EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent: 23.03.2005 Bulletin 2005/12

(21) Application number: 98200404.6

(22) Date of filing: 10.02.1998

(54) Occlusion device

Okklusionsvorrichtung
Dispositif d’occlusion

(84) Designated Contracting States: DE FR GB IT

(30) Priority: 12.02.1997 US 797983

(43) Date of publication of application: 16.09.1998 Bulletin 1998/38

(73) Proprietor: SCHNEIDER (USA) INC. Plymouth, Minnesota 55442 (US)

(72) Inventors:
• Clerc, Claude O. Eden Prairie, Minnesota 55347 (US)

• Thompson, Paul J. New Hope, Minnesota 55427 (US)

(74) Representative: VOSSIUS & PARTNER Postfach 86 07 67 81634 München (DE)

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WO-A-96/01599 DE-U-9 205 797
US-A-5 382 261

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Description

[0001] The present invention relates generally to implantable, radially expandable medical devices for occluding fluid flow in a body lumen. In particular, the present invention is an occlusion device having an interwoven support structure and fluid flow-occluding membrane.

[0002] Medical devices adapted for implantation in body lumens that support fluid flow are well known and commercially available. One such device is the self-expanding stent of the type disclosed in the Wallsten U.S. Patent No. 4,655,771. Self-expanding stents can be used to treat vascular stenosis and to maintain openings in the urinary, biliary, esophageal, tracheal and bronchial tracts of a patient. Self-expanding stents are typically not used to occlude fluid flow within a body lumen. The delivery device is then detached from the treatment site comprised of the stent. When subjected to inwardly-directed radial forces, the stents are forced into a reduced-radius and extended length form, known as the loaded or compressed state. After the stent is positioned at the treatment site, the delivery device is actuated to release the stent, thereby allowing the stent to self-expand and engage the body lumen. The delivery device is then detached from the stent and removed from the body.

[0003] Another type of implantable device is a vena cava filter. Vena cava filters are implanted in the vena cava that leads to a patient's heart in order to trap emboli in the fluid flow that would otherwise be carried into the heart and lungs. Vena cava filters can include a structure similar to the self-expanding stents described above, but act as a filter that traps large particles and emboli in the flow while allowing the remaining fluid flow to pass through the device.

[0004] It is sometimes desirable, however, to completely occlude a body lumen or stop fluid flow to a lumen that has been bypassed. By way of example, occlusion can be used to control internal bleeding, bypass a lumen, relieve the pressure created by an aneurysm in a lumen, or stop the flow of fluid to a tumor in a lumen. Because of their generally porous nature and substantially tubular expanded form, self-expanding stents are typically not used to occlude a fluid flow within a body lumen. Similarly, vena cava filters are specifically designed to filter and trap only emboli while allowing the remaining fluid flow in a lumen to pass through the filter, and thus are not typically used to occlude a lumen.

[0005] Implantable medical devices have been designed, however, to occlude fluid flow in a body lumen. One such device is a balloon that is carried to a treatment site by a catheter or other similar instrument. When positioned at the treatment site, the balloon is filled with a fluid, such as a polymerized resin, thereby occluding the fluid flow in the body lumen.

[0006] Another type of implantable occlusion device is a wire coil that is first linearly stretched and then positioned at a treatment site in the body lumen. Devices of this type are generally disclosed in the Ritchart et al. U.S. Patent 4,994,069 and the Phelps et al. U.S. Patent 5,522,822. The coil is delivered to a treatment site by catheter. Upon being released from the catheter the coil assumes the form of a randomly shaped mass that substantially fills the lumen. The coil can also be coated with fibers or a braided fibrous element to promote clotting of the fluid flow at the treatment site.

[0007] The prior art according to US-A-5 382 261 describes a vessel occluding device for providing permanent occlusion of a vessel in a person. The device includes at least one metallic tubular shaped member, having an outer surface and first and second open ends. The tubular shaped member has a first diameter which permits intraluminal delivery thereof into the vessel to be occluded. Furthermore, the device comprises a flexible closure member attached to the first open end of the tubular member, wherein the flexible closure member seals the first open end. The closure member has a first diameter which is substantially the same as that of the tubular member. The tubular shaped member and at least a portion of the flexible closure member have a second expanded diameter, upon the application from the interior of the tubular shaped member of a radially outwardly extending force, which second diameter is variable and controlled by the amount of force applied to the tubular shape member. The force deforms at least the portion of the at least one tubular shaped member to retain it and the portion of the closure member with the second expanded diameter, whereby the closure member is disposed in sealing engagement with the inner wall surface of the vessel to prevent the body fluid from flowing past the closure member.

[0008] DE-U-92 05 797 relates to a self-expandable occlusion device in a form of a wire coil that is first linearly stretched and then positioned at a treatment site in the body lumen. The wires of this device are interwoven and form a tube shaped wire mesh both ends of which are fixed in a radially compressed condition.

[0009] US-A-4 705 517 relates to an intravascular prosthesis comprising a lining rolled upon itself around an axis so that it is introducible into a vascular lumen. An inflatable channel is included for unrolling the lining when the prosthesis is positioned within the lumen so that the lining may engage the vascular wall to provide support therefor. An occlusion member is provided for occluding the vascular lumen, when the lining is unrolled, by preventing blood from passing through the prosthesis.

[0010] US-A-4 710 192 relates to a umbrella-like occlusion device comprising a flexible and substantially circular element and a plurality of resilient ribs having
inner and outer ends supporting the circular element.

[0011] A continuing need exists, however, for implantable medical devices that will effectively occlude fluid flow in a body lumen. Occlusion devices exhibiting a relatively high degree of biocompatibility, that are efficient to manufacture, and that can be deployed using known techniques would be especially desirable.

[0012] The present invention is an improved medical device adapted for implantation into a body lumen as defined in claim 1. The device includes a support structure and a flexible fluid flow-occluding member. In one embodiment, the flexible fluid-flow occluding member is an interwoven membrane. At least a portion of the support structure is expandable from a reduced-diameter compressed state to a self-supporting and lumen-engaging expanded state. The flexible fluid flow-occluding membrane has at least a first tubular end that is concentrically oriented and circumferentially engaged with the support structure, and a constricted region. At least a portion of the membrane is expandable with the support structure from a reduced-diameter compressed state to an expanded state for occluding fluid flow through the body lumen when the support structure is in the lumen-engaging expanded state.

[0013] In a second embodiment, the support structure includes a plurality of elongate structural filaments that are interwoven. The support structure is radially self-expandable from a reduced-diameter compressed state to a self-supporting and lumen-engaging expanded state. The flexible fluid flow-occluding membrane includes polymeric filaments that are interwoven with the structural filaments. The membrane has a first tubular end that is co-extensive with at least a portion of the length of the support structure and a constricted region. The membrane is expandable with the support structure from a reduced-diameter compressed state to an expanded state for occluding fluid flow through the body lumen when the support structure is in the lumen-engaging expanded state.

[0014] In a third embodiment of the present invention, the support structure includes a plurality of elongate structural filaments that are interwoven. The support structure is radially self-expandable from a reduced-diameter compressed state to a self-supporting and lumen-engaging expanded state. The flexible fluid flow-occluding membrane includes polymeric filaments that are interwoven with the structural filaments. The membrane has a first tubular end that is co-extensive with at least a portion of the length of the support structure and a constricted region. The membrane is expandable with the support structure from a reduced-diameter compressed state to an expanded state for occluding fluid flow through the body lumen when the support structure is in the lumen-engaging expanded state.

[0015] In a fourth embodiment of the present invention, the medical device includes a radially self-expandable support structure, a flexible fluid flow-occluding membrane, and constriction means for constricting a portion of the support structure and the membrane for occluding fluid flow through the body lumen. The support structure has first and second opposite ends and includes a plurality of elongate structural filaments that are interwoven. The support structure is expandable from a reduced-diameter compressed state to a self-supporting and lumen-engaging expanded state. The flexible fluid-flow occluding membrane includes polymeric filaments that are interwoven with the structural filaments. The membrane is coextensive with at least a portion of the length of the support structure.

[0016] In a fifth embodiment of the present invention, the medical device is comprised of a radially self-expandable support structure and a flexible fluid flow-occluding membrane. The support structure includes a plurality of elongated structural filaments that are interwoven. The support structure is expandable from a reduced-diameter compressed state to a self-supporting and lumen-engaging expanded state. The flexible fluid flow-occluding membrane has at least a first tubular end that is concentrically oriented and circumferentially engaged with the support structure and a constricted region. The membrane is expandable with the support structure from a reduced diameter compressed state to an expanded state for occluding fluid flow through the body lumen when the support structure is in the lumen-engaging expanded state.

[0017] In the following preferred embodiments of the invention will be described in connection with the drawings, in which:

Figure 1 is a side view of an interbraided occlusion device in accordance with the present invention in its expanded state and implanted in a body lumen;

Figure 2 is a side view of the occlusion device shown in Figures 1-5;

Figure 3 is a side view of a second embodiment of an interbraided occlusion device in accordance with the present invention;

Figure 4 is a side view of a third embodiment of an interbraided occlusion device in accordance with the present invention;

Figure 5 is a detailed side view of a portion of an interbraided occlusion device showing the interwoven filamentous of the device;

Figures 6-8 schematically illustrate a process for manufacturing the interbraided occlusion devices shown in Figures 1-5;

Figure 9 is a side view of a sheath occlusion device in accordance with the present invention.
Figure 10 is a side view of a sheath occlusion device shown in Figure 9 with portions removed to show the membrane surrounding the support structure of the device.

Figure 11 is a side view of a second embodiment of a sheath occlusion device in accordance with the present invention;

Figure 12 is a side view of a third embodiment of a sheath occlusion device in accordance with the present invention

Figure 13 is a side view of a fourth embodiment of a sheath occlusion device in accordance with the present invention

Figure 14 is a detailed side view of a portion of the occlusion device shown in Figures 1 and 2 having a fusion seal; and

Figure 15 is a detailed side view of a portion of the occlusion device shown in Figures 1 and 2 having a suture.

A first embodiment of an occlusion device 10 in accordance with the present invention is shown in Figures 1 and 2. Occlusion device 10 is substantially tubular, axially flexible, and radially compressible over at least a portion of the device, and is adapted to be implanted in a body lumen 6 that can support a fluid flow 8. As shown in Figure 2, occlusion device 10 can be compressed in part or over the entire length of the device to a reduced-diameter state by subjecting the device to radially directed forces. When the entire length of occlusion device 10 is in this compressed state, the device can be inserted into body lumen 6 using conventional techniques and tools such as an insertion catheter (not shown). When released from the insertion catheter, the radial forces are removed from occlusion device 10, and it expands to the enlarged-diameter state shown in Figure 1. When in this expanded state, occlusion device 10 engages body lumen 6, thereby anchoring the device in the lumen.

Occlusion device 10 is generally comprised of a support structure 13 and a fluid flow-occluding membrane 20. In the embodiment shown, support structure 13 is substantially tubular, axially flexible, and radially compressible over at least a portion of the structure, and has a first tubular end 14. Support structure 13 can be comprised of two sets of oppositely-directed elongate filaments 16 that are helically wound and interwoven to form a support structure 13 that is self-expandable. The sets of filaments 16 are interwoven in an over and under configuration, and intersect to form an open mesh construction. The first set of filaments 16 have a common direction of winding, are parallel and axially displaced relative to each other, and cross a second set of filaments 16 that are also parallel and axially displaced relative to each other, but have an opposite direction of winding.

Figure 6 shows a method for manufacturing a support structure 13 wherein two structural filaments 32a and 32b, one from each set of oppositely directed filaments, are wound about a mandrel 60 and supported by respective bobbins 62 and 64. While just filaments 32a and 32b are illustrated as a matter of convenience, it is to be appreciated that all of the structural filaments are wound about the mandrel and maintained together for shaping. The filaments are age-hardened within a furnace 66 in a vacuum or a protective atmosphere. Temperatures in furnace 66 range between about 350-1000 °C., with the specific temperature depending upon the material used for the structural filaments. Filaments 32a and 32b overlie one another to form multiple intersections, one of which is indicated at 68. Bobbins, including 62 and 64, are set to tension their respective filaments during age-hardening. The appropriate duration for age-hardening varies with materials and dimensions, but can range from as brief as 30 seconds, to about 5 hours.

After age-hardening, the structural filaments are allowed to cool, whereupon each filament retains the helical shape as its nominal shape. In the context of elastic materials, "nominal shape" refers to the shape in a relaxed state, i.e. when under no external stress. The age-hardened filaments are highly resilient, i.e. deformable under external stress, but elastically return to the nominal shape when free of the external stress. In this manner, support structure 13 can be radially compressed into a reduced-radius, extended-length configuration suitable for delivery to a treatment site in body lumen 6. When released from this compressed state, support structure 13 will self-expand, thereby causing occlusion device 10 to engage body lumen 6.

Fluid flow-occluding membrane 20 has a first tubular end 22 that is concentrically oriented and circumferentially engages support structure 13. Membrane 20 further includes at least one constricted region 24 that operates to occlude fluid flow 8 in lumen 6, and membrane 20 is expandable along with support structure 13 from the compressed state to the expanded state of the occlusion device 10. Membrane 20 can be closed at constricted region 24 by any of a number of constriction techniques, such as mechanical seal 28, in order to occlude fluid flow. Those skilled in the art will recognize that other constriction techniques, such as a sealing member, a fusion seal 28a, or a suture 28b, can also be
used.

[0024] In the embodiment shown in Figures 1 and 2, membrane 20 includes a plurality of polymeric filaments 26 that, as shown in greater detail in Figure 5, are interbraided with support structure filaments 16 in forming occlusion device 10. Figures 7 and 8 schematically illustrate a method for interbraiding membrane filaments with structural filaments. Figure 7 shows a braiding apparatus 70 including a cylindrical carrier assembly 72 including several annular arrays of bobbins, two of the bobbins being indicated at 80a and 80b. The apparatus further includes a mandrel 78, centered within the cylindrical assembly and movable longitudinally relative to the assembly as indicated by the arrow.

[0025] Figure 8 illustrates part of a carrier assembly 72 in greater detail, to reveal five annular arrays or sets of carrier bobbins indicated at 80, 82, 84, 86, and 88. The sets are coaxial and axially spaced apart, each including forty-eight bobbins, twenty-four bobbins for respective clockwise and counterclockwise windings about mandrel 78. While those skilled in the art are acquainted with the use of braiding machinery, it is emphasized here that braiding apparatus 70 is configured as described in detail in the commonly assigned P. Thompson U.S. Patent Applications, Serial Nos. 08/640,091 and 08/640,062 entitled “Three-Dimensional Braided Composite Prosthesis.” Suitable braiding machinery is available from Albany International Research Company of Mansfield, Massachusetts.

[0026] Support structure filaments 16 and membrane filaments 26 can be tightly interwoven so that membrane 20 is generally non-porous in order to occlude fluid flow. Membrane filaments 26 can also be formed from a thrombogenic material in order to promote clotting of fluid flow 8 and thereby occlude the fluid flow. The resulting structure will preferably have a porosity of less than 5,000 ml/cm²/min at 120 mmHg. More preferred are porosities of between about 100 and 3,000 ml/cm²/min, and even more preferably, between about 300 and 2,000 ml/cm²/min at 120 mmHg.

[0027] In the interbraided occlusion device 10 shown in Figures 1 and 2, first tubular end 14 of support structure 13 extends beyond first tubular end 22 of membrane 20, and the constricted region 24 of membrane 20 extends beyond a second tubular end 15 of support structure 13. The individual membrane fibers 26 of membrane 20 are drawn together in the constricted region 24 and sealed together with mechanical seal 28.

[0028] Figure 3 shows a second embodiment of an interbraided occlusion device 110 in its expanded state. Features of occlusion device 110 that correspond to features of occlusion device 10 shown in Figures 1 and 2 and described above are designated with corresponding reference numbers that are preceded by the prefix “1.” In this embodiment, support structure filaments 116 and membrane filaments 126 are interbraided throughout the entire length of occlusion device 110. Mechanical seal 128 compresses both support structure 113 and membrane 120 at the constricted region 124, thereby closing occlusion device 110 and occluding fluid flow through the device.

[0029] Figure 4 shows a third embodiment of an interbraided occlusion device 210 in its expanded state. Features of occlusion device 210 that correspond to features of occlusion device 10 shown in Figures 1 and 2 and described above are designated with corresponding reference numbers that are preceded by the prefix “2.” Support structure 213 includes first and second tubular ends 214 and 215, respectively, and fluid flow-occluding membrane 220 includes first and second tubular ends 222 and 223, respectively. In this embodiment, support structure filaments 216 and membrane filaments 226 are interbraided throughout the entire length of occlusion device 210, and the respective first and second ends of structure 213 and membrane 220 are thus concentric and substantially coextensive. Mechanical seal 228 is positioned between the first and second tubular ends of the occlusion device 210, and constricts both the support structure 213 and the membrane 220 in order to occlude fluid flow in a body lumen. Support structure 213 and membrane 220 radially expand in the areas adjacent mechanical seal 228 to form first and second constricted regions 224 and 225.

[0030] Figures 9 and 10 show a sheath occlusion device 310 in accordance with the present invention. Sheath occlusion device 310 is comprised of support structure 313 and a separately fabricated fluid flow-occluding membrane 320. Support structure 313 can be comprised of a plurality of interbraided elongate filaments 316, and can be manufactured using the method for manufacturing support structure 13 described above and shown in Figure 6. Membrane 320 circumferentially engages support structure 313, and in the embodiment shown in Figure 9, membrane 320 is positioned within support structure 313. In this manner, support structure 313 acts as a “sheath” that covers membrane 320. Alternatively, as in the embodiment shown in Figure 10, membrane 320 can encompass support structure 313, thereby acting as a sheath that covers structure 313.

[0031] Membrane 320 can be formed from a plurality of filaments 326 that are either tightly interwoven to occlude fluid flow, or are thrombogenic in order to promote clotting of the fluid flow, and thereby occlude the flow. Alternatively, membrane 320 can be formed from a sheet of flexible material that is substantially non-porous, is thrombogenic, or is covered with a non-porous coating in order to occlude fluid flow.

[0032] The sheath occlusion device 310 shown in Figures 9 and 10 includes a first tubular end 314 of support structure 313 and a first tubular end 322 of membrane 320 that are concentric and substantially coextensive, and support structure 313 extends the entire length of membrane 320. Membrane 320 and support structure 313 of occlusion device 310 are separately fabricated, and membrane 320 engages structure 313 using con-
vention techniques, such as adhesive or thread stitching. Mechanical seal 328 closes the support structure 313 and membrane 320 at the constricted region 324, thereby occluding fluid flow.

[0033] Figure 11 shows a second embodiment of a sheath occlusion device 410 in accordance with the present invention. Features of occlusion device 410 that correspond to features of occlusion device 310 shown in Figures 9 and 10 and described above are designated with "400" series reference numbers as opposed to the "300" series used in Figures 9 and 10. Sheath occlusion device 410 includes a support structure 413 and membrane 420 that are separately fabricated, and a first tubular end 414 of support structure 413 extends beyond a first tubular end 422 of membrane 420. Support structure 413 thus acts as a sheath that surrounds a portion of membrane 420. A constricted region 424 of membrane 420 extends beyond a second tubular end 415 of support structure 413, and is closed at constricted region 424 with mechanical seal 428.

[0034] Figure 12 shows a third embodiment of a sheath occlusion device 510. Features of occlusion device 510 that correspond to features of occlusion device 310 shown in Figures 9 and 10 and described above are designated with "500" series reference numbers as opposed to the "300" series used in Figures 9 and 10. Sheath occlusion device 510 includes a support structure 513 and membrane 520 that are separately fabricated. First tubular ends 514 and 522 of support structure 513 and membrane 520, respectively, are concentric and substantially coextensive, as are second tubular ends 515 and 523 of the structure and the membrane. Mechanical seal 528 is positioned between the first and second ends of the device, and engages both support structure 513 and membrane 520 at the constricted region 524. Due to the self-expanding nature of support structure 513, the areas adjacent mechanical seal 528 expand, thereby creating a second constricted region 525. While occlusion device 510 is shown with membrane 520 positioned within support structure 513, those skilled in the art will recognize that membrane 520 can alternatively surround support structure 513.

[0035] Figure 13 shows a fourth embodiment of a sheath occlusion device 610. Features of occlusion device 610 that correspond to features of occlusion device 310 shown in Figures 9 and 10 and described above are designated with "600" series reference numbers as opposed to the "300" series used in Figures 9 and 10. A separately fabricated membrane 620 is positioned within and engages support structure 613. In this embodiment, mechanical seal 628 is also positioned within support structure 613, and thus closes only membrane 620 at the constricted region 624. Because membrane 620 engages support structure 613, membrane 620 expands in the areas adjacent mechanical seal 628, thereby creating a second constricted region 625.

[0036] The elongate filaments of the support structures described above can be formed from a metal or other resilient material, including Elgiloy® alloy (available from Carpenter Technology Corporation of Reading, Pennsylvania), Phynox® alloy (available from Metal Imphy of Imply, France), 316 stainless steel and MP35N alloy (both of which are available from Carpenter Technology Corporation and Latrobe Steel Company of Latrobe, Pennsylvania), and superelastic Nitinol nickel-titanium alloy (available from Shape Memory Applications of Santa Clara, California).

[0037] The fluid flow-occluding membranes of the present invention described above generally have a high degree of compliance, which may or may not include elasticity. These membranes can be formed from a plurality of filaments that are either tightly woven to occlude fluid flow, or are thrombogenic to promote clotting of the fluid flow, and thereby occlude the flow. Suitable materials for the plurality of filaments include polyethylene and polyethylene terephthalate. One suitable high molecular weight polyethylene that can be used for the filaments is sold under the brand name "Spectra". Alternatively, these membranes can be formed from a sheet of flexible material that is non-porous, is thrombogenic, or is covered with a non-porous coating to occlude fluid flow. Suitable materials for a sheet of flexible material used to form the membranes include silicone, polyurethane, polycarbonate, urethane, polytetrafluoroethylene, or expanded polytetrafluoroethylene.

[0038] The occlusion device described above has many advantages. The device exhibits a relatively high degree of biocompatibility. The support structure securely engages the device in a body lumen while the membrane effectively occludes fluid flow in the lumen. In addition, the occlusion device can be deployed using conventional insertion techniques and tools, such as an insertion catheter. The present invention is also efficient to manufacture.

Claims

1. A medical device (10) adapted for implantation into a body lumen having a tubular interior surface, including:

   a support structure (13) of which at least a tubular portion is expandable from a reduced-diameter compressed state to a self-supporting and lumen-engaging expanded state, the tubular portion for engaging the tubular interior surface of the lumen in the expanded state; and

   a flexible, interwoven fluid flow-occluding membrane (20) having at least a first tubular end (22) concentrically oriented and circumferentially engaged with the tubular portion of the support structure, and a constricted region (24), the membrane having a porosity of greater than 0 ml/cm²/min and less than 5,000 ml/cm²/
min when measured at a fluid pressure of 120 mm Hg, and at least a portion of the membrane (20) being expandable with the support structure (13) from a reduced-diameter compressed state to an expanded state for occluding fluid flow through the body lumen when the support structure (13) is in the lumen-engaging expanded state.

2. The medical device (10) of claim 1 wherein the flow-occluding membrane (20) further includes a second tubular end opposite the constricted region (24) from the first tubular end (22), the second tubular end concentrically oriented and circumferentially engaged with the support structure.

3. The medical device (610) of claim 2 wherein the flow-occluding membrane (620) is a tubular member and the device further includes constriction means (628) for closing the tubular member at the constricted region (624) within the support structure (613) and enabling portions of the support structure (613) adjacent to the constricted region (624) to expand.

4. The medical device (210) of claim 2 wherein the fluid flow-occluding membrane (220) is a tubular member and the device further includes constriction means (228) for closing the tubular member and the support structure (213) at the constricted region (224).

5. The medical device (110) of claim 1 wherein the fluid flow-occluding membrane (120) is a tubular member having at least a portion including the first end (122) that is coextensive with at least a portion of the length of the support structure (113) and the device further includes constriction means (128) for closing the tubular member and the support structure at the constricted region (124).

6. The medical device (10) of claim 1 wherein the fluid flow-occluding membrane (20) is a tubular member having at least a first portion including the first tubular end (22) that is coextensive with at least a portion of the length of the support structure (13), and a second portion including the constricted region (24) that is capable of extending beyond an end of the support structure (13).

7. The medical device (10) of claim 1 wherein:
the support structure (13) includes a metal structure; and the flow-occluding membrane (20) is formed of polymeric material.

8. The medical device (10) of claim 1 wherein:
the support structure (13) is radially compressible and a self-expandable structure including one or more elongate filaments (16); and the fluid flow-occluding membrane (20) is formed of polymeric material.

9. The medical device (10) of claim 8, wherein the radially self-expandable support structure (13) includes a plurality of elongate structural filaments (16) that are interwoven, and the flexible fluid flow-occluding membrane (20) includes polymeric filaments (26) interwoven with the structural filaments (16) and has at least a first tubular end (22) coextensive with at least a portion of the length of the support structure (13), and a constricted region (24), the membrane (20) being expandable with the support structure (13) from a reduced-diameter compressed state to an expanded state for occluding fluid flow through the body lumen when the support structure (13) is in the lumen-engaging expanded state.

10. The medical device (10) of claim 9 wherein:
the support structure (13) includes first and second opposite ends (14, 15); and the constricted region (24) of flow-occluding membrane (20) extends beyond the second end (15) of the support structure (13).

11. The medical device (110) of claim 9 wherein:
the support structure (113) includes first and second opposite ends (114, 115); and the constricted region (124) includes constriction means (128) for constricting a portion of the support structure (113) and the membrane (120).

12. The medical device (210) of claim 11 wherein the constriction means (228) is located between the first and second opposite ends (214, 215) of the support structure (213).

13. The medical device (110) of claim 11 wherein the constriction means (128) is located on the first end of the support structure (113).

14. The medical device (310) of claim 1, wherein the support structure (313) is radially self-expandable and includes a plurality of elongated structural filaments (316) that are interwoven, the support structure (313) being expandable from a reduced-diameter compressed state to a self-supporting and lumen-engaging expanded state.

15. The medical device (310) of claim 14, wherein the fluid flow-occluding membrane (320) further com-
prises a second portion including the constricted region (324) that is capable of extending beyond a second end of the support structure (313).

16. The medical device (610) of claim 14 wherein the fluid flow-occluding membrane (620) is positioned within the support structure (613), the device further including constriction means (628) for closing the fluid-flow occluding membrane (620) within the support structure (613).

17. The medical device (310) of claim 14 further including constriction means (328) for closing the support structure (313) and membrane (320) at the constricted region (324).

Patentansprüche

1. Medizinische Vorrichtung (10), die zur Implantation in ein Körperlumen mit einer röhrenförmigen Innenfläche geeignet ist, mit:

   einer Stützstruktur (13), von der mindestens ein röhrenförmiger Abschnitt aus einem komprimierten Zustand mit reduziertem Durchmesser in einen selbstragenden und in das Lumen eingleitenden expansierten Zustand expandierbar ist, wobei der röhrenförmige Abschnitt zum Eingreifen in die röhrenförmige Innenfläche des Lumens im expansierten Zustand dient; und
einer flexiblen, verflochtenen, Fluidströmung okkludierenden Membran (20) mit mindestens einem röhrenförmigen Ende (22), das zum röhrenförmigen Abschnitt der Stützstruktur konzentrisch orientiert ist und einen Umfangseingriff damit herstellt, und einem konstringierten Bereich (24), wobei die Membran eine Peristaltik über 0 ml/cm²/min und unter 5000 ml/cm²/min bei Messung mit einem Fluiddruck von 120 mmHg hat und mindestens ein Abschnitt der Membran (20) mit der Stützstruktur (13) aus einem komprimierten Zustand mit reduziertem Durchmesser in einen expansierten Zustand zum Okkludieren von Fluidströmung durch das Körperlumen expandierbar ist, wenn sich die Stützstruktur (13) in dem in das Lumen eingreifenden expansierten Zustand befindet.

2. Medizinische Vorrichtung. (10) nach Anspruch 1, wobei die Fluidströmung okkludierende Membran (20) ferner ein zweites röhrenförmiges Ende gegenüber dem konstringierten Bereich (24) vom ersten röhrenförmigen Ende (22) aufweist, wobei das zweite röhrenförmige Ende konzentrisch zur Stützstruktur orientiert ist und einen Umfangseingriff mit ihr herstellt.

3. Medizinische Vorrichtung (610) nach Anspruch 2, wobei die Fluidströmung okkludierende Membran (620) ein röhrenförmiges Teil ist und die Vorrichtung ferner eine Konstruktionsrichtung (628) aufweist zum Verschließen des röhrenförmigen Teils am konstringierten Bereich (624) innerhalb der Stützstruktur (613) und zum Ermöglichen, daß Abschnitte der Stützstruktur (613) benachbart zum konstringierten Bereich (624) expandieren.

4. Medizinische Vorrichtung (210) nach Anspruch 2, wobei die Fluidströmung okkludierende Membran (220) ein röhrenförmiges Teil ist und die Vorrichtung ferner eine Konstruktionsrichtung (228) zum Verschließen des röhrenförmigen Teils und der Stützstruktur (213) am konstringierten Bereich (224) aufweist.

5. Medizinische Vorrichtung (110) nach Anspruch 1, wobei die Fluidströmung okkludierende Membran (120) ein röhrenförmiges Teil ist, das mindestens einen Abschnitt mit dem ersten Ende (122) hat, der mindestens mit einem Abschnitt der Länge der Stützstruktur (113) koextensiv ist, und die Vorrichtung ferner eine Konstruktionsrichtung (128) zum Verschließen des röhrenförmigen Teils und der Stützstruktur am konstringierten Bereich (124) aufweist.

6. Medizinische Vorrichtung (10) nach Anspruch 1, wobei die Fluidströmung okkludierende Membran (20) ein röhrenförmiges Teil ist, das mindestens einen ersten Abschnitt mit dem ersten röhrenförmigen Ende (22), der mindestens mit einem Abschnitt der Länge der Stützstruktur (13) koextensiv ist, und einen zweiten Abschnitt mit dem konstringierten Bereich (24) hat, der sich über ein Ende der Stützstruktur (13) hinaus erstrecken kann.

7. Medizinische Vorrichtung (10) nach Anspruch 1, wobei:

die Stützstruktur (13) eine Metallstruktur aufweist; und
die Fluidströmung okkludierende Membran (20) aus Polymermaterial gebildet ist.

8. Medizinische Vorrichtung (10) nach Anspruch 1, wobei:

die Stützstruktur (13) radial komprimierbar und eine selbstexpandierbare Struktur mit einem oder mehreren länglichen Filamenten (16) ist; und
die Fluidströmung okkludierende Membran (20) aus Polymermaterial gebildet ist.

9. Medizinische Vorrichtung (10) nach Anspruch 8,
wobei die radial selbstexpandierbare Stützstruktur (13) mehrere längliche Strukturfilamente (16) aufweist, die verflochten sind, und die flexible, Fluidströmung okkludierende Membran (20) Polymerfilamente (26) aufweist, die mit den Strukturfilamenten (16) verflochten sind, und mindestens ein erstes röhrenförmiges Ende (22), das mindestens mit einem Abschnitt der Länge der Stützstruktur (13) konextensiv ist, und einen konstringierten Bereich (24) hat, wobei die Membran (20) mit der Stützstruktur (13) aus einem komprimierten Zustand mit reduziertem Durchmesser in einen expandierten Zustand zum Okkludieren von Fluidströmung durch das Körperlumen expandierbar ist, wenn sich die Stützstruktur (13) in den in das Lumen eingreifenden expandierten Zustand befindet.

10. Medizinische Vorrichtung (10) nach Anspruch 9, wobei:

die Stützstruktur (13) ein erstes und ein zweites gegenüberliegendes Ende (14, 15) aufweist;

11. Medizinische Vorrichtung (110) nach Anspruch 9, wobei:

die Stützstruktur (113) ein erstes und ein zweites gegenüberliegendes Ende (114, 115) aufweist;

12. Medizinische Vorrichtung (210) nach Anspruch 11, wobei die Konstruktionseinrichtung (228) zwischen dem ersten und zweiten entgegengesetzten Ende (214, 215) der Stützstruktur (213) liegt.

13. Medizinische Vorrichtung (110) nach Anspruch 11, wobei die Konstruktionseinrichtung (128) am ersten Ende der Stützstruktur (113) liegt.

14. Medizinische Vorrichtung (310) nach Anspruch 1, wobei die Stützstruktur (313) radial selbstexpandierbar ist und mehrere längliche Strukturfilamente (316) aufweist, die verflochten sind, wobei die Stützstruktur (313) aus einem komprimierten Zustand mit reduziertem Durchmesser in einen selbsttragenden und in das Lumen eingreifenden expandierten Zustand expandierbar ist.

15. Medizinische Vorrichtung (310) nach Anspruch 14, wobei die Fluidströmung okkludierende Membran (320) ferner einen zweiten Abschnitt mit dem konstringierten Bereich (324) aufweist, der sich über ein zweites Ende der Stützstruktur (313) hinaus erstrecken kann.

16. Medizinische Vorrichtung (610) nach Anspruch 14, wobei die Fluidströmung okkludierende Membran (620) innerhalb der Stützstruktur (613) positioniert ist, wobei die Vorrichtung ferner eine Konstruktionseinrichtung (628) zum Verschließen der Fluidströmung okkludierender Membran (620) innerhalb der Stützstruktur (613) aufweist.

17. Medizinische Vorrichtung (310) nach Anspruch 14, ferner mit einer Konstruktionseinrichtung (328) zum Verschließen der Stützstruktur (313) und Membran (320) am konstringierten Bereich (324).

Revendications

1. Dispositif médical (10) prévu pour l'implantation dans un orifice corporel ayant une surface intérieure tubulaire, comprenant :

une structure de support (13) dont au moins une partie tubulaire est expansible depuis un état comprimé à diamètre réduit jusqu'à un état dilaté autoporteur et d'engagement d'orifice, la partie tubulaire étant destinée à engager la surface intérieure tubulaire de l'orifice dans l'état dilaté; et;

une membrane d'occlusion d'écoulement de fluide entrelacée flexible (20) ayant au moins une première extrémité tubulaire (22) orientée de manière concentrique et engagée de manière circonférentielle avec la partie tubulaire de la structure de support, et une zone contractée (24), la membrane ayant une porosité supérieure à 0 ml/cm²/minute et inférieure à 5000 ml/cm²/minute lorsqu'elle est mesurée à une pression de fluide de 120 mm de mercure, et au moins une partie de la membrane (20) pouvant être dilatée avec la structure de support (13) depuis un état comprimé à diamètre réduit jusqu'à un état dilaté afin d'arrêter l'écoulement de fluide à travers l'orifice corporel lorsque la structure de support (13) est dans l'état dilaté d'engagement d'orifice.

2. Dispositif médical (10) selon la revendication 1, dans lequel la membrane d'occlusion d'écoulement (20) comprend en outre une deuxième extrémité tubulaire opposée à la zone contractée (24) par rapport à la première extrémité tubulaire (22), la deuxième extrémité tubulaire étant orientée de manière concentrique et engagée de manière circon-
férentielle avec la structure de support.

3. Dispositif médical (610) selon la revendication 2, dans laquelle la membrane d'occlusion d'écoulement (620) est un élément tubulaire et le dispositif comprend en outre des moyens de contraction (628) destinés à fermer l'élément tubulaire au niveau de la zone contractée (624) dans la structure de support (613) et à permettre à des parties de la structure de support (613) adjacentes à la zone contractée (624) de se dilater.

4. Dispositif médical (210) selon la revendication 2, dans lequel la membrane d'occlusion d'écoulement de fluide (220) est un élément tubulaire et le dispositif comprend en outre des moyens de contraction (228) destinés à fermer l'élément tubulaire et la structure de support (213) au niveau de la zone contractée (224).

5. Dispositif médical (110) selon la revendication 1, dans lequel la membrane d'occlusion d'écoulement de fluide (120) est un élément tubulaire ayant au moins une partie comprenant la première extrémité (122) qui s'étend dans le prolongement d'au moins une partie de la longueur de la structure de support (113) et le dispositif comprend en outre des moyens de contraction (128) destinés à fermer l'élément tubulaire et la structure de support au niveau de la zone contractée (124).

6. Dispositif médical (10) selon la revendication 1, dans lequel la membrane d'occlusion d'écoulement de fluide (20) est un élément tubulaire ayant au moins une première partie comprenant la première extrémité tubulaire (22) qui s'étend dans le prolongement d'au moins une partie de la longueur de la structure de support (13), et une deuxième partie comprenant la zone contractée (24) qui est capable de s'étendre au-delà d'une extrémité de la structure de support (13).

7. Dispositif médical (10) selon la revendication 1, dans lequel la structure de support (13) comprend une structure métallique; et la membrane d'occlusion d'écoulement (20) est formée en matière polymère.

8. Dispositif médical (10) selon la revendication 1, dans lequel la structure de support (13) est une structure qui peut être comprimée radialement et auto expansible comprenant un ou plusieurs fils allongés (16); et la membrane d'occlusion d'écoulement (20) est formée en matière polymère.

9. Dispositif médical (10) selon la revendication 8, dans lequel la structure de support radialement auto expansible (13) comprend une multiplicité de filaments structurels allongés (16) qui sont entrelacés; et la membrane d'occlusion d'écoulement de fluide flexible (20) comprend des filaments polymères (26) entrelacés avec les filaments structurels (16) et a au moins une première extrémité tubulaire (22) qui s'étend dans le prolongement d'au moins une partie de la longueur de la structure de support (13), et une zone contractée (24), la membrane (20) pouvant être dilatée avec la structure de support (13) depuis un état comprimé à diamètre réduit jusqu'à un état dilaté afin d'arrêter l'écoulement de fluide à travers l'orifice corporel lorsque la structure de support (13) est dans l'état dilaté d'engagement d'orifice.

10. Dispositif médical (10) selon la revendication 9, dans lequel la structure de support (13) comprend des premières et deuxième extrémités opposées (14, 15); et la zone contractée (24) de la membrane d'occlusion d'écoulement (20) s'étend au-delà de la deuxième extrémité (15) de la structure de support (13).

11. Dispositif médical (110) selon la revendication 9, dans lequel la structure de support (113) comprend des premières et deuxième extrémités opposées (114, 115); et la zone contractée (124) comprend des moyens de contraction (128) destinés à rétrécir une partie de la structure de support (113) et de la membrane (120).

12. Dispositif médical (210) selon la revendication 11, dans lequel les moyens de contraction (228) sont disposés entre les deux premières et deuxième extrémités opposées (214, 215) de la structure de support (213).

13. Dispositif médical (110) selon la revendication 11, dans lequel les moyens de contraction (128) sont disposés sur la première extrémité de la structure de support (113).

14. Dispositif médical (310) selon la revendication 1, dans lequel la structure de support (313) est radialement auto expansible et comprend une multiplicité de filaments structurels allongés (316) qui sont entrelacés; la structure de support (313) pouvant être dilatée depuis un état comprimé à diamètre réduit jusqu'à un état dilaté autoporteur et d'engagement d'orifice.

15. Dispositif médical (310) selon la revendication 14, dans lequel la membrane d'occlusion d'écoulement de fluide (320) comprend en outre une deuxième partie comprenant la zone contractée (324) qui est capable de s'étendre au-delà d'une deuxième extrémité de la structure de support (313).
16. Dispositif médical (610) selon la revendication 14, dans lequel la membrane d'occlusion d'écoulement de fluide (620) est positionnée à l'intérieur de la structure de support (613), le dispositif comprenant en outre des moyens de contraction (628) destinés à fermer la membrane d'occlusion d'écoulement de fluide (620) avec la structure de support (613).

17. Dispositif médical (310) selon la revendication 14, comprenant en outre des moyens de contraction (328) destinés à fermer la structure de support (313) et la membrane (320) au niveau de la zone contractée (324).