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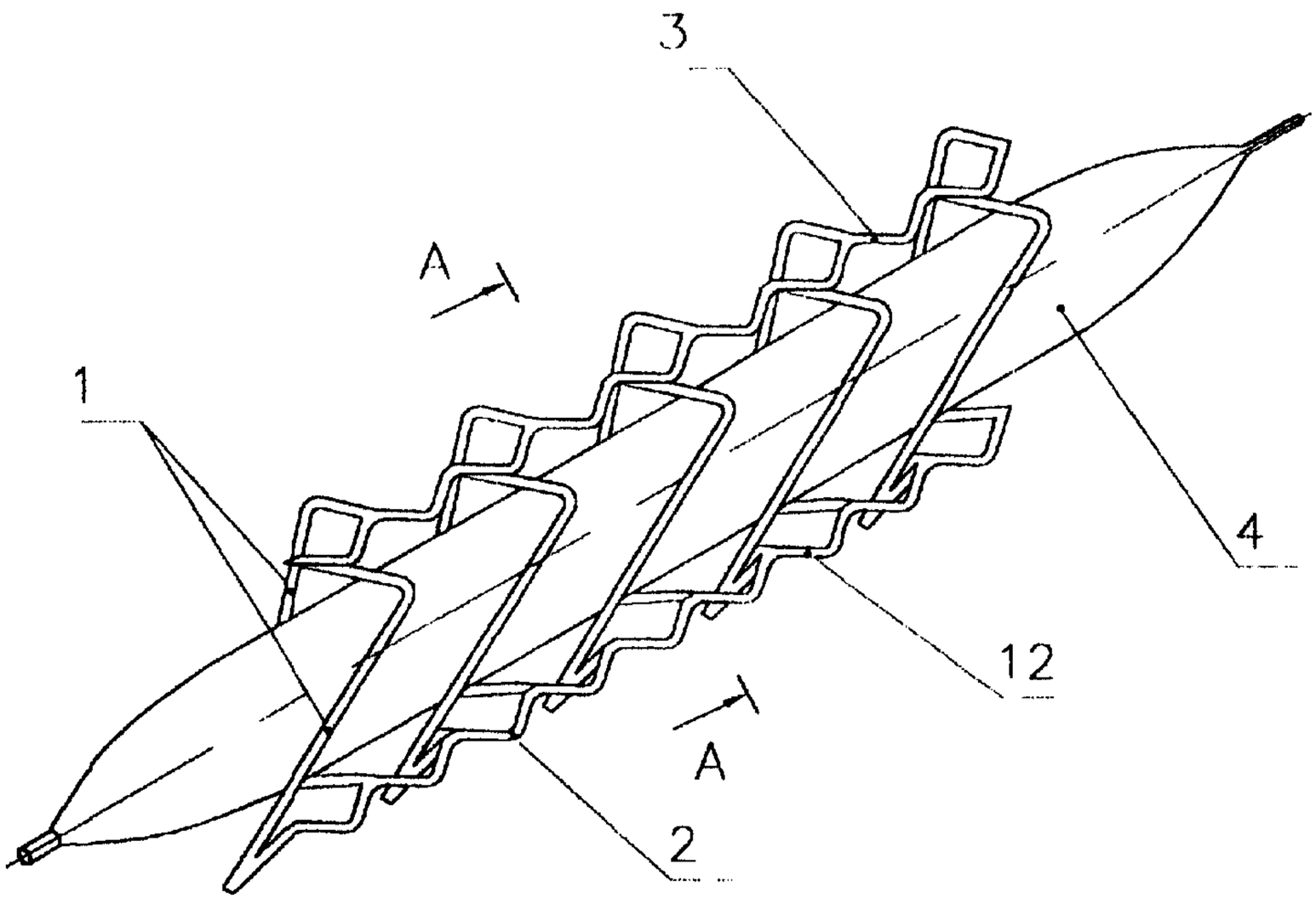
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(54) **TUTEUR INTRAVASCULAIRE A FEUILLE EXPANSIBLE, FLEXIBLE, ET TECHNOLOGIE DE FABRICATION**

(54) **FLEXIBLE EXPANDABLE SHEET STENT AND TECHNOLOGY OF ITS MANUFACTURING**



(57) Flexible expandable sheet stent is intended for the better support of a diseased vessel wall on the basis of securing the very best characteristics and raise in the service ability of a stent in a vessel. The stent comprises constructive elements (7), preliminary formed in a shape of a stencil on the thin sheet metallic blank surface (5). The stent constructive elements (7) include a saw-shaped profile made of teeth (8) from which the relatively rigid band in a shape of consecutively united pockets is formed, the long twisting sides (9, 10) of the closed free loops and the short sides (11) of the closed ring outline. In a passage, formed of consecutively united pockets, a polymer thread (21) with a fixed length loaded with medicinal preparations for local drugs delivery is deployed. The implantation of the stent in the vessel under the X-ray controls performed in such a way as to locate the relatively rigid band of consecutively united pockets on the side of the vessel wall adjoining the cardiac muscle.

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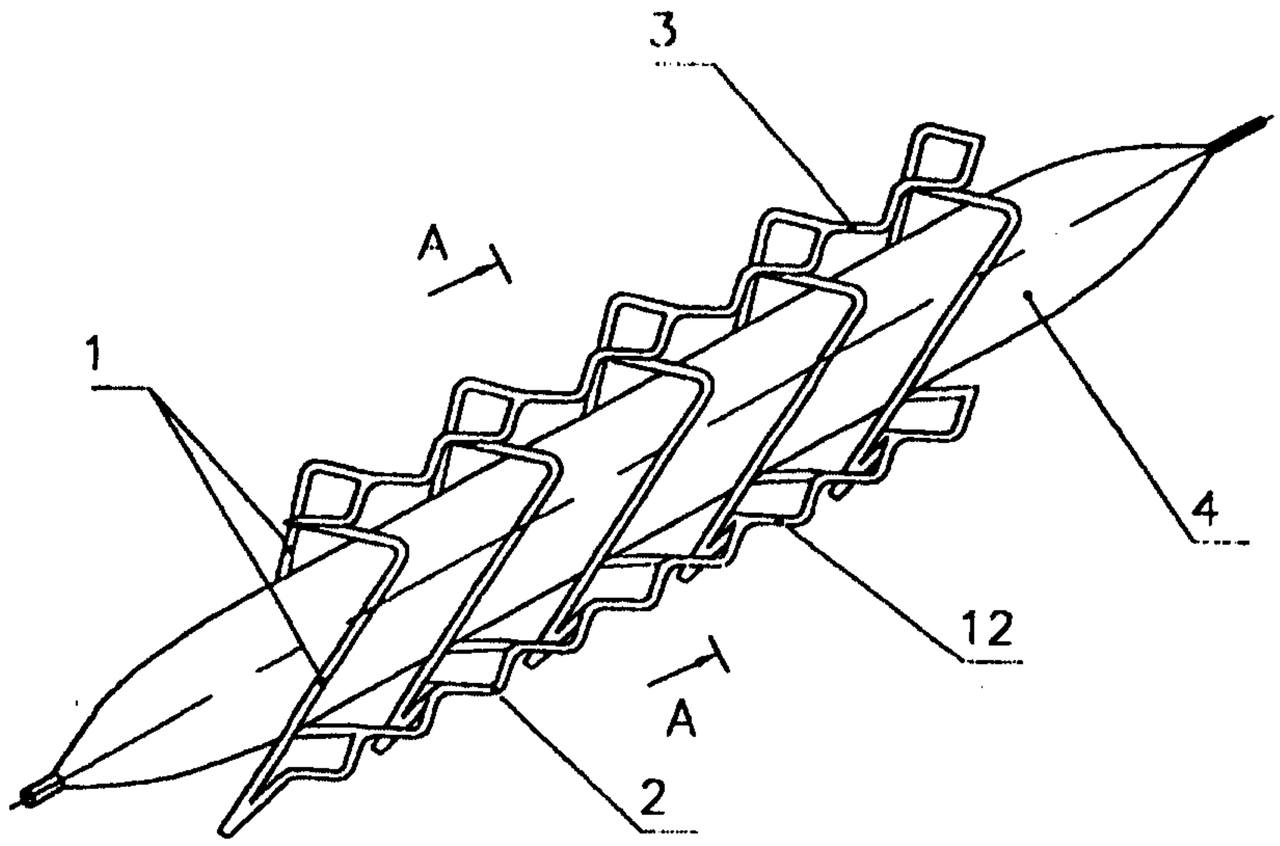
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(57) Abstract

Flexible expandable sheet stent is intended for the better support of a diseased vessel wall on the basis of securing the very best characteristics and raise in the service ability of a stent in a vessel. The stent comprises constructive elements (7), preliminary formed in a shape of a stencil on the thin sheet metallic blank surface (5). The stent constructive elements (7) include a saw–shaped profile made of teeth (8) from which the relatively rigid band in a shape of consecutively united pockets is formed, the long twisting sides (9, 10) of the closed free loops and the short sides (11) of the closed ring outline. In a passage, formed of consecutively united pockets, a polymer thread (21) with a fixed length loaded with medicinal preparations for local drugs delivery is deployed. The implantation of the stent in the vessel under the X–ray controls performed in such a way as to locate the relatively rigid band of consecutively united pockets on the side of the vessel wall adjoining the cardiac muscle.

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FLEXIBLE EXPANDABLE SHEET STENT and TECHNOLOGY of its MANUFACTURING

Field and Background of the Invention

The present invention relates generally to medical technology, particularly to expandable cardiovascular stents, which are intended for the radical arterial lumen recovery with subsequent restoring of the normal blood flow.

In the present application the term "stent" refers to the device designed to expand the blood vessel and to maintain the achieved size of a lumen. Traditionally, stents are delivered to the target area in the cardiovascular system on the inflatable balloon located on the tip of a transluminal catheter. Then, the balloon is inflated leading to the expansion of the stent thereby widening the lumen of the vessel. Other less common systems for stent delivery also exist.

Most of the existent stents are made from metals. The examples of common designs described in patents are: US 4.733.665, US 4.969.458, US 5.102.417, US 5.195.994, US 5.513.444, WO 91FR013820. Certain properties of any metallic surface lead to thrombogenicity of the stent once it is implanted within the human cardiovascular system. Therefore, one of the important directions in the stent development is the improvement of the stent thromboresistance because this would reduce the systemic anticoagulation therapy thereby reducing complication rate after stent implantation. At present, none of the metallic stents designs have achieved the delicate balance between the desired durability to sufficiently support the vessel wall and flexibility to reduce the thrombogenicity and intimal hyperplasia. Thus, there is a substantial need for anticoagulation and thrombolitic therapy following stent implantation.

Utilization of metal in the stent design leads to further flaws. One of the limitations of metallic stent is a presence of more or less rigid kinematic link between constructive elements of radial strength and flexibility. This factor creates additional difficulties during the delivery of the stent to the target area in the coronary artery, especially in distal segments of the vessel. This factor also plays a major role in the shortening of the stent upon stent inflation, which may lead to the suboptimal implantation of the stent, especially in diseased segments of blood vessels, and also this may activate undesirable post-procedural processes, such as thrombosis and restenosis.

The rigidity of a kinematic link between the constructive elements of radial strength and flexibility in already complicated geometrical forms of the stent structure does not allow to use thin metal plates in the stent manufacturing, on the contrary, it requires high inflation pressures upon the deployment of the stent to prevent the stent from collapsing into the vessel lumen. However, ideally, a stent structure should combine the longitudinal flexibility and radial rigidity, which would correspond optimally to the characteristics of pulsating coronary arteries.

Despite the fact that the descriptions of most conventional stents claim that these are low profile stents, in fact, all known stents have profiles in the range of 1.3-1.6 mm. This is due to the limitations of the technology of stent manufacturing. All stents are placed on balloons with a minimal diameter of 1.6 mm, which already restricts clinical applications of stents in small vessels. There is no known stent, the parameters of which would permit it to be used in vessels of 2 mm or less. The additional advantage of a stent structure is an ability to perform an adjunctive

angioplasty after the deployment of the stent. This also permits the better adjusment of the stent to the arterial wall due to the deeper penetration of the stent outer elements into the media and the atherosclerotic plaque.

One of the disadvantages, on the other hand, is the metallic surface of a stent in general, and especially the texture of the surface, which can attract the blood elements and activate the formation of the thrombus, as well as initiate the exaggerated healing process, which through the proliferation of the smooth muscle cells results in restenosis. Therefore, the important part of the stent design is the ability to accommodate various bioabsorbable polymers within itself, which can be loaded with antithrombotic and/or antiproliferative pharmacologic agents with high concentrations. Thus, these agents, delivered locally into the arterial wall, can prevent thrombosis, neointimal proliferation and also avoid unwanted systemic side effects. However, so far the results of clinical experiments with polymer coated stents show frequent occurrence of inflammatory reactions to the polymers by the vessel wall, which limits their clinical applications.

Another important limitation of the stenting is an expensive technology of stents' manufacturing, which involves the laser technology in almost all known stents, which lowers the cost-effectiveness of the device, and, therefore its utilization in clinical practice. This technology also leaves the quality of stents' surface suboptimal, with subsequent higher percentage of thrombus formation on this surface.

In summary, the "ideal" stent should possess the following high quality properties: flexibility, trackability, non-shortness, ultra-low profile, visibility in the X-rays, thromboresistance, biocompatibility, reliable expandability, wide range of

available sizes, optional capability of the local drug delivery, and low cost (see, P. Ruygrok and P. Serruys Intracoronary stenting. "Circulation", 1996, 882-890). These features will widen clinical applications of stenting, enable the reduction of unwanted side effects, and ultimately improve the clinical outcome.

The Prior Art

The effective technical stent design executed from the slotted tubes simultaneously combine the flexibility and the sufficient radial strength, as is shown, for example, in patent WO 98/20927 of 12.11.1996. The more progressive stent design, presented in the patent application PCT/IL 98/00189 of 21.04.1998 is also known. In this design (Figs. 1, 2) the constructive elements, preliminary shaped as a stencil on the thin sheet metallic blank surface, form the flexible twisting loops (1), closed on the two bands (2) and (3) as consecutively united pockets. Before the installation of the stent, branches of the loops (1) are in turns oppositely moved apart in such a way that each pair of loops is transformed into a shape close to that of a circle (ring). Then, after the calibration, the stent is located on an inflated balloon (4) of the conductive catheter for its subsequent introduction into the afflicted vessel. However, the prototype-stent has a substantial disadvantage: the presence of a critical plane on which the oppositively located bands (2, 3) in a shape of the consecutively united pockets are located. This plane proved to be very rigid and upon the deformation for bending can hamper the overcoming of vessel's anatomic curvature. The said circumstance hinders the location of a prototype--stent in the curved vessels as well as the creation of stents of the required length. In practice several stents in a row had to be implanted, the fact that prolongs the time of intravascular intervention and causes the additional vessel traumatism.

In the other axial planes the prototype-stent bending rigidity reduces to a minimal in the plane perpendicular to a critical one. However, in all cases, excluding the last one, the bands (2, 3) with the chains of the united pockets change their length owing to the bending deformation: the bands length increases on the outward radius and decreases on the inward one upon the bending of a stent in a vessel. This does not also allow to strictly fix the length of the polymer thread loaded with the medicinal preparations for the local drug delivery. The thread's length should not be less than that of an extent of the united pockets chain on the stent bending outward radius, corresponding to its maximal tension. This could lead to the sag of the polymer loaded thread on the stent bending inward radius and to the jamming of it among the loops (1).

A shift from the critical plane in such a stent design could be partially done by twisting the bands (2, 3) in relation to the longitudinal axis in such a way that the chain bands of the consecutively united pockets locate in the spirals. However, it does not fully solve the said rigidity problems and, besides, the twisting (and a possible untwisting) of the stent leads to the changing of its axial and radial sizes, as well as to the changing in the distance among the loops (1).

The restriction of the vessel wall natural movements could promote the development of stenosis. An attempt to prevent the vascular stenosis with a help of a stent will be more successful the more flexible the stent and the less it restricts the possible natural local vessel wall movements. The presence in a prototype-stent of the two comparatively rigid bands (2, 3) with consecutively united pockets chains upon the close contact with a vessel wall greatly limits the degrees of freedom of its wall. This may become the cause for restenosis. The practical work

shows that after the installation of the sufficiently rigid stent in a vessel of a developed length restenosis occurs in more than 25% of the clinical cases.

Summary of the Invention

The purpose of the invention is to create a stent design of an increased flexibility with a container for the polymer loaded thread of a fixed length, whereas the construction peculiarity should consist in the support for the favorable dynamic action on a vessel wall (of a massage type).

The purpose of the invention is also to avoid the consequences of edge effects from the blood flow action on the stent face end surface sections in a vessel.

The purpose of the invention is also to create a stent configuration with the diameters differentiated in length for a simultaneous deployment in the main vessel and in one of its bifurcations with an increased rigidity for a better fixation of the stent in the place of vessel diameters transition.

The set purpose is achieved by the fact that in a Flexible Expandable Sheet Stent design constructive elements, preliminary formed as a stencil on the thin sheet metallic blank surface, in their regular form represent one relatively rigid band consisting of consecutively united pockets, the branches of which form periodically repeating winding closed outlines, whereas the components of the longest sides of each outline are oppositively located in a form of a closed free loop with a configuration that approximates to that of a circle, forming an independent ring with a fastening point on the said relatively rigid band.

In the said, preliminary formed stencil, the said stent constructive elements occupy the primary part of the area, excluding that which falls at the said stencil slots, at the radii of the formed pockets rounding off and the radii of free loops short closed

sides, whereas the width of the said slots is executed minimally possible technologically.

In a proposed stent the said pockets are formed by the bending of a saw-shaped profile that is a component of the said closed free loops foundation, whereas the bending of the said pockets is executed into one or alternatively into different sides for an angle of the order of 120°.

In the proposed stent the polymer loaded thread of a fixed length is placed in the said consecutively united pockets.

In the proposed stent the said short sides of the closed free loops on the stent end side surfaces are fastened by the fragments of the said relatively rigid band in a shape of the said pockets, whereas in case of stent diameter differentiated in its length according to the different diameters and extent of the afflicted vessel by the said fragments of the relatively rigid band in a shape of the said pockets are fastened the said short sides of the said closed free loops in the place of their transition from one stent diameter to the other.

The proposed stent contains the single closed free loops, uniformly distributed along the stent length or in places, where the increased flexibility is most desirable, including a construction variant with one closed free loop, placed in the stent middle part, whereas the other short sides of the said loops are executed in a shape of a relatively rigid band consisting of the said consecutively united pockets.

The technological process of the proposed stent design manufacturing includes the following steps:

- separation of the thin sheet metallic blank with a multiple unwasted quantity of the stent designs;

- execution of a calculated geometrical profile stencil of stent constructive elements on the surface of the said thin sheet metallic blank;

- shaping of consecutively united pockets by bending;

- deployment of the said stencil into a step-by-step gauge fixing the distances among the closed free loops;

- introduction of cylindrical gauges into all said loops, positioning oppositively the long sides of the each said loop and trying to achieve the stent minimal diameter necessary for an uninflated balloon;

- fixation of the said stent on an uninflated balloon of the conductive catheter;

- positioning and fixation of the polymer loaded thread in a passage formed by the chain of the said consecutively united pockets;

- packing of a ready device.

In case of using the variant of stent design with single free loops, uniformly distributed along the stent length or in the places where the increased flexibility is most desirable, the technological process includes the set of prototype-stent steps exclusively.

The implantation of the proposed stent in a vessel controlled by the X-ray, is executed in such a way as to provide the location of the said relatively rigid band of the said consecutively united pockets on the vessel wall adjoining the cardiac muscle.

As a result, the proposed stent, with one relatively rigid band of the consecutively united pockets, preserves all the positive properties of the prototype-stent while possessing an increased flexibility making it possible to carry out successively the complex intravascular angioplasty and, in case of necessity, to install the stents

of enlarged length. The maximal flexible rigidity of the proposed stent is at least twice as less as the minimal rigidity of the prototype-stent. Since the band with consecutively united pockets (a container for the polymer loaded thread) can bend in all the spatial directions but does not share in the stent bending, determined by its cross-sections, then the size of the axial band, and consequently of the polymer loaded thread, remains invariable. In case of the band with the consecutively united pockets adjoining the cardiac muscle, the flexibility of this band in the direction of the cardiac muscle functioning is minimal. Therefore, any pulsation of the cardiac muscle (dynamic action) is taken by the band effectively enough. The dynamic actions from this band are transmitted to the loops, independently to some extent, and the loops, resting against the opposite vessel wall, exert a massaging action on it, without practically limiting the pulsating vessel degrees of freedom.

The proposed stent can have a partially increased rigidity at any place of its linear length at the expense of fastening the loops short sides by the fragments of the relatively rigid band in a shape of the pockets. For example, by fastening in this way the stent end loops, the rigidity of end surfaces sections increases, and the possibility of their deformation from the blood flow action decreases. By fastening the joining loops of the stent, differentiated in diameter, the rigidity of the design middle part heightens, thus increasing the fixation reliability of a stent part with a greater diameter, preventing its penetration into a vessel with a lesser diameter. At the same time the relatively heightened stent rigidity in a transitional section of a vessel promotes a more efficient destruction of the pathological formations in the place of implantation.

The stent sections with fragments, increasing its rigidity, resemble the prototype--stent design. Since the relative rise in the stent rigidity takes place on the longitudinal extent of small length fragments only, then the general design flexibility does not decrease and remains at the patent application level.

It is possible to fragmentarily insert into the proposed stent not only the increased rigidity but also a heightened flexibility with the help of saparate single free loops arranged in the prototype-stent along the stent's length. The increased stent flexibility takes place in the zones of separate single free loops location.

Brief Description of the Drawings

This invention is herein described with the use of examples and references to the accompanying drawings, wherein:

Fig. 1 shows the prototype-stent located on an uninflated balloon of the conductive catheter.

Fig. 2 shows a design cross-section in accordance with Fig. 1.

Fig. 3 shows a stent constructive elements stencil executed on a thin sheet metallic blank surface, according to the invention.

Fig. 4 shows the same as on Fig. 3, but with one of the opposite free branches being blackened (for example, the blackened loop branch will be located under the balloon, whereas the unblackened one over it).

Fig. 5 shows the same as on Fig. 3, but with the blackened stencil constructive elements and with unblackened slots.

Fig. 6 shows a stent before the expansion, located on an uninflated balloon of the conductive catheter, according to the invention.

Fig. 7 shows a design cross-section in accordance with Fig. 6.

Fig. 8 shows a stent after expansion, according to the invention.

Fig. 9 shows a fragment of Fig. 8 in a place of polymer loaded thread fixation in a last pocket of the relatively rigid band with the consecutively united pockets.

Fig. 10a shows schematically a stent with a zero bend for the minimal rigidity plane, according to the invention.

Fig. 10b shows schematically a stent with a bend into the positive direction for the minimal rigidity plane, according to the invention.

Fig. 10c shows schematically a stent with a bend into the negative direction for the minimal rigidity plane, according to the invention.

Fig. 10d shows schematically a stent bend in its maximal rigidity plane, according to the invention.

Fig. 11 shows a stent constructive elements stencil with the fragments of the relatively rigid bands in a shape of blanks for the pockets located on the design end surfaces sections, according to the invention.

Fig. 12 shows schematically a stent, differentiated as to the diameter length, with the fragments of the relatively rigid bands in a shape of the pockets located on the end surfaces sections of the design and in the place of diameters transition, according to the invention.

Fig. 13 shows schematically a stent with separate free loops distributed uniformly along the stent length, according to the invention.

Fig. 14 shows a stent upon the calibration with the free sides of the closed rings oriented in a mandrel, according to the invention.

Fig. 15 shows a cross-section of an assembled design in accordance with Fig. 14.

Specific Description

Fig. 3 shows a thin sheet metallic blank (5) on which a stencil with stent geometrical sizes conditioned in advance is formed. At the same time the slots (6) forming the constructive elements (7) of the future stent are also shown: the free loops long sides, the saw-shaped profile, the free loops short sides and the necessary radii of their rounding-offs. The constructive elements (7) consist of four parts. To these parts belong the saw-shaped profile tooth (8) from which a pocket will be formed. For forming a pocket the saw-shaped tooth (8) is bent for an angle of the order of 120°. The chain of the consecutively united pockets form a relatively rigid band along the future stent longitudinal axis. The two other parts are free loops twisting long sides (9) and (10). Position (11) denotes the short side of the twisting closed outline in the stencil constructive elements.

Thus, every closed loop is based on the pockets branches.

Fig. 4 shows the stent constructive elements formed on the thin sheet metallic blank surface with one of the outline twisting closed sides (9) blackened and with the other outline closed side (10) left clear. This figure helps to explain how in the future the stent volumetric cylindrical design with closed rings is formed from the thin sheet metallic blank (5). For example, the uninflated balloon is threaded through the design elements in such a way that every blackened free loop branch (9) is placed under the balloon whereas every unblackened free loop branch (10) is placed over the balloon. The stencil relative sizes do not allow to depict it graphically and therefore Fig. 5 shows schematically for how much the unblackened slots (6) width is less than that of the future stent design elements (blackened).

Fig. 6 shows schematically a stent (12) before expansion located on an uninflated balloon (13) of the conductive catheter. Fig. 7 shows a design cross-section in accordance with Fig. 6. Positions (14) and (15) denote the closed ring elements formed from the long twisting sides (9, 10) of free loop. Position (16) denotes the closed ring elements formed from the free loop short side (11), while position (17) shows a pocket executed by the bending of tooth (8), see Fig. 3.

Fig. 8 shows a stent in an expanded state where closed loops are seen, i.e. rings (18) fastened to the relatively rigid band (19) formed by the chain of the consecutively united pockets (20). The fixation of the polymer thread loaded with the medicinal preparations for local drug delivery is seen here.

The installation of a stent in a vessel is performed according to the generally adopted Balloon Expandable Stent method after the fixation on a partially inflated balloon and conducting to the place of a vessel pathological formation. Due to the control of the intravascular procedure in the X-ray, stent is turned around the axis to make the rigid band from the chain of the consecutively united pockets face the cardiac muscle. The expansion of the stent is done by the inflation of the balloon over the limits of a plastical deformation up to its close adjoining, i.e. fixation on the vessel wall. In conclusion of the procedure the balloon is uninflated and withdrawn with a catheter outside.

Figs.10 a, b, c, d show schematically the possible location of stent (22) in a vessel with the different bending variants. The profiles of closed rings (23) and of relatively rigid band (24) with a chain of consecutively united pockets are marked on them. It is easy to imagine that if the band (24) is lying on the cardiac muscle then the closed rings (23) do not limit the degrees of freedom of the vessel wall

natural movements. In accordance with the executed stent design of 20 mm length 44 closed rings (23) are located on a band (24) from the chain of the consecutively united pockets. Such a frequency of rings deployment excludes the possibility of their "folding" (the loss of a radial size) under any actions from the pulsating vessel or cardiac muscle.

Fig. 11 shows a constructive elements stencil of the same stent as in Fig. 3 with a saw-shaped profile (25) and closed loops (26). However, there are some distinctions here, the fragments of the saw-shaped profile (27) and (28) are introduced on the future stent end surfaces sections for the relative heightening of its rigidity. The edges of section (27) and partially (25) as well as of section (28) and partially (25) in their design resemble a prototype-stent.

Fig. 12 shows schematically a stent (29) differentiated in respect to the diameter length, consisting of a relatively rigid band (30) in a form of a chain of consecutively united pockets and closed loops of lesser (31) and greater (32) diameters. The fragments from the relatively rigid bands (33) and (34), consisting of pockets, secure the relative heightening of the rigidity on the stent end surfaces sections, whereas the band (35) relatively heightens the stent (29) rigidity in place of transition from the greater (32) to the lesser (31) diameter.

Fig. 13 shows schematically a stent (36) with two single free loops (37) and (38) distributed uniformly along the stent length. These free loops (37, 38) divide the stent into three relatively rigid parts, fastened by the bands (39, 40, 41) and consisting of the consecutively united pockets. Like in the main design (see Figs. 3, 4, 5, 10) the whole stent is united by the relatively rigid band (42) a chain of the consecutively united pockets.

The technology of the proposed stent design manufacturing is given in the Summary of the Invention and in general outline corresponds to the process of a prototype-stent manufacturing. The only distinction is the necessity of orienting the rings free sides during the stent calibration or, in other words, orienting of the closed outline short sides. Such an order of the loops short sides disposition can be fulfilled, for example, with the help of a ridged mandrel as is shown in Figs. 14, 15. Upon the calibration by the cylindrical mandrel (44) the stent rings (43) free ends (45) of the closed ring are displaced in a ridged mandrel (46), see Fig.14. Fig. 15 shows the way how the ridged mandrel (46) with the increasing of the diameter by the cylindrical mandrel (44) gradually shifts into the direction of the arrow up to the acquiring by the stent of a minimal diameter necessary for its deployment and fixation on an uninflated balloon of the conductive catheter. The deployment of an uninflated balloon in a stent lumen should be performed with the help of the ridged mandrel (46) in a position corresponding to that upon the use of the maximal diameter cylindrical mandrel (44). The described manipulation is concluded by the fixation of a stent on the balloon by one of the ways of the generally adopted practice (mechanical tension, partial inflation of the balloon etc.).

The manufacturing of a stent with separate single free loops (37, 38) does not need the use of an additional special equipment (Figs. 14, 15). The manufacturing technology of this stent contains the same steps that are needed for the prototype--stent manufacturing.

As a result, from thin sheet metallic blank a stent of a heightened flexibility is produced that does not practically limit the design necessary length, thus securing

the properties of transmitting the dynamic impulses from a cardiac muscle to a vessel and practically does not hinder the action on a vessel by a blood flow pulsation. The multitude of relatively free rings are effective also in a vessel longitudinal extent, since they render not simultaneously but individually a massaging action on a vessel during the transmission of impulses from the cardiac muscle. This to a great extent prevents the possibility of restenosis. At the same time with the help of small fragments of the relatively rigid bands in a shape of pockets it is possible somewhat to increase purposefully the rigidity of the stent conditioned sections. By fragmentarily varying the stent flexibility value with the help of separate single free loops, it is possible to achieve by various means the more positive implantation of the stent into the vessels of different anatomic forms, including the cases of the most complicated vessel bifurcations. As a whole the use of the proposed stent allows to consider the stenting procedure still more progressive and more purposeful for the wide application in the clinical practice.

What is claimed is:

1. Flexible Expandable Sheet Stent for insertion in a lumen of a vessel of a living being, comprising:

- stent constructive elements, preliminary formed in a shape of a stencil on the thin sheet metallic blank surface, which in the established shape represent one relatively rigid band, consisting of consecutively united pockets, the branches of which form periodically repeating twisting closed outlines, whereas the longer sides components of each outline are oppositively located in a shape of a relatively free loop, the configuration of which is approaching to a circular shape, forming an independent ring with the fastening point on the said relatively rigid band;

- in the said, preliminary formed, stencil the stent constructive elements occupy the primary part of the area, excluding that which falls at the said stencil slots, radii of formed pockets round-offs and radii of closed free loops short sides round--offs, whereas the width of the said slots is executed minimally possible technologically.

2. Flexible Expandable Sheet Stent as in claim 1, in which the said pockets are formed by the saw-shaped profile bend, a component of the said closed free loops bases, whereas the bend of the said pockets is executed into one or alternatively in different sides for an angle of the order of 120°.

3. Flexible Expandable Sheet Stent as in claims 1, 2, in which the polymer loaded thread of a fixed length is located in the said consecutively united pockets.

4. Flexible Expandable Sheet Stent as in claims 1, 2, 3, in which the said short sides of the closed free loops on the stent end side surfaces are fastened by the fragments of the said relatively rigid band in a shape of the said pockets, whereas in case

of stent diameter differentiated in its length according to the different diameters and extent of the afflicted vessel by the said fragments of the said relatively rigid band in a shape of the said pockets the said short sides of the said closed free loops are fastened in the place of their transition from one stent diameter to the other.

5. Flexible Expandable Sheet Stent as in claims 1, 2, 3, which contains the single closed free loops, uniformly distributed along the stent length or in places, where the increased flexibility is most desirable, including a construction variant with one closed free loop, placed in the middle stent part, whereas the other short sides of the said loops are executed in a shape of a relatively rigid band consisting of the said consecutively united pockets.

6. Flexible Expandable Sheet Stent as in claims 1, 2, 3, 4, the technological process of manufacturing of which includes the following steps:

- separation of a thin sheet metallic blank with multiple unwasted quantity of the manufactured stents;

- execution of a calculated geometrical profile stencil of stent constructive elements on the surface of the said thin sheet metallic blank;

- shaping of consecutively united pockets by bending;

- deployment of the said stencil into a step-by-step gauge fixing the distances among the closed free loops;

- introduction of cylindrical gauges consecutively into all said loops, positioning oppositively the long sides of the each said loop and trying to achieve the stent minimal diameter necessary for an uninflated balloon;

- fixation of the said stent on an uninflated balloon of the conductive catheter;

- installation and fixation of the polymer loaded thread in a passage formed by the chain of the said consecutively united pockets;

- packing of a ready device.

7. Flexible Expandable Sheet Stent as in claims 1, 5, the technological process of manufacturing of which does not require the application of the said step-by- step gauge and includes as a whole the set of technological operations for prototype-stent.

8. Flexible Expandable Sheet Stent as in claims 1, 2, 3, 4, 5, the implantation of which into a vessel under the X-ray control is performed in such a way as to locate the said rigid band of the said consecutively united pockets on the side of the vessel wall adjoining the cardiac muscle.

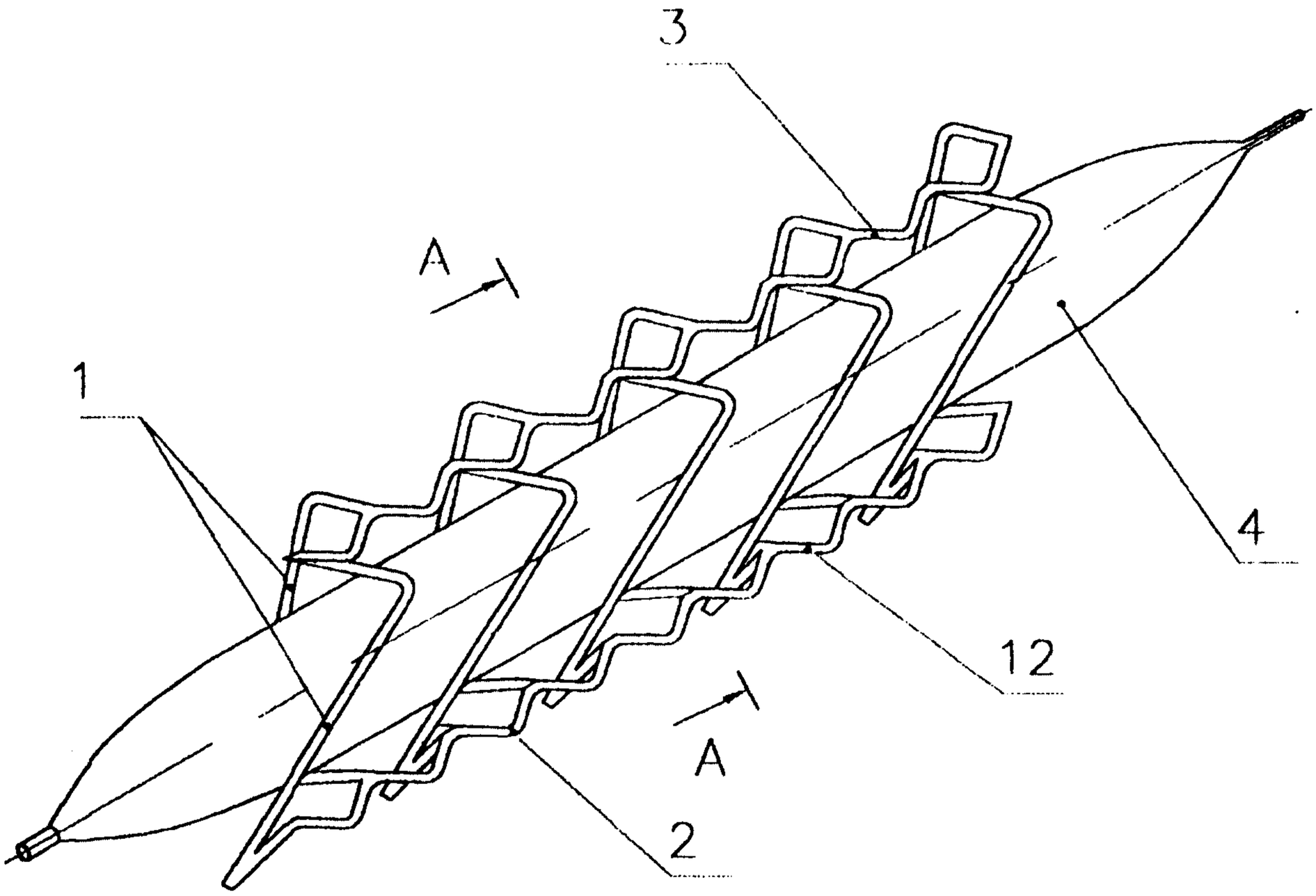


Fig.1

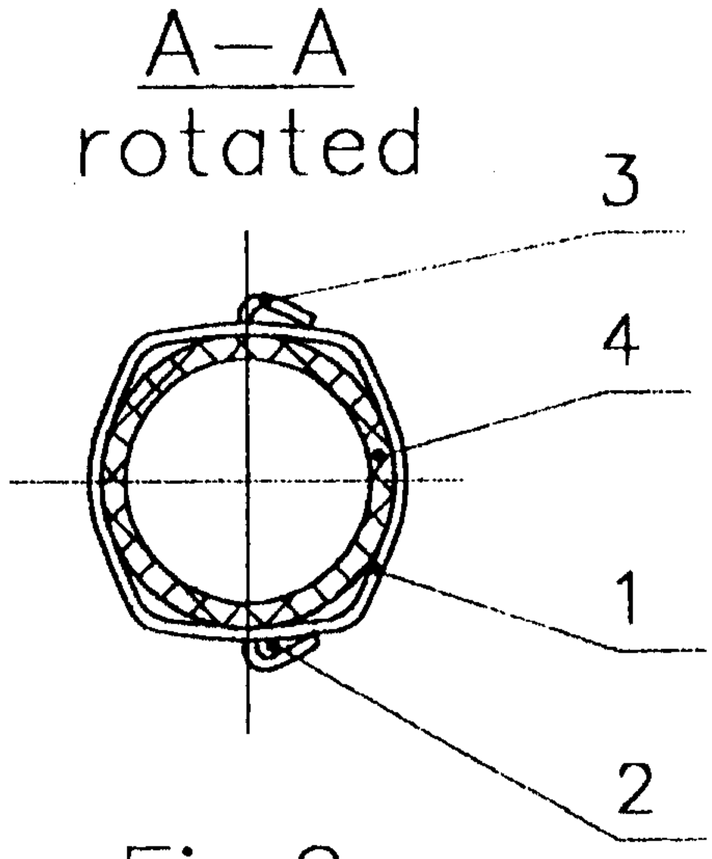


Fig.2

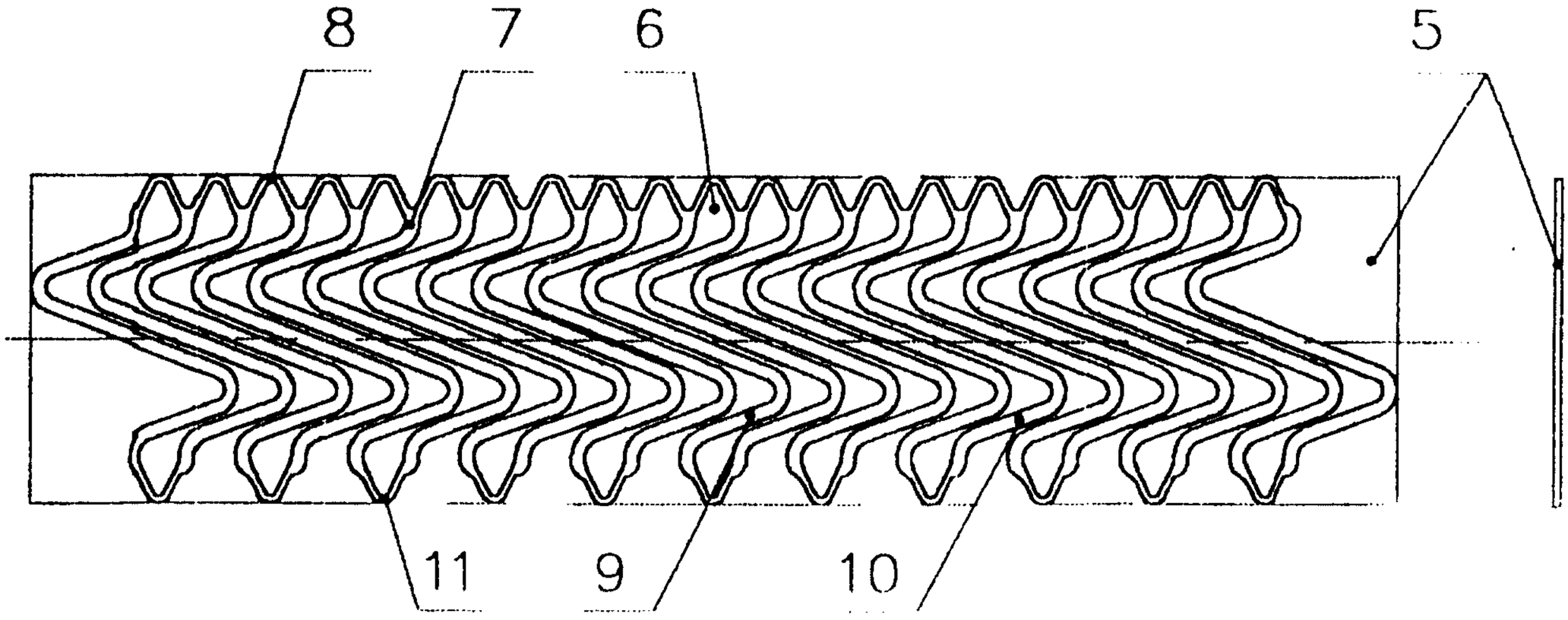


Fig.3

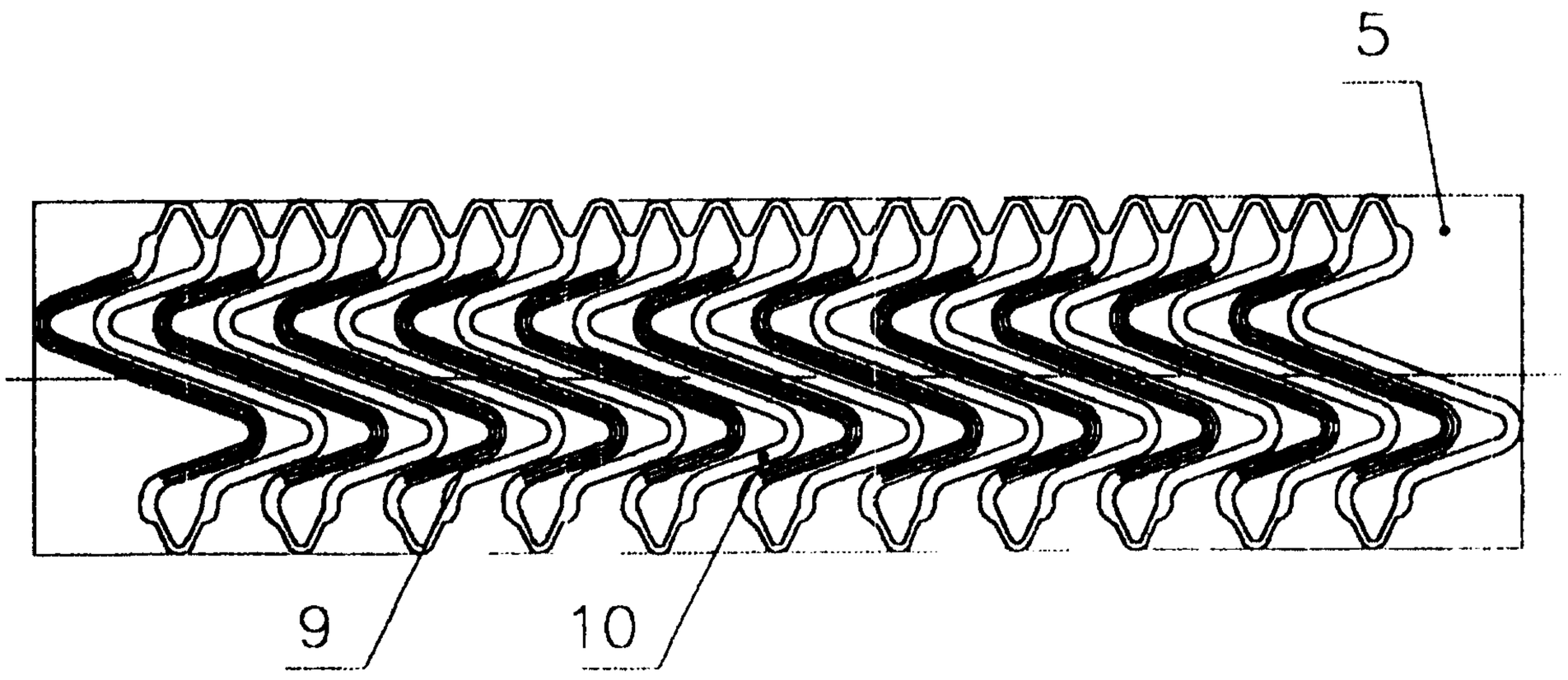


Fig. 4

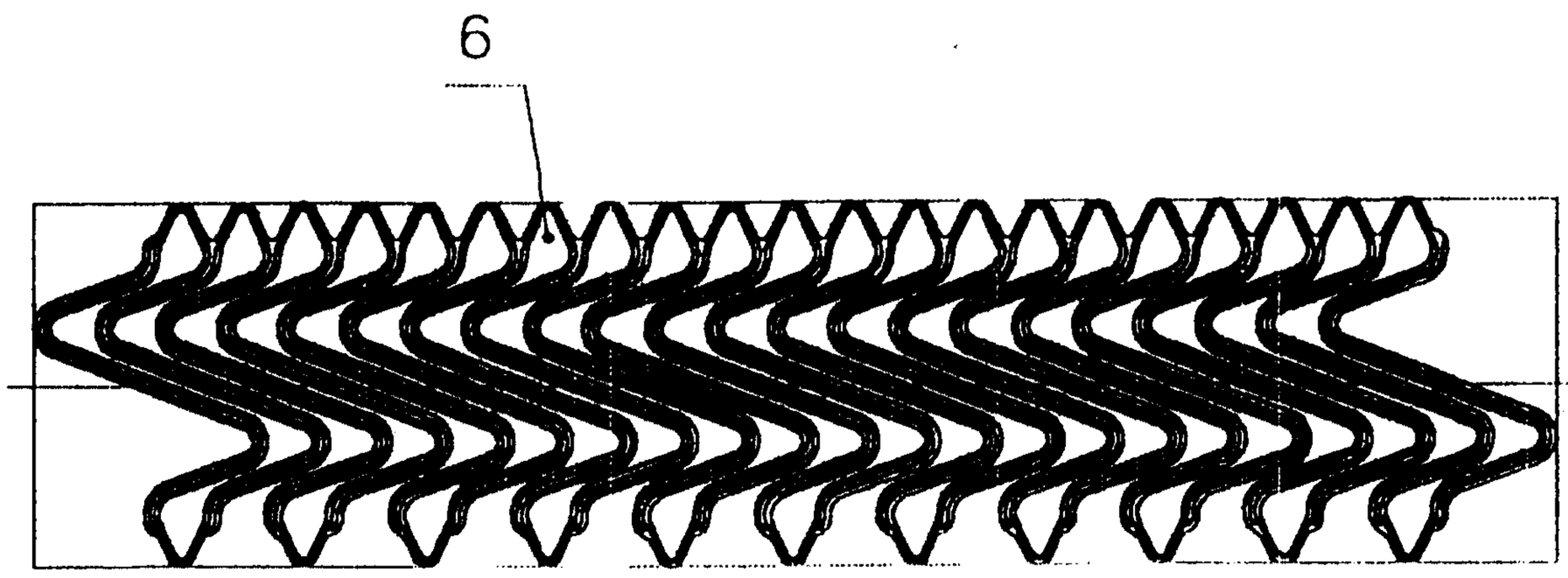


Fig.5

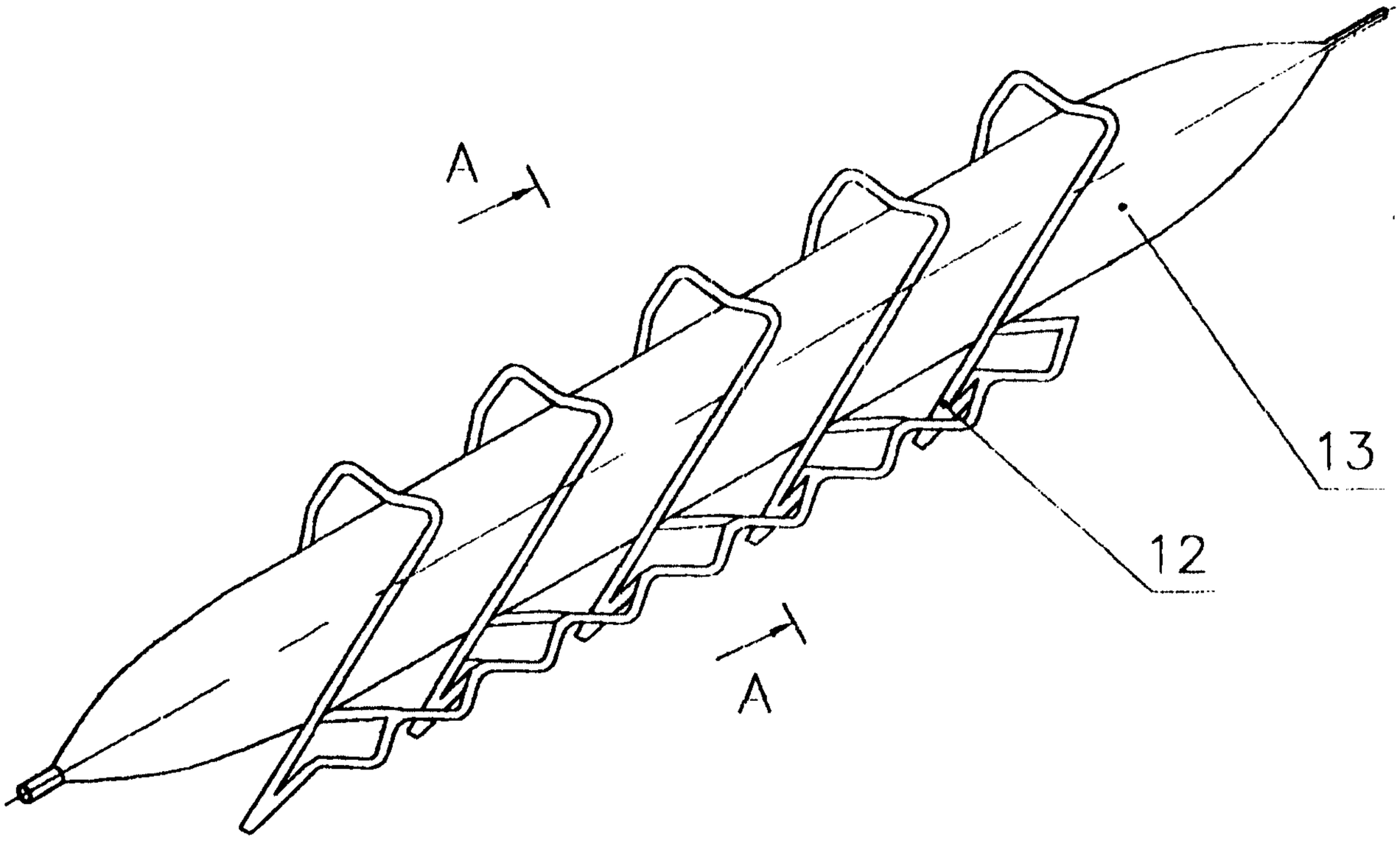


Fig.6

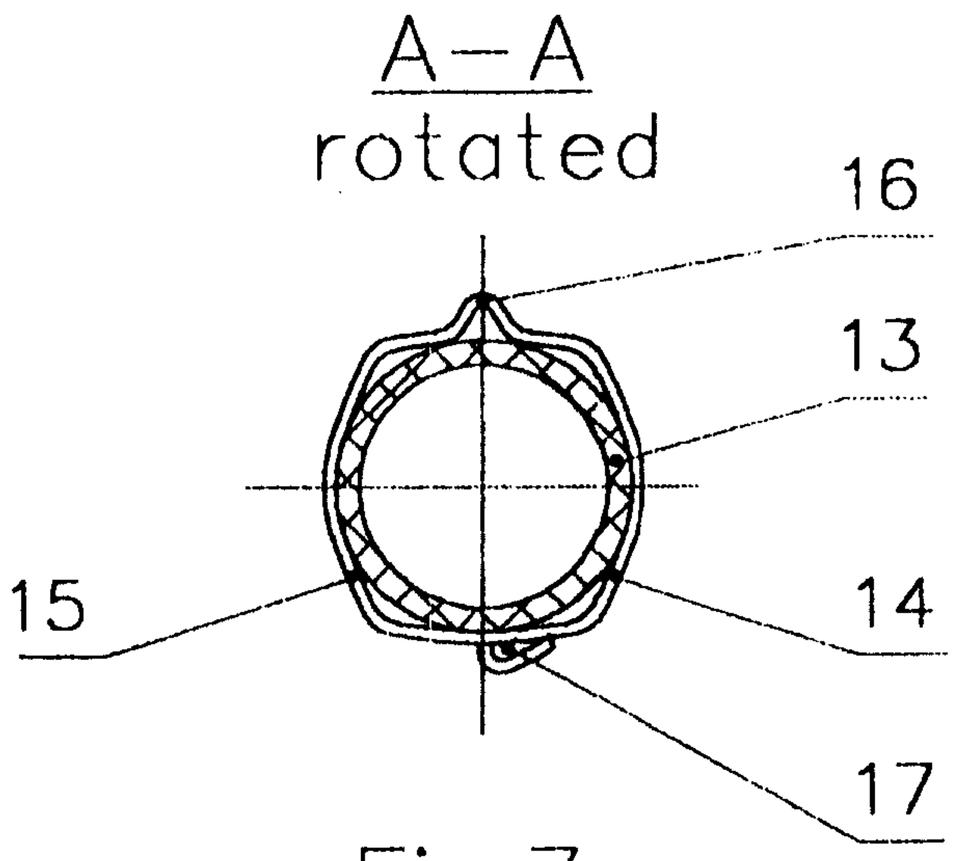


Fig.7

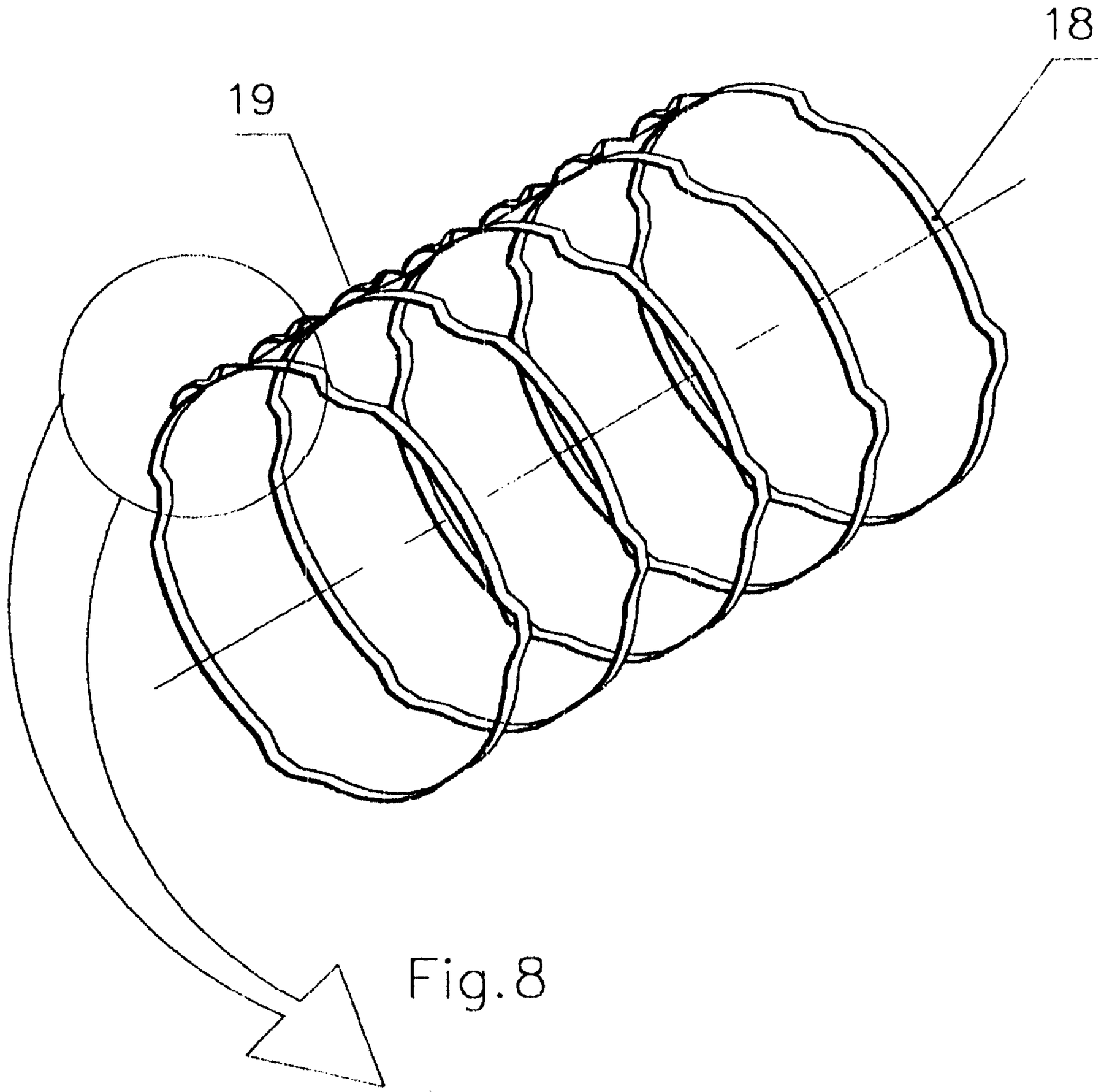


Fig.8

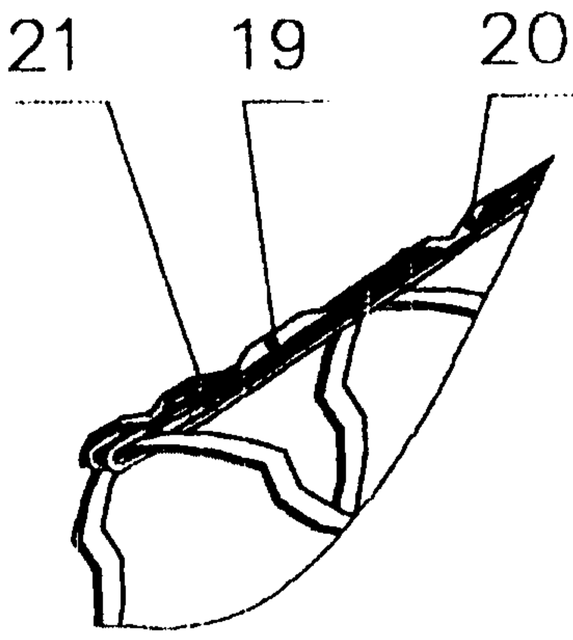


Fig.9

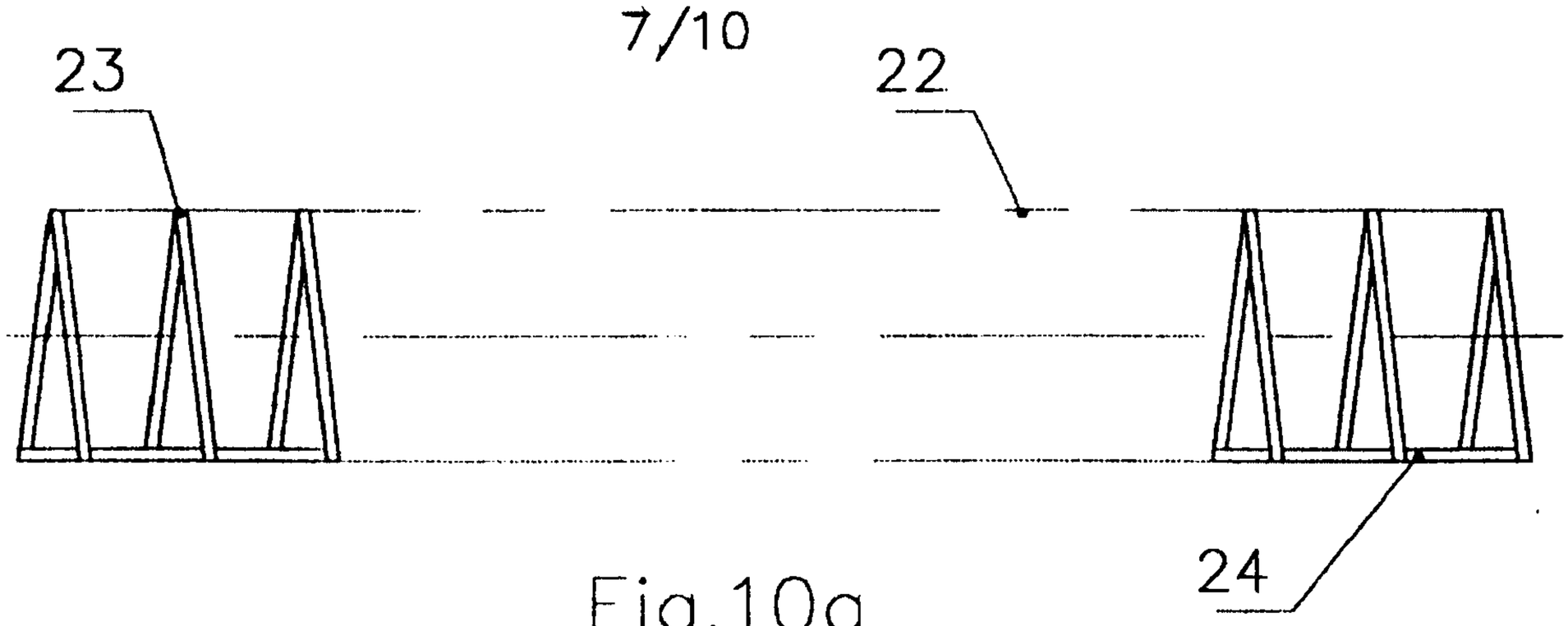


Fig.10a

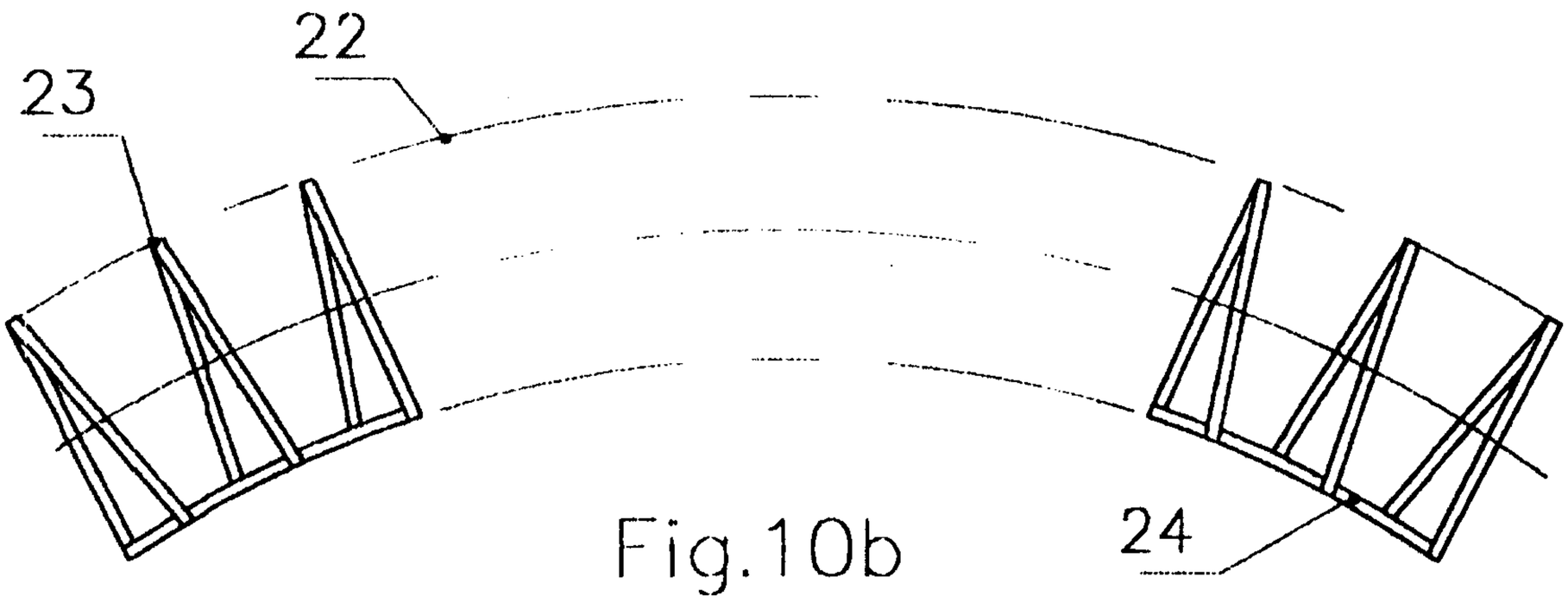


Fig.10b

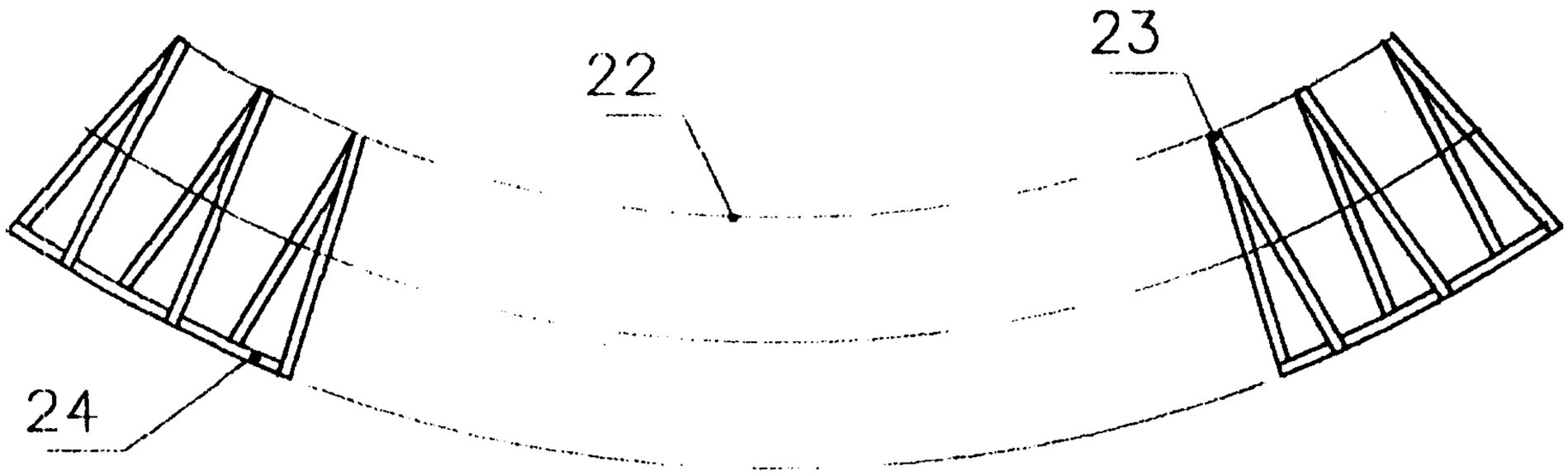


Fig.10c

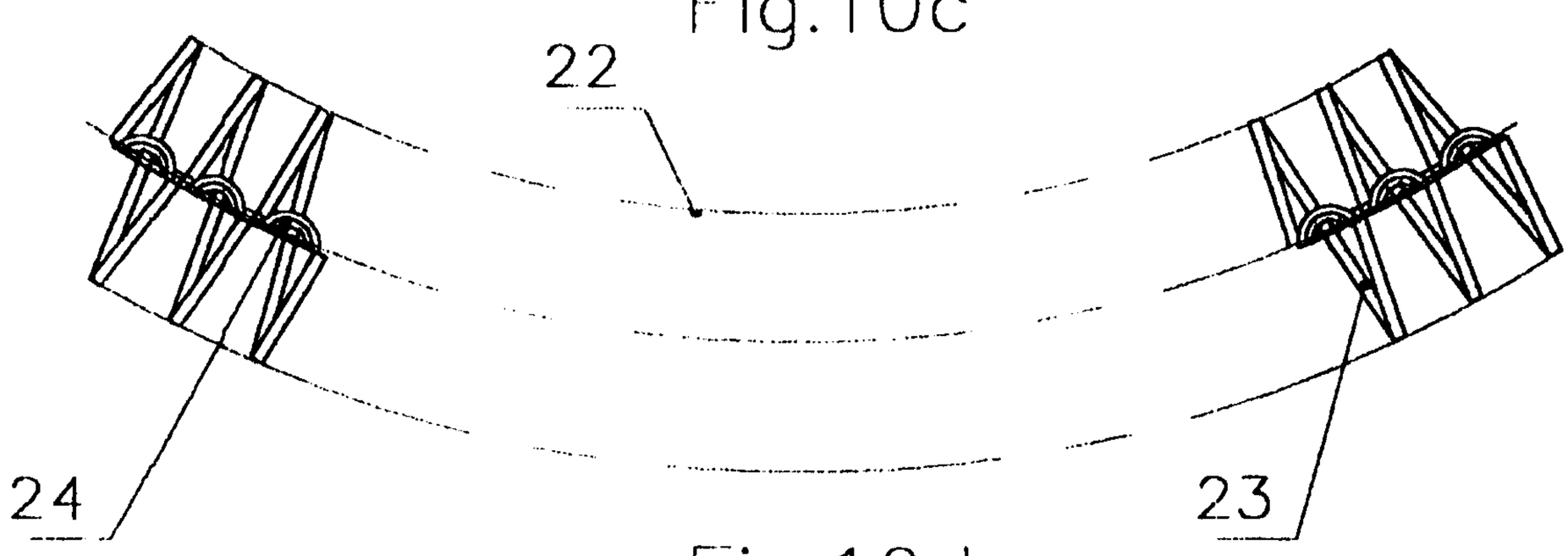


Fig.10d

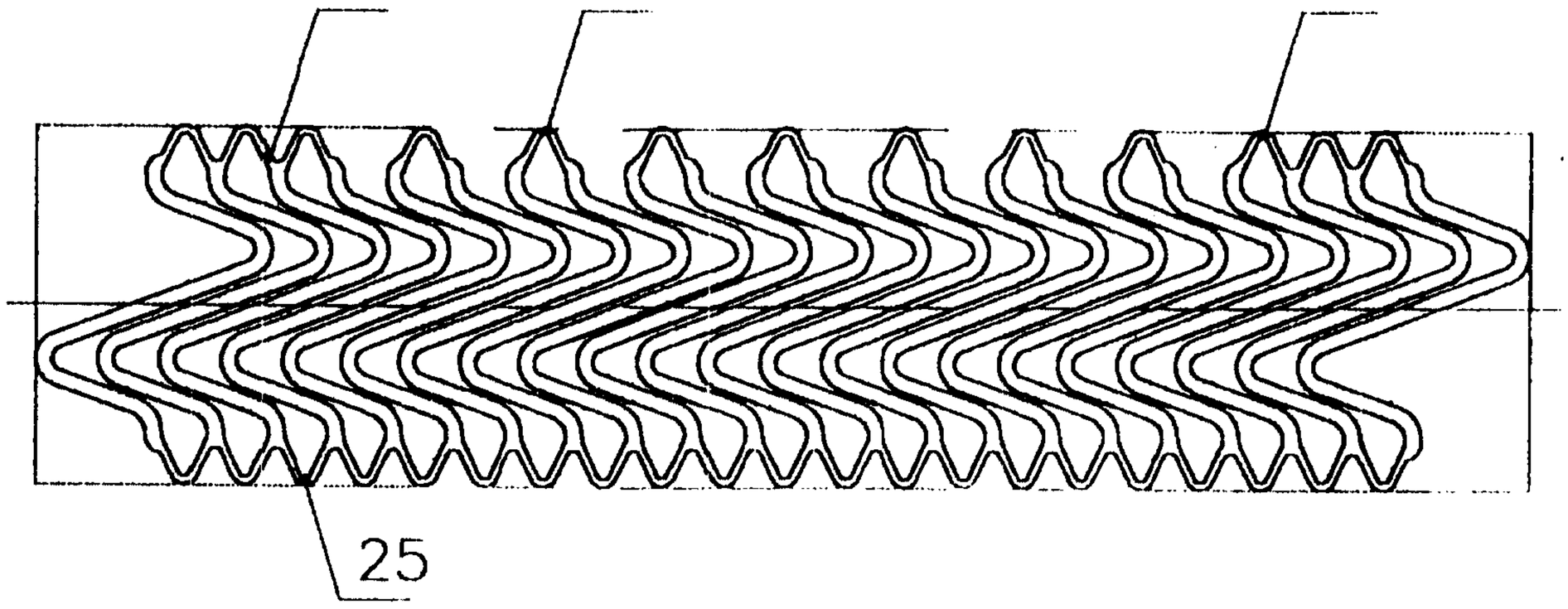


Fig.11

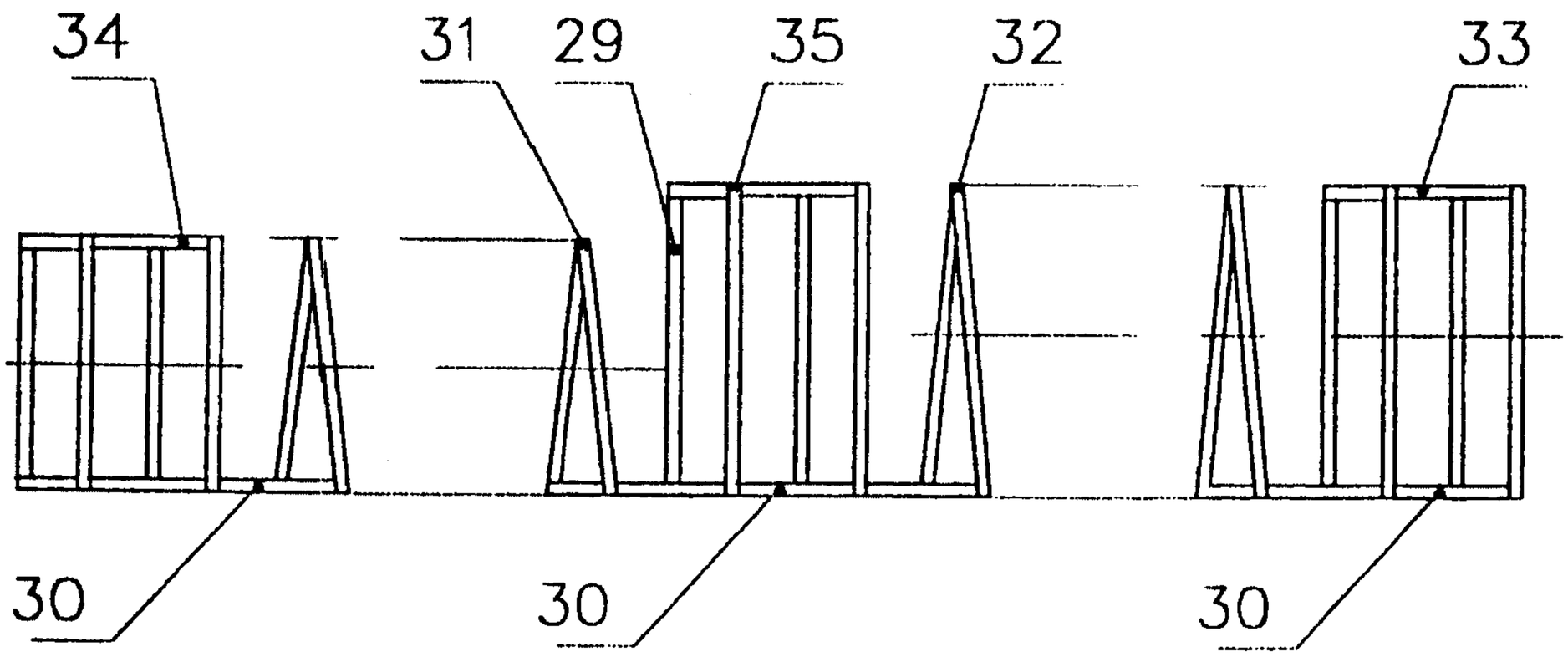


Fig.12

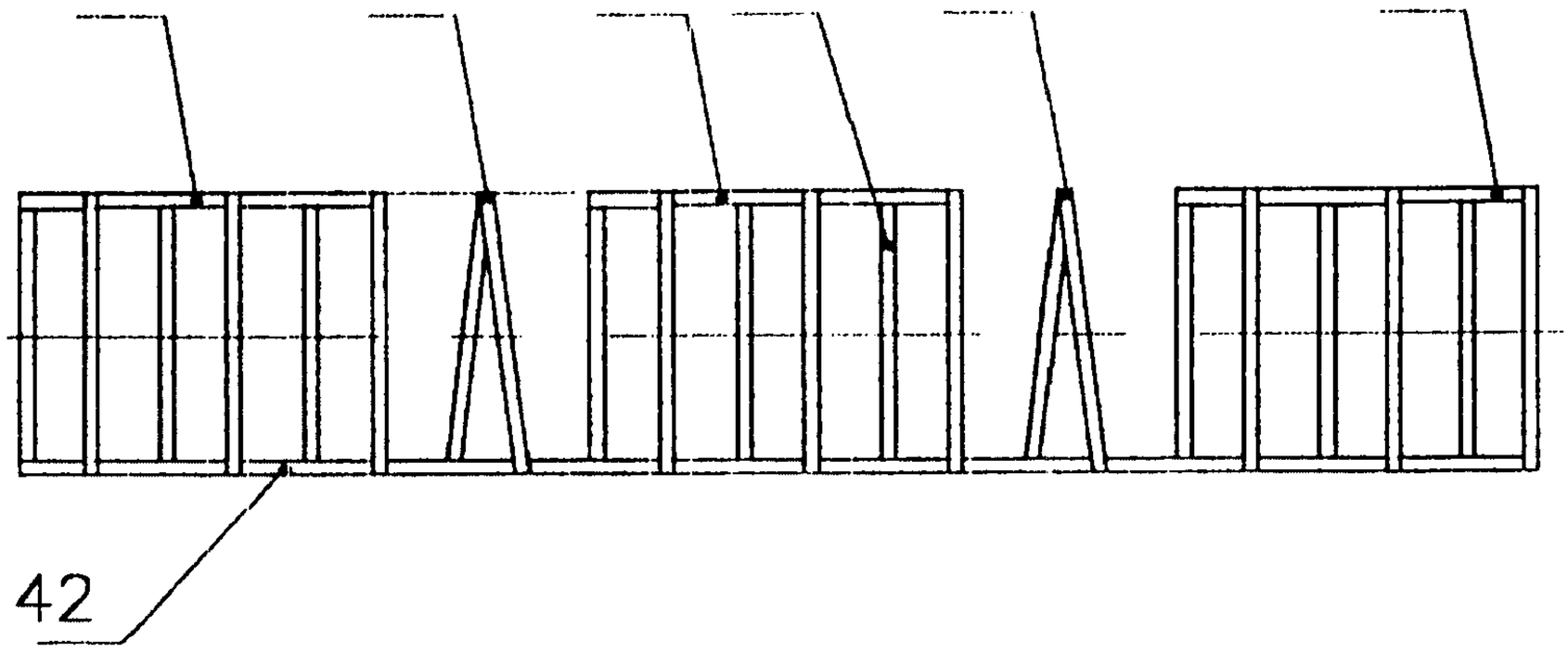


Fig.13

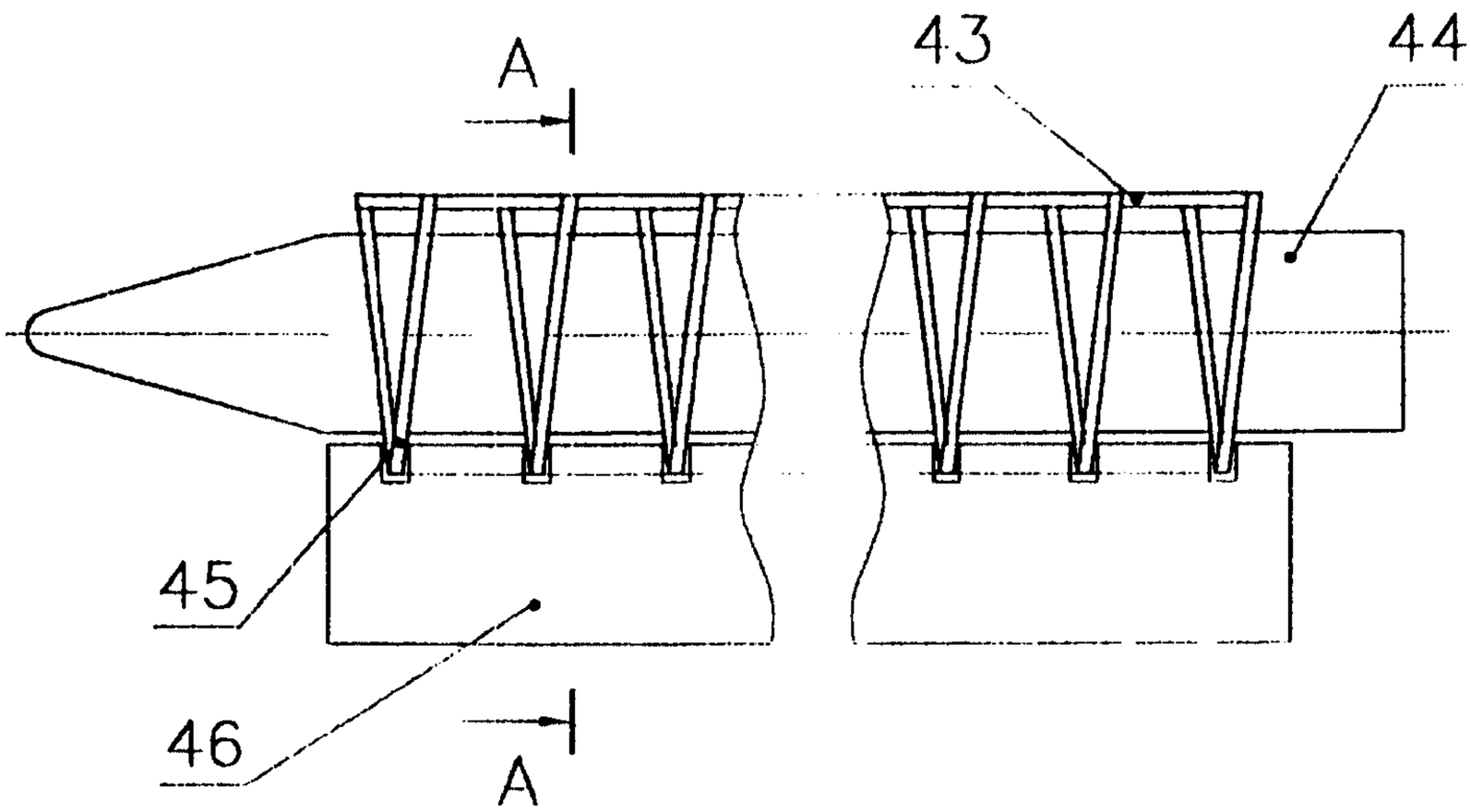


Fig.14

A—A

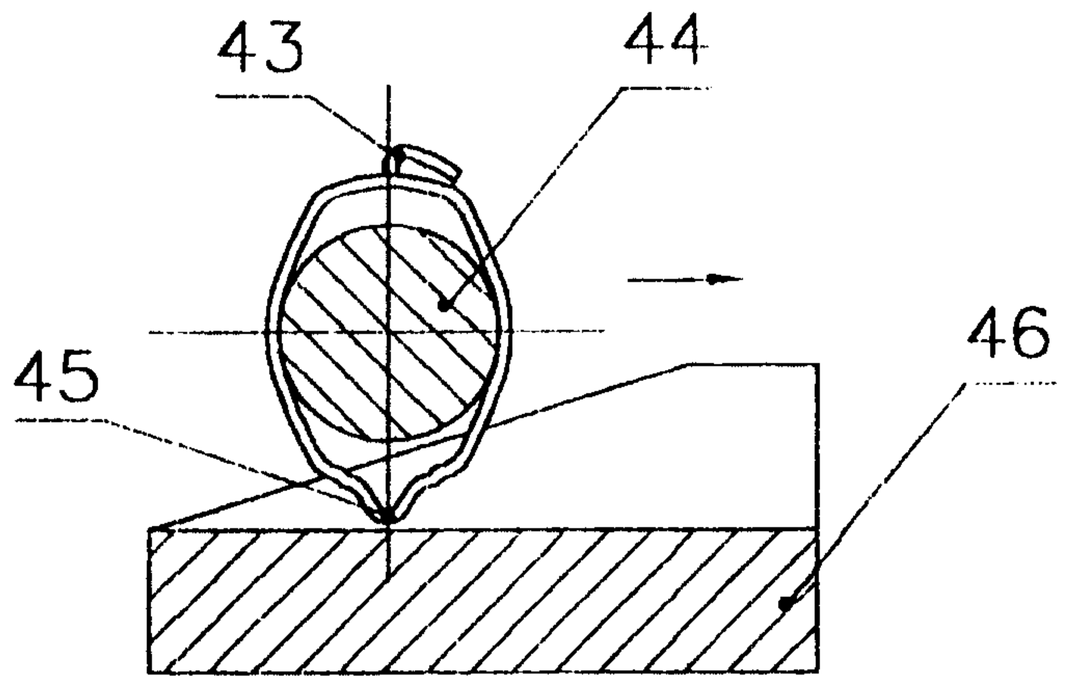
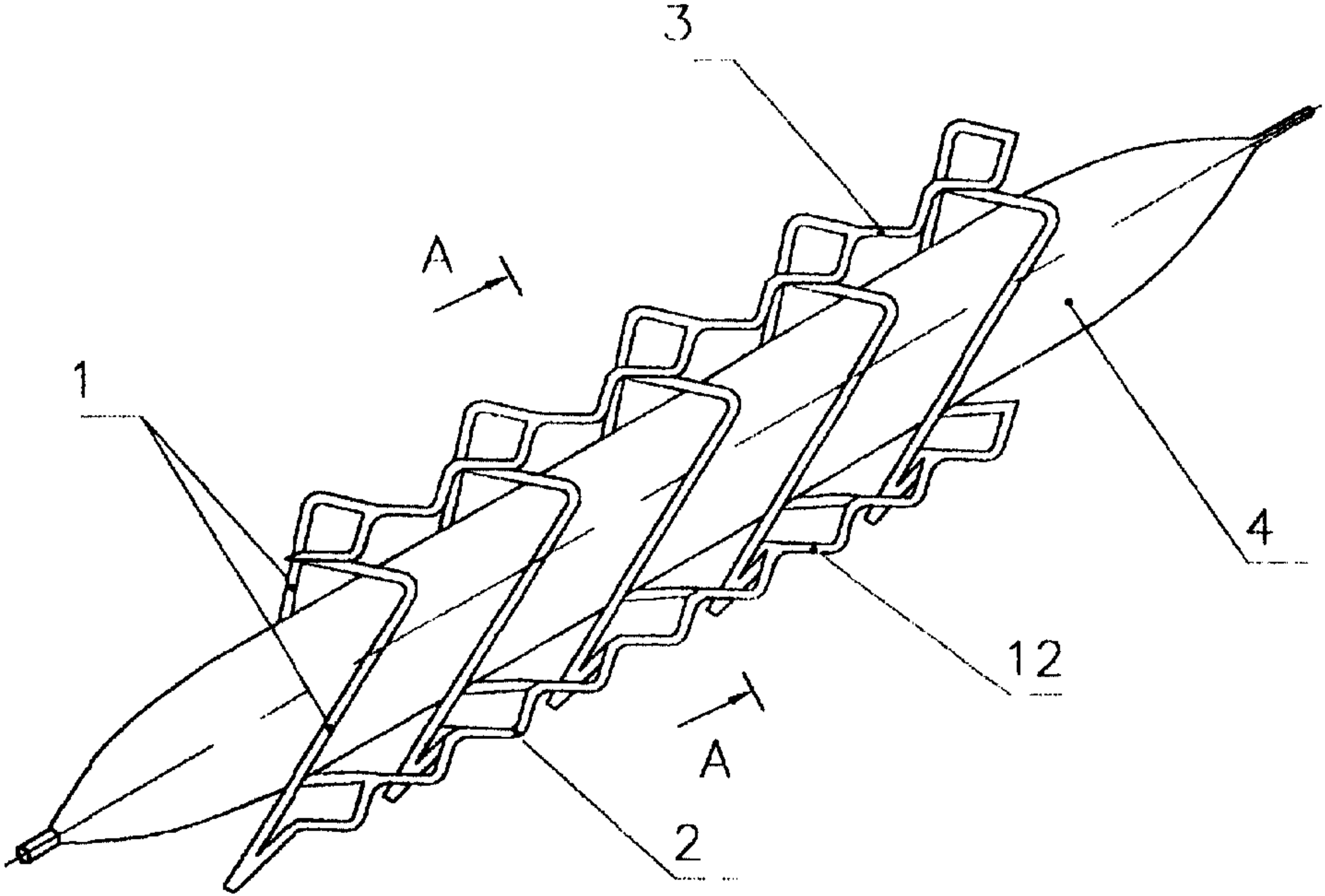


Fig.15


3
A
1
4
12
A
2