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(54) Benævnelse: **FØRINGSTRÅD TIL MINIMALT INVASIVE INDGREB OG FREMGANGSMÅDE TIL FREMSTILLING AF EN FØRINGSTRÅD**

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Guidewire for minimally invasive interventions and method for producing a guidewire

The invention relates to a guidewire according to the preamble of claim 1 and to a method for producing a guidewire according to the preamble of claim 11.

EP 1 348 461 B1 discloses a guidewire in which an inner shaft of the guidewire made of a metal or of a plastic with a relatively high degree of stiffness is surrounded by a plastic layer. At the distal wire endpiece of the guidewire, the core is tapered conically in order to obtain a greater degree of flexibility of the wire endpiece.

US 2014/0121648 A1 discloses a guidewire with a tapering at the distal end of a core made of a composite material, wherein the tapering is intended to increase the flexibility of the wire endpiece. The shaping of the core tip is carried out by grinding or cutting.

US 2004/0167438 A1 likewise discloses a guidewire with a tapering at the distal end of a core, wherein the tapering of the core can be provided in several steps. Here too, the shape of the core tip is intended to obtain desired mechanical properties, e.g. as regards the flexibility of the wire endpiece.

EP 2 098 262 A1 discloses a catheter guidewire with a core, in the basic material of which twisted fibers, preferably glass fibers, are embedded, and of which the distal wire endpiece can have a tapering shape generated by grinding.

DE 10 2005 022 688 A1 likewise discloses a guidewire with a core tapered at the distal end.

Depending on the production method for the core of a guidewire, a reduction of the diameter of the core is complicated, regardless of whether it is provided conically or in steps. In particular, grinding methods are time-consuming and costly.

EP 2 548 604 A1 discloses a guidewire and method of the types mentioned at the outset. The guidewire has a core which also extends into a distal wire endpiece and which has randomly distributed non-metallic fibers or fiber segments and a resin filling the spaces between the fibers. In one illustrative embodiment, the core has radially oriented incisions on its circumference, which are intended to make the distal wire endpiece more flexible. The incisions can be generated by cutting or etching. The depth or width of the incisions or the distance between the incisions can be adapted according to the desired flexibility.

The technical problem addressed by the invention is to make available a guidewire having a higher degree of flexibility in a wire endpiece, and also a method for production of said guidewire, wherein the distal wire endpiece of the guidewire has an alternative structure to the prior art, and one that is easier to produce.

In the case a guidewire of the type mentioned at the outset, the technical problem is solved by the characterizing features of claim 1. In the case of a method of the type mentioned at the outset, the technical problem is solved by the features of claim 11. Advantageous embodiments of the invention are set out in the dependent claims.

Accordingly, it is proposed that an inner shaft, at least in a distal wire endpiece, has a multiplicity of weakened sites which are generated by mechanical interventions, namely by buckling loads, bending loads and/or breaking loads.

The weakened sites reduce the flexural stiffness of the inner shaft and thus of the distal wire endpiece, that is to say its flexural modulus is reduced. With the reduced flexural stiffness, the flexibility of the guidewire increases, as does its ability to follow curved trajectories.

The breaking, buckling or bending acts on the entire cross section of the core, without causing complete separation of the core. In particular, the fine fibers of the fiber composite material are at least in part not separated by the bending, buckling or breaking movement and, despite the weakening, cause the core to hold together. The breaking, buckling or bending for introducing the weakened sites can additionally save considerably on costs and time compared to the incising or etching of the weakened sites into the inner shaft, as is known from the prior art.

The number of weakened sites depends in particular on the length of the distal wire endpiece. Thus, the distal wire endpiece can measure 10 mm to 50 mm, for example. Shorter or longer distal wire endpieces are likewise possible. The weakened sites are preferably at regular distances from each other in the axial direction of the guidewire.

The distances between the weakened sites are preferably in the millimeter range. Preferably, a distal wire endpiece can have weakened sites over a length of 30 to 60 mm, preferably 40 mm, which weakened sites are preferably spaced apart from each other by approximately 1 mm to 3 mm, e.g. 2 mm +/- 0.5 mm.

For the production of the distal wire endpiece, a method is proposed in which the inner shaft provided at least in the distal wire endpiece is provided, by mechanical intervention, with a multiplicity of weakened sites, wherein the weakened sites are generated by buckling loads, bending loads and/or breaking loads.

The method according to the invention can be carried out in particular such that, for the mechanical interventions, the inner shaft is placed over at least one mechanical edge and is subjected to a force acting transversely with respect to the longitudinal axis of the unweakened wire endpiece. For example, the inner shaft can be placed over the mechanical edge, and the force can act on a part of the inner shaft protruding beyond the edge. To generate the successive weakened sites, the inner shaft merely needs to be advanced by a suitable distance, e.g. by a distance length of 1 mm to 3 mm. The force can be the weight force of a mass fixed to the inner shaft, e.g. by clamping.

The method according to the invention can be such that the mechanical interventions are carried out in at least two different rotation angle positions of the inner shaft. The rotation angle position relates to a rotation about the longitudinal axis of the inner shaft. For example, the inner shaft can be made weaker at a multiplicity of weakened sites without rotating it about its longitudinal axis. Thereafter, the inner shaft can be rotated about the longitudinal axis by a defined rotation angle, e.g. of 90° or in a range of 80° to 100°, relative to the acting force, in order thereafter to introduce further weakened sites in the region already weakened in the first pass or to further weaken already existing weakened sites. In this way, it is ensured that the weakening the flexural stiffness of the inner shaft in the wire end region is reduced not only in one bending direction.

The mechanical intervention is preferably carried out directly on the inner shaft, i.e. without enveloping the inner shaft with a protective layer. However, a protective layer may also already be applied.

In the weakening process, material can break out from the inner shaft. However, apart from said breakouts of generally small material particles, the diameter of the inner shaft preferably remains substantially constant in the weakened region at least on average.

The inner shaft of the guidewire preferably has a first fiber composite material. The fibers of the fiber composite material, which are preferably enveloped by a plastic matrix material and/or adhesively bonded to one another, confer suitable stability on the shaft. In particular, in the mechanical weakening of the inner shaft, the fibers can give the inner shaft a sufficient hold, such that no complete break occurs, i.e. no complete separation of the inner shaft.

Alternatively, in the mechanical weakening, the inner shaft can however also be prevented from coming apart by means of the at least one protective layer enveloping the inner shaft.

With the method according to the invention, it can be advantageous to configure the inner shaft such that it has a core and at least one envelope layer surrounding the core. The core can have or consist of the first fiber composite material. Moreover, the at least one envelope layer or at least one of the envelope layers can advantageously have a second fiber composite material, wherein the second fiber composite material is preferably different than the first fiber composite material.

With the combination of core and envelope layer, desired mechanical properties of the inner shaft can be set. Thus, the two fiber composite materials can be the same as regards their materials, or they can differ in terms of the fiber material and/or in terms of the matrix material adhesively connecting the fibers to one another or enveloping them. The matrix material can be a resin, for example synthetic resin, in particular epoxy resin, or some other plastic.

The fibers of the envelope layer, at least a subset of said fibers, are preferably guided helically about the circumference of the core. Helical guiding of the fibers signifies that they do not extend continuously in the axial direction but instead surround the core in the shape of a helix. The helical guiding of the fibers ensures an increased torsional stiffness in particular outside the region provided with the weakened sites, i.e. ensures improved transmission of torques. Outside the region provided with weakened sites, the flexural stiffness can be defined substantially by the core with its fibers adhesively bonded to one another by the matrix material of the core.

In the distal wire endpiece, by contrast, the flexural stiffness can be reduced to a desired extent by the introduction of the weakened sites, wherein the degree of reduction of the flexural stiffness can be influenced by the given density of the weakened sites in the axial direction.

Preferably, at least a subset of the fibers are guided in at least two different helical orientations about the circumference of the core, such that the torsional stiffness is increased for both circumferential directions. The fibers of the envelope layer are encased by a matrix material and/or adhesively bonded to one another by means of the matrix material. The matrix material can be a resin, for example synthetic resin, or some other plastic. The matrix material can be the same matrix material as that of the core or can be another matrix material.

In the core, at least a plurality of the fibers are preferably oriented in the axial direction of the guidewire.

For the fibers of the inner shaft, it is possible, for example, to use non-conductive fiber materials, e.g. made of plastic and/or inorganic materials. Non-conductive materials are particularly advantageously used in MRT. Suitable plastics for the fibers may be, for example: glass, nylon (polyamide), polyester, PEEK, polyacryl, ultra-high molecular weight polyethylene (UHMWPE), liquid crystal polymers (LCP), aramids. Polymer optical fibers (POF) can also be used. In the case of a structure of the inner shaft composed of core and envelope layer(s), these fiber materials can be used both for the core and also for the at least one envelope layer. Preferably, glass fibers are used in the core and an aramid in the envelope layer of the inner shaft.

The guidewire according to the invention can preferably be configured, by the method according to the invention, such that at least one marking element serving for marking purposes in an imaging method is applied to the outer circumference of the inner shaft.

In this way, the profile of the guidewire can be monitored during use. The at least one marking element or at least one of the marking elements is preferably an MRT marking element which is suitable for marking in magnetic resonance tomography and which has at least one marking agent which, during use in a magnetic resonance tomography (MRT) apparatus, is visible on account of its interaction with the electromagnetic alternating fields of the MRT. The marking agent is preferably one that generates a positive contrast, more preferably one that reduces the T1 relaxation time and/or the T2 relaxation time. These include, for example, the salts of the lanthanides GD^{3+}, Ho^{3+}, Dy^{3+}, Eu^{3+}, the complexes of some transition metals, e.g. Fe^{3+}, Mn^{2+}, Mn^{3+} and Co^{3+}. Such agents permit visibility of the medical instrument in the current MRT methods without special measures. Further agents, including those that generate positive or negative contrasts in other imaging methods, e.g. MPI (magnetic particle imaging) or in methods using X-rays, can likewise be provided.

At least one active marking element can also be used, alone or in addition to passive marking elements. Active means that the marking element not only passively influences an electrical or magnetic field, and therefore the imaging, but actively emits an electrical and/or magnetic field, in particular an alternating field. For this purpose, the active marking element can have, for example, a coil, in particular a high-frequency coil (HF coil). The active marking element can be supplied with voltage through fine conducting wires extending through the guidewire. However, for operation in MRT, it is advantageous to dispense with such wires. The active marking element can also be powered by means of induction from the alternating field of the magnetic resonance tomography apparatus or another external source of an alternating field.

The guidewire according to the invention can also be configured such that the at least one marking element is applied externally to the envelope layer. The marking element can be applied, for example, in a printing method, i.e. by being printed on. This procedure can also be provided in the case of an active marking element.

The at least one marking element preferably forms a ring enclosing the envelope layer. In the case of a plurality of marking elements, they can be at defined distances from one another as seen in the axial direction of the guidewire. These distances can be uniform. However, it is also conceivable to vary the distances and use these as indexing means for defined positions of the guidewire. Alternatively or in addition, indexing can be provided by varying the length of the marking elements in the longitudinal direction of the guidewire. Moreover, alternatively or additionally, different marking elements can have different concentrations of the marking agent.

The guidewire according to the invention can also be configured such that the protective layer surrounding the inner shaft is a protective jacket. In the case of several protective layers, the protective jacket forms the outermost layer. The protective jacket is preferably made of PTFE (polytetrafluoroethylene) or at least has PTFE, although it can also have one or more other plastics. The protective jacket is preferably applied directly to the inner shaft or, if the inner shaft is intended to be surrounded by further inner protective layers, the protective jacket is applied to the outermost of the inner protective layers, preferably by shrink-fitting. The use of special adhesives for fixing the protective jacket is thus omitted. Moreover, an adhesive is not needed for closing the guidewire at the ends, since the protective jacket can be already closed at the distal or proximal end, or the material of the protective jacket, particularly in the case of PTFE, can be welded at one or both ends. Moreover, a cohesively bonded connection between the protective jacket and the underlying layer, in particular the envelope layer, can be generated by the action of temperature.

Moreover, it can be advantageous to carry out the method according to the invention such that, before the protective jacket is shrink-fitted, the wire endpiece provided with the protective jacket is fixed in a shape-fixing device predefining the shape of the wire endpiece, and the protective jacket is shrunk on over the fixed wire endpiece. Through the shrink-fitting process, the wire endpiece remains stable in its predefined shape. In the shape-fixing device, the wire endpiece is preferably given a curved shape. The shape-fixing device can have, for example, a groove with the desired profile, into which groove the wire endpiece is placed before the shrink fitting of the protective jacket. The groove can be closed with a cover. Alternatively to a groove, the shape-fixing device can have a modifiable shape definer, e.g. by displaceable or plug-in limiting elements which, for example, can be pin-shaped.

According to the invention the guidewire is configured such or the method according to the invention is carried out in such a way that the guidewire has a free proximal wire endpiece which adjoins the end of the wire main piece opposite the distal wire endpiece. A free proximal wire endpiece affords a user the option of using the proximal wire endpiece as a guide tip too. The functions of the proximal wire endpiece and those of the distal wire endpiece can thus be changed around.

The free proximal wire endpiece and the distal wire endpiece can be designed corresponding to one another or can also be different. In the case of a different design, different properties, e.g. different flexibility or different shapes, can be obtained, which can be exploited during use.

It may be expedient to provide a multiplicity of weakened sites in the distal wire endpiece alone, such that the user has available a more flexible and stiffer wire endpiece. However, it is also possible for both wire endpieces to be provided with a multiplicity of weakened sites.

Furthermore, the proximal wire endpiece or the distal wire endpiece, or both wire endpieces, can be given a bent shape, preferably with a bending angle of at least 45° and at most 90°.

As in the distal wire endpiece, it is also possible for the proximal wire endpiece to have an inner shaft having a first fiber composite material and at least one protective layer enveloping the inner shaft. The wire main piece can also have such an inner shaft having a fiber composite material, and at least one protective layer enveloping the inner shaft. Inner shaft and protective layer are preferably at least substantially of the same material in the wire endpieces and the wire main piece and, apart from the weakened sites, are of at least substantially the same structure, such that the wire endpieces together with the wire main piece are in one part with a continuous core, continuous envelope layer and continuous protective layer. If necessary, however, weakened sites can also be provided in the wire main piece.

Finally, the at least one marking element already mentioned above can be applied at the distal wire endpiece, at the proximal wire endpiece or at both wire endpieces.

It may also be expedient to provide at least one marking element alone in the wire main piece or in the wire main piece and additionally at least one marking element in one or both of the wire endpieces.

The at least one marking element or at least one of the marking elements can be applied to the outer circumference of the inner shaft in the distal wire endpiece, in the proximal wire endpiece and/or in the wire main piece. The at least one marking element or at least one of the marking elements can also be an MRT marking element suitable for marking in magnetic resonance tomography, wherein preferably the at least one MRT marking element or at least one of the MRT marking elements is an active marking element.

Preferred embodiments of the guidewire according to the invention and of the production method according to the invention are set out below with reference to figures.

In the schematic figures:

Fig. 1 shows the front region of a first guidewire with a distal wire endpiece,

Fig. 2 shows a second guidewire with a distal and a proximal wire endpiece, and

Fig. 3 shows an enlarged detail from the proximal wire endpiece.

Fig. 1 shows the front region of a guidewire 1 with a wire main piece 2 and with a distal wire endpiece 3 seamlessly adjoining the latter. A free proximal wire end piece belonging to the invention is not shown in Fig. 1. The first guidewire 1 has an inner shaft 4, which consists of a core 5 and of an envelope layer 6 surrounding the core 5. A protective jacket 7, preferably of PTFE, is pulled over the inner shaft 4 and shrink-fitted. To make matters clearer, the size ratios are not true to scale in the figure. The length of the wire endpiece 3 is in fact of the order of preferably 30 mm to 60 mm, and the diameter of the first guidewire 1 is of the order of less than 1 mm.

The core 5 consists of a fiber composite material which has glass fibers and, as plastic matrix, an epoxy resin. The glass fibers (not shown in the figure) are at least predominantly oriented in the longitudinal direction of the first guidewire 1. To produce the core, the glass fibers, which are preferably continuous over the length of the first guidewire 1, are provided with the plastic matrix in a pultrusion method.

The envelope layer 6 likewise consists of a fiber composite material, wherein fibers of an aramid are preferably used here. The fibers (not shown) are preferably wound helically in two different orientations about the core 5. Thereafter, the plastic matrix for the envelope layer 6 is applied, likewise in a pultrusion method. Preferably, the plastic matrix is likewise epoxy resin. The two pultrusion methods can be carried out during a common drawing process.

After the inner shaft 4 has been finished, it is provided in the distal wire endpiece 3, by mechanical intervention, with a multiplicity of weakened sites 8, of which only the rear three weakened sites 8, as seen from the distal end 9, are provided with the reference number in the figure. The weakened sites 8 serve to reduce the flexural stiffness of the guidewire 1 in the wire endpiece 3. The weakened sites 8 thus replace the much more complicated reduction of the diameter of the inner shaft 4, as known from the prior art.

In order to generate the weakened sites 8, the inner shaft 4 can be placed with its distal end over a mechanical edge (not shown here). On a part of the inner shaft 4 protruding beyond the mechanical edge, a force with a component perpendicular to the longitudinal direction of the inner shaft 4 is applied to the inner shaft 4. With sufficient force, this causes a movement of the inner shaft 4 with a bending, buckling and/or breaking load, which leads to formation of cracks in the inner shaft 4. Since in particular the glass fibers in the core 5 are largely not broken during said movement, the inner shaft 4 remains in one piece, and complete breaking-off of part of the inner shaft 4 can be avoided. The bending, buckling and/or breaking load leads instead to a partial tearing open of the plastic matrix, as a result of which the flexural stiffness of the inner shaft 4 is reduced considerably at the weakened site 8 that is generated.

The mechanical weakening is then repeated many times, for example by means of the inner shaft 4 being pushed farther out over the mechanical edge until the acting force generates the next weakened site 8. In a distal wire endpiece 3 with a length of 40 mm, for example, twenty weakened sites 8 are preferably formed at an interval of approximately 2 mm. However, the distal wire endpiece 3 can also have a length of 30 mm to 60 mm, for example, in which case the intervals between the weakened sites preferably measure 1 to 3 mm. The entire process can then be repeated with a modified rotation angle position of the inner shaft 4. For example, after the first pass for introducing a multiplicity of weakened sites 8, the inner shaft 4 is rotated about the longitudinal axis by approximately 90° relative to the direction of the acting force and is treated correspondingly in a second pass.

The acting force can be generated, for example, by means of the weight force of a mass (not shown here) fixed at the distal end of the inner shaft 4.

After the inner shaft 4 has been provided with the desired number of weakened sites 8, the protective jacket 7 is pulled over the inner shaft 4. Thereafter, at least the distal wire endpiece 3 is optionally brought to a desired shape and is fixed in a shape-fixing device (not shown here). Thereafter, the protective jacket 7 is shrink-fitted onto the inner structure 4 at a suitable temperature. After cooling, the shape of the wire endpiece 3 remains on account of the stabilizing effect of the shrink-fitted protective jacket 7, even after removal from the shape-fixing device. The conferred shape, at least in a subportion, is preferably an arc shape.

Fig. 2 shows a second guidewire 10 with a distal wire endpiece 11 and a proximal wire endpiece 12. A wire main piece is not shown here and falls in the gap 13 in the depiction of the second guidewire 10. Apart from weakened sites explained below, the wire endpieces 11 and 12 have substantially a matching structure. A region of the proximal wire endpiece 12 marked “Z” in Fig. 2 is shown enlarged in Fig. 3. A core 15 of the second guidewire 10, an envelope layer 16 surrounding the core 15, and a protective layer in the form of a protective jacket 7 can be seen in the enlargement. Core 15 and envelope layer 16 together form the inner shaft 14. Thus, the second guidewire 10 corresponds in structure to the wire main piece 2 and the distal wire endpiece 3 of the first guidewire 1 according to Fig. 1.

The distal wire endpiece 11 has, in the inner shaft 14, a multiplicity of weakened sites 18, which are symbolized by lines perpendicular to the longitudinal axis of the second guidewire 10, and of which only four are labeled with reference signs. The weakened sites 18 are distributed over the entire length of the distal wire endpiece 11 shown and result in an increased flexibility of the distal wire endpiece 11. The weakened sites can be produced in the same way as already described with reference to Fig. 1 or in another suitable way.

By contrast, in the illustrative embodiment in Fig. 2, the proximal wire endpiece 12 is formed without weakened sites. A user can decide whether to use the distal wire endpiece 11 or the proximal wire endpiece 12 as the tip of the second guidewire 10 for guiding another instrument, e.g. a catheter (not shown here).

The distal wire endpiece 11 is bent in a subportion 19, wherein the bending angle α measures approximately 63°. The bending can be regular with a constant bending radius R or irregular with a changing bending radius R. The production of the bend and/or the application of the protective jacket 17 can also take place in the same way as already described with reference to Fig. 1 or in another suitable way.

List of reference signs

1	first guidewire
2	wire main piece
3	wire endpiece
4	inner shaft
5	core
6	envelope layer
7	protective jacket
8	weakened site
9	distal end
10	second guidewire
11	distal wire endpiece
12	proximal wire endpiece
13	gap
14	inner shaft
15	core
16	envelope layer
17	protective jacket
18	weakened sites
19	subportion
α	bending angle
R	bending radius

Patentkrav

1. Føringstråd til minimalt invasive indgreb med et distalt trådendestykke (3, 11) der støder op til et trådhovedstykke (2), hvor

a) føringstråden (1, 10) har mindst i det distale trådendestykke (3, 11) et indvendigt skaft (4, 14) og mindst et beskyttelseslag der omgiver det indvendige skaft (4, 14),

b) det indvendige skaft (4, 14) har et første fiberkompositmateriale, og

c) mindst i det distale trådendestykke (3, 11) det indvendige skaft (4, 14) har en flerhed af svækkelsessteder (8, 18), der er genereret af mekaniske indgreb,

kendetegnet ved, at

d) det indvendige skaft (4, 14) har en kerne (5, 15) og mindst et indhylningslag (6, 16) der omgiver kernen (5, 15),

e) kernen (5, 15) har det første fiberkompositmateriale, hvor det første fiberkompositmateriale har glasfibre,

f) det mindst ene indhylningslag (6, 16) eller mindst et af indhylningslagene (6, 16) har et andet fiberkompositmateriale, hvor det andet fiberkompositmateriale har aramidfibre der er indkapslet af et matrixmateriale af kunstharpiks,

g) svækkelsesstederne (8, 18) er genereret ved knækbelastning, bøjningsbelastning og/eller brudbelastning, og

h) et frit proksimalt trådendestykke (12) er givet, hvilket støder op til enden af trådhovedstykket (2) modstående det distale trådendestykke (11).

2. Føringstråd ifølge krav 1, **kendetegnet ved, at** mindst en delmængde af fibrene af det andet fiberkompositmateriale er spiralformet ført omkring omkredsen af kernen (5, 15), hvor den mindst ene delmængde af fibre af det andet fiberkompositmateriale er fortrinsvis ført i to modsatrettede, forskellige spiralorienteringer omkring omkredsen af kernen (5, 15).

3. Føringstråd ifølge et af de foregående krav, **kendetegnet ved, at** beskyttelseslaget eller, i tilfældet af flere beskyttelseslag, det yderste beskyttelseslag er en beskyttelseskappe (7, 17) bestående af PTFE eller mindst indeholdende PTFE.

4. Føringstråd ifølge et af de foregående krav, **kendetegnet ved** mindst et markeringselement egnet til markering i en afbildningsfremgangsmåde, hvor markeringselementet eller mindst et af markeringselementerne er fortrinsvis anvendt på den udvendige omkreds af det indvendige skaft (4, 14).

5. Føringstråd ifølge krav 4, **kendetegnet ved, at** det mindst ene markeringselement eller mindst et af markeringselementerne er et MRT-markeringselement egnet til markering i magnetresonanstomografi, hvor det mindst ene MRT-markeringselement eller mindst et af MRT-markeringselementerne er fortrinsvis et aktivt markeringselement.

6. Føringstråd ifølge et af de foregående krav, **kendetegnet ved, at** føringstråden (1, 10) også har i det proksimale trådendestykke (12) et indvendigt skaft (4, 14) med et første fiberkompositmateriale og mindst et beskyttelseslag der omgiver det indvendige skaft (4, 14).

7. Føringstråd ifølge krav 6, **kendetegnet ved, at** i det proksimale trådendestykke (12) det indvendige skaft (4, 14) har en flerhed af svækkelsessteder (8, 18) der er genereret af mekaniske indgreb, fortrinsvis ved knækbelastning, bøjningsbelastning og/eller brudbelastning.

8. Føringstråd ifølge et af de foregående krav, **kendetegnet ved** mindst et markeringselement ifølge et hvilket som helst af kravene 4 og 5 er anbragt i det proksimale trådendestykke (12).

9. Føringstråd ifølge et af de foregående krav, **kendetegnet ved, at** det distale trådendestykke (3, 11) og/eller det proksimale trådendestykke (12) får en bøjet form.

10. Føringstråd ifølge krav 9, **kendetegnet ved, at** den bøjede form har en bøjningsvinkel (α) på mindst 45° og højst 90°.

11. Fremgangsmåde til fremstilling af en føringstråd til minimalt invasive indgreb med et distalt trådendestykke (3, 11) der støder op til et trådhovedstykke (2), hvor mindst i det distale trådendestykke (3) et indvendigt skaft (4, 14) med et første fiberkompositmateriale er til stede,

og mindst i det distale trådendestykke (3, 11) det indvendige skaft (4,14) forsynes med en flerhed af svækkelsessteder (8, 18) genereret af mekaniske indgreb,

kendetegnet ved, at

svækkelsesstederne (8, 18) genereres ved knækbelastning, bøjningsbelastning og/eller brudbelastning og

på føringstråden (1, 10) et frit proksimalt trådendestykke (12) fremstilles, som støder op til enden af trådhovedstykket (2) modstående det distale trådendestykke (11).

12. Fremgangsmåde ifølge krav 11, **kendetegnet ved, at** et indvendigt skaft (4, 14) med et første fiberkompositmateriale og endvidere mindst et beskyttelseslag der omgiver det indvendige skaft (4, 14) også anbringes i det proksimale trådendestykke (12).

13. Fremgangsmåde ifølge krav 12, **kendetegnet ved, at** i det indvendige skaft (4, 14) i det proksimale trådendestykke (12) en flerhed af svækkelsessteder (8, 18) genereres af mekaniske indgreb, fortrinsvis ved knækbelastning, bøjningsbelastning og/eller brudbelastning.

14. Fremgangsmåde ifølge et af kravene 11 til 13, **kendetegnet ved, at** for de mekaniske indgreb det indvendige skaft (4, 14) er placeret over mindst en mekanisk kant og udsættes for en kraft der virker tværgående i forhold til den langsgående akse af det usvækkede trådendestykke, hvor kraften fortrinsvis påføres langs det indvendige skaft ved intervaller på 1 mm til 3 mm.

15. Fremgangsmåde ifølge et af kravene 11 til 14, **kendetegnet ved, at** de mekaniske indgreb udføres i mindst to forskellige rotationsvinkelpositioner af det indvendige skaft (4, 14) i forhold til en rotation omkring den langsgående akse af det indvendige skaft (4, 14), fortrinsvis i rotationsvinkelpositioner der afviger fra hinanden med 90° +/- 10°.

16. Fremgangsmåde ifølge et af kravene 11 til 15, **kendetegnet ved, at** for at generere det indvendige skaft (4, 14) en kerne (5, 15) lavet af et første fiberkompositmateriale omgives af mindst et indhylningslag (6, 16) lavet af et andet fiberkompositmateriale fortrinsvis forskelligt fra det første fiberkompositmateriale, hvor fibre af det andet fiberkompositmateriale føres omkring kernen (5, 15) med modsatrettede spiralorienteringer.

17. Fremgangsmåde ifølge et af kravene 11 til 16, **kendetegnet ved, at** mindst et markeringselement der tjener til markeringsformål i en afbildningsfremgangsmåde anvendes på den udvendige omkreds af det indvendige skaft (4, 14).

18. Fremgangsmåde ifølge krav 17, **kendetegnet ved, at** det mindst ene markeringselement også anvendes på mindst det distale trådendestykke (3, 11) og/eller på det proksimale trådendestykke (12).

19. Fremgangsmåde ifølge et af kravene 11 til 18, **kendetegnet ved, at** det indvendige skaft (4, 14) omgives af mindst et beskyttelseslag efter det mekaniske indgreb, hvor en beskyttelseskappe (7, 17), fortrinsvis af PTFE, fortrinsvis krympetilpasses som beskyttelseslaget eller i tilfældet af flere beskyttelseslag som det yderste beskyttelseslag.

20. Fremgangsmåde ifølge et af kravene 11 til 19, **kendetegnet ved, at** det distale trådendestykke (3, 11) og/eller på det proksimale trådendestykke (12) får en bøjet form.

21. Fremgangsmåde ifølge krav 20, **kendetegnet ved, at** den bøjede form har en bøjningsvinkel (α) på mindst 45° og højst 90°.

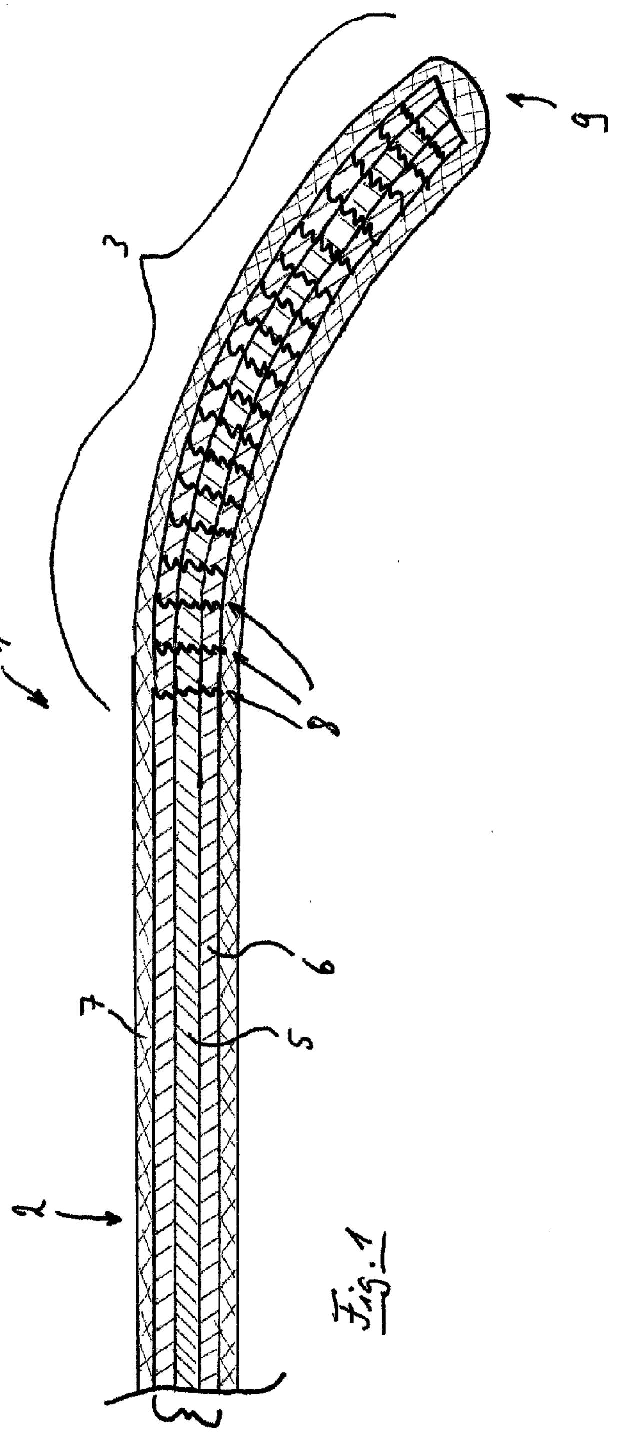

Fig. 1

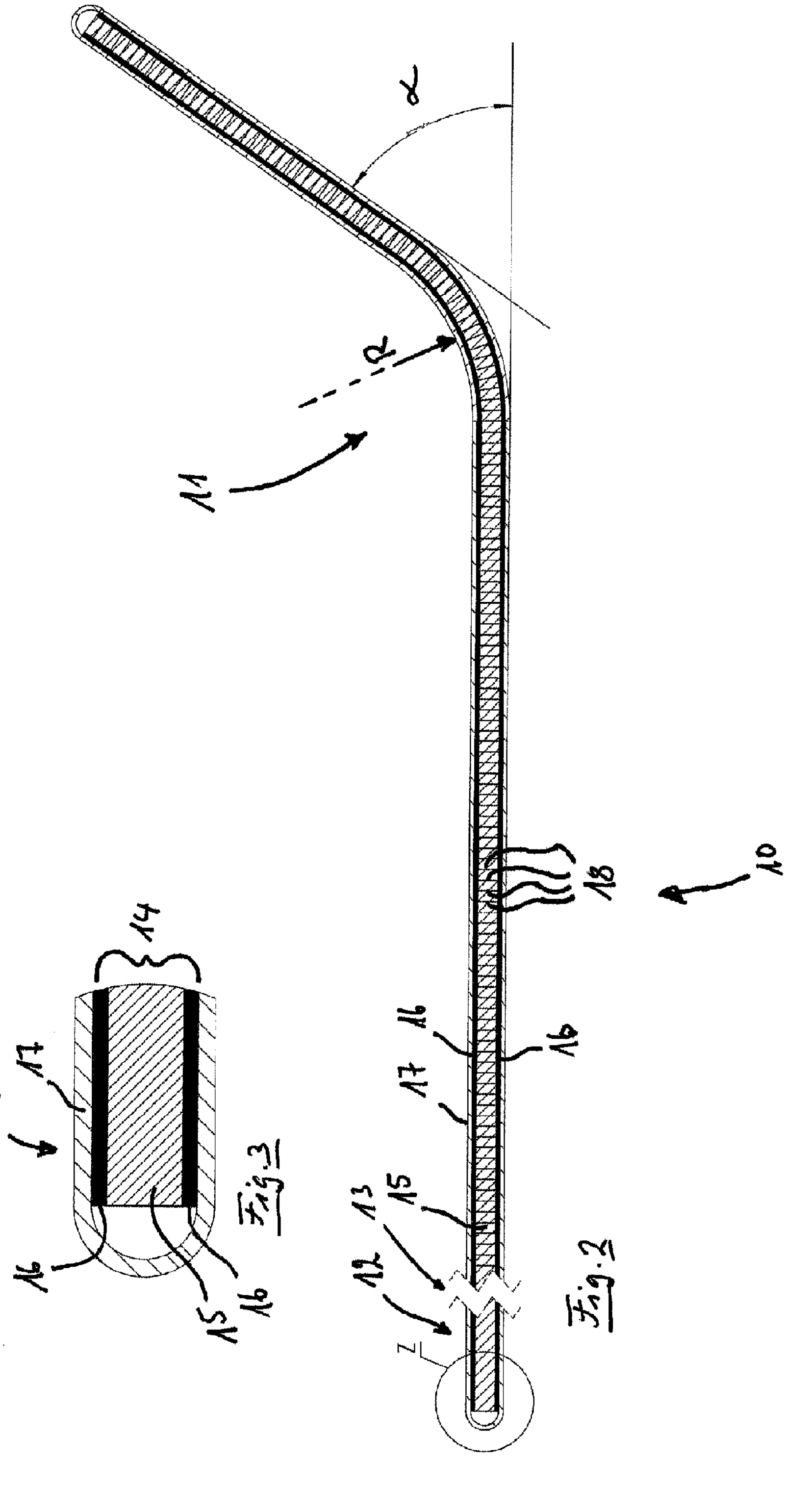

Fig. 2

Fig. 3