fig. 1 for rotating the device;

Figs. 6a and 6b show how the device of Fig. 1 may be rotated when positioned in the septal defect;
Fig. 7 show a device for occluding a septal defect according to a second embodiment of the present invention, with control rods connected to the device for rotating the anchor portions of the device independently;

Fig. 8 shows how the device of Fig. 7 may be rotated when positioned in the septal defect.

Fig. 9 shows an oblique view of a device for occluding a septal defect according to a third embodiment of the present invention;

Fig. 10 shows an end view of the device of Fig. 9;

Fig. 11 shows a side view of the device of Fig. 9;

Fig. 12 shows the area over which anchor portions of the device of Fig. 9 can pass upon rotation;

Fig. 13 shows a cross-sectional view of the device of Fig. 9 occluding a defect with a plurality of fenestrations;

Fig. 14a shows a plan view of a defect having a plurality of fenestrations;

Fig. 14b shows a plan view of the device of Fig. 9 occluding the defect of Fig. 14b;

Fig. 15 shows an oblique view of a device for occluding a septal defect according to a fourth embodiment of the present invention;

Fig. 16 shows an oblique view of a device for occluding a septal defect according to a fifth embodiment of the present invention;

Fig. 17 shows an oblique view of a device for occluding a septal defect according to a sixth embodiment of the present invention;

Fig. 18 shows an oblique view of a device for occluding a septal defect according to a seventh embodiment of the present invention;

Fig. 19 shows an oblique view of a device for occluding a septal defect according to an eighth embodiment of the present invention;

Fig. 20 shows the area over which anchor portions of the device of Fig. 19 can pass upon rotation;

Figs. 21a and 21b show a side view and an end view respectively of a device for occluding a septal defect according to a ninth embodiment of the present invention;

Fig. 22 shows a cross-sectional side view of the device of Figs. 21a and 21b; and

Figs. 23a and 23b show cross-sectional side views of the device of Figs. 21a and 21b with a core catheter and a delivery catheter being withdrawn from the device respectively.
With reference to Figs. 1, 2 and 3, a device 11 for occluding a septal defect according to the first embodiment comprises first and second anchor portions 21a, 21b connected together by an elongate connection member 3 at connection points 203.

The first and second anchor portions 21a, 21b each comprise a plurality of arms 201 that extend radially, in a direction generally perpendicular to the longitudinal axis of the connection member 3, from the connection points 203. The radial arms of each anchor portion 21a, 21b support a membrane 202. When viewed end on, in a direction generally aligned with the axis of the elongate connection member 3 (see Fig. 2), the perimeter of each membrane 202 defines a circular envelope.

The radial arms 201 are formed of a shape memory alloy, e.g. nitinol. In their natural state, the arms maintain the anchor portions 21a, 21b in an expanded form, as shown in Figs. 1 and 2. However, the anchor portions 21a, 21b can be collapsed, e.g. so that they device can be placed in a catheter 5 for delivery to a defect, as discussed further below.

The connection point 203 between each anchor portion 21a, 21b and the connection member 3 is offset from the centre of the circular envelope defined by the membrane 202 of the anchor portion 21a, 21b. In this embodiment, the connection points 203 are offset from the centre by a distance that is approximately 25% of the radius of the circular envelope.

The connection member 3 is a straight, rigid, elongate tube; however, in alternative embodiments, it may be curved and/or flexible, to conform to the anatomy of the septal defect.

Referring to Fig. 4, to locate the device 11 at a septal defect 4 (a PFO 4 in this example), the device is held in a collapsed state (i.e. the anchor portions are collapsed) in a catheter 5. To deploy the device 11, the distal end 51 of the catheter 5 is pushed, along a guidewire 52 that extends through the elongate connection member of the device, through the septal defect opening 4. Using a control rod 6, the first (distal) anchor portion 21a is pushed out of the distal end 51 of the catheter 5 at the distal side 41 of the defect 4. The distal anchor portion 21a expands automatically, since it is no longer constrained by the catheter 5. The catheter 5 is then fully withdrawn, causing the distal anchor portion 21a to engage the septal (atrial) wall 43 (septum) at the distal side 41 of the defect 4 and
causing the second (proximal) anchor portion 21b to be exposed. The proximal anchor portion 21b expands automatically, since it is no longer constrained by the catheter, and engages the atrial wall 43 at the proximal side 42 of the defect. In this example, the device 11 has an "over the wire" mounting to the guidewire 52, in which the guidewire 52 extends through the entire length of the connection member tube 3. However, alternatively, the device could have a "monorail" mounting to the guidewire 52, wherein the guidewire 52 extends through only a portion of the connection member tube 3.

Referring to Fig. 5, the control rod 6 can be used to rotate the device 1. The control rod is connected at the connection point 203 of the proximal anchor portion 21b and the connection member 3, and is generally coaxial with the connection member 3. Thus, the axis of rotation extends generally through the elongation axis of the connection member 3, as indicated by line A-A. The control rod 6 can rotate the device 1 about the axis of rotation in either direction.

In Fig. 6a, the device 11 is shown located in the septal defect 4. Since the device 11 is mounted on the guidewire 52, the axis of rotation extends along the guidewire 52. Using the control rod 6 (not shown in Fig. 6a or 6b for clarity), the device 11 can be rotated about the axis of rotation to an optimum position for engagement with the atrial wall 43 adjacent the defect 4. Referring to Fig. 6b, the device 11 has been rotated 180 degrees about the axis of rotation. Since the axis of rotation of the device 11 is offset from the centre of the circular envelopes defined by the membranes 22 of the anchor portions 2a, 2b, rotation of the device 11 causes the device to change its configuration relative to the atrial wall 43. As seen in Figs. 5a and 5b, rotation of the device 1 by 180 degrees in this example causes more of the anchor portions 21a, 21b to engage the atrial wall 43 at the upper side of the defect than the lower side of the defect.

With reference to Fig. 7, according to a second embodiment, a device 12 for occluding a septal defect 4 is provided which differs from the device 11 of the first embodiment in that its first and second anchor portions 22a, 22b are relatively rotatable (about the axis A-A). To control the relative rotation, two control rods 61, 62 are provided. The control rods 61, 62 are concentric overlapping tubes, e.g. catheters. The outer control rod 61 is fixed to the second (proximal) anchor portion 22b and the inner control rod 62 is fixed to the first (distal) anchor portion 22a. Relative rotation of the control rods 61, 62 causes relative rotation of the anchor portions 22a, 22b about the axis of rotation. The two control rods
61, 62 may be slideable over one another so as to vary the length of the connection member 3.

As an example, shown in Fig. 8, the proximal anchor portions 22b has been rotated from its position shown in Fig. 6a, whilst the distal anchor portion 22a has been kept in the same position.

Figs. 9 to 10 show a device 13 according to a third embodiment of the present invention, which differs from the device 12 of the second embodiment in that the envelopes of the first and second anchor portions 23a, 23b are elliptical, rather than circular. The connection points 203 between the anchor portions 23a, 23b and the connection member 3 are positioned at a focus of the ellipses.

Fig. 12 provides an indication of the area 71 over which the anchor portions 23a, 23b can cover upon rotation. In this example, the second anchor portion 23b has been kept stationary, and the first anchor portion 23a has been rotated in 90 degree increments. The area 71 is substantially greater than the area of each envelope of the anchor portions 23a, 23b.

Fig. 13 shows a cross-sectional view of the device 13 occluding three fenestrations 81a-81c of a defect in a septal wall 82 of a heart, adjacent the coronary sinus 84. The connection member 3 extends through the middle fenestration 81b. The anchor portions 23a, 23b are relatively rotated from an aligned position by approximately 180 degrees such that one of the anchor portions 23a occludes one side of the left and middle fenestrations 81a, 81b and the other anchor portions 23b occludes the other side of the middle and right fenestrations 81b, 81c. Notably, only one side of each fenestration 81a-81c needs to be occluded to prevent potentially harmful emboli passing therethrough. Furthermore, the arrangement means that the anchor portion 23b can be positioned, as shown, such that it does not block the coronary sinus 84.

Fig. 14a shows a plan view of three fenestrations 83a-83c of a defect in a septal wall 82 of a heart, again adjacent the coronary sinus 84, the fenestrations 81a-81c positioned in a generally triangular formation. Fig. 14b shows the device 13 occluding the three fenestrations 83a-83c. The connection member 3 extends through the top left fenestration 83a. The anchor portions 23a, 23b are relatively rotated from an aligned
position by approximately 45 degrees such that one of the anchor portions 23a occludes
one side of the top left and bottom fenestrations 83a, 83b and the other anchor portions
23b occludes the other side of the top left and top right fenestrations 83a, 83c. The
arrangement means that the anchor portion 23b can be positioned, as shown, such that it
does not block the coronary sinus 84.

Figs. 15 shows a device 14 according to a fourth embodiment of the present invention,
which differs from the device 13 of the third embodiment in that, although the envelopes
of the first and second anchor portions 24a, 24b are elliptical, the connection point 203
between the connection member 3 and the second anchor portion 23b is at the centre of
the respective ellipse.

Figs. 16 shows a device 15 according to a fifth embodiment of the present invention,
which differs from the device 13 of the third embodiment in that, although the envelopes
of the first and second anchor portions 25a, 25b are elliptical, the envelope of the second
anchor portion 25b is circular and the connection point 203 between the connection
member 3 and the second anchor portion 25b is at the centre of the respective circle.

Figs. 17 shows a device 16 according to a sixth embodiment of the present invention,
which differs from the device 13 of the third embodiment in that the second anchor
portions 26b is not intended for occluding a defect. The second anchor portion 26b has
anchor struts 261, and no membrane. The sole purpose of the second anchor portion
26b is to anchor the respective side of the device 16 to a septal wall.

Figs. 18 shows a device 17 according to a seventh embodiment of the present invention,
which differs from the device 13 of the third embodiment in that the envelopes of the first
and second anchor portions 27a, 27b are kidney-shaped (reniform). The connection
points 203 between the connection member 3 and the anchor portions 27a, 27b are
located at the centres of the kidney-shapes. Nevertheless, since the envelopes are non-
circular, the area over which the anchor portions 27a, 27b can cover upon rotation is
greater than the area of each envelope of the anchor portions 27a, 27b.

Figs. 19 shows a device 18 according to an eighth embodiment of the present invention,
which differs from the device 13 of the third embodiment in that its anchor portions 28a,
28b, with elliptical envelopes, are connected to the connection member 3 at connection points 203 which are positioned at the centres of the ellipses. Nevertheless, since the envelopes are non-circular, as shown in Fig. 20, the area 72 over which the anchor portions 28a, 28b can cover upon rotation is greater than the area of each envelope of the anchor portions 28a, 28b.

Although not shown, the devices of Figs. 9 to 20 are mountable on guidewires, as described above with respect to the device 11 of the first embodiment of the present invention.

Figs. 21a and 21b show a device 19 according to a ninth embodiment of the present invention. The device 19 has pear-shaped first and second anchor portions 29a, 29b. The first and second anchor portions are connected together via a spring section 31. The spring section 31 comprises a plurality of leaf springs 32 connected at either end between a cap 33 and a collet 34. When in their natural states, the leaf springs are arched, but can be straightened so that the distance between the first and second anchor portions 29a, 29b can be increased. As an alternative to leaf springs 32, other resiliently flexible elements, such as helical springs, may be used.

Referring to Fig. 22, which shows a cross section of the device 19, the cap 33 is fixed to the second anchor portion 29b. The collet 34 has an outwardly extending circumferential flange 341, which is accommodated within a ring element 35 that is fixed to the first anchor portion 29a. The ring element 35 has an inwardly extending circumferential flange 351, arranged to abut the flange 341 of the collet, preventing separation of the collet 34 and the ring element 35, if the first and second anchor portions 29a, 29b are forced apart. The flange 341 of the collet is rotatable within the ring element 35, allowing the first and second anchor portions 29a, 29b to rotate independently of one another.

A delivery apparatus is provided for delivering the device 19 to a septal defect, along a guidewire 53, and for relatively rotating the first and second anchor portions 29a, 29b. The delivery apparatus comprises a delivery catheter 61' and a core catheter 62' extending axially through the delivery catheter 61'. The delivery catheter 61' and the core catheter 62' are both arranged to travel along the guidewire 53. The core catheter 62' and the delivery catheter 61' are independently rotatable about the longitudinal axis of the guidewire.
The distal end 621 of the core catheter 62' can extend out of a distal opening 612 at the distal end 611 of the delivery catheter 61', through the ring element 35, and between the leaf springs 32, and can fit tightly within a recess 331 provided within the cap 33, as shown in Fig. 22. By fitting within the recess 331, the distal end 621 of the core catheter 62' frictionally engages the cap 33 such that, upon rotation of the core catheter 62', the cap 33, and thus the second anchor portion 29b, will also rotate. Although rotation of the cap 33 will cause the entire spring section 3 to rotate, since the flange 341 of the collet 34 can rotate freely within the ring element 35, the first anchor portion 29a can remain stationary during this process.

The ring element 35, which is fixed to the first anchor portion 29a, is mounted to the delivery catheter 61' via monofilaments 63 (seen in Fig. 23b). The monofilaments 63 can be tightened, causing the distal end 611 of the delivery catheter 61' and the ring element 35 to engage one another. When they are engaged, since the ring element 35 is fixed to the first anchor portion 29a, rotation of the delivery catheter 61' causes the ring element 35, and thus the first anchor portion 29b, to rotate.

As indicated above, the spring section 31 allows the distance between the first and second anchor portions 29a, 29b to be varied. This is advantageous when rotation of the first and/or second anchor portion 29a, 29b is required in situ. In more detail, if the device 19 is positioned, using the delivery catheter 61', across a septal defect (not shown), its anchor portions 29a, 29b will engage the surface of the septal walls at either side of the defect. For the purpose of further description, the surface of the septal wall engaged by the first anchor portion on one side of the defect is referred to as the "first septal surface", and the surface of the septal wall engaged by the second anchor portion on the other side of the defect is referred to as the "second septal surface". When engaged with the first and second septal surfaces, the first and second anchor portions 29a, 29b may not be rotatable due to friction between the anchor portions 29a, 29b and the first and second septal surfaces. If rotation is possible, chafing of the first and second septal surfaces during the rotation is a risk, leading to possible damage. In the present embodiment, the problems described above may be overcome by increasing the distance between the first and second anchor portions 29a, 29b so that each anchor portion 29a, 29b is separated from the respective septal surface during rotation.
The distance between the anchor portions 29a, 29b can be varied by varying the extent to which the distal end 621 of the core catheter 62' extends from the distal opening 611 of the delivery catheter 61'. If the distal end 621 of the core catheter 62' is advanced out of the delivery catheter 61', whilst engaged with the cap 33, it will force the cap 33, and thus the second anchor portion 29b, away from the first anchor portion 29a. This places the spring section 31 in an extended state. Therefore, a certain force must be applied to the core catheter 62' to maintain it in the advanced position, in order to counteract opposing biasing forces applied to it by the spring section 31. If these steps are performed whilst maintaining engagement between the first anchor portion 29a and the first septal surface, the second anchor portion 29b will forced to separate from the second septal surface, whereupon the core catheter 62' can be rotated to rotate the second anchor portion 29b, without damaging the septal surface. After rotation, the force maintaining the core catheter 62' in the advanced position can be released, whereupon the spring section 31 will force the second anchor portion 29b to its natural position, where it engages the second septal surface.

To separate the first anchor portion 29a from the first septal surface, whilst the second anchor portion 29b is engaged with the second septal surface, the delivery catheter 61' is simply pulled away from the defect. This increases the distance between the first and second anchor portions 29a, 29b since the second anchor portion is held by the second septal surface whilst the first anchor portion is pulled. This results in the first anchor portion 29a separating from the first septal surface. The delivery catheter 61' can then be rotated to rotate the first anchor portion 29a without damaging the septal wall. Whilst the anchor portions 29a, 29b are pulled part, the spring section 31 is placed in an extended state, and thus a certain force will need to be applied to maintain the separation between the first anchor portion 29a and the first septal surface, counteracting the opposing biasing force from the spring section 31. After rotation, the force pulling the delivery catheter 61' away from the defect can be released, whereupon the spring section 31 will force the first anchor portion 29a to its natural position, where it engages the first septal surface.

Once the device 19 has been positioned in the defect, using the delivery catheter 61', and the first and second anchor portions 29a, 29b have been rotated as desired, the delivery catheter 61', and the core catheter 62', can be removed. The core catheter 62' can be pulled out of the recess 331 in the cap 33 and back through the delivery catheter 61' for
removal, as shown in Fig. 23a. The delivery catheter 61' is removed by releasing the tension on the monofilaments 63, so that the delivery catheter 61' can disengage and withdraw from the ring element 35, as shown in Fig. 23b. The monofilaments 63 may be provided in a looped arrangement, so that they can be cut at a proximal end of the delivery apparatus, and pulled through the delivery catheter 61', releasing the delivery catheter entirely from the ring element 35.
Claims

1. A device for occluding a septal defect opening, the device comprising:
   first and second anchor portions, each anchor portion being adjustable between a 
collapsed configuration, for delivery to the septal defect opening, and an expanded 
configuration, for engagement with the septum at a respective side of the septal defect 
opening; and
   a connection member for extending through the septal defect opening, the 
connection member extending along an axis between the first and second anchor portions 
and being connected to the first and second anchor portions at respective connection 
points,
   wherein the first and/or second anchor portion defines, in the expanded state, an 
envelope for occluding a respective side of the septal defect opening, and (i) the 
connection point is offset from the centre of the envelope and/or (ii) the perimeter of the 
envelope has a non-circular shape,
   wherein the first and second anchor portions are relatively rotatable about the axis 
of extension of the connection member.

2. The device of claim 1, wherein the first and second anchor portion both define, in 
the expanded state, respective envelopes for occluding respective sides of the septal 
defect opening, and (i) the connection point of each anchor portion is offset from the 
centre of the respective envelope, and/or (ii) the perimeter of each envelope has a non-
circular closed-curved shape.

3. The device of claim 1 or 2, wherein the connection member is extendable such 
that the distance between the first and second anchor portions can be varied.

4. The device of claim 3, wherein the first and second anchor portions can be rotated 
relative to each other whilst the connection member is placed in an extended state.

5. The device of claim 3 or 4, wherein the connection member is resiliently flexible so 
that it can be placed in an extended state.

6. The device of claim 5, wherein the connection member comprises one or more 
leaf springs.
7. The device of claim 5, wherein the connection member comprises a helical spring.

8. The device of any one of the preceding claims, wherein the envelopes are circular, elliptical, ovoid, oblong, pear-shaped or kidney-shaped.

9. The device of any one of the preceding claims, wherein the anchor portions are spring-biased such that they can move from the collapsed state to the expanded state automatically.

10. The device of any one of the preceding claims, wherein the anchor portions comprise a membrane supported by a support structure.

11. The device of claim 10, wherein the support structure is a plurality of arms.

12. The device of any one of the preceding claims, which is entirely or partially biodegradable.

13. The device of any one of the preceding claims, wherein the connection member is rotatably mounted to the first anchor portion and is fixed to the second anchor portion.

14. An apparatus comprising:
   the device of any one of the preceding claims, and
   first and second catheters, each having proximal and distal ends, wherein the first and second catheters are relatively rotatable about their longitudinal axes to relatively rotate the first and second anchor portions.

15. The apparatus of claim 14, wherein the distal end of the first catheter is releasably connected to the first anchor portion, and the distal end of the second catheter is releasably connected to the second anchor portion

16. The apparatus of claim 15, wherein the second catheter is releasably connected to the second anchor portion by engaging the connection member.
17. The apparatus of claim 15 or 16, wherein the first catheter is held in releasable engagement with the first anchor portion by one or more monofilaments.

18. The apparatus of claim 17, wherein the one or more monofilaments are provided in a loop, which loop extends to a proximal end of the apparatus where it can be cut to completely separate the first catheter and the first anchor portion.

19. The apparatus of any one of claims 14 to 18, wherein the second catheter is arranged to extend through a core cavity in the first catheter.

20. The apparatus of claim 19, comprising the device according to claim 3, wherein the distance between the first and second anchor portions can be increased by extending the second catheter out of the core cavity of the first catheter, via a distal opening of the first catheter.