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(54) Title: HEART IMPLANT

(57) Abstract: The invention relates to a heart implant comprising a closure element (1), being positionable in the annulus of a valve of the heart, particularly for closing or at least reducing a remaining gap between the closing leaflets and at least one anchoring element (2, 2'), particularly being resiliently compressible and attachable to the tip of the ventricle (4), particularly due to compression by the myocard, preferably by form-fit and/or force-fit and at least one connecting element (3, 3'), connecting the closure element (1) and a respective anchoring element (2, 2') to each other wherein the at least one connecting element (3, 3') being formed of only one strand at least in a part of its extension, particularly being formed of one metal strand.

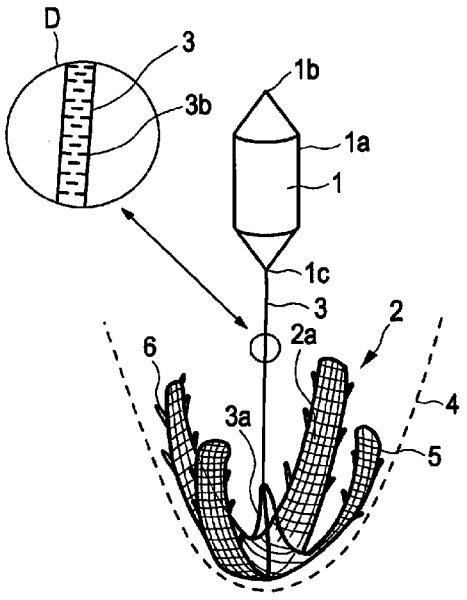

Fig. 1

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Heart implant

Technical Field

The invention relates to a heart implant, particularly a heart implant being configured to reduce or eliminate a heart valve insufficiency after implantation into the heart, the heart implant furthermore comprising at least one closure element, being positionable in the annulus of a valve of the heart, preferably the tricuspid or mitral valve, particularly for closing or at least reducing a remaining gap between the closing leaflets and at least one anchoring element, and at least one connecting element, connecting the closure element and the anchoring element to each other. An anchoring element, particularly the one being attachable to the ventricle, preferably the tip of the ventricle, may be resiliently compressible, particularly due to compression by the myocard or a vessel. Attachment is preferably performed by form-fit and/or force-fit.

Background of the invention

Typically, such implants are positioned in such a way that the closure element of the implant is situated in the valve annulus and closes a remaining gap of the closed valve leaflets. For that purpose, the closure element is connected to at least one anchoring element being configured to fix the closure element within the heart in the desired position i.e. in the valve annulus preferably to be contacted by the closing valve leaflets.

It is known in the state of art to use an anchoring element punctured into the myocardium of the ventricle for fixation of the closure element. Besides this

invasive way modern implants provide a less invasive fixation just by contacting the interior wall of the atrium and/or the ventricle with the outer surface areas of an anchoring. For this purpose, it is known that an anchoring element may be formed of an expandable / expanded cage that is connected to the closure element. Anchoring elements, particularly the ones formed as a cage may be attached to the closure element on the atrial and/or ventricular side, hitherto most preferred only on the atrial side of the closure element.

Generally, the at least one anchoring element and a closure element are typically in a collapsed state for feeding the entire implant through a catheter into the heart where it is expanded after release from the catheter for fixation purposes. The invention relates to such implants having an expandable closure element and at least one anchoring element, no matter how these elements are realized in detail.

Applicants own patent applications having the serial numbers DE 10 2015 005 934.3 and EP 16000475.0 already disclose such heart implants having a closure element comprising a tubular attachment element for attaching a sheath to it. In these documents the sheath is formed of an inflatable membrane. After attaching, particular fluid tight attaching an inflatable membrane that may be inflated by a liquid the expanded membrane and the tubular attachment element surrounded, preferably coaxially surrounded by the membrane form an aforementioned closure element that is to be positioned in the respective heart valve annulus. The membrane may be made of a flexible or elastic material, preferably a foil. An expanded membrane encircles a space surrounding the tubular attachment element that reduces or eliminates a gap between the leaflets.

The invention also relates to implants having such kind of closure elements, wherein the inflatable sheath may in addition be covered by a covering, for example a scaffold structure and/or a textile covering element on the outside and or supported by a scaffold structure on the inside. Accordingly, the invention may have such afore-mentioned closure element and at least one pair of connecting / anchoring elements.

As mentioned, the implants known from the above-mentioned documents typically have an anchoring element formed of an expandable cage on the atrial side of the closure element. Such a construction may be problematic if the atrium of the heart has a very diverse geometry since in such a case the anchoring cage is not sufficiently adapted to the specific shape of the atrium. Furthermore, this concept brings force on the top atrial wall structure of the heart that comprises the sensitive openings of vessels, particularly the pulmonary veins.

Accordingly, it is an object of the invention to provide an implant having a closure element and at least one anchoring element attached to it that avoids exerting fixation forces to the atrial walls and preferably is non-invasive with respect to fixation. Furthermore, it is an object to provide axial fixation and to allow a self-adjustment of the position of the closure element within the valve annulus, preferably the annulus of the tricuspid or mitral valve. Accordingly, the implant of the invention shall be suitable to be place in the passage between right ventricle and right atrium or left ventricle and left atrium.

Any direction mentioned in this application text is to be understood in relation to the implant correctly implanted in the heart, preferably if the closure element is positioned in the valve annulus, preferably of the tricuspid or mitral valve. An axial direction is to be understood as the direction of an imaginary connecting line connecting the ventricle and the atrium and passing through the valve annulus. This axial direction preferably corresponds to the longitudinal extension of the closure element and preferably also corresponds to the extension of the at least one connecting element that connects the closure element and the at least one anchoring element. A radial direction is understood as perpendicular to the axial direction.

Even though the application of the implant is preferred in regard to humans the implant may be also applied to animals, particularly mammalian animals.

Summary of the invention

The object is solved by a heart implant, particularly being configured to reduce or eliminate a heart valve insufficiency after implantation into the heart, wherein the at least one connecting element is formed of only one strand at least in a part of its extension, particularly being formed of one metal strand. Particularly such strand may be understood as a single filament or as a single linear element, i.e. having no other element being positioned parallel.

According to a first embodiment the implant may have a connecting element and a respective anchoring element being positioned on both sides of the closure element. In this embodiment anchoring takes place at the ventricular side and at the atrial side with respective anchoring elements, each anchoring element being attached to the closure element by means of a respective connecting element.

In a preferred improvement the connecting element on the atrial side may be adapted in length to entirely pass through the atrium, essentially in axial direction, and the atrial anchoring element being adapted to be fixed in a vessel leading into the atrium. Accordingly, at the atrial side the anchoring element is not attached to the atrial myocard but fixed inside a vessel that leads into the atrium. An anchoring element may be formed as a stent in order to be positioned within the vessel and expandable after setting in place.

According to another embodiment solely one connecting element and solely one anchoring element are positioned on one side of the closure element only, particularly on the ventricular side of the closure element, particularly the closure element having no connecting and anchoring element on the other opposite, i.e. atrial side. Accordingly, in this embodiment only one pair of connecting / anchoring element exists and fixation of the implant is performed at the ventricular side only.

Such a construction provides that the closure element is axially fixed within the valve annulus, particularly of the tricuspid or mitral valve but may free float in the valve annulus in radial direction and thus may adapt its position between the

closing leaflets automatically. By fixing the implant only to the ventricle, particular the tip of the ventricle no force at all is transferred to the sensitive atrial walls.

The connecting element formed of just one strand in at least a part of its extension, preferably along the entire extension provides the necessary radial movability, preferably a movability around the point of fixation of the anchoring element in the ventricle. The axial position of the closure element within the annulus is essentially not effected by a radial movement since the radial movement is restricted to the boundary of the valve annulus.

Any axial pulling or pushing force that may be generated in systole or diastole is directed via the connecting element to the anchoring element positioned in the ventricle, preferably the tip of the ventricle.

A pulling force will tend to stretch the one strand of the connecting element. Accordingly, by choosing the necessary length of the connection element the desired axial position of the closure element may be achieved. Furthermore, particularly if no atrial fixation is performed, the connecting element may be chosen to have enough axial stiffness to withstand a pushing force directed from the closure element to the ventricle in order to avoid a displacement of the closure element towards the tip of the ventricle or to avoid a collapse of the connecting element in axial direction and thus a shorting of the distance between closure element and anchoring element.

The following description of ventricular anchoring elements is generally valid for embodiments in which a fixation is only done at the ventricular side and also for embodiment in which fixation is done at the atrial and ventricular side.

In a preferred embodiment the one strand of the connecting element may be made of a material having a solid cross section perpendicular to the axial extension, in particular the cross section (diameter) being between 1 mm and 4 mm. The material may be nitinol or other shape memory material or in general a metal.

According to another embodiment the one strand may be formed of the single hollow tube, preferably having slits / cuts in its lateral surface, preferably several cuts in a direction perpendicular to the axial direction and going entirely through the thickness of the tubular wall, particularly thus forming a slit shaped opening between the outside and inside of the tube. Such cuts / slits provide the flexibility of the tube in radial direction, particularly if the tube itself has not enough flexibility. In such an embodiment the hollow tube may have a diameter between 1 and 4 mm.

Accordingly, such a slit tube is reversibly bendable out of a straight linear extension. The cuts / slits may be arranged in pairs of two cuts / slits positioned on opposite (radial) sides of the tube. Several of such pairs may be equally spaced in axial direction. Neighboring pairs (regarded in axial direction) may have different angular position on the circumference of the regarded tube. Particularly the angular position of axially spaced pairs may change form one pair to another by 90 degrees.

According to preferred embodiments of the invention an anchoring element provides non-invasive fixation to the ventricular wall of the heart. Preferably the anchoring element is adapted to allow ingrowth of the myocard, thus improving the fixation by time.

In a first possible embodiment the anchoring element comprises at least three arms, the lower ends of the arms at the ventricular side being connected and the upper ends on the atrial side being free and not connected. Such an anchoring element may be positioned with the connected lower ends of the arms in the tip of the ventricle, the remaining parts of the arms pointing towards the atrium and being guided along the ventricular myocard. Accordingly, the outer surface of these arms that point to the myocard is contacting the myocard if the anchoring element is correctly positioned in the desired place.

The at least three arms may be equally spaced in circumferential direction, i.e. around the axial extension of the connecting element. Each one of the arms may also have a circumferential extension thus forming a contact surface to be contacted by the myocard. Such circumferential extension may be at the lower end of a respective arm in the range of 5 to 90 degrees, preferably 30 to 60 degrees. The surface of each arm formed this way may be tapered towards the upper end of the respective arm.

The upper ends of the at least three arms, preferably exact three arms may be resilient with respect to their distance from the connecting element that is surrounded by the arms. Preferably the upper ends may be biased by a force that tends to increase separation of the ends from the connecting element. Accordingly, in such a construction the arms exert a fixation force directed essentially in radial direction towards the myocard of the ventricle. The separating force may be exerted by spring elements near or in the connection area, where the lower ends of the arms are connected or may be generated by intrinsic force in the material of the arms

In such an embodiment the connecting element may be connected to the anchoring element below the upper ends of the arms, preferably at the lower ends, most preferred, where the lower ends of neighbouring arms are connected. The connecting area of the at least three arms may form a common area for all arms being opposite to or connecting the tip of the ventricle, the at least three arms emerging upwards (towards the closure element) from this area.

This embodiment provides that a pulling force exerted by the closure element to the anchoring element via the connecting element is introduced into the anchoring element near or at the lowermost position of the anchoring element, thus effecting a furthermore separation of the upper ends of the arms if the closure elements pulls. This improves the fixation of the anchoring element and prevents axial displacement of the closure element towards the atrium if the closure element pulls in the different phases of heart contraction.

In a preferred embodiment the anchoring element of this kind may comprise a wire, preferably being separate to the connection element, the wire forming the rims of the at least three arms by its course and connecting the at least three arms by transiting at the respective lower/distal ends of the arms from one arm to a neighbouring arm. Such a wire may form a frame of the anchoring element.

In order to provide spring elements already mentioned before, the wire may be formed as a spring having at least one winding, the spring being positioned in the respective connecting area between two arms, i.e. where the wire transits from one arm to the other, the spring furthermore generating a force for separating the upper ends of neighbouring arms.

In a furthermore preferred embodiment the wire forms a frame supporting a net, particularly a wire net, preferably the wire being spanned by a net. Such a net has meshes that allow ingrowth of myocard, thus promoting a long term fixation. According to another embodiment and particularly in addition to the afore-mentioned one a respective free upper / proximal end of an arm may be covered by a sleeve, particularly a sleeve made of a textile or metal mesh / net. Also this sleeve preferably promotes tissue ingrowth.

Particularly in order to promote fixation during a time prior to ingrowth the respective sleeve may comprise hooks or projections on its outer surface, particularly the hooks /projections pointing to the closure element. Such hooks / projections may provide barbs in regard to an axial pulling force and prevent slipping of the anchoring element out of the ventricular tip. The improved surface connection between the upper ends of the arms and the myocard furthermore by means of such hooks / projections provide that a pulling force exerted to the anchoring element results in a further separation of the upper ends from the connecting element and thus an even further fixation that counteracts the pulling force.

According to another embodiment the anchoring element may comprise a sleeve / stent, being tapered in its cross section towards the ventricular tip, the surface of the sleeve / stent being formed of a mesh, particularly an expanded or expandable mesh, preferably each mesh having two opposite tips being spaced in the direction of the extension of the connection element.

Such a stent-shaped sleeve has a radial resilience that provides a force towards the myocard that promotes fixation. Also in this embodiment it is preferred that the connection element is attached to the sleeve in an area below the upper end of the sleeve, preferably at the lowermost end of the sleeve. In this embodiment any pulling force exerted from the closure element to the sleeve is introduced into the sleeve in or near its lower end and thus tends to compress the sleeve in its axial length upon pulling on it in view of the fact that the area of the sleeve above the attachment area is fixed to the myocard. A compression of such a sleeve in length automatically broadens the diameter of the sleeve and thus improves the fixation to the myocard.

In another embodiment the anchoring element may comprise a wire being formed to a spiral spring, the spiral spring having a slope and expansion in cross section towards the closure element. Accordingly, such spiral is tapered towards the tip of the ventricle and preferably may be adapted in shape to fit to the tip area of the ventricle.

Particularly in the top area of such a spiral the wire may form a circular-shaped loop., particularly a closed, circular-shaped loop. An additional improvement may provide wires that extend from this top area / top loop towards the atrium. Such wires may connect the ventricular myocard just below the valve annulus.

Also in this embodiment the connecting element may be attached to the spiral anchoring element below the upper end / top loop of the anchoring element and preferably at the lowermost area, thus effecting a shortening in axial length upon exerting a pulling force to it. Shortening the axial length of a spirally wound wire

that has a helical slope broadens the diameter of the anchoring element in radial direction and as such promotes further fixation when pulling on it.

In general, and irrespective of the aforementioned constructions an anchoring element may be expandable in at least one direction crosswise, preferably perpendicular to the extension of the strand, preferably in the axial direction, by exerting a pulling force from the closure element to the anchoring element via the connection element. Such a construction always leads to a broadening of the cross section of the anchoring element in radial direction if a pulling force is exerted to it and consequently improves the fixation.

Preferably the anchoring element is compressible in length in a first direction and automatically expandable in width in a second direction if compressed in the first direction, the first direction being the direction of the pulling force and the second direction being crosswise, preferably perpendicular to the first direction. The first direction is in such a case the axial extension of the connecting element between closure element and anchoring element. Consequently, pulling on the anchoring element expands the anchoring element in (all) radial directions.

In order to facilitate a compression of the anchoring element in length the connection element is preferably attached to the anchoring element below the upper end of the anchoring element, preferably at the lower end. In other words the connecting element is entering the inside of the anchoring element at its top and passing through the anchoring element until it is attached to it near or at the lowermost end of the anchoring element.

In order to promote an expansion (in radial direction) of the anchoring element upon exerting a pulling force to it the implant may comprises a crank mechanism, particularly being positioned between the connection element, particularly the lower end of the connecting element and the anchoring element, the crank mechanism being configured to split the pulling force being exerted from the

closure element to the connection element into a force component that expands the cross section of the anchoring element.

To facilitate this the construction may provide, that the connection element is split into several (at least three) branches at its end pointing towards the anchoring element, the branches being connected to the anchoring element. Regarded in a direction between closure element and anchoring element the end area where the connection element is split into branches has a bigger distance to the closure element than the point where the ends of the branches are connected to the anchoring element. Accordingly, the branches extend upwards towards the atrium and their upper ends will separate from each other if a force pulls a the connecting element. This separation exerts an expanding force to the anchoring element, this the upper ends of the branches are connected to the inside of the anchoring element, preferably near or at the top of the anchoring element.

In another embodiment the branches at the lower end of the connecting element may also be connected to the winding of the respective aforementioned spring in a position opposite to the arm. This embodiment explicitly relates to the anchoring element comprising at least three arms as previously explained. Here the branches extend downwards towards the spring shaped winding. Due to the fact that each lower end of a branch is attached to the winding in a position opposite the respective arm a pivoting point is generated around that the respective arm pivots if a pulling force is exerted. The pivoting point is preferably positioned within the area encircled by the wound wire. Consequently, a pulling force urges the lower ends of the arms upwards and the upper ends of the arms downwards, simultaneously enhancing their separation from each other and their separation from the connecting element, thus enhancing the radial cross section of the anchoring and fixation to the myocard.

In general, in an embodiment comprising an anchoring element having at least three arms the number of branches at the lower end of the closure element may equal the number of arms.

Description of the figures

Figure 1: illustrates a first embodiment of the invention having a closure element connected via a connecting element to the anchoring element, the anchoring element having at least three, namely four arms

Figure 2: illustrates a second embodiment of the invention comprising an anchoring element with three arms

Figure 3: illustrates a third embodiment of the invention having an anchoring element with three spring loaded arms

Figure 4: illustrates a forth embodiment having a crank mechanism to separate the arms of an anchoring element upon pulling on it

Figure 5: illustrates a fifth embodiment having a stent shaped tapered anchoring element

Figure 6: illustrates the mechanism of expanding the cross section of the anchoring element upon pulling

Figure 7: illustrates an implant having a spiral shaped anchoring element

Figure 8: illustrates an embodiment having anchoring elements on atrial and ventricular side.

Detailed description of the figures

Figure 1 illustrates a first embodiment in which the implant comprises a closure element 1, an anchoring element 2 and a connecting element 3, that connects closure and anchoring element 1,2.

The closure element 1 is configured to be positioned in the valve annulus of a valve of the heart (not shown), preferably the tricuspid valve. The closure element 1 comprises an inflatable sheath / membrane 1a, that may be essentially hose shaped and that is fluid tight connected at its respective lower and upper end to an

internal structure, preferably a tube shaped attachment element (not shown) that extends between the upper tip 1b and lower tip 1c of the closure element 1. Accordingly, the sheath 1a encircles a hollow space surrounding the internal structure. This space is inflatable by a fluid, preferably a liquid. The hollow space may be circular in cross section or may form the shape of a star having three armes.

After inflation and positioning the closure element 1 within the valve annulus the valve leaflets may coapt the outer surface of the closure element and consequently any remaining gap between the leaflets, that would exist without the closure element, is at least reduced, preferably eliminated. Blood regurgitation may be avoided this way. The sheath of the closure element may be furthermore at least partially covered, for example with a textile to promote endothelialisation.

The connecting element 3 may be simply formed of a single wire strand having a solid cross section, the upper end of this element 3 being attached to the closure element, preferably to the internal structure of it and the lower end being attached to the anchoring element 2, preferably after splitting into several branches 3a at the lower end.

According to the encircled detail D the one strand 3 may also be formed of a slit tube. The slits 3b are passing through the lateral surface of the tube and may be arranged in opposite pairs, axially neighboured pairs may have different angular orientation regarded in the circumferential direction. Here the angular difference is 90 degrees from one pair to the next.

The aforementioned description of a preferred closure element and connecting element is preferably applicable also to all other embodiments shown in the figures.

The anchoring element 2 comprises at least three arms 2a, in this case four arms 2a that are connected at their lower ends and that extend upwards, i.e. towards

the closure element 1. Along their extension the outer surface of the arms 2a, i.e. the surface pointing to the myocard is intended to contact the myocard after placing the implant into the correct position thus providing a fixation of the anchoring element to the myocard primarily by means of friction.

In order to provide such friction the arms 2a exert a force to the myocard, generated by the arms 2a that tend to expand, i.e. to separate from each other. The force is essentially generated by a resilient flexibility of the arms 2a towards the connecting element 3. Accordingly, the anchoring element may be compressed by the myocard if it is pushed towards the tip of the ventricle and tends to expand afterwards. Here the wall of the ventricle is depicted by the dashed line 4. Just for better visibility in the Figure 1 the dashed line 4 has a small distance to the anchoring element 2 that does not really exist.

The anchoring element 2 and the total of four arms 2a is formed of preferably a single wire 5, the course of the wire 5 defining the rim of the arms 2a and the rim of the entire anchoring element. Accordingly, the wire 5 forms a frame that is spanned by a mesh, preferably a mesh made of metal, for example nitinol or made of a textile, preferably a polymeric textile, most preferred of a polymer known under the tradename DACRON.

The rim of each arm 2a furthermore comprises hooks or projections 6 pointing upwards, i.e. towards the closure element 1, thus furthermore enhancing fixation of the anchoring element in the tip of the ventricle.

The force generated by compressing the arms and the hooks / projections 6 temporarily provide a sufficient fixation until ingrowth of myocard tissue into the mesh has taken place.

The connecting element is split at its lower end into a number of branches 3a, each of the branches being attached to the anchoring element. The number of branches corresponds preferably to the number of arms. The branches are

furthermore preferred attached to the anchoring element 2 in the transition area, where the wire 5 transits from one arm to the next neighbouring arm.

In this embodiment

Figure 2 shows a second embodiment of the implant. The entire description of figure 1 also applies to figure 2, but here the anchoring element has just three arms. Furthermore, the wire 5 that defines the arms 2a by its course forms ondulations, corrugations or in general a wavy structure 2b along the sides of the respective arms. Such structure enhances the surface contact and may replace the hooks / projections 6 of Figure 1. The wavy structure 2b extend from the lower end of the respective arm towards the upper end. At the upper end the wire 5 transits to the other side of the arms in preferably just one loop, thus making a 180 degree turn.

Figure 3 illustrates another third embodiment. The description of figure 1 also applies to figure 3, but just three arms 2a are provided in the anchoring element 2. In addition, the wire 5 forms a spring 7 having at least one winding, the spring 7 being positioned in the area in which the wire 5 transits from one arms to the next neighbouring arm at the respective lower ends of the arms.

Each respective spring 7 may provide a biasing force that tends to separate the upper ends of the arms, particularly thus urging the arms towards the myocard.

In this specific embodiment the lower ends of the branches 3a are attached to a respective spring in a position of the wire winding that is opposite to the emerging arm that originates form the respective spring, i.e. the attachment position is pointing to the inner center of the anchoring element.

This provides and expansion effect of the anchoring element upon pulling on the connection element and thus enhances the fixation by such force. Such forces may result from the different heart phases (diastole / systole). Accordingly, any

force that tends to pull the anchoring element out of the tip of the ventricle is counteracted by improving the fixation due to expanding the anchoring element by means of the same force. Expansion originates from the fact that a pivot point is generated that is positioned preferably within the winding of the spring if the force pulls on the connecting element 3.

In addition, the upper ends of the arms 2a may be covered by sleeves 8, these sleeves preferably formed of a meshed metal (for example nitinol) or meshed textile. Also these sleeve may carry hooks or projections 6, pointing upwards, i.e. towards the closure element 1.

Figure 4 illustrate a schematic view of a crank mechanism providing the expansion of the anchoring element upon pulling on the connection element 3. The anchoring element comprises 3 arms, but may have more. The crank mechanism is established by splitting the lower end of the connecting element 3 into a number of branches 3a corresponding to the number of arms 2a.

The ends of the branches being near / connected to the connecting element 3 in point P1 are positioned below the attachment points P2, P3 P4 of each respective branch 3a. These attachment points are preferably near or at the upper ends of the arms 2a. This effects that a force pulling point P1 upwards separates the points P2, P3 and P4 from the connection element 3 and thus expands the cross section (regarded radial) of the anchoring element. Consequently, a pulling force urges the upper ends of the arms 2a towards the myocard thus enhancing the fixation.

Also in this embodiment the anchoring element may have all further details described in figure 1,2 and 3.

Figure 5 illustrates a totally different anchoring element, but the implant may have the same construction of the closure element and connecting element 3 as described before in regard to the other figures. Accordingly, the closure element 1

is omitted here. The anchoring element comprises a sleeve being tapered towards the tip of the ventricle, i.e. towards the lower end. The sleeve hasa stent shaped lateral surface, the rhombic meshes having tips 2c lying in the axial direction of the connecting element 3.

Fixation is provided again by means of friction generated by compressing the stent shaped sleeve when it is pushed into the tip of the ventricle. Also here myocard tissue may grow into the stent openings by time.

The lower end of the connecting element 3 is attached to the anchoring element 2 below the upper end, preferably at the lower end of the sleeve. This construction also provides an expansion effect upon pulling in a direction towards the atrium along the connecting element 3. The principle of operation is depicted in figure 6.

In case that such a rhombic mesh is compressed in axial direction A the compression in length automatically results in an enlarged width, or diameter if a sleeve is regarded. The compression is effected be the pulling force introduced into the sleeve at its lower end, thus urging the lower end upwards. Since the areas of the sleeve above the lower end are held in place by friction the axial length is reduced by the pulling force and the width / diameter enlarged.

Also here the pulling force that tends to pull the anchoring element out of the tip of the ventricle generates its own countermeasure and enhances friction by expanding the cross section (regarded radial) of the anchoring element.

Figure 7 depicts an embodiment in which the anchoring element is formed of a single wire 5 being wound to form a sloped spiral spring having windings around the axial extension, i.e. around the connecting element 3. The spiral spring is tapered towards the tip of the ventricle and may be adapted in shape to perfectly fit into this tip.

The connecting element 3 again may be attached to the anchoring element at the lower end, thus urging this end upwards upon exertion of a pulling force. Also a spiral spring tends to enlarge in diameter if the axial length is reduced and accordingly the fixation is improved if a force pulls the lower end of the anchoring element upwards.

Additional anchoring wires 9 may be attached to the spiral spring, preferably to the last winding at the top end, these wires 9 extending upwards towards the closure element. Such wires will be guide along the wall of the myocard ending below the valve annulus and will furthermore improve fixation.

One of the wires 9 may originate from the wire 5 wound to form the spiral sloped spring.

In figure 8 another embodiment is shown that corresponds in its construction at the ventricular side to the embodiment of figure 1. At the atrial side, i.e. the top of the closure element 1, the closure element is additionally connected by another connecting element 3′ to another anchoring element 2′. The anchoring element here is formed as a meshed sleeve, preferably as a stent. Such an anchoring element is intended to be placed in a vessel 12 leading into the atrium 11. As can be seen the connecting element 3′ has a bent section to adapt the axial linear extension of the anchoring element to the axial direction of the vessel 12. Vessel 12 and atrium are depicted by dashed lines only.

All the described anchoring elements, and anchoring element according to the invention in general may also have an anchoring projection 10 being positioned at the lowermost end of the anchoring element 2 and projecting towards the tip of the ventricle. Such projection 10 may be intended to puncture the tip of the ventricle, particularly in cases in which the invention does not make use of the described expansion effect upon pulling the anchoring element. Also in case in which the invention makes use of the expansion effect the use of such projection may not be

counterproductive since the punctured myocard tissue may move in the direction of the pulling force.

After puncturing the tip of the ventricle the projection 10 will hold the anchoring element at least temporarily in place until ingrowth of tissue into the anchoring element has taken place.

Claims

1. Heart implant comprising
    a. a closure element (1), being positionable in the annulus of a valve of the heart, particularly for closing or at least reducing a remaining gap between the closing leaflets and
    b. at least one anchoring element (2, 2´), particularly being resiliently compressible and attachable to the tip of the ventricle (4), particularly due to compression by the myocard, preferably by form-fit and/or force-fit and
    c. at least one connecting element (3, 3´), connecting the closure element (1) and a respective anchoring element (2, 2´) to each other

    wherein

    d. the at least one connecting element (3, 3´) being formed of only one strand at least in a part of its extension, particularly being formed of one metal strand.

2. Heart implant according to claim 1, **wherein** a respective connecting element (3, 3´) and a respective anchoring element (3, 3`) being positioned on both sides of the closure element (1), preferably the connecting element (3´) on the atrial side being adapted in length to entirely pass through the atrium (11) and the atrial anchoring element (3´) being adapted to be fixed in a vessel (12) leading into the atrium (11).

3. Heart implant according to claim 1, **wherein** solely one connecting element (3) and solely one anchoring element (2) being positioned on one side of the closure element (1) only, particularly on the ventricular side of the closure element (1), particularly the closure element (1) having no connecting and anchoring element on the other opposite side.

4. Heart implant according to anyone of the preceding claims, **wherein** the anchoring element (2), particularly the one of the ventricular side, comprises at least three arms (2a), the lower ends of the arms (2a) at the ventricular/lower

side being connected and the upper ends on the atrial side being free and not connected, particularly the connection element (3) being connected to the anchoring element (2) below the upper ends, preferably near or at the lower ends of the arm (2a).

5. Heart implant according to claim 4, **wherein** the anchoring element (2) comprises a wire (5), preferably being separate to the connection element (3), the wire (5) forming the rims of the at least three arms (2a) by its course and connecting the at least three arms (2a) by transiting at the respective lower/distal ends of the arms from one arm (2a) to a neighbouring arm (2a).

6. Heart implant according to claim 4 or 5, **wherein** the wire (5) is formed as a spring (7) having at least one winding, the spring (7) being positioned in the respective connecting area between two arms (2a), the spring (7) furthermore generating a force for separating the upper ends of neighbouring arms (2a).

7. Heart implant according to claim 5 or 6, **wherein** the wire (5) forms a frame supporting a net, particularly a wire net, preferably the wire (5) being spanned by a net.

8. Heart implant according to anyone of the preceding claims 4 to 7, **wherein** a respective free upper / proximal end of an arm (2a) is covered by a sleeve (8), particularly a sleeve (8) made of a textile or metal mesh / net.

9. Heart implant according to claim 8, **wherein** the sleeve (8) comprises hooks(6) or projections (6) on its outer surface, particularly the hooks /projections (6) pointing to the closure element (1).

10. Heart implant according to anyone of the preceding claims 1 to 3, **wherein** the anchoring element (2), particularly the one on the ventricular side, comprises a sleeve / stent, being tapered in its cross section towards the ventricular tip, the surface of the sleeve / stent being formed of a mesh, particularly an expanded mesh, preferably each mesh having two opposite tips (2c) being spaced in the direction of the extension of the connection element (3).

11. Heart implant according to anyone of the preceding claims 1 to 3, **wherein** the anchoring element (2) comprises a wire (5) being formed to a spiral spring, the

spiral spring having an axial slope and expansion in cross section towards the closure element (1).

12. Heart implant according to anyone of the preceding claims, **wherein** the anchoring element (2) is expandable in at least one direction crosswise, preferably perpendicular to the extension of the strand (3) by exerting a pulling force from the closure element (1) to the anchoring element (2) via the connection element (3).

13. Heart implant according to claim 12, **wherein** the anchoring element (2) is compressible in length in a first direction and automatically expandable in width in a second direction if compressed in the first direction, the first direction being the direction of the pulling force and the second direction being crosswise, preferably perpendicular to the first direction.

14. Heart implant according to claim 12 or 13, **wherein** the anchoring element (2) comprises an upper end, particularly on the atrial side and a lower end, particularly on the ventricular side, the connection element (3) being attached to the anchoring element (2) below the upper end, preferably at or near the lower end.

15. Heart implant according to anyone of the preceding claims, **wherein** it comprises a crank mechanism (3a), particularly being positioned between the connection element (3) and the anchoring element (2), the crank mechanism (3a) being configured to split the pulling force being exerted from the closure element (1) to the connection element (3) into a force component that expands the cross section of the anchoring element (2).

16. Heart implant according to anyone of the preceding claims, **wherein** the connection element (3) is split into several branches (3a) at its end pointing towards the anchoring element (2), particularly for forming the crank mechanism of claim 15, the branches (3a) being connected to the anchoring element (2).

17. Heart implant according to claim 15 and 16, **wherein** regarded in a direction between closure element (1) and anchoring element (2) the end area where the connection element (3) is split into branches (3a) has a bigger distance to

the closure element (1) than the point where the ends of the branches (3a) are connected to the anchoring element (2).

18. Heart implant according to anyone of the preceding claims 6 and 16, **wherein** each branch (3a) is connected to the winding of the respective spring in a position opposite to the arm.

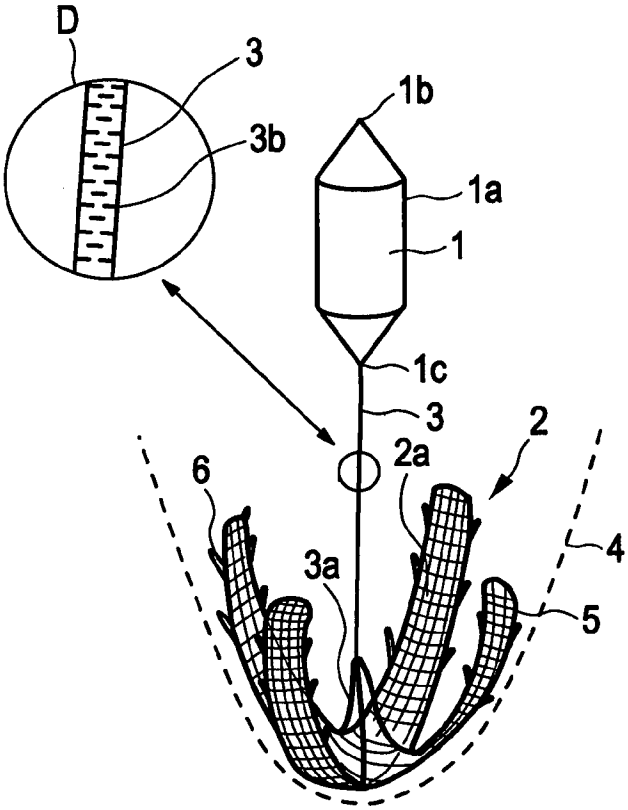


Fig. 1

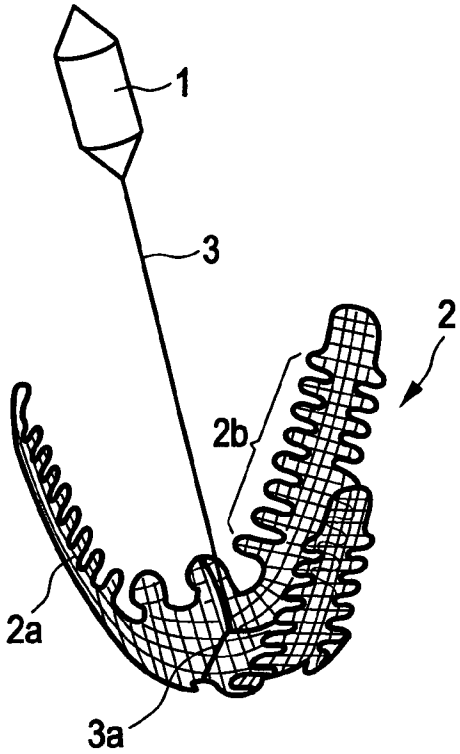


Fig. 2

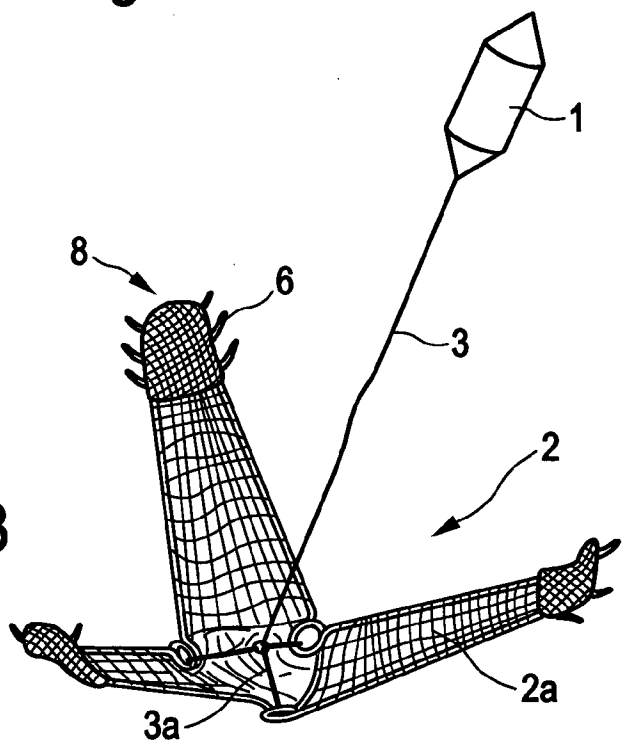


Fig. 3

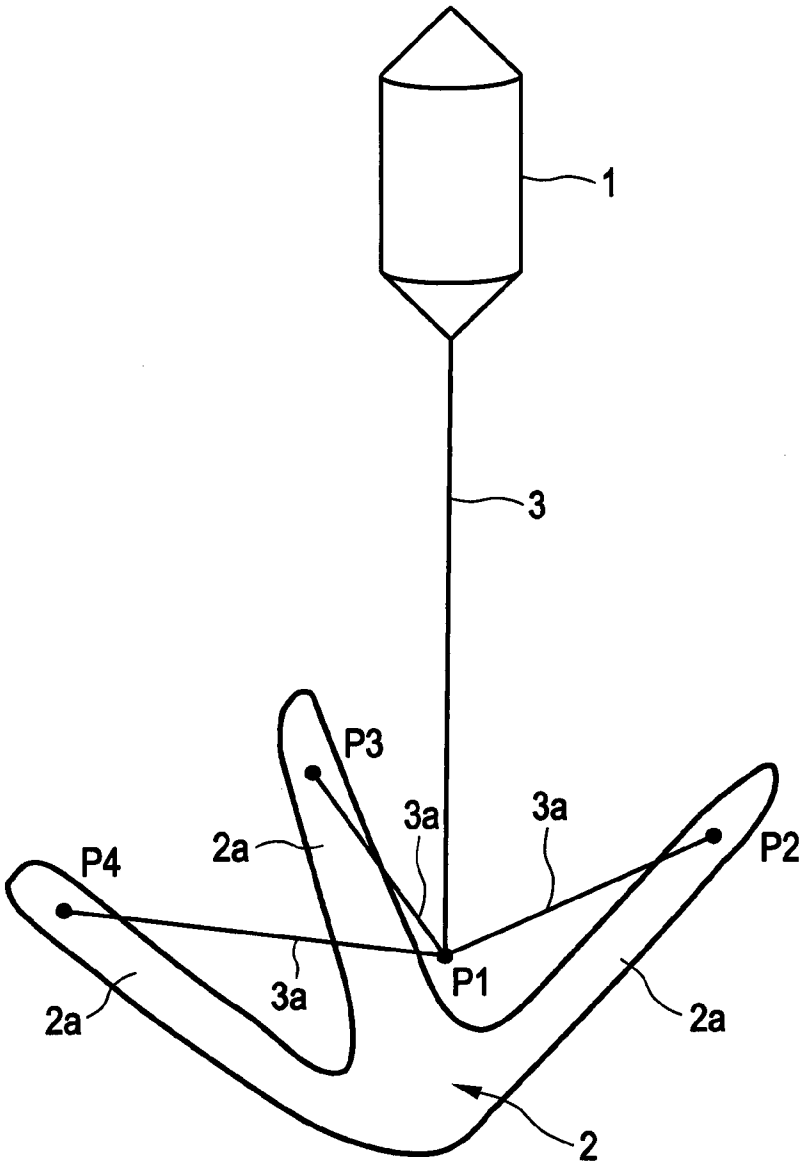


Fig. 4

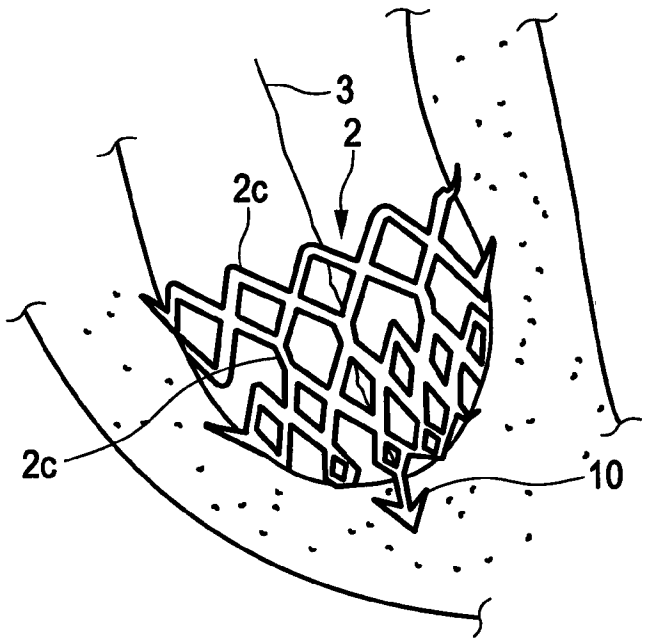


Fig. 5

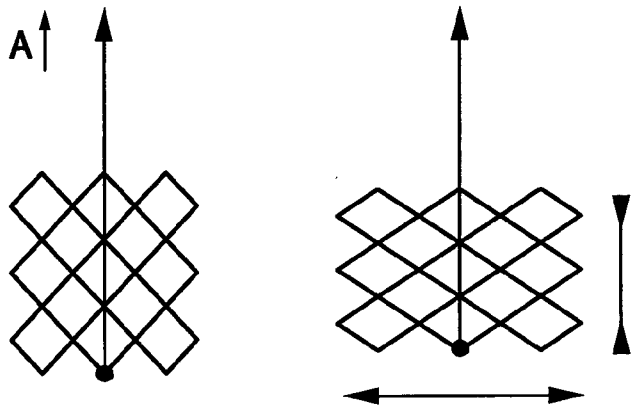
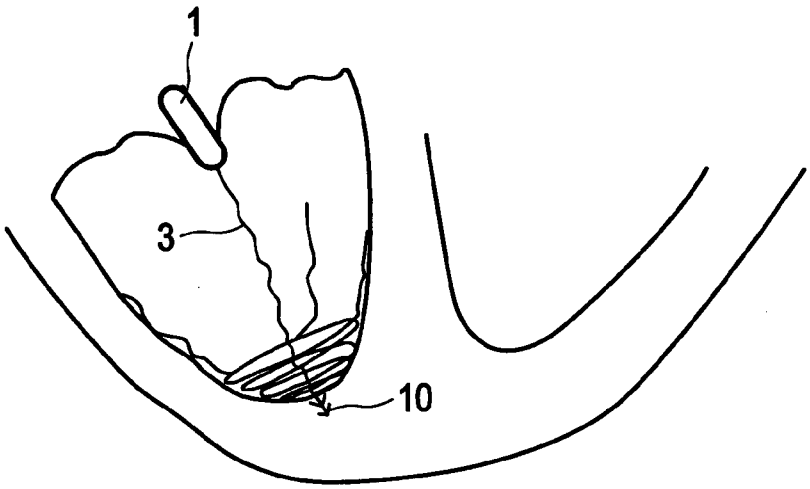


Fig. 6



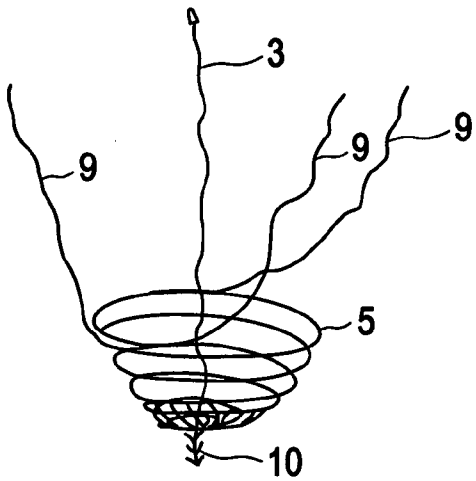


Fig. 7

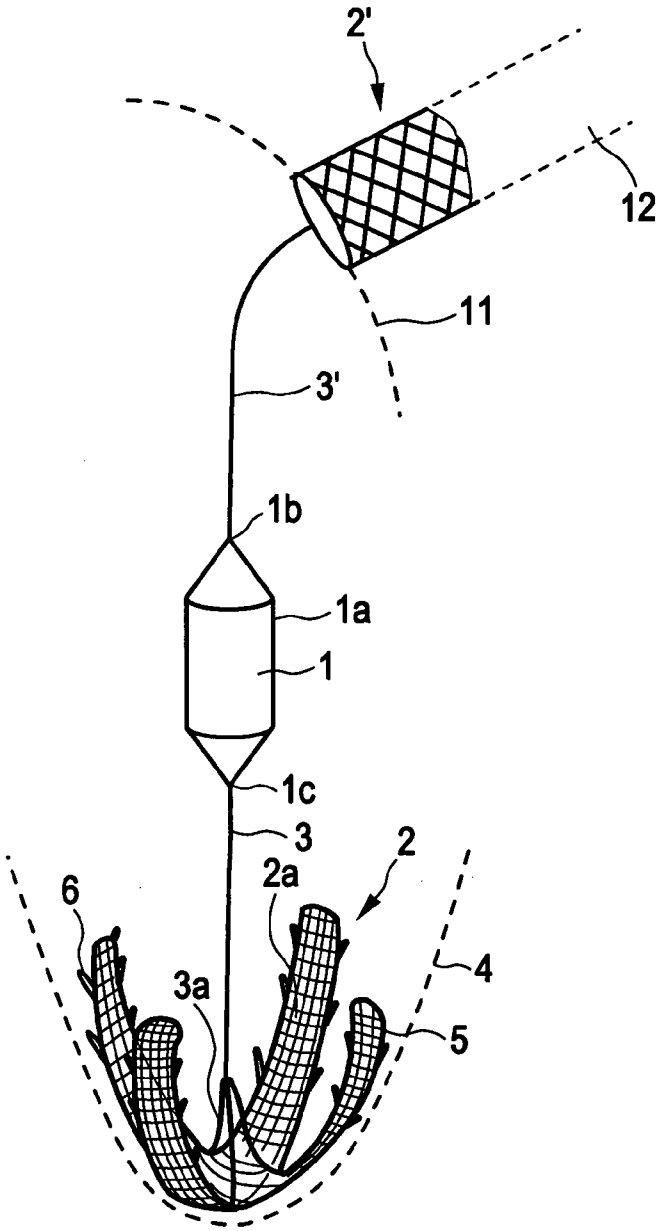


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/001948

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/325110 A1 (KHALIL VIVIAN [US] ET AL) 5 December 2013 (2013-12-05) paragraphs [0095] - [0099]; figures 21A,21B,23 paragraphs [0111] - [0114]; figure 34	1-18
X	WO 2009/072114 A2 (MOR RESEARCH APPLIC LTD [IL]; ORLOV BORIS [IL]) 11 June 2009 (2009-06-11) page 45, line 21 - page 46, line 24; figures 10A,10B	1-18
A	EP 2 478 868 A1 (PROVOST FELLOWS FOUNDATION SCHOLARS AND THE OTHER MEMBERS OF BOARD OF) 25 July 2012 (2012-07-25) paragraphs [0115] - [0121]; figures 18-21B paragraphs [0122] - [0126]; figure 22D paragraphs [0130], [0131]; figure 25	1,4-10

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 June 2017	07/07/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Chevalot, Nicolas

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/001948

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/001948

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