Description

The invention relates to an occlusion assembly according to the preamble of claim 1.

An occlusion assembly of this type is disclosed in US Patent 4,744,364. In this patent it is stated that there is a possibility for sliding a locking element over the retaining element, said locking element then lying against the skin of the user. That is to say, the force necessary to hold the occlusion element against the wall of the blood vessel is led by the retaining element through the outside of the wall of the blood vessel through the skin to the outside of the skin.

With this arrangement, as already indicated, the occlusion member is located on the inside of the blood vessel. This occlusion member is in general a material which dissolves in time, so that after a few weeks the opening in the wall of the blood vessel is sealed and no further traces of the occlusion member are found. Because the retaining element extends both through the wall of the blood vessel and the adjacent skin, it is very difficult to apply a controlled tension thereto. After all, it is highly conceivable that movement takes place between the blood vessel and the skin, which will result in an uncontrolled high or low tension. In practice, however, it has been found that it is necessary to apply some tension to the retaining element in order to press the occlusion member in a guaranteed manner against the wall of the blood vessel. If this tension is inadequate or is not present, there is a risk that the occlusion member no longer performs its function well, with the possible complication that the occlusion member no longer completely seals the openings, as a result of which very serious consequences can arise. If the tension is too high, there is a risk of rupture or of the occlusion element being pulled through the opening in the blood vessel. This means that the occlusion assembly according to US Patent 4,744,364 is either not admissible or is admissible only in situations where it can be guaranteed that there will be no mutual movement between the wall of the blood vessel and the skin during the first few days, that is to say that the patient must remain immobile.

The aim of the present invention is to overcome this disadvantage and to provide an occlusion assembly with which it is possible to apply more tension to the retaining element.

This aim is achieved with an occlusion assembly as described above, having the characterizing features according to claim 1. In contrast to the locking element according to the US specification, the locking member according to the present invention is fitted so that it lies horizontally against the wall of the blood vessel. By this means problems relating to mutual shifting of the wall of the blood vessel and the skin, with resultant tension concentrations on the retaining element, are avoided. Because it is now possible to apply greater tension to the retaining element, it can be guaranteed that the occlusion member remains in its place. In practice it has been found that there is then a risk that the occlusion member is pulled through the opening in the wall of the blood vessel. In order to avoid this, a fixing element is fitted.

According to a preferred embodiment of the invention, the fixing element is a curved rod-shaped element and the retaining element is fitted in the centre thereof in such a way that when a force is applied the centre of the rod-shaped element touches the occlusion member first. In this way an even force distribution over the occlusion member is provided.

According to a further advantageous embodiment of the invention, the locking member is to be fitted movably over the retaining element against the outside of the blood vessel.

According to a further advantageous embodiment, at least one of the occlusion member or the other elements or members is made from bioabsorbable material. Consequently this part will disappear in time without leaving any trace. According to an advantageous embodiment, the bioabsorbable material comprises collagen or alginate. According to an advantageous embodiment, the occlusion member is in sheet form and essentially circular, heart-shaped or oval. According to a further advantageous embodiment, the occlusion member contains agents which combat stenosis, such as angiotensin II-converting enzyme inhibitor.

The invention is illustrated in more detail below with reference to the illustrative embodiments shown in the drawing. In the drawing:

Fig. 1 shows a side view of a first embodiment of the occlusion assembly according to the invention, the locking member not being represented;

Fig. 2 shows a top view of the same embodiment, the locking member not being represented;

Fig. 3 shows the fitting of the occlusion assembly according to Fig. 1 and 2 in a blood vessel, the locking member not being represented;

Fig. 4 shows the occlusion assembly according to the above embodiment fitted in a blood vessel, the locking member not being represented;

Fig. 5a, b, c show a top view of further embodiments of the occlusion assembly according to the invention, the locking member not being represented;

Fig. 6 shows a further embodiment of the occlusion assembly according to the invention fitted in a blood vessel;

Fig. 7 shows a side view of a further embodiment of the occlusion assembly according to the invention fitted in a blood vessel.

A partial side view of a first embodiment of the occlusion assembly according to the invention is shown in Fig. 1. This comprises a flexible sheet 1 as occlusion member and a retaining element 2, which in this case is in the form of a thread, connected to the centre of said occlusion member. A top view of the various features is drawn in Fig. 2.

Fig. 3 shows a blood vessel 8 in which a sheath 6, known for any medical application, has been inserted. After removing the sheath 6, the problem up to now has been that an appreciable opening was formed in the blood vessel which had to be sealed in some way. The means of sealing described in the prior art were found to be unreliable or to impose restrictions in movement on the patient. According to the invention, the assembly shown partially in Fig. 1 and 2 is inserted through the sheath, as shown. After the occlusion member 1 has been fitted in the blood vessel 8, the unfoldable sheet 1 unfolds in such a way that the surface area thereof is larger than the surface area of the opening to be occluded. Sheath 6 is then moved out of the opening, as a result of which the latter will become somewhat smaller. By pulling on the retaining element or thread, sheet 1 will come to lie against blood vessel 8 in the manner shown in Fig. 4. By making both the sheet 1 and retaining element 2 of bioabsorbable material, it is ensured that after the opening in the blood vessel has occluded these parts will disappear, for example after a few weeks.

Various other embodiments of the flexible occlusion member or plug 1 are partially shown in Fig. 5a, b, c. Depending on the possibilities for insertion through the sheath and the opening made in the blood vessel, these can be used.

A further embodiment of the occlusion assembly according to the invention is shown in Fig. 6. This essentially corresponds to the occlusion assembly described with reference to the above figures, except that a locking ring 10 is represented as fitted over the retaining element or thread. This ring 10 or locking member serves for accurate determination of the position of occlusion member and is likewise made of a biologically absorbable material. The ring 10 has an internal diameter such that, on the one hand, it can slide in a supple manner over retaining element 2 but, on the other hand, provides some mutual clamping force on these two parts. In contrast to the prior art, the locking member 10 lies against the outside of the blood vessel 8. Consequently, there is tension in the retaining thread only in the part which must bridge the wall thickness of the blood vessel.

A further embodiment of the invention is shown in Fig. 7. The same reference numerals as in the preceding figures have been used for corresponding parts in this figure. In contrast to the earlier embodiments, the retaining thread 2 is now attached to a fixing element 12 which in this case consists of a rod-shaped curved-plated part. The occlusion member, indicated by 13, is provided with an opening 14 located in the centre, through which the retaining element 2 passes. As a result of the use of the fixing element 12, the tension in the retaining element or thread 2 can be increased, by which means it is guaranteed that the occlusion member 13 remains in its place. With this arrangement, because of the greater strength of the fixing element, pulling of the occlusion through the opening in the blood vessel is prevented. The fixing element, as well as the occlusion member and the locking member, can be made of a biocompatible material. The occlusion member can contain angiotensin II-converting enzyme inhibitor, an agent which combats constriction of the blood vessels.

It must be understood that the embodiments described above are merely examples and that the invention is not restricted to these. Thus, the fixing element can comprise all means known in the prior art and is not restricted to the thread shown in the drawing. Likewise, the unfoldable element to be inserted in the blood vessel can comprise all possible imaginable configurations.

The invention also relates to the use of bioabsorbable material for the production of an occlusion means for sealing puncture holes in blood vessels, as described above.

Claims

1. An occlusion assembly for sealing openings in blood vessels, comprising an occlusion member (1,13) which is to be fitted through the opening in the blood vessel and on which a flexible retaining element (2) passes through the wall of the blood vessel and wherein the occlusion member is unfoldable with respect to the retaiing element and a locking member (10) which engages the retaining element, characterizined in that the locking member is adaped to lie against the outside of the blood vessel so that the portion of the retaining element which passes through the wall of the blood vessel between the locking member and the occlusion member is in tension to thereby clamp the wall of the blood vessel therebetween.

2. An occlusion assembly according to claim 1 wherein the locking member is movable along the retaining element.

Fig. 7 shows a side view of a further embodiment of the occlusion assembly according to the invention fitted in a blood vessel.

A partial side view of a first embodiment of the occlusion assembly according to the invention is shown in Fig. 1. This comprises a flexible sheet 1 as occlusion member and a retaining element 2, which in this case is in the form of a thread, connected to the centre of said occlusion member. A top view of the various features is drawn in Fig. 2.

Fig. 3 shows a blood vessel 8 in which a sheath 6, known for any medical application, has been inserted. After removing the sheath 6, the problem up to now has been that an appreciable opening was formed in the blood vessel which had to be sealed in some way. The means of sealing described in the prior art were found to be unreliable or to impose restrictions in movement on the patient. According to the invention, the assembly shown partially in Fig. 1 and 2 is inserted through the sheath, as shown. After the occlusion member 1 has been fitted in the blood vessel 8, the unfoldable sheet 1 unfolds in such a way that the surface area thereof is larger than the surface area of the opening to be occluded. Sheath 6 is then moved out of the opening, as a result of which the latter will become somewhat smaller. By pulling on the retaining element or thread, sheet 1 will come to lie against blood vessel 8 in the manner shown in Fig. 4. By making both the sheet 1 and retaining element 2 of bioabsorbable material, it is ensured that after the opening in the blood vessel has occluded these parts will disappear, for example after a few weeks.

Various other embodiments of the flexible occlusion member or plug 1 are partially shown in Fig. 5a, b, c. Depending on the possibilities for insertion through the sheath and the opening made in the blood vessel, these can be used.

A further embodiment of the occlusion assembly according to the invention is shown in Fig. 6. This essentially corresponds to the occlusion assembly described with reference to the above figures, except that a locking ring 10 is represented as fitted over the retaining element or thread. This ring 10 or locking member serves for accurate determination of the position of occlusion member and is likewise made of a biologically absorbable material. The ring 10 has an internal diameter such that, on the one hand, it can slide in a supple manner over retaining element 2 but, on the other hand, provides some mutual clamping force on these two parts. In contrast to the prior art, the locking member 10 lies against the outside of the blood vessel 8. Consequently, there is tension in the retaining thread only in the part which must bridge the wall thickness of the blood vessel.

A further embodiment of the invention is shown in Fig. 7. The same reference numerals as in the preceding figures have been used for corresponding parts in this figure. In contrast to the earlier embodiments, the retaining thread 2 is now attached to a fixing element 12 which in this case consists of a rod-shaped curved-plated part. The occlusion member, indicated by 13, is provided with an opening 14 located in the centre, through which the retaining element 2 passes. As a result of the use of the fixing element 12, the tension in the retaining element or thread 2 can be increased, by which means it is guaranteed that the occlusion member 13 remains in its place. With this arrangement, because of the greater strength of the fixing element, pulling of the occlusion through the opening in the blood vessel is prevented. The fixing element, as well as the occlusion member and the locking member, can be made of a biocompatible material. The occlusion member can contain angiotensin II-converting enzyme inhibitor, an agent which combats constriction of the blood vessels.

It must be understood that the embodiments described above are merely examples and that the invention is not restricted to these. Thus, the fixing element can comprise all means known in the prior art and is not restricted to the thread shown in the drawing. Likewise, the unfoldable element to be inserted in the blood vessel can comprise all possible imaginable configurations.

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Claims

1. An occlusion assembly for sealing openings in blood vessels, comprising an occlusion member (1,13) which is to be fitted through the opening in the blood vessel and on which a flexible retaining element (2) passes through the wall of the blood vessel and wherein the occlusion member is unfoldable with respect to the retaiing element and a locking member (10) which engages the retaining element, characterizined in that the locking member is adaped to lie against the outside of the blood vessel so that the portion of the retaining element which passes through the wall of the blood vessel between the locking member and the occlusion member is in tension to thereby clamp the wall of the blood vessel therebetween.

2. An occlusion assembly according to claim 1 wherein the locking member is movable along the retaining element.

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3. An occlusion assembly accoridng to claim 1 or 2 wherein the occlusion member is movable along the retaining element.

4. An occlusion assembly according to claims 1 to 3 wherein the occlusion member contains a stenosis combating agent therein.

5. An occlusion assembly according to claims 1 to 4 wherein the occlusion member contains an agent therein which combats constriction of the wall of the blood vessel.

6. An occlusion assembly according to any one of claims 1 to 5 wherein the occlusion member is adapted to be fitted through the opening in the blood vessel and then unfolded to engage the inner surface of the blood vessel.

Patentansprüche

1. Okklusionsanordnung zum Verschließen von Öffnungen in Blutgefäßen, mit einem Okklusionsteil (1, 13), das durch die Öffnung in das Blutgefäß einzubringen ist und an dem ein flexibles Halteelement (2) sitzt, das durch die Wand des Blutgefäßes hindurchreicht, wobei das Okklusionsteil mit Bezug auf das Halteelement aufgefaltet werden kann, sowie mit einem Blockierteil (10), das mit dem Halteelement in Eingriff steht, dadurch gekennzeichnet, daß das Blockierteil gegen die Außenseite des Blutgefäßes anlegbar ist, so daß der Teil des Halteelements, der durch die Wand des Blutgefäßes hindurchreicht, zwischen dem Blokkierteil und dem Okklusionsteil unter Spannung steht, um dadurch die Wand des Blutgefäßes zwischen beiden einzuklemmen.

2. Okklusionsanordnung nach Anspruch 1, bei welcher das Blockierteil entlang dem Halteelement bewegbar ist.

3. Okklusionsanordnung nach Anspruch 1 oder 2, bei welchem das Okklusionsteil entlang dem Halteelement bewegbar ist.

4. Okklusionsanordnung nach Ansprüchen 1 bis 3, bei welchem das Okklusionsteil ein Mittel gegen Stenosebildung enthält.

5. Okklusionsanordnung nach Ansprüchen 1 bis 4, bei welcher das Okklusionsteil ein Mittel gegen eine Konstriktion der Wand des Blutgefäßes enthält.

6. Okklusionsanordnung nach einem der Ansprüche 1 bis 5, bei welcher das Okklusionsteil durch die Öffnung hindurch in das Blutgefäß einbringbar ist und dann aufgefaltet werden kann, um mit der Innenfläche des Blutgefäßes in Eingriff zu kommen.

Revendications

1. Ensemble d'occlusion pour l'obturation d'ouvertures dans des vaisseaux sanguins, comprenant un membre d'occlusion (1, 13) qui doit être ajusté à travers l'ouverture dans le vaisseau sanguin et porte un élément de retenue (2) flexible qui traverse la paroi du vaisseau sanguin et dans lequel le membre d'occlusion est dépliable relativement à l'élement de retenue et un élément de verrouillage (10) qui est engagé avec l'élément de retenue, caractérisé en ce que le membre de verrouillage est adopté de façon à reposer contre l'extérieur du vaisseau sanguin de telle sorte que la partie de l'élément de retenue qui traverse la paroi du vaisseau sanguin entre le membre de verrouillage et le membre d'occlusion est sous tension de façon à serrer la paroi du vaisseau sanguin entre eux.

2. Ensemble d'occlusion suivant la revendication 1, dans lequel le membre de verrouillage peut être déplacé le long de l'élément de retenue.

3. Ensemble d'occlusion suivant les revendications 1 ou 2, dans lequel le membre d'occlusion peut être déplacé le long de l'élément de retenue.

4. Ensemble d'occlusion suivant les revendications 1 à 3, dans lequel le membre d'occlusion renferme un agent luttant contre la sténose.

5. Ensemble d'occlusion suivant les revendications 1 à 4, dans lequel le membre d'occlusion renferme un agent luttant contre la constriction de la paroi du vaisseau sanguin.

6. Ensemble d'occlusion suivant l'une quelconque des revendications 1 à 5, dans lequel le membre d'occlusion est adapté pour être ajusté à travers l'ouverture dans le vaisseau sanguin et ensuite déplié pour être en contact avec la surface intérieure du vaisseau sanguin.