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(54) **DEVICE FOR PLACING A VASCULAR IMPLANT**

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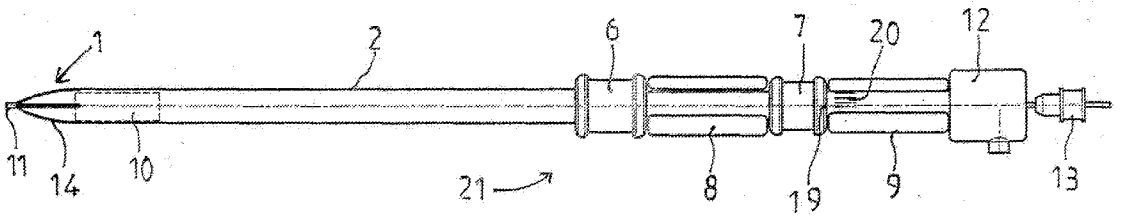
CPC ***A61F 2/966*** (2013.01); ***A61B 17/12109*** (2013.01); ***A61B 17/12172*** (2013.01); *A61F 2002/9665* (2013.01); *A61B 2017/00867* (2013.01)

(57) **ABSTRACT**

Provided is an implant placement device that includes an envelope that contains an implant with a first auto-expandable element expandable in a radial direction, a nose at a distal end of the envelope, a sheath that confines a portion of the implant therein and restricts expansion of a second auto-expandable element of the implant, and a plunger. The sheath moves within the envelope in a longitudinal direction perpendicular to the radial direction and the plunger moves in the longitudinal direction within the sheath with the implant positioned between an end of the plunger and the nose, to discharge the implant from the device at a desired position. The sheath slides in the longitudinal direction towards the nose to bring the first auto-expandable element in contact with an interior of the plurality of slots, thereby opening the nose.



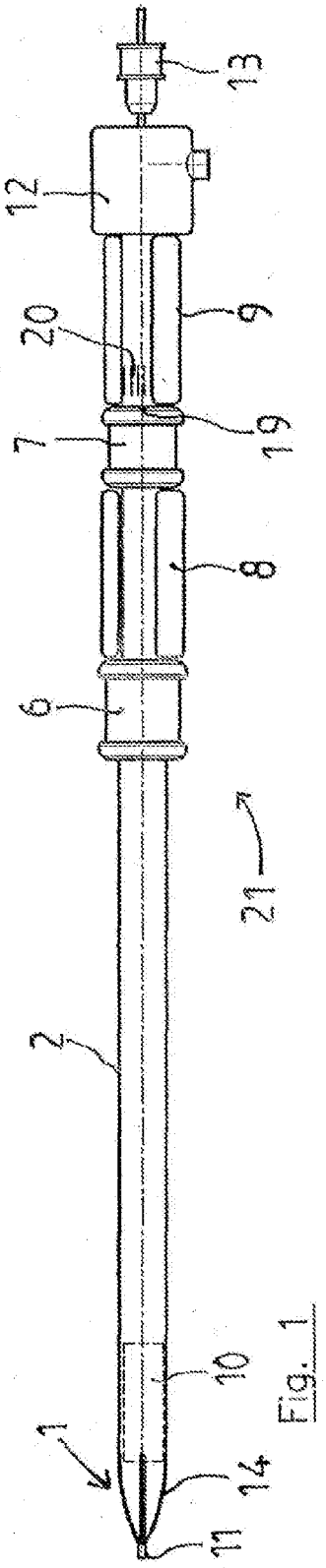


Fig. 1

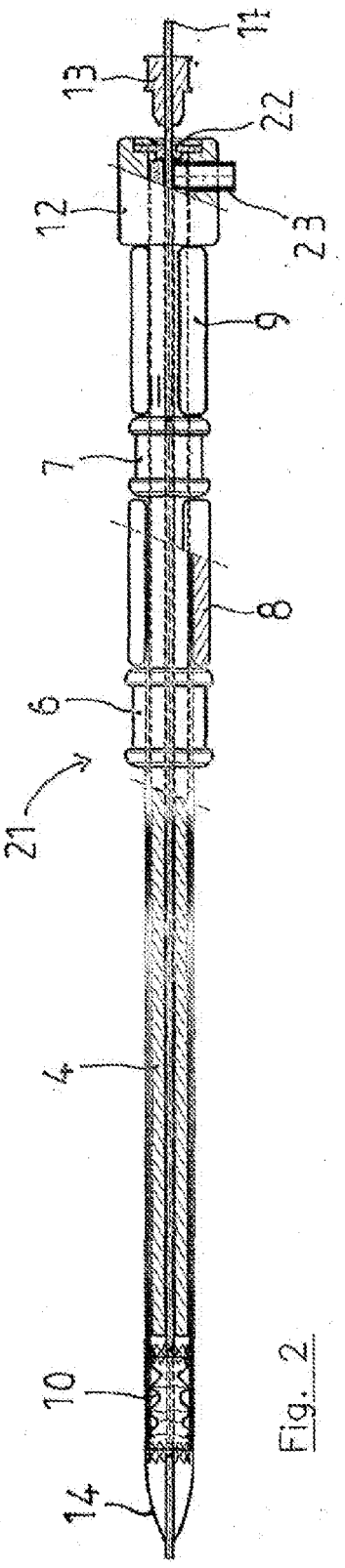
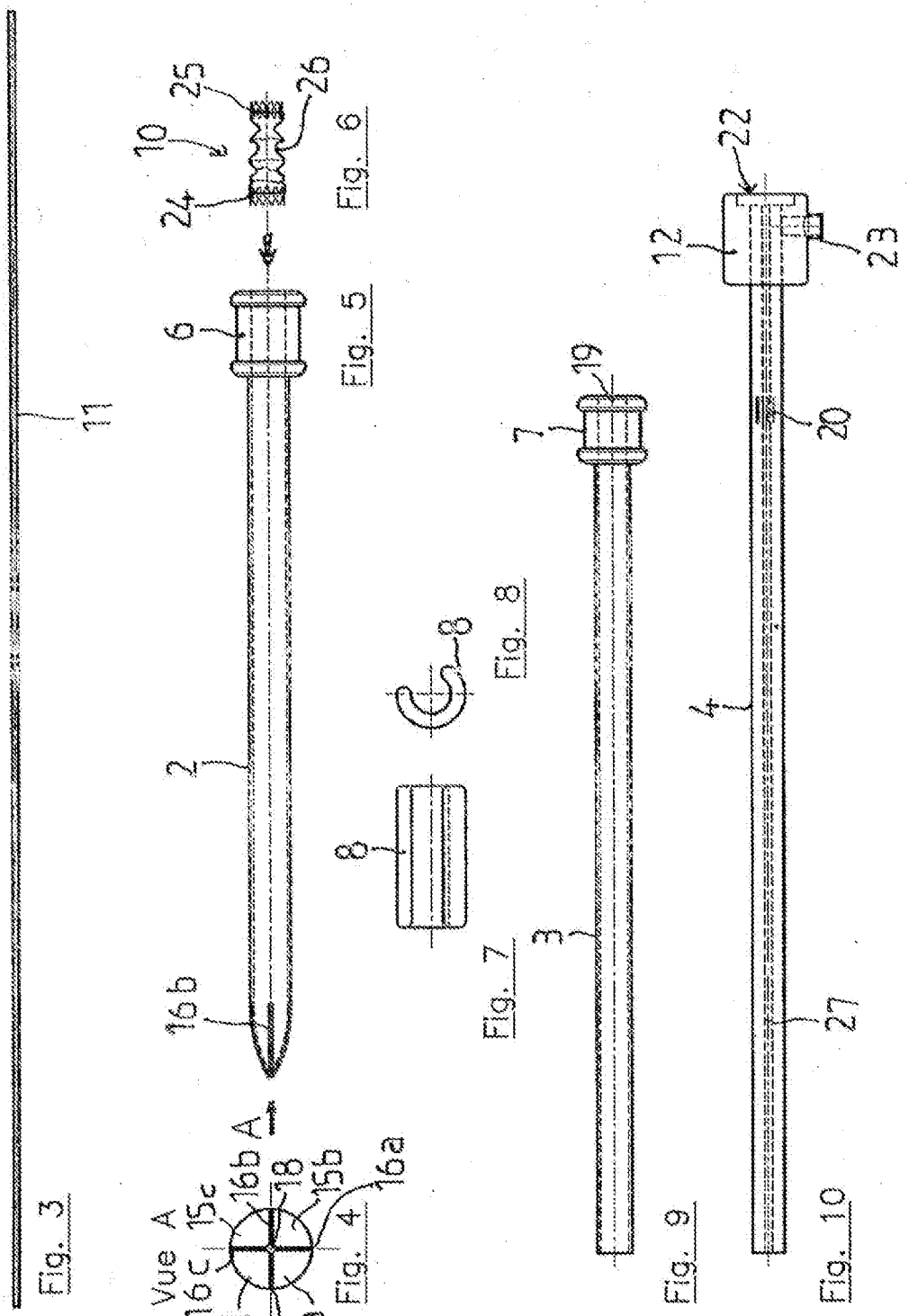


Fig. 2


11
Fig. 3
Vue A
16c
15c
16b
18
15b
16a
15d
16d
15a
Fig. 4
A
16b
2
6
Fig. 5
10
25
26
24
Fig. 6
8
8
Fig. 7
7
19
3
Fig. 8
12
22
23
20
4
27
Fig. 9
Fig. 10

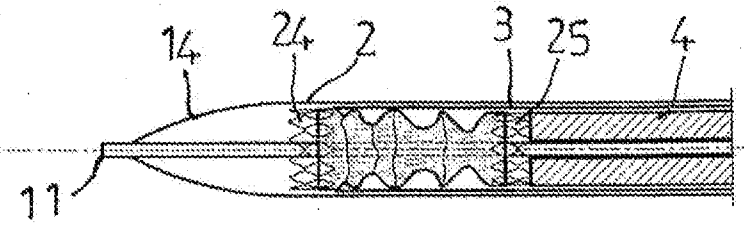


Fig.11

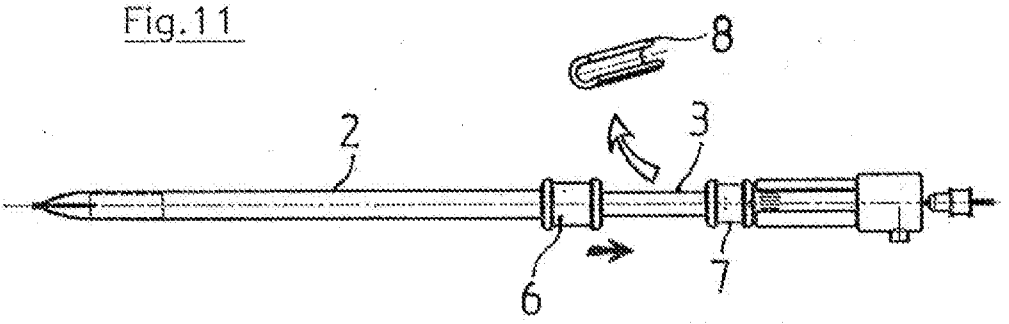


Fig.12

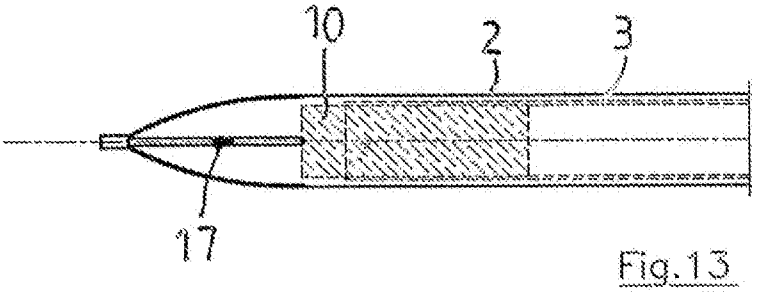


Fig.13

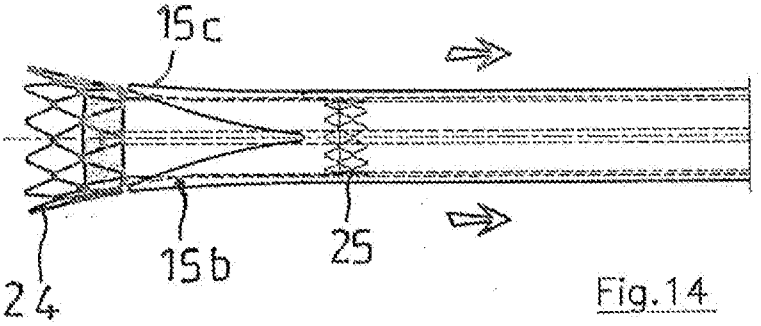


Fig.14

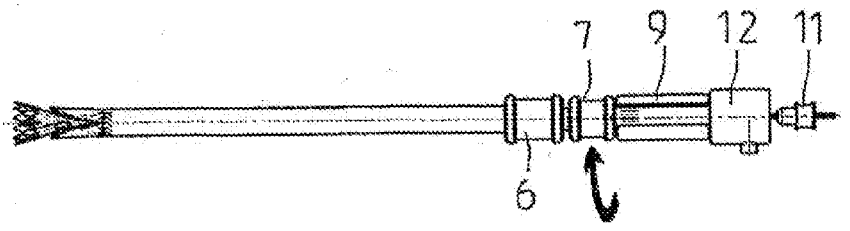


Fig. 15

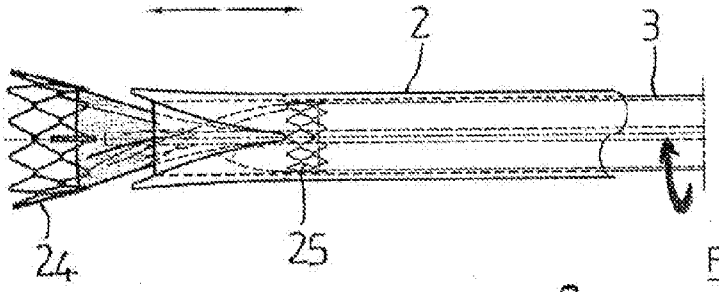


Fig. 16

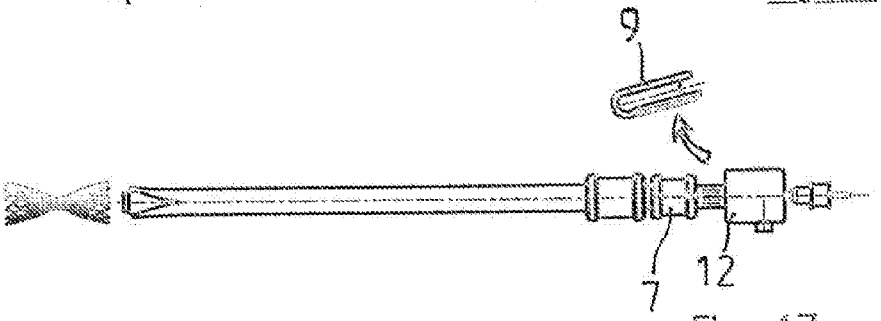


Fig. 17

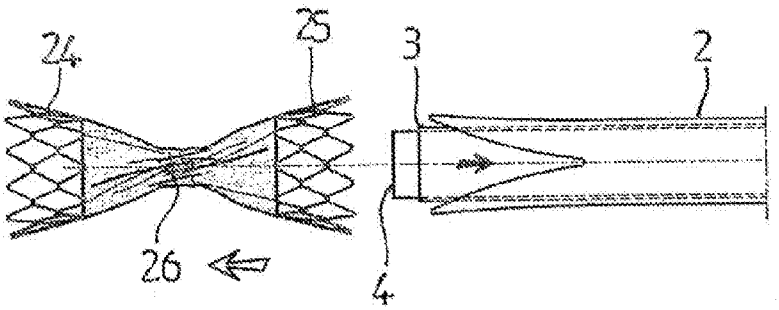


Fig. 18

DEVICE FOR PLACING A VASCULAR IMPLANT

PRIORITY

[0001] This application is a Continuation Application of U.S. patent application Ser. No. 10/553,007, which was filed in the U.S. Patent and Trademark Office on Aug. 7, 2006, which is a National Phase Entry of International Application No. PCT/FRO4/50118, which was filed on Mar. 22, 2004, and claims priority to French Patent Application Serial No. 0350096, filed on Apr. 4, 2003, the entire disclosure of each of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to a device for placing an implant.

[0004] 2. Description of the Related Art

[0005] In general, the related art includes the use of catheters or any other instrument for placing an implant in a vessel of the human or animal body.

[0006] The invention may be used for placing objects in a vessel in the form of implants of the stent type or a vascular occlusion device as presented for example in the document WO-A-02 19 926, or implants of the coil type.

[0007] The invention can also apply to the placing of transparietal occlusion devices for closing an opening in a vessel. The term implant therefore applies here in the broad sense.

[0008] The placing of implants in a vessel requires the formation of a transparietal opening (by penetration of the various layers of tissue) to reach the internal lumen of said vessel.

[0009] In general, a dilation instrument is used for this purpose, comprising a tapered end part able to produce a gradual increase in the diameter of the passage produced in the vascular wall.

[0010] In general, the first step is to introduce a needle through the vascular wall and a guide element, generally in the form of a guide cable the end of which is held in position in the lumen, is positioned. The guide cable makes it possible to insert other instruments and to guide them through the opening produced in the vascular wall. These instruments generally comprise an introducing element with a central tapered end part enabling the diameter of the parietal opening to be gradually increased. This central tapered element is surrounded by an external sheath that ultimately comes to be introduced through the vascular wall after the central tapered part has produced its effect. The latter can then be withdrawn while the external sheath is held in position and used to perform the required surgical action.

[0011] For example, it is through the residual external sheath that it is possible to effect the placing of a vascular implant. During these operations, the guide cable can remain in position.

[0012] The usual technique described above has many drawbacks.

[0013] First, the tapered part for gradual introduction is implemented in an element internal to the instrument until it arrives at the diameter of the external sheath. In this context, the internal tapered part encumbers the internal volume of the external sheath throughout part of the operation, which in particular excludes any possibility of the presence of another functional or implantable element (for example a vascular implant) in the internal space of the external sheath, before having finalized insertion.

[0014] Another drawback of current inserters is that there remains a dimension transition zone between the internal tapered element and the external wall of the external sheath: this creates a discontinuity in diameter, which may be detrimental to the continuity of the insertion movement and damage the internal wall of the vessels.

[0015] The aforementioned document WO-A-02 19 926 concerns a vascular occlusion device comprising two expandable members for fixing thereof by abutment on two portions of the wall of the vessel. It furthermore comprises an intermediate part deformable in torsion to a degree adjustable according to the relative positions of the two expandable members so as to create a maximum stricture zone defining a degree of occlusion. This document also presents a method of use as well as an appliance for placing this occlusion device.

[0016] The dilation instruments currently known prove to be unsuitable for techniques of the type described in WO-A-02 19 926 in particular because they exclude the presence of a functional element in the internal space thereof before the end of insertion in the vessel.

[0017] From the document US-A1-2002 0042622, a medical device for interventions of the anastomosis type is known. This device comprises a trocar serving to transfix the wall of a vessel. This trocar, with a tapered and openable end, does however have a highly limited function according to this prior art since it serves only for perforation.

[0018] A device for delivering a vascular occlusion plug is known from the document U.S. Pat. No. 5,320,639. The device comprises a channel in which the plug is inserted, which is placed in contact with a lateral opening in the wall of a vessel. The channel may have a tapered and openable end. This device is intended for a specific use of occlusion through the outside of a vascular vessel.

SUMMARY OF THE INVENTION

[0019] The present invention has been made to address at least the above problems and/or disadvantages and to provide at least the advantages described below.

[0020] The present invention remedies the drawbacks of the devices known up to the present time. Thus it enables gradual insertion, an increase in the diameter of the parietal opening and a centering in a vessel by means of a single external member that also participates in the release of the implant.

[0021] The present invention does not require the encumbering of the internal space of the device since there is no tapered central part to withdraw.

[0022] The internal space of the device is therefore kept free, for the integration in particular, from the start, of an implant in the device. It is thus possible, for example, to offer for sale an instrument fully equipped with the implant to place.

[0023] It furthermore proves possible to perform several operations in the vessel during the same surgery: by forming a shape-memory system, the invention can provide a first insertion, and be closed again in order to reach another vascular section and to be re-employed therein.

[0024] The invention characteristically comprises a casing with a dilation device fulfilling both a dilation function and a function of holding the implant directly applied at least

partially to the internal wall thereof. In this way a compact assembly is produced (fewer superimposed sheaths) facilitating placing while being guidable by a conventional central guide of the guide cable type.

[0025] The casing therefore also serves as a centering member inside the vessel. A free space is moreover preserved at the center of the assembly, for example for the passage of an expansion balloon.

[0026] It should also be noted that the implant is fully protected during the placing movements. When an expandable member is released, the tapered nose of the casing ensures the progressiveness of the release, preventing any "jump" effect normally encountered through the abrupt variation in the diameter of a stent when it is expelled from the housing thereof.

[0027] Other aims and advantages will emerge during the following description of a preferred embodiment of the invention, which however is not limitative.

[0028] The present invention concerns a device for placing a vascular implant, comprising:

[0029] a device for dilating a vessel with an outer casing and a tapered end part for insertion into the vessel, said end part consisting of a nose formed at the distal end of the outer casing and the dilating device, comprising means for opening the nose with at least two longitudinal slots dividing the nose into several deployable segments in order to open the nose,

[0030] an implant placed in the outer casing, characterized by the fact that

[0031] the implant comprises an expandable member bearing on the inner wall of the outer casing,

[0032] it has means for the translational movement of the implant relative to the outer casing so that the expandable body bears on the inner wall of the nose so as to deploy the segments thereof.

[0033] This device may be presented in advantageous but non-limitative variants indicated below:

[0034] the translation means comprise an inner sheath mounted so as to slide in the outer casing and pushing the expandable member,

[0035] the implant comprises a second hollow expandable member and a hollow intermediate part deformable in torsion,

[0036] the second expandable member bears on the inner wall of the inner sheath,

[0037] the inner sheath is mounted slidably and rotatably in the outer casing,

[0038] it comprises a gripping handle secured to the outer casing,

[0039] it comprises a gripping handle secured to the inner sheath,

[0040] the gripping handle of the inner sheath is situated at the rear of the gripping handle and the outer casing and comprises a removable spacer interposed between said handles so as to maintain the spacing thereof,

[0041] the deployable segments are joined at isolated points along the slots in the closed position of the nose,

[0042] it comprises one isolated join per slot between the segments,

[0043] the nose comprises a residual central passage,

[0044] the nose has a shape memory so as to be closed by default when the opening means are inactive,

[0045] it comprises a pusher mounted slidably in the inner sheath and able to bear on the free end of the second expandable member,

[0046] it comprises a gripping handle secured to the pusher situated at the rear of a gripping handle secured to the inner sheath and comprises a removable spacer interposed between said handles in order to maintain separation thereof,

[0047] it comprises means for adjusting the angular position of the inner sheath,

[0048] it comprises a central channel along the axis of the outer casing for passage of a guide cable.

BRIEF DESCRIPTION OF DRAWINGS

[0049] The above and other aspects, features, and advantages of certain embodiments of the present invention will become more apparent from the following detailed description when taken in conjunction with the accompanying drawings, in which:

[0050] FIG. **1** is a general side view of a placing device according to the invention.

[0051] FIG. **2** is a view in section thereof.

[0052] FIG. **3** illustrates an example embodiment of a guide cable.

[0053] FIG. **5** is a side view of an outer casing and FIG. **4** is a front view thereof.

[0054] FIG. **6** illustrates a possible but non-limitative configuration of an implantable device for vascular occlusion.

[0055] FIGS. **7** and **8** illustrate respectively side and front views of a spacer that can be used in the placing device of the invention.

[0056] FIG. **9** is a side view of an inner sheath that can be used according to the invention, and FIG. **10** is a side view of a pusher.

[0057] FIGS. **11** to **18** illustrate chronologically various phases of use of the device according to the invention for placing an implant.

[0058] In this context, FIG. **11** is a partial view in section of the dilation device equipped with an implant.

[0059] FIG. **12** shows a step of modifying the configuration of the instrument with removal of a spacer.

[0060] FIG. **13** shows a partial side view of the invention showing an example embodiment of a tapered nose on the outer casing.

[0061] FIG. **14** shows the relative movement of various members of the device of the invention for the opening of the nose.

[0062] FIG. **15** shows another phase of functioning of the placing device according to the invention.

[0063] FIG. **16** is a detail view thereof.

[0064] FIG. **17** shows a last phase of use of the instrument with removal of a second spacer.

[0065] FIG. **18** is a detail view thereof.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0066] Various embodiments of the present invention are described in detail with reference to the accompanying drawings. The same or similar components may be designated by the same or similar reference numerals. Detailed descriptions of constructions or processes known in the art may be omitted to avoid obscuring the subject matter of the present invention.

[0067] The term dilation means, in the context of the invention, both:

[0068] the dilation of a narrowed area by a solid instrument of gradually increasing size. The tapered end makes it possible to effect a channel-type broadening by forcing the gradual separation of the walls or by extension of the separation of the tissues over the penetration area. The profile of the dilator also enables the instrument to be self-centered. This type of profile limits the risk of lesion of the internal wall of the vessels, often covered with calcified patches, use for "therapeutic" dilation as effected by the inflation of a balloon with endoprosthesis. The pressure exerted on the walls makes it possible to fracture the calcified patches and to hope for an increase in caliber that persists after deflation of the balloon. An incomplete result is supplemented by the placing of an endoprosthesis.

[0069] The document WO-A 02 19 926 presents a special vascular occlusion device comprising two expandable end members and an intermediate part deformable under torsion by modification of the relative angular positions of the two expandable end members.

[0070] In the following description, the use of the device according to the invention for placing of the vascular occlusion device indicated in the above document is described. This being the case, this example of use is purely indicative and could not be considered to be a limitation of the application of the present invention. In particular, the device may have an implant of other types, in particular with a single member expandable over the width thereof The expandable member may be self-expandable or expandable by balloon.

[0071] FIGS. **1** and **2** present in side view and cross-section a placing device according to the invention. This device **21** comprises in the front part thereof a device **1** for dilating a vessel. Opposite the dilation device **1**, the placing device **21** comprises a part allowing manipulation by the practitioner. In particular, handles **6**, **7** and **12** are formed for gripping. The handle **12** may integrate or receive various accessories such as a valve **22** preserving the fluid tightness of the instrument and a coupling **23** for connection of additional tubes.

[0072] The various elements constituting the dilation device **1** and the placing device **21** according to the invention are described below more precisely in the embodiment illustrated.

[0073] In this context, FIG. **3** shows the formation of a guide cable **11** (also referred to as a guide wire) that can be placed and preserved in the central part of the device **1** and of the placing device **21** throughout the phases of use of the invention.

[0074] FIGS. **4** and **5** show an outer casing **2** able to implement the main body and to delimit an inner working space. The outer casing comprises a distal end formed by a nose **14** with a tapered shape configured to enable insertion in the vessel through the wall thereof.

[0075] During use, the nose **14** is first of all in the default closed position so as to constitute the tapered insertion profile. When the nose **14** is sufficiently inserted in the vessel, opening means are present to open the nose **14**.

[0076] An example embodiment of these opening means is presented below. Thus, in the context of FIGS. **4** and **5**, the nose **14** is equipped with a plurality of slots **16***a*, **16***b*, **16***c*, **16***d* implementing a partitioning of the nose **14** into several segments **15***a*, **15***b*, **15***c*, **15***d*. The segments **15***a*, **15***b*, **15***c*, **15***d* thus have a relative freedom of movement enabling the nose **14** to be opened in a movement substantially corresponding to that of the petals of a flower.

[0077] The number of slots **16***a*, **16***b*, **16***c*, **16***d* and the length thereof in the longitudinal direction of the device **1** are not limited to the example illustrated.

[0078] Advantageously, the segments **15***a*, **15***b*, **15***c*, **15***d* of the nose **14** have a shape memory in order to regain the closed idle position thereof when the opening means are no longer active. It is thus possible to open and close the nose **14** on several occasions, according to the requirements of the practitioner.

[0079] It is possible to provide other means for closing the nose **14**, in the form of an active closure system for example by slipping a wire into the various segments **15***a*, **15***b*, **15***c*, **15***d* between the end of the nose **14** and a peripheral handle: the tension of the wire closes the nose **14** and release may also serve for opening the nose **14**.

[0080] At the opposite end of the outer casing **2**, a handle **6** is present for gripping by the operator. It should be noted that the outer casing **2** delimits an inner space enabling, for example, insertion of a vascular occlusion device **10** presented in FIG. **10** and comprising two expandable members **24**, **25** as well as a flexible intermediate part **26** deformable under torsion.

[0081] Docket: **2160-15** CON

[0082] The device **1** and the placing device **21** also comprise an inner sheath **3** able to be mounted slidably in the internal space of the outer casing **2**. Just like the outer casing **2**, the inner sheath **3** may consist of a substantially cylindrical portion with a circular cross-section. The distal end of the inner sheath is left free while the other end comprises a handle **7** for gripping by the practitioner.

[0083] The invention also comprises a pusher **4** visible in FIG. **10** in a preferred embodiment in which it has a central channel **27** producing a residual passage in the core of the device as well as a handle **12** receiving, in the case depicted, an end valve **22** and a coupling **23** for ancillary connections. The pusher **4** is mounted slidably in the internal space of the inner sheath **3**.

[0084] Through this assembly, the configuration illustrated in FIGS. **1** and **2** is arrived at. The handles **6**, **7** and **12** are kept separated by means of spacers **8**, **9** formed removably so as to be able to be successively removed during the surgery.

[0085] The guide cable **11** is here positioned in the residual central channel **27** of the pusher **4** and its proximal end is associated with a sleeve also allowing manipulation.

[0086] In the example illustrated, the opening of the nose **14** takes place as follows. From a closed position, appearing for example in FIG. **11**, the practitioner removes the first spacer **8** so as to enable the outer casing **2** to be withdrawn relative to the inner sheath **3** until the handles **6**, **7** are put in abutment. During this withdrawal movement, the distal end of the inner sheath **3** exerts an abutment on the internal wall of the outer casing **2** via an expandable member **24** of the implant **10**. This abutment causes the deployment of the segments **15***a*, **15***b*, **15***c*, **15***d* of the nose **14** as is clear from FIG. **14**.

[0087] According to one possibility, isolated joins **17** are present over the length of the slots **16***a*, **16***b*, **16***c*, **16***d* so as to preserve an adjusted cohesion between the various segments **15***a*, **15***b*, **15***c*, **15***d* during the insertion phase. These joins **17** are nevertheless designed so as to not to interfere

with the deployment of the nose **14** and to make it possible to detach the various segments **15***a*, **15***b*, **15***c*, **15***d* through the abutment exerted by the inner sheath **3** when the outer casing **2** is withdrawn.

[0088] Spot welds may serve as joins **17**.

[0089] An example embodiment of a device for placing implants is described more precisely below, in the non-limitative case of the placing of vascular occlusion implants as shown in FIG. **6**.

[0090] In this context, the implant **10** is positioned in the internal space of the outer casing **2** before the start of the operation. More precisely, the distal expandable member **24** is held by the internal wall of the outer casing **2**. At the rear, another expandable member **25** is held in position against the internal wall of the inner sheath **3**. Advantageously, the rear end of the expandable member **24** is put in abutment on the front end of the inner sheath **3**. In parallel, the rear end of the expandable member **25** is put in abutment against the distal end of the pusher **4**. This configuration is shown clearly in FIG. **11**.

[0091] First, the practitioner inserts the nose **14** through the vascular wall until it arrives at the required implantation. At this stage, the spacer **8** is removed, which enables the practitioner to withdraw the outer casing **2** relative to the inner sheath **3**, by means of the handle **6**. This movement is illustrated in FIG. **12**. It gives rise to an abutment of the expandable member **24** and inner sheath **3** on the internal wall of the outer casing **2** able to deploy the nose **14** by separation of the various segments **15***a*, **15***b*, **15***c*, **15***d*. This situation is shown in FIG. **14**, where the expansion of the expandable member **24** once released can be noted.

[0092] At this level, the other expandable member **25** is also held inside the inner sheath **3**.

[0093] For an application to vascular occlusion, it is then possible to effect a rotation of the inner sheath **3** so as to modify the relative angular positions of the expandable members **24**, **25**. To this end, the practitioner uses the handle **7** to modify the angular position thereof. Naturally, in this application, it is necessary for the inner sheath **3** to have a possibility of rotational movement on the longitudinal axis of the device. Furthermore, it is advantageous to provide means for adjusting the angular position of the inner sheath **3**, for example in the form of a reference **19** situated on the handle **7** opposite a plurality of graduations **20** formed on the external surface of the pusher **4** at a point visible to the user. He can thus adjust the torsion imposed on the intermediate part **26** in order to adjust the degree of occlusion, which may also produce an adjustment of the length of the implant **10** by effecting a greater or lesser number of turns. This possibility is illustrated by the double arrow in FIG. **16**.

[0094] By removal of the spacer **9**, the assembly consisting of the outer casing **2** and the inner sheath **3** is withdrawn by a rearward translation movement exerted at the handle **6** in order to move it closer to the handle **12** as far as abutment.

[0095] At this stage, the abutment exerted by the pusher **4** on the rear end of the expandable member **25** produces the release of said expandable member **25** from the internal wall of the inner sheath **3**. This release causes the expansion of the member **25** for placing thereof on the vascular wall. In this way the situation illustrated in detail in FIG. **18** is arrived at, where the nose **14** is retracted with respect to the inner sheath **3**, the latter itself being retracted with respect to the pusher **4**. Naturally, here, the relative retraction positions are accentuated for good comprehension.

[0096] The guide cable **11** can be withdrawn or could have been withdrawn previously. It will be noted that the nose **14** comprises a residual central passage **14** visible in front view in FIG. **4** to enable the cable **11** to be inserted and removed.

[0097] The spacers **8** and **9** here consist of the elements having an annular cross-section in a lunar crescent of more than 180°. The remaining opening makes it possible to act on the elasticity of the material of the spacer in order to achieve removal thereof. An example of a shape of the spacers **8**, **9** is present in the case of the spacer **8** in FIGS. **7** and **8**. Naturally, another configuration is possible with other means enabling the spacer to be removed.

[0098] The main constituents of the invention are, by way of example, made from polyurethane or polyethylene.

[0099] While the present invention has been shown and described with reference to certain embodiments thereof, it will be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed:

1. An implant placement device comprising:

an envelope configured to contain an implant, which includes a first auto-expandable element, which is expandable in a radial direction;

a nose positioned at a distal end of the envelope having a plurality of slots configured to divide the nose into a plurality of outwardly opening segments;

a sheath configured to confine a portion of the implant therein and to restrict expansion of a second auto-expandable element of the implant, wherein the sheath is configured to move within the envelope in a longitudinal direction perpendicular to the radial direction; and

a plunger configured to move in the longitudinal direction within the sheath with the implant positioned between an end of the plunger and the nose, to discharge the implant from the device at a desired position,

wherein the sheath is configured to slide in the longitudinal direction towards the nose to bring the first auto-expandable element in contact with an interior of the plurality of slots, thereby opening the nose.

2. The device of claim **1**, further comprising:

a central residual passage in the nose, which includes a shape memory that closes the nose as a default position.

3. The device of claim **1**, further comprising:

a first grip configured to move the envelope; and

a second grip configured to move to the sheath,

wherein moving the second grip slides the sheath within the envelope.

4. The device of claim **3**, wherein the second grip is configured to move in the longitudinal direction towards the first grip to expose a front end of the first auto-expandable element of the implant.

5. The device of claim **4**, wherein the second grip is configured to move the sheath away from the distal end of the envelope.

6. The device of claim **4**, further comprising:

a removable spacer situated between said the first grip and the second grip to maintain a space between the first grip and the second grip.

7. The device of claim **3**, wherein the second grip is located closer to a third grip than the first grip, wherein the third grip is configured to move the plunger.

8. The device of claim **1**, wherein the plunger is configured to exert a second force against a rear end of the second auto-expandable element, to discharge the implant.

9. The device of claim **1**, wherein the implant further comprises a hollow intermediate section.

10. The device of claim **9**, wherein the implant is configured to be maintained in the envelope with the first auto-expandable element positioned closer to the nose than the hollow intermediate section, with the intermediate section positioned closer to the nose than the second auto-expandable element.

11. The device of claim **9**, wherein the hollow intermediate section is configured to be deformed by twisting upon rotation of the sheath around a longitudinal axis of the device.

12. The device of claim **11**, wherein the device detects an angle of rotation of the sheath in relation to the envelope.

13. An implant placement device comprising:

an envelope configured to house an implant;

a plunger;

a sheath configured to confine a portion of the implant to restrict expansion of an auto-expandable element of the implant in a first position of the device and in a second position of the device, wherein the envelope is disposed around the sheath; and

a nose positioned at a distal end of the envelope and having a plurality of slots configured to divide the nose into a plurality of outwardly opening segments,

wherein a longitudinal axis of the device is perpendicular to a radial direction of expansion of the auto-expandable element of the implant, and

wherein:

when in the first position of the device, the implant is contained within the sheath between the plunger and the nose,

when in the second position of the device, the auto expandable element is in contact with an interior of the plurality of outwardly opening segments and is configured to open the nose when the envelope is slid around the sheath, and

when in a third position of the device, the implant is discharged from the sheath, when the plunger is moved in a longitudinal direction.

14. The device of claim **13**, wherein the nose includes a shape memory that closes the nose as a default position.

15. The device of claim **13**, further comprising:

a first grip configured to slide the envelope on the sheath; and

the first grip configured to move towards a second grip to expose a front end of the auto-expandable element of the implant.

16. The device of claim **13**, comprising a spacer configured to move between a first position of the spacer and a second position of the spacer to stop a sliding movement of the envelope around the sheath and to enable the sliding movement of the envelope around the sheath, respectively, and

wherein the spacer is in the first position of the spacer when in the first position of the device, and wherein the spacer is in the second position of the spacer when the device is either in the second position of the device or in the third position of the device.

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