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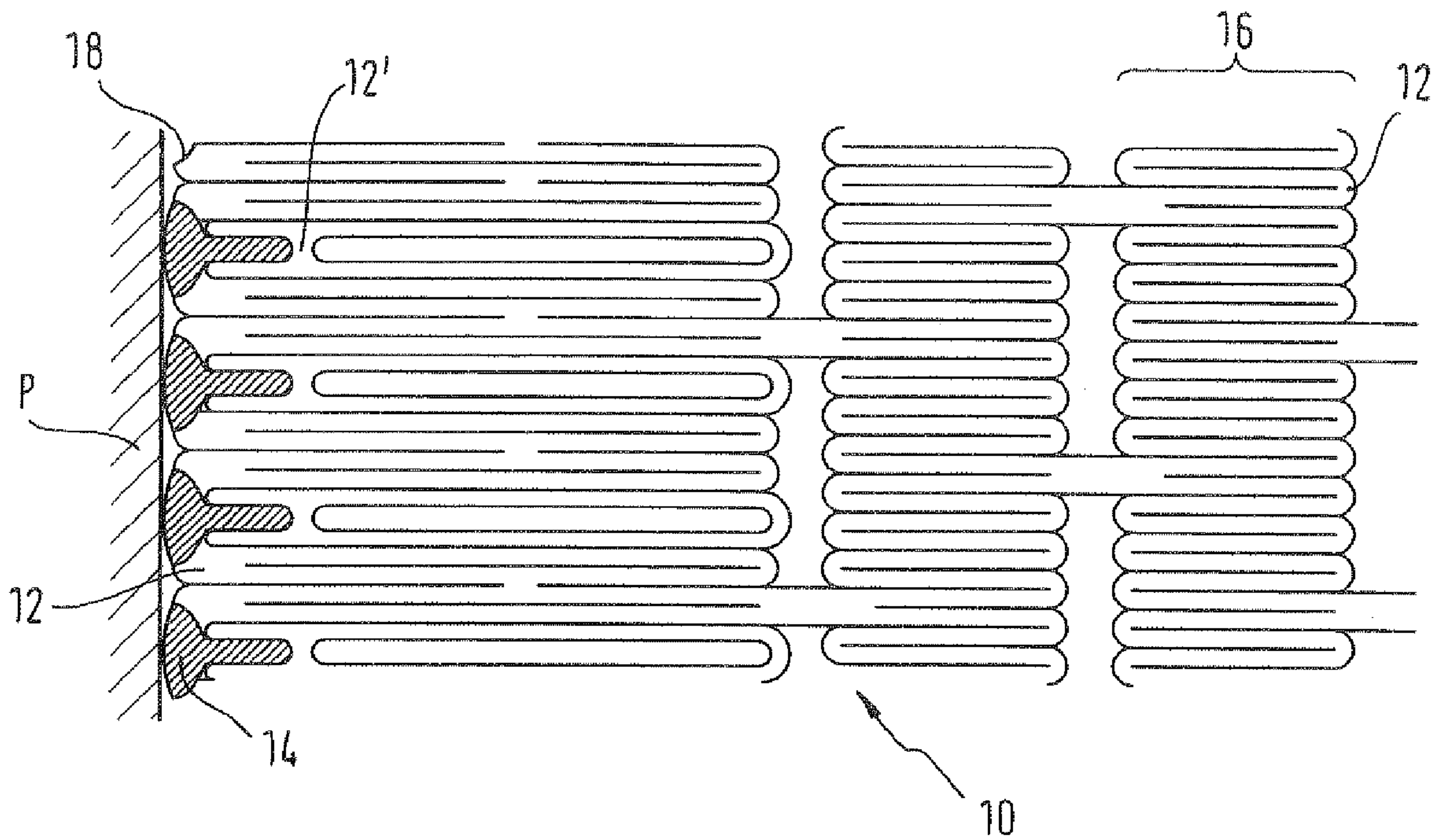
(54) Title: SELF-EXPANSIBLE STENT WITH RADIOPAQUE MARKERS AND METHOD OF MAKING SUCH A STENT



(57) Abrégé/Abstract:
Pushing a self-expanding stent from one of its ends, during release of the stent at a stenting site in a bodily lumen, by proximal withdrawal of a surrounding sheath, can impose unacceptably high stresses on parts of the strut network of the stent. For location of stents in a bodily lumen, it is customary to equip the end annulus of a stent with radiopaque markers. The present invention involves arranging the markers so that they share with non-marker portions of the end annulus the stresses imposed in the stent by the end pushing, whereby the high stresses are shared more equally by all the struts of the stent in the end annulus.

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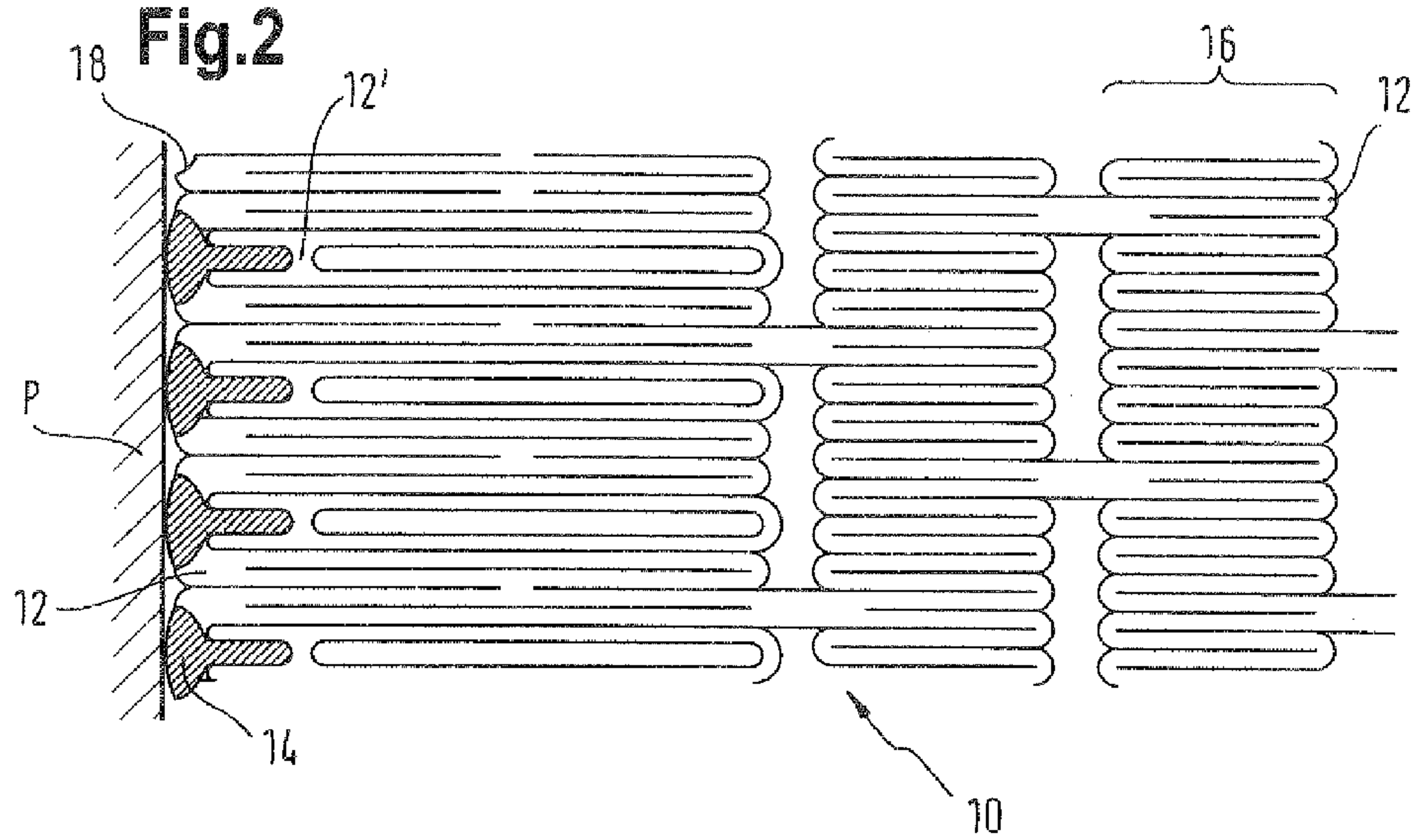
(54) **Title:** SELF-EXPANSIBLE STENT WITH RADIOPAQUE MARKERS AND METHOD OF MAKING SUCH A STENT

Fig.2



(57) **Abstract:** Pushing a self-expanding stent from one of its ends, during release of the stent at a stenting site in a bodily lumen, by proximal withdrawal of a surrounding sheath, can impose unacceptably high stresses on parts of the strut network of the stent. For location of stents in a bodily lumen, it is customary to equip the end annulus of a stent with radiopaque markers. The present invention involves arranging the markers so that they share with non-marker portions of the end annulus the stresses imposed in the stent by the end pushing, whereby the high stresses are shared more equally by all the struts of the stent in the end annulus.

WO 2009/030748 A3

Self-expansible Stent with Radiopaque Markers and Method of Making such a Stent

Field of the Invention

This invention relates to a radially self-expansible stent with a plurality of radiopaque markers attached to at least one of its ends, and to a method of making such a stent.

Background Art

Vascular stents are commonly used for the treatment of various vessel diseases. They are implanted transluminally using a catheter delivery system, to advance them to a stenting site, where they expand in order to widen the clogged or narrowed blood vessel. During the implantation procedure, the exact position of the stent within the vessel is monitored, mainly using X-ray imaging techniques. In order to ensure accurate placement, a good visibility of the stent is crucial. In general, this is achieved by attaching suitable markers which are made from materials with a radiopacity larger than that of the stent material. In addition, these markers have to be sufficiently large to provide a good X-ray contrast. For a precise determination of the stent position during delivery, it is advantageous to place the markers at both ends of the stent.

A tubular stent with a plurality of radiopaque markers attached to selected inflection zones around its circumference is disclosed in WO-A-2002/015820. The markers are spoon-shaped in a way that almost a complete ring of marker material is formed in the radially compressed state of the stent, providing a particularly high level of radiopacity during transluminal delivery. Thereby, an increase in visibility to radiation is achieved without any increase in the wall thickness of the stent at the position of the markers, maintaining a large radial opening for fluid flow as well as a small cross-sectional profile. Ideally, the number of markers in such a ring of markers as described above is to be kept small, so that each marker is large enough to facilitate sufficient visibility even in the radially expanded state of the stent. Furthermore, the number of marker/inflection zone joints should be kept at a minimum in order to reduce the risk of loss of a marker in the body following failure of such a joint after the stent has been placed.

For the case of self-expansible stents, delivery to the narrowed portion of the blood vessel is performed with the use of a co-axial catheter delivery system. Hereby, the stent is kept in its radially compressed state by an outer sheath. A co-axial cylinder inside the sheath is used for displacing the stent axially, relative to the outer sheath. Once the stent has been placed at the desired position within the vessel, the outer sheath is withdrawn while the inner cylinder pushes against one end of the compressed stent, precipitating the release of the stent from the delivery system. This procedure can impose on a stent such as the one disclosed in WO-A-2002/015820 stresses concentrated on the radiopaque markers which protrude axially beyond the axial end of the matrix of struts of the stent annulus. This stress, concentrating at the joints between the markers and the inflection zones from which they are cantilevered, has been identified by the present inventor as a feature that can and should be reduced or even eliminated.

This patent application declares the priority of GB 0 717 481.6. In that GB priority application the search report conducted on the claims by the UK Patent Office cited the following documents: WO 2006/047977; DE-U1-20 2004 014 789; WO 2004/028408 and EP-A-1 433 438. The disclosures of the first two citations are of the same invention from the same inventor.

WO 2006/047977 discloses a stent with an end annulus that carries radiopaque marker material in recesses in receiving elements of the stent metal. Thus, the marker material has exposed luminal and abluminal part-cylindrical opposed major surfaces and a thickness corresponding to that of the receiving element that surrounds the entire peripheral edge of the marker between its major surfaces. The marker has a width in the circumferential direction of the stent annulus, that is smaller than the circumferential length of the portion of the stent in which the marker is received. The marker enters the recess from a position radially outside the stent annulus, conical surface portions of the marker and the receiving portion serving to guide the marker into a snugly fitting disposition within the receiving portion, supported in all sides by the receiving portion.

The disclosure of WO 2004/028408 is similar. As to EP-A-1 433 438, it discloses other sorts of radiopaque markers on stents, notably a wire of radiopaque material wound around a strut of the stent, or a sleeve of radiopaque material crimped around a strut of the stent. Self-evidently, the stent is locally thicker in the radial direction, where such markers are located.

Summary of the Invention

The main objective of the present invention is to provide a self-expansible stent with radiopaque markers attached to it that offers a high degree of mechanical stability during release of the stent from the delivery system while maintaining a good visibility upon exposure to radiation.

The present invention provides a radially self-expansible stent with two end annuli for delivery by a co-axial catheter delivery system. The end annulus to be pushed during release of the stent has a plurality of spaced inflection zones distributed in its circumference, some of which carry a radiopaque marker. The idea is to get all the inflection zones to share the release stresses, not just the ones that carry a radiopaque marker. In general, the term "inflection zone" as used herein refers to a region where two or more strut ends are connected or where two or more struts intersect. It is, however, not restricted to this interpretation. A large number of different strut patterns are being used, or have at least been proposed, for tubular stents. Each of these patterns will have points which define an end to the stent tube and which allow for the attachment of a marker. Our definition of the term "inflection zone" is such that these end points are included.

The radiopaque markers are shaped and located on the selected inflection zones such that the compressive stress exerted on the end annulus during release of the stent is shared between the markers and the inflection zones that do not carry a marker. In this way, the strain on the marker/inflection zone joints is minimised, reducing the risk of physical damage, such as breakage or deformation. This concept is applicable to any stent design and allows for the use of only a small number of markers while the stability of the stent is secured. Keeping the number of markers at a minimum has significant advantages. First, having fewer marker/inflection zone joints reduces the danger of severed or bent markers. Self-expansible stents are extremely elastic but nevertheless not invulnerable to distortion. Fatigue performance is of vital importance with vascular stents, which flex with every heartbeat. Any stress that a stent matrix suffers locally, that exceeds the maximum planned for in the Government regulatory fatiguetesting protocol can adversely affect the fatigue life of the stent. This fact emphasizes the importance of a robust stent design, since even the slightest damage to the joints occurring during the release of the stent may shorten the service life of the stent. Furthermore, the circumference of the ring formed by the ensemble of markers in the radially compressed state of the stent is limited by the circumference of the stent tube itself. Thus, keeping the number of markers small allows for larger marker sizes and consequently an improved visibility of the stent in the radially expanded state.

So-called "ring stents" exhibit a plurality of rings arranged along their axial length which are interconnected between ring ends and have a plurality of inflection zones distributed in the circumference of the ring ends. In one embodiment, each of these ring ends comprises more inflection zones than the end annulus of the stent. Since, in the radially compressed state, the stent has a homogeneous circumference throughout its structure, the circumference of the end annulus of the stent will be the same as that of the ring ends, despite comprising less inflection zones. Therefore, the circumferential extent of the inflection zones that carry a marker can be increased, allowing for the attachment of larger markers, which is advantageous for reasons of visibility as discussed above. Even more space for the markers can be created within the end annulus of the stent if the inflection zones of the end annulus of the stent that do not carry a marker have a smaller circumferential extent than the inflection zones distributed in the circumference of the ring ends. Therefore, the above arrangement facilitates a possible increase in marker size without changing the number of inflection zones of the stent rings which may affect the mechanical properties of the stent, such as stability and elasticity.

A further way of creating more space for the markers within the end annulus of the stent is given in another preferred embodiment, where the inflection zones of the end annulus of the stent that do not carry a marker have a larger axial length parallel to the long axis of the stent than the inflection zones distributed in the circumference of the ring ends.

Preferably, the markers are bonded to the inflection zones at a glue interface, more preferably, by a weld. The form of the weld is hereby determined by the shape and the size of the marker.

In a preferred embodiment, the inflection zones that carry a marker differ in shape, size or both shape and size from the inflection zones that do not carry a marker. The inflection zones that carry a marker may, for example, have a smaller size so as to leave more space for the attached markers or a shape particularly suited for a certain type of weld (depending on the shape and size of the marker). In one embodiment, each inflection zone is present as a stem with an axial length parallel to the long axis of the stent. Preferably, the inflection zone stems that carry a marker have a smaller length than the inflection zone stems that do not carry a marker. This arrangement allows for the accommodation of portions of the markers (or even whole markers) between the neighbouring longer inflection zones.

Preferably, the markers and the inflection zones have the same thickness but markers with a greater radial thickness are not excluded. On the one hand, an increase in marker thickness beyond the stent annulus wall thickness is not desirable, since a large radial opening for fluid flow as well as a small cross-sectional profile of the stent ought to be maintained. On the other hand, both the radiopacity and the mechanical properties of the markers depend on their thickness. Consequently, too thin a marker will give a poor contrast when exposed to radiation and may be prone to deformation or even breakage.

In a preferred embodiment, each marker subtends a larger arc of the circumference of the end annulus than each inflection zone that does not carry a marker, improving the visibility of the stent ends. In any event, the width of the marker, in the circumferential direction, will generally be as larges as, or larger than, but not smaller than, the circumferential width of the inflection zone to which the marker is attached.

A number of different materials may be used for the fabrication of the stent and the radiopaque markers. Preferably, the stent is made from a nickel titanium shape memory alloy. Such an alloy provides the mechanical properties necessary for reliable stent operation, namely a high degree of elasticity and physical stability. The radiopaque markers are preferably made from tantalum, gold, or a ternary alloy made from nickel, titanium and a third, radiopaque metal. All these metals offer a high level of radiopacity. Both the above stent and marker materials are non-toxic and provide a good biological compatibility with the human body. For nickel titanium stents, markers of tantalum are of special interest because their electrochemical potentials are so similar.

In another preferred embodiment, the markers do not extend axially beyond the inflection zones which do not carry a marker, in the radially compressed state of the stent. This arrangement can be accomplished, for example, by making the inflection zones that carry a marker shorter than the ones that do not carry a marker. Preferably, during release of the stent from the delivery system, both the markers and the inflection zones which do not carry a marker abut, or are otherwise in physical contact with, the pushing part of the delivery system, i.e., the co-axial inner cylinder. In such a configuration, the compressive stress exerted on the end annulus during release of the stent is shared between the markers and the inflection zones without markers, minimising the risk of physical damage to the stent. A marker size large enough for excellent visibility can still be maintained by choosing a small number of inflection zones in the end annulus of the stent and by making the inflection zones that carry a marker sufficiently short.

In another preferred embodiment, portions of the periphery of the markers rest on the neighbouring inflection zones in the radially compressed state of the stent, such that the compressive stress exerted by the delivery system on the markers during release of the stent is delivered to the neighbouring inflection zones by the markers. Preferably, in this configuration the markers stand axially proud of the inflection zones that do not carry a marker. In this configuration, an increase in marker size can be achieved, while the distribution of the applied pressure between markers and inflection zones without markers is still maintained.

The markers can be welded to the inflection zones by methods described in above-mentioned WO-A-2002/015820. In a variation, however, the markers and inflection zones can be advanced towards each other along the longitudinal axis of the stent without any relative radial movement, for example by providing a form fit between the respective marker and inflection zone faces that face each other across the welding zone. The form fit can be accomplished by co-operating ramp surfaces on the marker and the inflection zone, that work together to inhibit any relative circumferential sliding movement in the width direction of the marker and inflection zone. In this way, the markers are guided into a position circumferentially aligned with the respective inflection zone, prior to being welded to that inflection zone.

Brief Description of the Drawings

Figure 1 shows a laser cutting of a stent with radiopaque markers attached to it, according to a first preferred embodiment;

Figure 2 shows one end of a laser cutting of a stent with radiopaque markers attached to it, according to a second preferred embodiment;

Figure 3 shows a portion of the end annulus in the radially expanded state of the stent, according to a second preferred embodiment; and

Figure 4 is a view of a fragment of one end of a stent, that shows an inflection zone comprising a marker and flanked by longer inflection zones that do not carry any marker.

Detailed Description of Preferred Embodiments

Figure 1 shows a laser cutting of a radially self-expansible stent 10 made from Nitinol with radiopaque markers 14 made from Tantalum attached, according to a first preferred embodiment. The markers 14 are welded to the inflection zones 12′ and extend as far as the inflection zones that do not carry a marker 12. In this way, the compressive stress exerted on the end annulus 11 by a stent pusher annulus P during release of the stent is shared between the markers 14 and the inflection zones 12 that do not carry a marker because what abuts the pusher P is not just the markers 14 but also the inflection zones 12 that carry no marker 14. The stent comprises four interconnected rings 16 with fourteen inflection zones 12′′ in the circumference of each ring end. In contrast to this, the end annuli 11, 11′ only have twelve inflection zones 12, 12′. This allows for a larger circumferential extent of the inflection zones 12′

and the markers 14 attached thereto since the circumferential extent of the inflection zones 12 is identical to that of the inflection zones 12′′. In addition to this, the axial length of inflection zones 12 is larger than that of inflection zones 12′′, allowing for longer markers. Thus, the present embodiment is specifically designed for accommodating large markers 14 in order to optimise the visibility of the stent 10.

Figure 2 shows one end of a laser cutting of a stent 10 made from Nitinol with radiopaque markers 14 made from Tantalum attached to it, according to a second preferred embodiment. The markers 14 are welded to the inflection zones 12' and stand axially proud of the inflection zones 12 that do not carry a marker 14. As can be seen, the shape of inflection zones 12′ is adapted in order to allow for a robust welded connection with marker 14 and differs significantly from that of inflection zones 12. The increased circumferential extent of inflection zones 12′ as compared to inflection zones 12 is facilitated by the difference in the number of inflection zones 12, 12′, 12′′ between the ends of rings 16 and the end annulus 11, analogous to the first preferred embodiment. Furthermore, inflection zones 12 have grooves 18 at their top ends which are shaped to accommodate the peripheral portions of the T-shaped markers 14 in the radially compressed state of the stent 10. In this way, despite the fact that during the release of the stent 10 only the markers 14 are in physical contact with the pushing part P of the delivery system, the compressive stress exerted on the markers is shared between the markers and the neighbouring inflection zones. The present configuration allows for the accommodation of particularly large markers 14 while at the same time maintaining the stability of the stent 10. Figure 3 shows a portion of the end annulus 11 in the radially expanded state of the stent 10, according to the present embodiment. Here, the grooves 18 are more clearly visible.

Turning to Figure 4, here we see a tantalum marker 14 located between two long inflection zones 12 and to be welded to a short inflection zone 12′. The marker is joined by two small bridges 48, 50 to a tantalum tube 40. These bridges 48, 50 facilitate separation of the marker 14 from the tantalum tube 40 in an uncomplicated manner by the application of an external force, once the welding has been performed. However, the bridges 48, 50 are not a required feature and other methods may be applied for separating the marker 14 from the tantalum tube 40. In particular, a single laser may be used for both welding the marker 14 to the inflection zone 12' and separating the marker 14 from the tantalum tube 40. In this case, first the welding step is performed and subsequently the separation step is carried out after increasing the output power of the laser. Both these steps can be carried out in a single operation, thus improving the efficiency of the fabrication process. If the above described separation method is used, the connection profile between tantalum tube 40 and marker 14 may be of any conceivable form, for example, a single wider bridge. As explained in WO 02/015820 mentioned above, the tantalum tube 40 and the tube of nickel titanium shape memory alloy of the stent and the inflection zones 12 are approximated axially, whereupon the facing surfaces 20 and 22 of the inflection zone 12 and marker 14 come into facing relationship, ready for welding together. The skilled reader will appreciate that during this approximation by axial approach there is no need for any relative radial movements between the two work pieces.

As to circumferential alignment between the marker 14 and the inflection zone 12, we see in Figure 4 how the facing surfaces 20, 22 incorporate form fit portions 24, 26, 28, 30 that work together to guide the advancing marker 14 into alignment with the inflection zone so there is clearance 60, 62 between the marker 14 and the two flanking inflection zones 12, respectively.

The facing surfaces 20, 22 achieve a circumferential guiding function through a mechanical "form fit". As the nose 70 of the marker 14 approaches the inflection zone 12′ it can slide along the facing surface 20 until it goes past the axially aligned straight edge 24 when straight edge 26 of the nose 70 will then be facing the straight edge 24.

By then, however, the V-shaped recess in the facing surface 22 of the marker, flanked by reverse-angled surface 30, will have received the V-shaped peak in the facing surface 20 of the inflection zone 12′ flanked by reverse-angled surface portion 28 in the facing surface 20. Any widening in the gap between surfaces 24 and 26 is prevented by the abutment of surfaces 28 and 30 (and *vice versa*). In this way, the marker 14, approximated to the inflection zone 12′ and ready for welding to it, has no freedom any more to move circumferentially relative to the inflection zone 12′. Exactly in this "welding ready" disposition, the end surface 56 of the marker 14 lies in the same plane, transverse to the axis of the stent, as the end surfaces 52 and 54 of the flanking inflection zones 12. Thus, when the stent is pushed by a pusher P, the pushing force is imposed equally on all of end surfaces 52, 54 and 56.

The illustrated embodiments are by way of example and the skilled reader will appreciate that features can be isolated from one embodiment and can be taken and used in other embodiments within the scope of the claims which follow.

Claims:

1. A radially self-expansible stent having a thickness in the radial direction and an axial length between end annuli for delivery by a co-axial catheter delivery system, a part of which during release of the stent from the delivery system pushes on one end of the stent while withdrawing a sheath from around the abluminal surface of the stent, whereupon the stent expands from a radially compressed into a radially expanded state,
the end annulus to be pushed having a circumference, with a plurality of spaced inflection zones being distributed in the circumference, selected inflection zones carrying a radiopaque marker,

characterised in that

the markers are shaped and located on the selected inflection zones such that the compressive stress exerted on the end annulus during release of the stent is shared between the markers and the inflection zones that do not carry a marker,

the markers are attached to the inflection zones in a fastening position by a weld, and

the markers and the inflection zones exhibit respective facing surfaces that face each other across the welding zone, said facing surfaces including a mechanical form fit that inhibits relative circumferential sliding movement and allows relative movement of the marker and the inflection zone into the fastening position devoid of movement with a component in a radial direction relative to the longitudinal axis of the stent.

2. A stent according to claim 1, wherein the stent comprises a plurality of rings arranged along its axial length, the rings being interconnected between ring ends and having a plurality of inflection zones distributed in the circumference of the ring ends, each of said ring ends comprising more inflection zones than the end annulus of the stent.

3. A stent according to claim 2, wherein the inflection zones of the end annulus of the stent that do not carry a marker have a larger axial length parallel to the long axis of the stent than the inflection zones distributed in the circumference of the ring ends.

4. A stent according to any one of claims 2 and 3, wherein the inflection zones of the end annulus of the stent that do not carry a marker have a smaller circumferential extent than the inflection zones distributed in the circumference of the ring ends.

5. A stent according to any one of claims 1 to 4, wherein the inflection zones that carry a marker are a different shape from the inflection zones that do not carry a marker.

6. A stent according to any one of claims 1 to 5, wherein the inflection zones that carry a marker are a different size from the inflection zones that do not carry a marker.

7. A stent according to any one of claims 1 to 6, wherein each inflection zone is present as a stem with an axial length parallel to the long axis of the stent, wherein the inflection zone stems that carry a marker have a smaller

length than the inflection zone stems that do not carry a marker.

8. A stent according to any one of claims 1 to 7, wherein the markers and the inflection zones have the same thickness.

9. A stent according to any one of claims 1 to 8, wherein each marker subtends a larger arc of the circumference of the end annulus than each inflection zone that does not carry a marker.

10. A stent according to any one of claims 1 to 9, wherein the stent is made from a nickel titanium shape memory alloy.

11. A stent according to any one of claims 1 to 10, wherein the radiopaque markers are made from tantalum, gold, or a ternary alloy made from nickel, titanium and a third, radiopaque metal.

12. A stent according to any one of claims 1 to 11, wherein, in the radially compressed state of the stent, the markers do not extend axially beyond the inflection zones which do not carry a marker.

13. A stent according to any one of claims 1 to 12, wherein, in the radially compressed state of the stent, during release of the stent from the delivery system, the markers and the inflection zones which do not carry a marker are both exposed on the end annulus of the stent to receive directly a pushing force from the pushing part of the delivery system.

14. A stent according to any one of claims 1 to 13, wherein, in the radially compressed state of the stent, portions of

the periphery of the markers rest on the neighbouring inflection zones such that the compressive stress exerted by the delivery system on the markers during release of the stent is delivered to the neighbouring inflection zones by the markers.

15. A stent according to claim 14, wherein the markers stand axially proud of the inflection zones that do not carry a marker.

16. A stent as claimed in any one of claims 1 to 15 and including a welded zone that extends across the full width of each inflection zone that carries a radiopaque marker and lies between the inflection zone and the marker.

17. Method of fastening a radiopaque marker to an inflection zone of a radially self-expanding stent, in which the marker is advanced into a fastening position relative to the said inflection zone and then welded to the inflection zone at a welding zone between the inflection zone and the marker,

characterized in that:

the relative movement of the marker and inflection zone, into the fastening position, is devoid of movement with a component in a radial direction, relative to the longitudinal axis of the stent, and

in the fastening position an end surface of the marker lies in the same plane, transverse to the axis of the stent, as end surfaces of inflection zones flanking the marker.

18. Method according to claim 17, wherein the marker and the inflection zone exhibit respective facing surfaces that face each other across the welding zone, said facing surfaces including a mechanical form fit that inhibits relative circumferential sliding movement, once the marker is in the fastening position.

19. Method according to claim 18, wherein the mechanical form fit is provided by ramp surfaces on the marker and the inflection zone which co-operate, as the marker approaches axially the inflection zone, to guide the marker and the inflection zone into a circumferentially aligned disposition, ready for welding together the marker and the inflection zone, in the welding zone.

20. A stent delivery system carrying a stent as claimed in any one of claims 1 to 16 or a stent made by a process according to any one of claims 17 to 19, that includes a stent pusher that abuts both the markers and the inflection zones which do not carry a marker at one end of the stent.

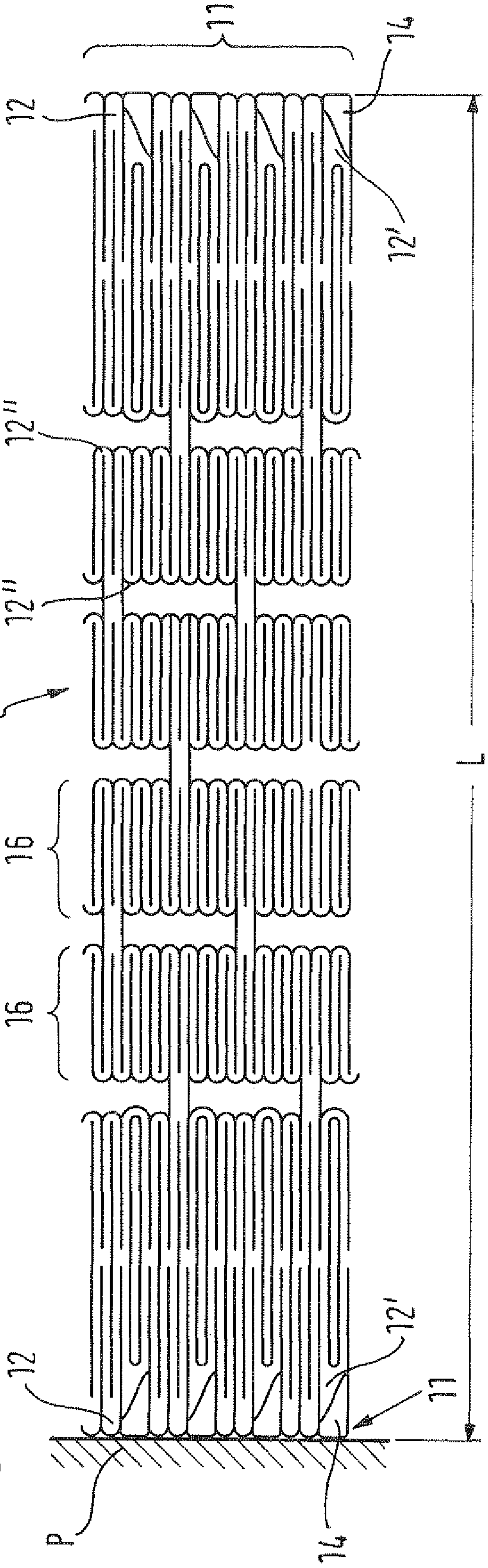


Fig.1

Fig.2

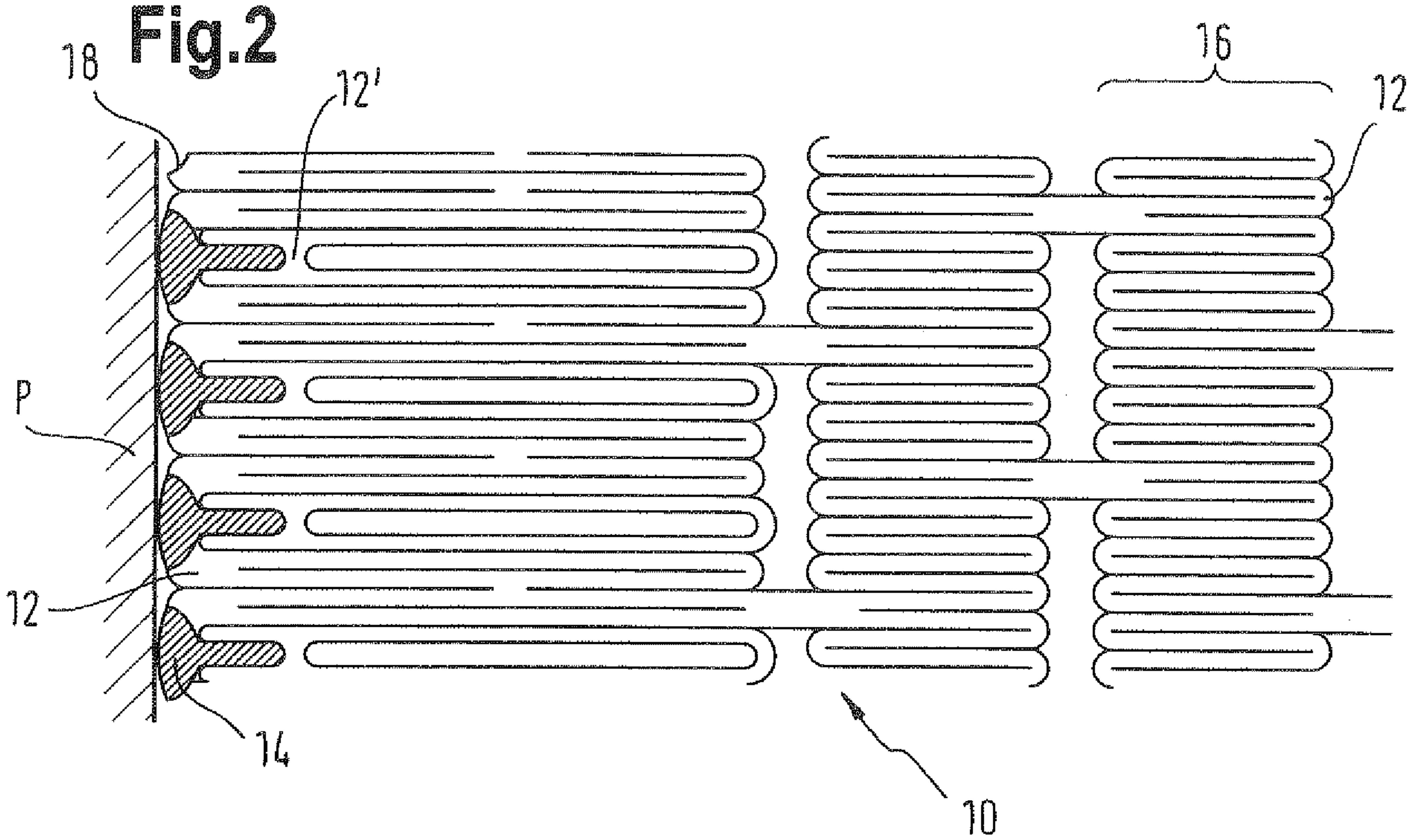


Fig.3

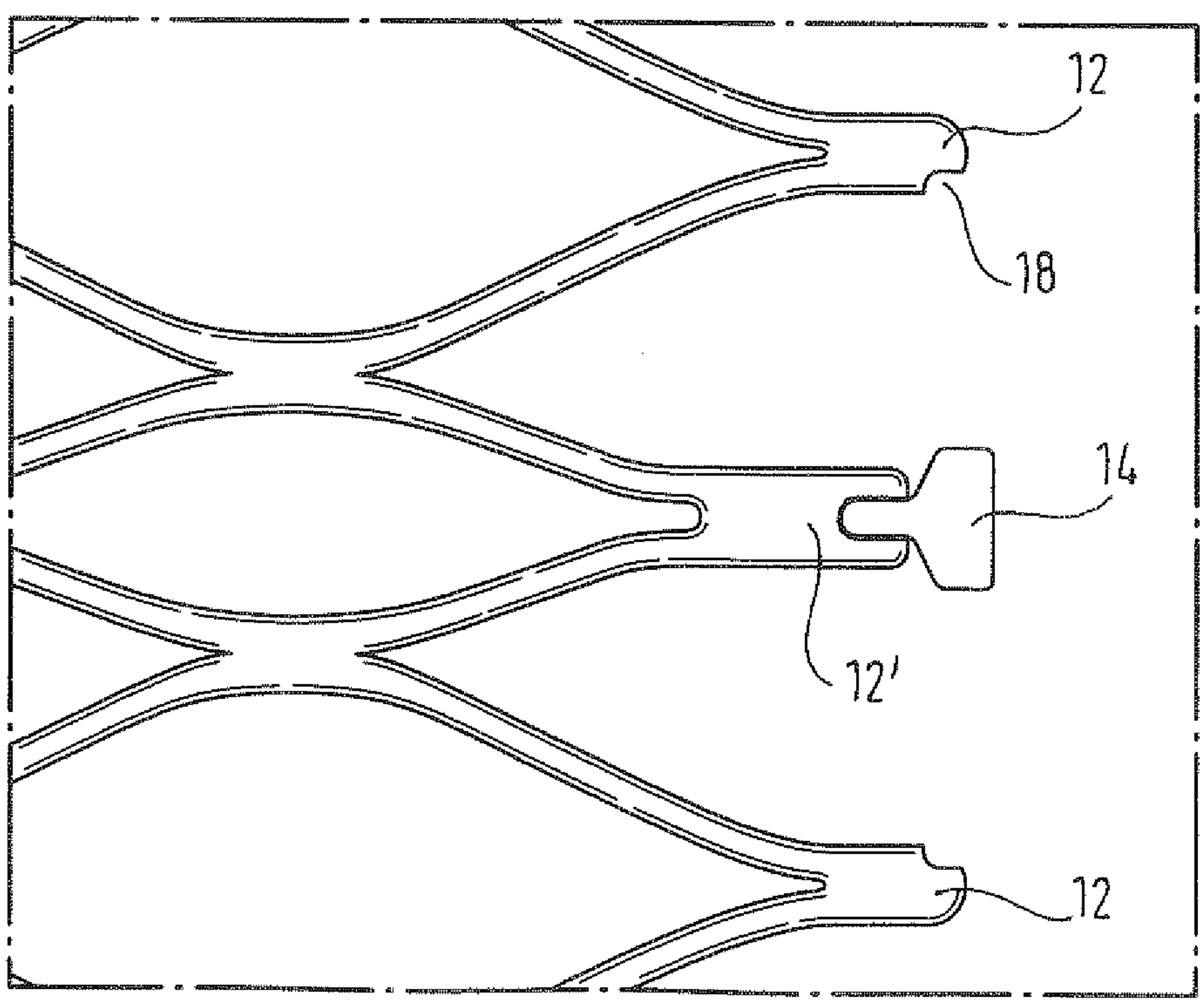
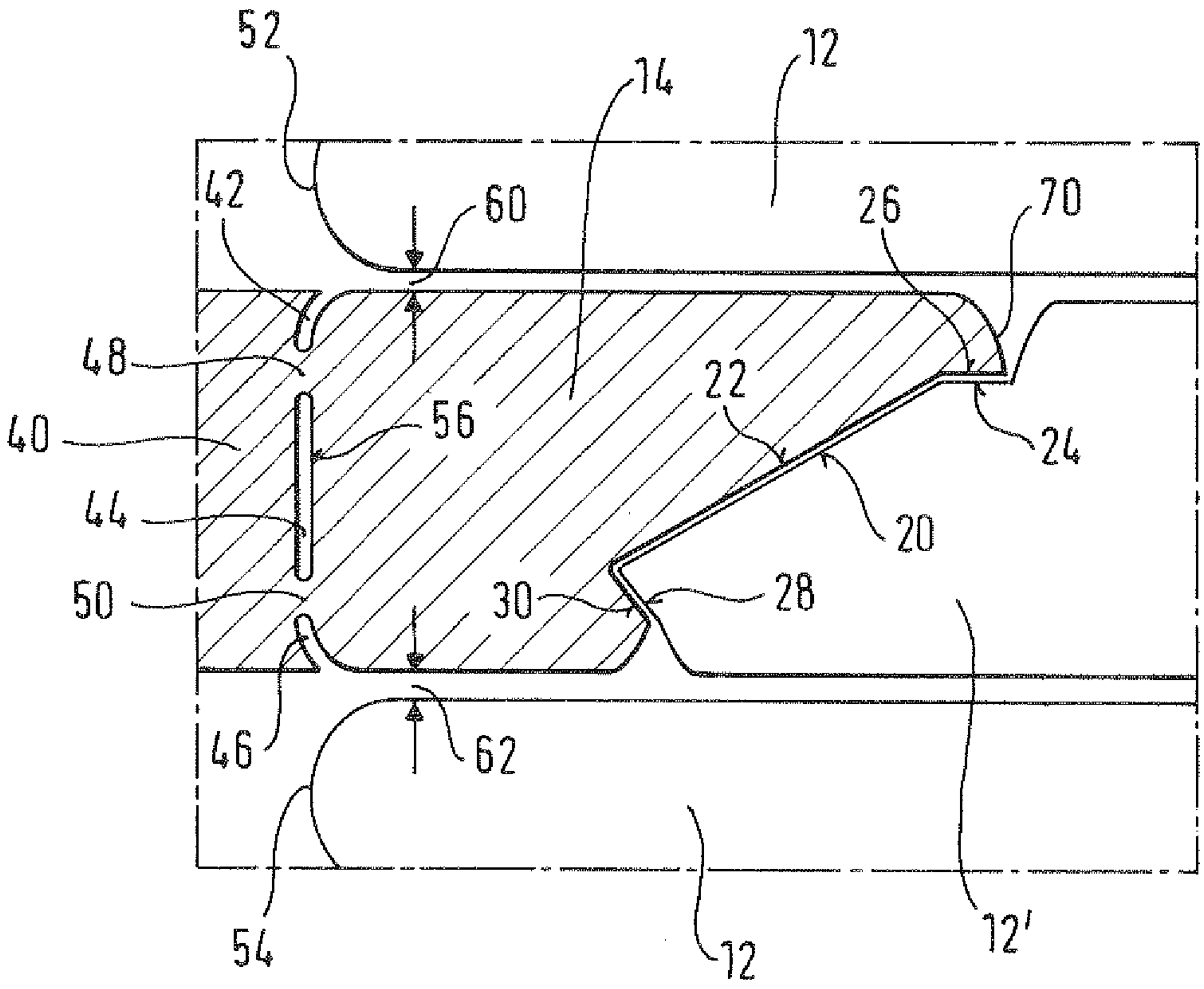
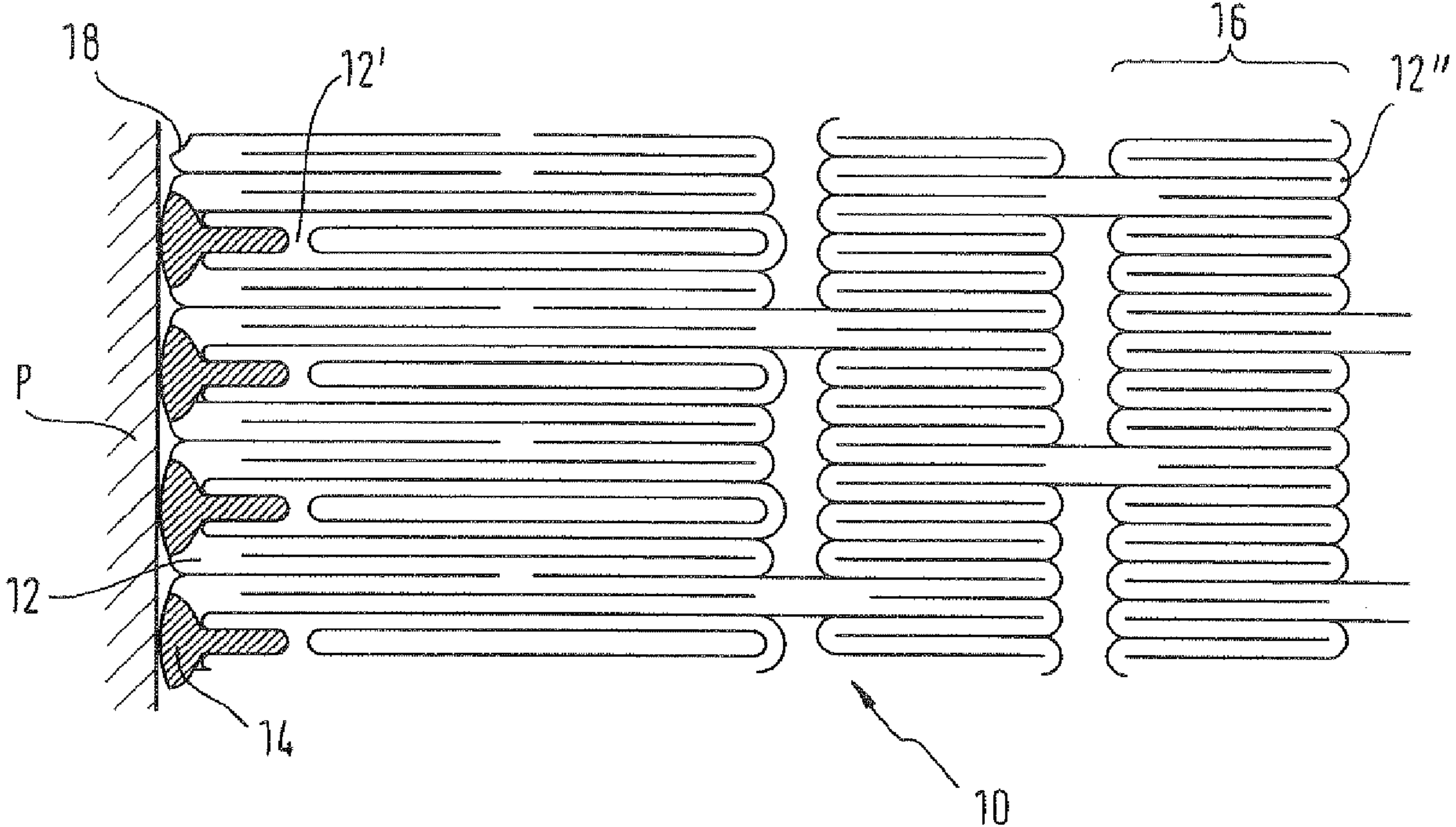


Fig. 4





18
12'
16
12''
P
12
14
10