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Stent having varied amounts of structural strength along its length

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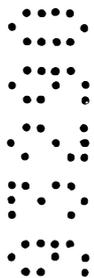
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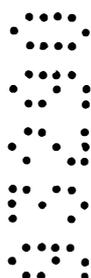
(56) Related Art
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US 5395390
US 5108417

ABSTRACT

The invention is directed to an expandable stent for implanting in a body lumen, such as a coronary artery. The stent has an open lattice structure and is constructed so that at least one end section has a thicker cross-section and corresponding greater radial strength than the remaining sections of the stent.



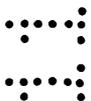
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COMPLETE SPECIFICATION
FOR A STANDARD PATENT
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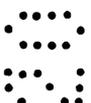
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Invention Title: **"Stent having varied amounts of structural strength along its
length"**

The following statement is a full description of this invention, including the best method of
performing it known to us:

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to expandable endoprosthesis devices, generally referred to as stents, which are adapted to be implanted into a body lumen of a patient, such as a blood vessel or coronary artery, to maintain the patency thereof.

5 These devices are useful in the treatment of atherosclerotic stenosis in blood vessels.

Stents generally are tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. Stents are particularly suitable for use to support and hold back a dissected arterial lining, which can occlude the fluid passageway therethrough, and to hold open a coronary artery after an angioplasty procedure.

Further details of prior art stents can be found in U.S. Patent 3,868,956 (Alfidi et al.); U.S. Patent 4,512,338 (Balko et al.); U.S. Patent 4,553,545 (Maass et al.); U.S. Patent 4,733,665 (Palmaz); U.S. Patent 4,762,128 (Rosenbluth); U.S. Patent 4,800,882 (Gianturco); U.S. Patent 4,856,516 (Hillstead); and U.S. Patent 4,886,062 (Wiktor), which are hereby incorporated herein in their entirety by reference thereto.

Various means have been described to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter.

Prior art stent designs provide a stent that is composed of wire mesh or weave having an open lattice structure or patterns. The open lattice structure of the prior art stents

generally provide uniform strength along the center of the stent, but may be weak at the ends. This configuration may cause the prior art stents to be weaker at the stent ends because each portion at the ends has only one neighbouring support portion.

This inherent weakness at the ends of the prior art stents could result in the ends
5 decreasing in diameter after implantation in a body lumen.

It may therefore be important to improve existing stent designs to provide stronger ends while allowing the centers to maintain the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery into the blood vessel. The present invention satisfies
10 these needs.

According to one aspect of this invention there is provided an intravascular stent for implanting in a body lumen, comprising:

an elongated tubular body laser cut from a single tubular member of a suitable bio-compatible material to define a wall having an open lattice structure and adapted for radial expansion
15 from a first, compressed diameter to a second, enlarged diameter;

said elongated tubular body having a first end section, a second end section, and a central section, wherein each said section is defined by the thickness of the material making up the wall of the tubular body; and

the wall thickness of at least one of said end sections being greater than said
20 central section wall thickness, whereby when said stent is expanded to said second, enlarged diameter, said end section with greater wall thickness is radially stronger and more crush resistant than said central section.

In one form of the invention the tubular body is composed of a plurality of cylindrical elements which are independently expandable in the radial direction and
25 which are interconnected so as to be generally aligned on a common longitudinal axis, said cylindrical elements being interconnected by a plurality of connecting elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other thereby producing a stent that is longitudinally flexible.

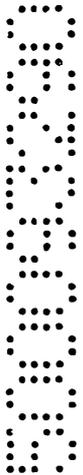
In another form of the invention the tubular body is made up of a plurality of independently radially-expandable cylindrical elements, that are interconnected so



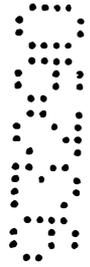
as to be concentrically aligned on a common longitudinal axis, said cylindrical elements being interconnected by a plurality of generally parallel connecting elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other so that said stent remains longitudinally
5 flexible while in its unexpanded configuration; and

said cylindrical elements and said connecting elements being integrally formed said biocompatible material and forming a generally serpentine lattice structure so that the stent retains its overall length without appreciable shortening as the cylindrical elements are expanded radially outward.

10 Preferably both the first end section and second end section have a greater wall thickness than does the central section, making the first and second end sections radially stronger than the central section. The thicker end section(s) can gradually become thicker from about the central section toward the first end section.



The stent embodying features of the invention can be delivered readily to the desired body lumen location by mounting it on an expandable member, for example, a balloon, of a delivery catheter, and passing the catheter-stent assembly through the body lumen to the implant site. A variety of means for securing the stent to the
5 expandable member on the catheter for delivery to the desired location are available. It presently is preferred to compress the stent onto the balloon. Other means to secure the stent to the balloon include providing a retractable sheath over the stent, providing ridges or collars on the inflatable member to restrain lateral



movement of the stent, or using bioresorbable temporary adhesives to hold the stent on the balloon.

5 The presently preferred structure for the expandable cylindrical elements which form the stents of the present invention generally are circumferential undulating patterns, e.g., a generally serpentine pattern. The transverse cross-section of the undulating component of the cylindrical element is relatively small, and preferably has an expansion ratio of about 1.0 to 4.5. The open, reticulated structure of
10 the stent allows for the perfusion of blood over a large portion of the arterial wall, which can accelerate the healing and repair of a damaged arterial lining.

15 The cylindrical structures of the stent are plastically deformed when expanded (except when nickel-titanium (NiTi) alloys are used to form the stent), so that the stent will remain in the expanded condition. Therefore, the cylindrical structures must be sufficiently rigid when expanded to prevent the collapse thereof in use. Furthermore, because
20 at least one end section of the stent is formed of material that is thicker than the material of the stent nearer the center section, there is less chance that an end (or ends) of the stent will collapse after the stent is expanded and placed in the desired body lumen. During expansion of the preferred
25 stent, portions of the undulating pattern will tip outwardly, resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embedded in the vessel wall and thereby help secure the expanded stent
30 became so that it does not move once it is implanted.

When the stent is made from superelastic NiTi alloys, expansion occurs when the stress of compression is removed, thereby allowing the phase transformation of the alloy from the austenite phase back to the martensite phase.

35 The elongated elements which interconnect adjacent cylindrical elements should have a transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements to which the

embodiment of the invention where one end of the stent is made of thicker material for added strength.

FIG. 6 is a schematic representation of laser equipment for selectively cutting tubing in the manufacture of the stents of the present invention.

FIGS. 7 through 11 are perspective views schematically illustrating different stent configurations wherein both end sections of the stent have expandable elements that are made of thicker material than the central section.

FIG. 12 is an enlarged, partial view of the stent of FIG. 5, taken along lines 12-12 with the various, non-end members slightly expanded.

FIG. 13 is a perspective view of a non-end portion of the stent of FIG. 4, after it is fully expanded, depicting some members projecting radially outwardly.

FIG. 14 is an enlarged, partial perspective view of one U-shaped member with its tip projecting outwardly after expansion.

FIG. 15 is a cross-sectional view depicting a stent configuration wherein the thickness of the cylindrical elements is substantially greater at each end of the stent than near the center of the stent.

FIG. 16 is a cross-sectional view depicting a stent configuration where the thickness of the cylindrical elements gradually increases from the center of the stent toward each end of the stent.

FIG. 17 is a cross-sectional view depicting a stent configuration where the thickness of the cylindrical elements substantially increases at only one end of the stent, and

wherein the thickened area may extend for more than one element.

FIG. 18 is a cross-sectional view depicting a stent configuration wherein the thickness of the cylindrical elements 5 gradually increases toward only one end of the stent.

FIG. 19 is an end-view depicting a stent configuration wherein the thickness of an arcuate section of the open lattice structure of the stent is substantially thicker than an adjacent arcuate section.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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The stent of the present invention generally is delivered intraluminally using a conventional balloon catheter, as is known in the art. The stent primarily is used to ensure the patency of the body lumen in which it is implanted. For example, the stent of the present invention preferably will be implanted in the coronary arteries after an angioplasty procedure, to reinforce the artery against recoil or to tack up a dissection in the arterial wall. The stent of the present invention is useful for implanting in other body lumens, such as the carotid arteries, the illiacs, and other peripheral veins and arteries.

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FIG. 1 illustrates a stent 10 incorporating features of the invention, mounted on a delivery catheter 11. The stent preferably comprises a plurality of radially-expandable cylindrical elements 12, disposed generally coaxially, and interconnected by elements 13, disposed between adjacent cylindrical elements. The delivery catheter 11 has an expandable portion or balloon 14 for expanding the stent 10 within coronary artery 15. The artery 15, as shown in FIG. 1, has a dissected lining 16 which has occluded a portion of the arterial passageway. The ends of the stent have thicker elements which provide greater strength and resistance to collapse from recoil of the body lumen or artery 15.

The delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter used for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as the ionomer manufactured under the trademark "SURLYN" by the Polymer Products Division of the Du Pont Company. Other polymers also may be used.

In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve 20 may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter 11, and to prevent abrasion of the body lumen by the open surface of the stent 10, during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 also may be used, such as providing collars or ridges on the ends of the working portion (i.e., the cylindrical portion) of the balloon.

Each radially-expandable cylindrical element 12 of the stent 10 may be expanded independently of any other. Therefore, the balloon 14 may be provided with an inflated shape that is other than cylindrical, for example, an inflated tapered shape, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

The delivery of the stent 10 is accomplished in the following manner. The stent 10 first is mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The balloon 14 is slightly inflated to secure the stent 10 onto the exterior of the balloon. The catheter-stent assembly is introduced to the vasculature of the patient with a conventional Seldinger technique through a guiding catheter (not shown). A guide wire 18 is disposed across a stenosed area or the damaged arterial section having a detached or dissected lining 16, and then the catheter-stent assembly is advanced over a guide wire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. The balloon

14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 preferably is expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded in order to facilitate passage of blood or other fluid therethrough.

In a preferred embodiment, stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and, as a result, do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of stent 10 which are pressed into the wall of the artery 15 eventually will be covered with endothelial cell growth, which cell growth further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Furthermore, the cylindrical elements 12, closely spaced at regular intervals, provide uniform support for the wall of the artery 15, and at least one end of the stent has expanded cylindrical elements that are stronger, due to the material or design incorporated in the stent, to prevent collapse of the stent at those locations in the body lumen. Consequently, the stents of this invention are well adapted to hold open a body lumen or artery against recoil or to tack up and hold in place small flaps or dissections in the wall of the artery 15 as illustrated in FIGS. 2 and 3.

In a preferred embodiment of the invention, FIG. 4 depicts an enlarged perspective view of the stent 10 shown in FIG. 1, with a first end section 36 of the stent having cylindrical elements 12 which are thicker, from a material standpoint than the central section 37, in order to provide a

stronger section at the first end location. The first section 36 is stronger and more crush-resistant to arterial recoil than is the central section 37 and the second end section 38 (FIGS. 1-3), neither of which have increased material thickness. FIG. 4 further shows the placement of interconnecting elements 13 between adjacent radially-expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 preferably are placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 4, the stent 10 has three interconnecting elements 13 between adjacent radially-expandable cylindrical elements 12 which are 120 degrees apart. Each pair of interconnecting elements 13 on one side of a cylindrical element 12 is offset radially 60 degrees from the pair on the other side of the cylindrical element. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions, yet is stronger at the first end section 36. FIG. 5 illustrates the stent of FIG. 4 in a flattened condition to more clearly depict the undulating pattern and the thicker cross-section of certain portions of the stent.

Referring to FIGS. 7-11, alternate embodiments of the stent 10 are depicted, wherein an open lattice structure, 37 central section is in the form of a tubular member. Each stent is capable of being expanded from a first, compressed diameter to a second enlarged diameter within a body lumen, such as within an artery 15 as depicted in FIGS. 1-3. Thus, as with the embodiment of the stent of FIG. 4, the embodiment of the stents depicted in FIGS. 7-11 are expandable and will deform beyond the elastic limit of each in order to maintain the patency of the body lumen or artery 15. As depicted, each of the embodiments shown in FIGS. 7-11 have a first section 36 and second section 38 which are of thicker material than is the material of central section 37. The first and second sections 36,38 are stronger and more resistant to recoil of the artery 15, and help secure the stent 10 within the artery. As described herein, the stents of FIGS. 7-11 can have either the

first end section 36 made of thicker material, or both the first and second sections 36,38 made of thicker material. Further, the material may become thicker in a tapered manner, as described with respect to the embodiments of FIGS. 16-18.

5 A preferred configuration for the stent 10 is depicted in FIG. 4 and FIGS. 12-14, where the cylindrical elements 12 are arranged in the form of a serpentine pattern 30. As previously mentioned, each cylindrical element 12 is connected to another by interconnecting elements 13. The
10 serpentine pattern 30 is comprised of a plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33, each having varying radii of curvature so that expansion forces are more evenly distributed over the various members.

As depicted in FIGS. 13 and 14, after cylindrical elements 12 have been radially-expandable, outwardly-projecting edges 34 are formed. That is, during radial expansion, U-shaped members 31 will tip outwardly thereby forming outwardly-projecting edges. These outwardly-projecting edges provide for a roughened outer wall surface of the stent 10 and
20 become embedded into the arterial wall, accordingly facilitating implantation. In other words, outwardly-projecting edges become embedded in the arterial wall, for example, into the wall of the artery 15, as depicted in
30 FIG. 3. Depending upon the dimensions of the stent 10 and the thickness of the various members making up the serpentine pattern 30, any of the U-shaped members 31, W-shaped members 32, and Y-shaped members 33 can tip radially outwardly to form a projecting edge 34. It is both most likely and preferred that the U-shaped members 31 tip outwardly, because these
35 members do not join with any other connecting member 13 which might prevent the U-shaped member from expanding outwardly. As can be seen in FIG. 13, the first end section 36 has thicker U-, W- and Y-shaped members than does the central section 37. The thicker members at the first end section 36 will provide substantially more support and will resist crushing by recoil of the artery 15 than will the central section 37. Likewise, when both of the end sections 36, 38, as depicted in FIGS.

15-16 are thicker, the end sections provide substantially more support in the artery 15, and securely become embedded in the artery 15, due to the projecting edges 34 tipping outwardly.

FIGS. 15-18 schematically depict various preferred
5 embodiments of the stents. One such configuration provides a stent where the thickness, and thus the strength, of the expandable cylindrical elements 12 substantially increase at the first and second end sections 36, 38 of the stent 10, as shown in FIG. 15. In another embodiment, the expandable
10 cylindrical elements 12 gradually increase in thickness toward the first and second end sections 36, 38, and thus gradually increase in strength, moving axially from the center section 37 of the stent toward either end, as shown in FIG. 16. In another embodiment shown in FIG. 17, the thickness of the
15 expandable cylindrical elements 12 substantially increases at the first end section 36 of the stent 10. Increased thickness at only the end 36 of the stent 10, could occur gradually as depicted in FIG. 18.

FIG. 19 schematically depicts another preferred
20 embodiment of the stent of the invention, wherein the thickness, and thus the strength, of the expandable cylindrical elements 12 substantially increases at arcuate sections 40 of the open lattice structure of the stent 10. The thicker arcuate section 40 can be limited to a portion of the first end section 36 or the entire first end section, or it can extend
25 longitudinally to a plurality of sections, even to the entire length of the stent.

In the preferred embodiment, the stent 10 is formed from a metal alloy tube such as stainless steel tubing, however, it can be made from other metal alloys including, but not limited to, tantalum, nickel-titanium (NiTi), or from
30 thermoplastic polymers. Presently, a preferred mode of making the stent is by direct laser cutting of a stainless steel tube, as is described in commonly owned U.S. Patent No. 5,780,807,
35 issued July 14, 1998 on an application filed November 28, 1994, entitled METHOD AND APPARATUS FOR DIRECT LASER CUTTING OF METAL STENTS, which is



incorporated herein in its entirety by reference. Other modes of making the stent of the invention also are contemplated.

While the invention has been illustrated and described herein in terms of its use as an intravascular stent in the coronary arteries, it is envisioned that the stent will be useful in other body lumens as well. Due to the high strength characteristics of the stent of the present invention, primarily due to the thicker wall elements at the ends of the stent, it is particularly adapted for use in the coronary arteries, for anchoring a graft for repairing an aortic aneurysm, and for deployment in peripheral veins and arteries throughout the body. Other modifications and improvements can be made to the invention without departing from the scope thereof.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that that prior art forms part of the common general knowledge in Australia.



The claims defining the invention are as follows:

1. An intravascular stent for implanting in a body lumen, comprising:

an elongated tubular body laser cut from a single tubular member formed of a suitable bio-compatible material to define a wall having an open lattice structure and adapted for radial expansion from a first, compressed diameter to a second, enlarged diameter;

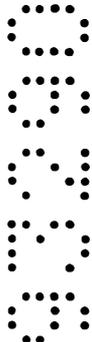
said elongated tubular body having a first end section, a second end section, and a central section, wherein each said section is defined by the thickness of the material making up the wall of the tubular body; and

the wall thickness of at least one of said end sections being greater than said central section wall thickness, whereby when said stent is expanded to said second, enlarged diameter, said end section with greater wall thickness is radially stronger and more crush resistant than said central section.

2. The intravascular stent of claim 1, wherein the tubular body is composed of a plurality of cylindrical elements that are independently expandable in the radial direction and that are interconnected so as to be generally aligned on a common longitudinal axis, said cylindrical elements being interconnected by a plurality of connecting elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other thereby producing a stent that is longitudinally flexible.

3. The stent of claim 1, wherein said tubular body is made up of a plurality of independently radially-expandable cylindrical elements that are interconnected so as to be concentrically aligned on a common longitudinal axis, said cylindrical elements being interconnected by a plurality of generally parallel connecting elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other so that said stent remains longitudinally flexible while in its unexpanded configuration; and

said cylindrical elements and said connecting elements being integrally formed from said bio-compatible material and forming a generally serpentine lattice structure so that the stent retains its overall length without appreciable shortening as the cylindrical elements are expanded radially outward.



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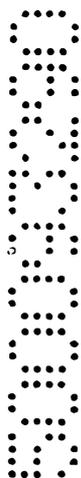
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4. The stent of any one of claims 1, 2 or 3, wherein both said first end section and second end section have a greater wall thickness than does said central section, making said first and second end sections radially stronger than said central section.
- 5 5. The stent of claim 1, wherein said at least one thicker end section gradually becomes thicker from about said central section toward said at least one thicker end section.
6. The stent of any of claims 1, 2 or 3, wherein said at least one thicker end section is on an arcuate section of said at least one thicker end section.
- 10 7. The stent of any of claims 1, 2 or 3, wherein said at least one thicker end section of said stent is on an arcuate section of all of said end sections of said stent.
8. A stent of any of claims 1, 2 or 3, wherein said bio-compatible material is selected from the group of materials consisting of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers.
- 15 9. The stent of any of the claims 1, 2 or 3, wherein said stent is coated with a bio-compatible coating.
10. The stent of claim 3, wherein said radially-expandable cylindrical elements in an expanded condition have a length less than the diameter thereof.
- 20 11. The stent of claim 3, wherein said connecting elements between adjacent cylindrical elements are in axial alignment.
12. The stent of claim 3, wherein said connecting elements between adjacent cylindrical elements are circumferentially displaced with respect to said longitudinal axis.
- 25 13. The stent of claim 12, wherein the circumferential displacement of said connecting elements between adjacent cylindrical elements is uniform.
14. The stent of claim 3, wherein there are up to four of said connecting elements disposed between adjacent radially-expandable cylindrical elements.
15. An intravascular stent for implanting in a body lumen, said stent being substantially as described with reference to Figures 1 to 6 and 12 to 14 or



- 17 -

Figures 1 to 6 and 12 to 14 as modified by any one of Figures 7 to 11 or
Figures 15 to 19.

DATED this 9th day of May, 2000.

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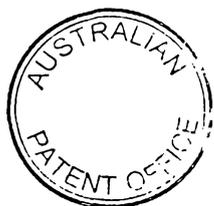
Advanced Cardiovascular Systems, Inc.

DAVIES COLLISON CAVE

Patent Attorneys for the Applicant

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FIG. 1

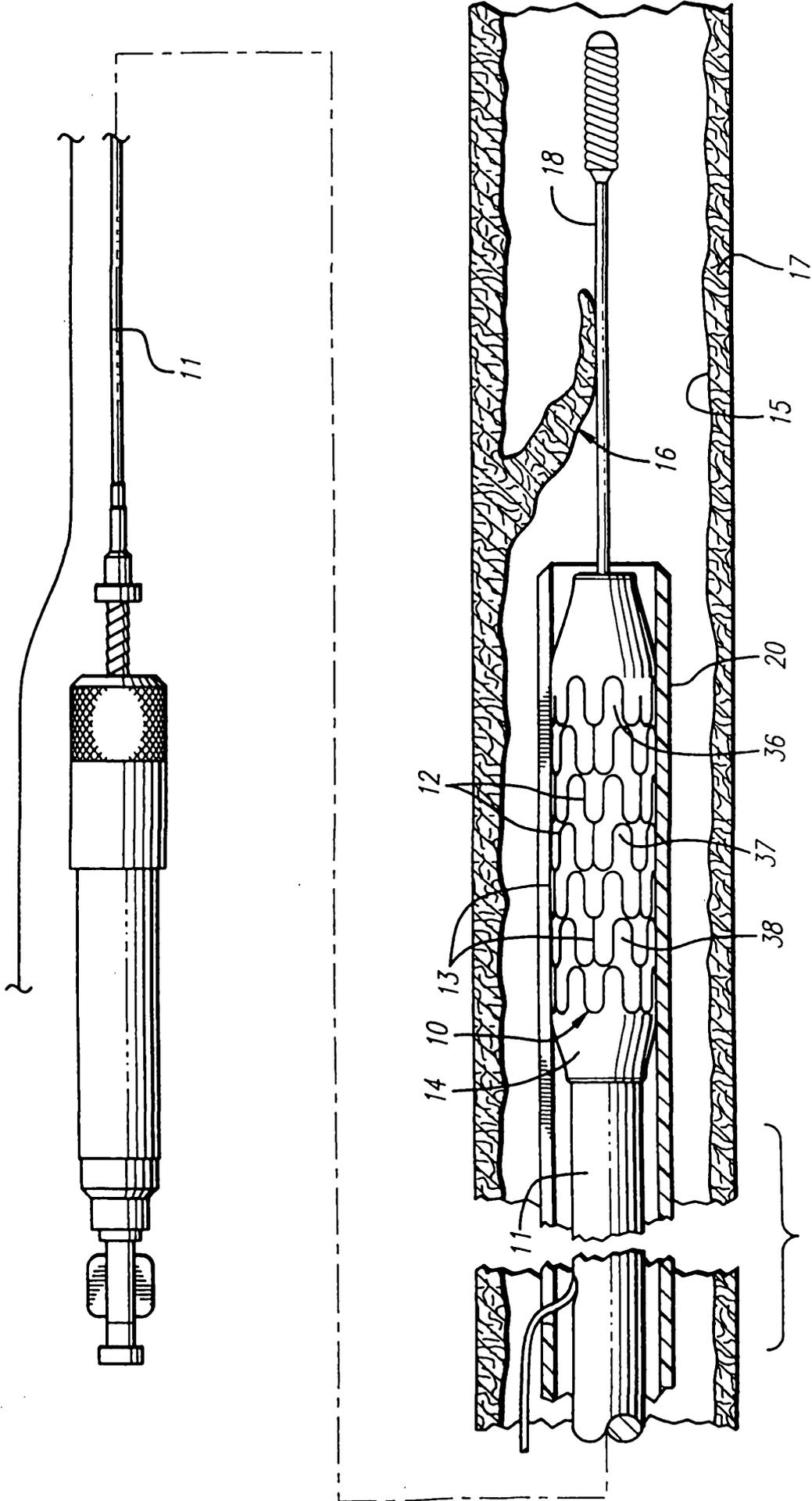


FIG. 2

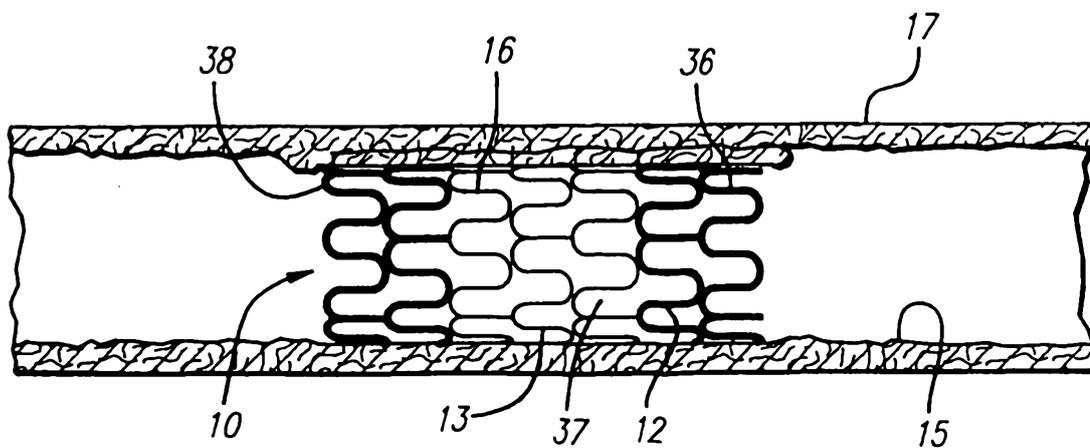
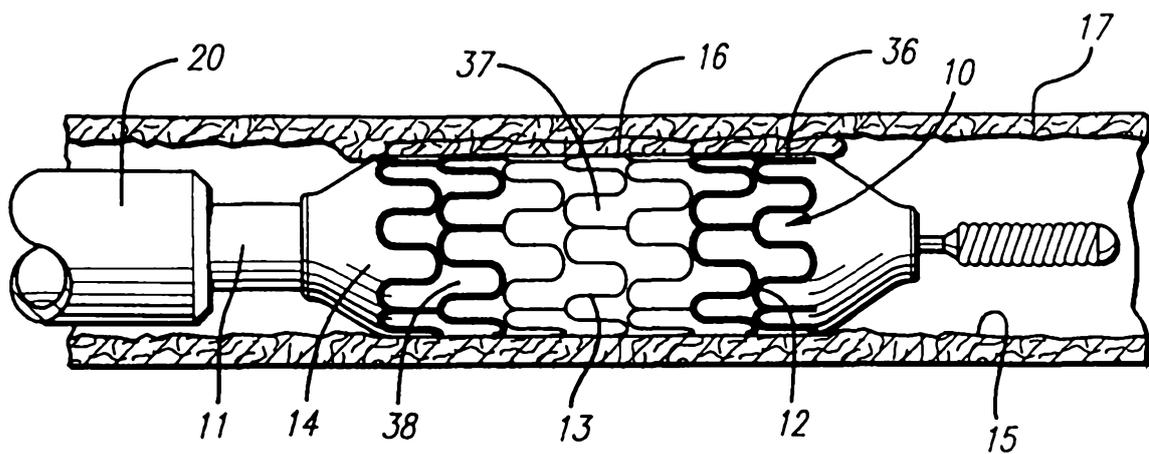


FIG. 3

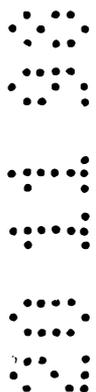
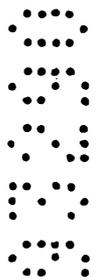


FIG. 4

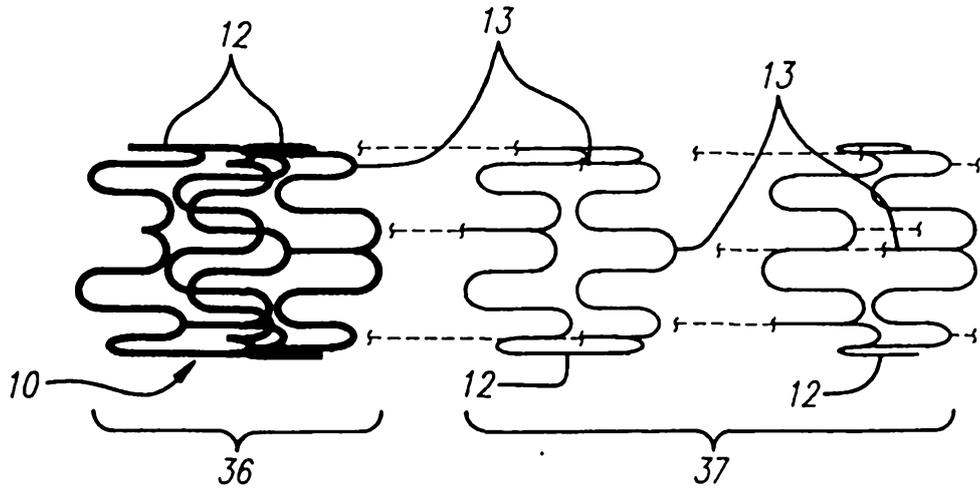


FIG. 5

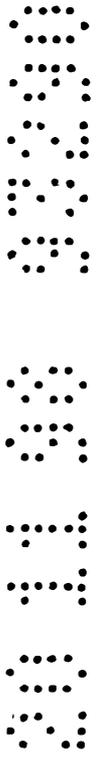
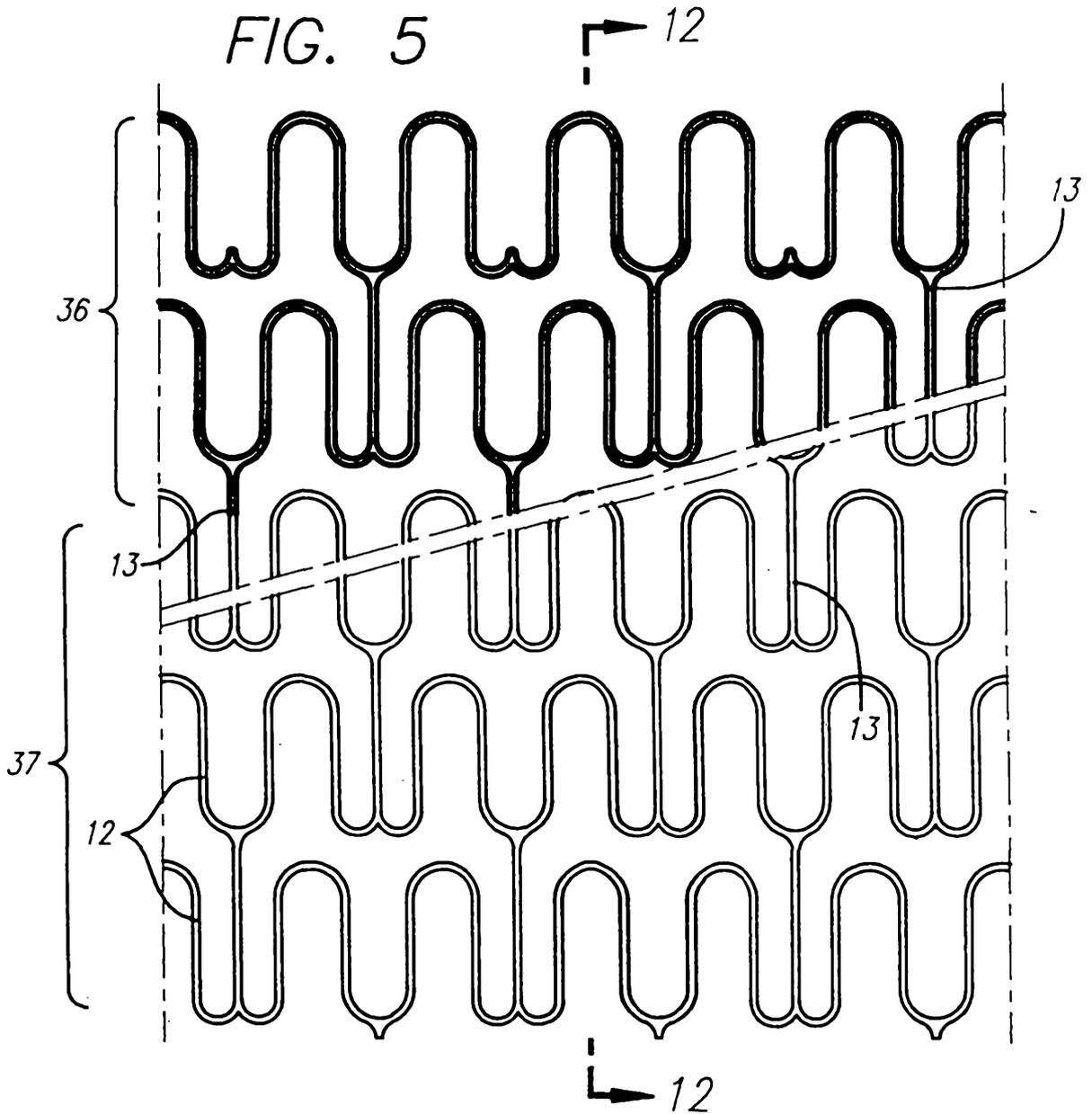


FIG. 6

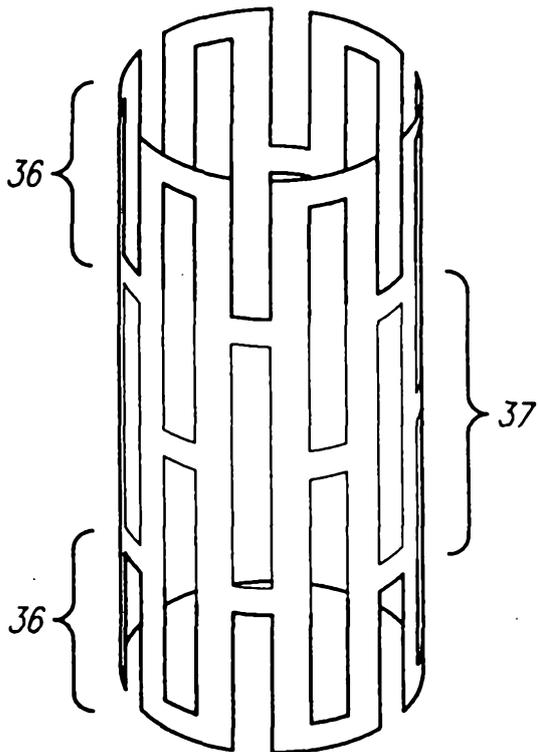
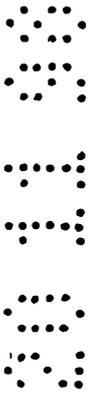
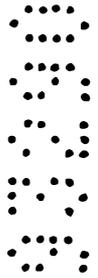
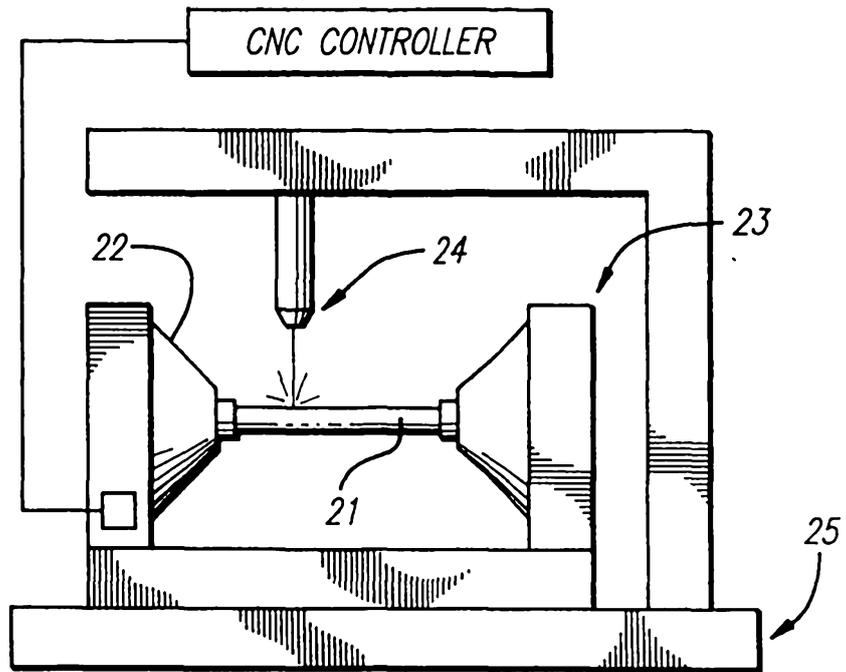


FIG. 7

FIG. 8

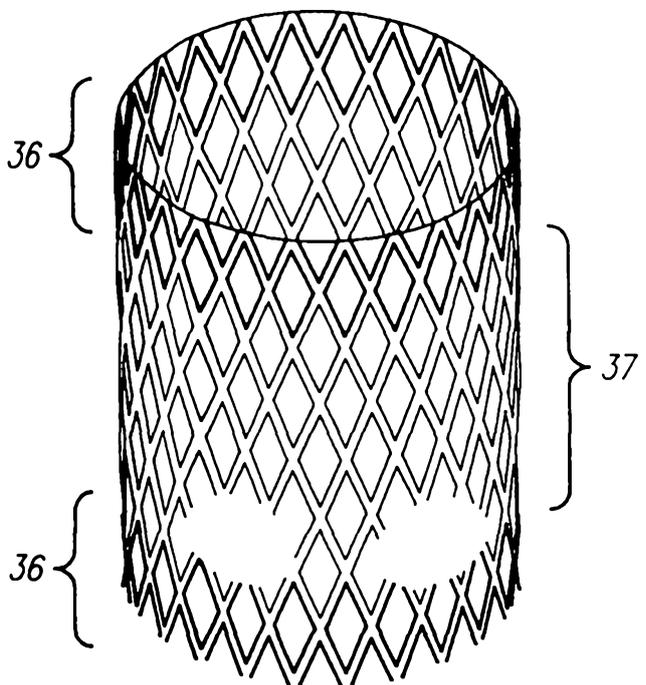


FIG. 9

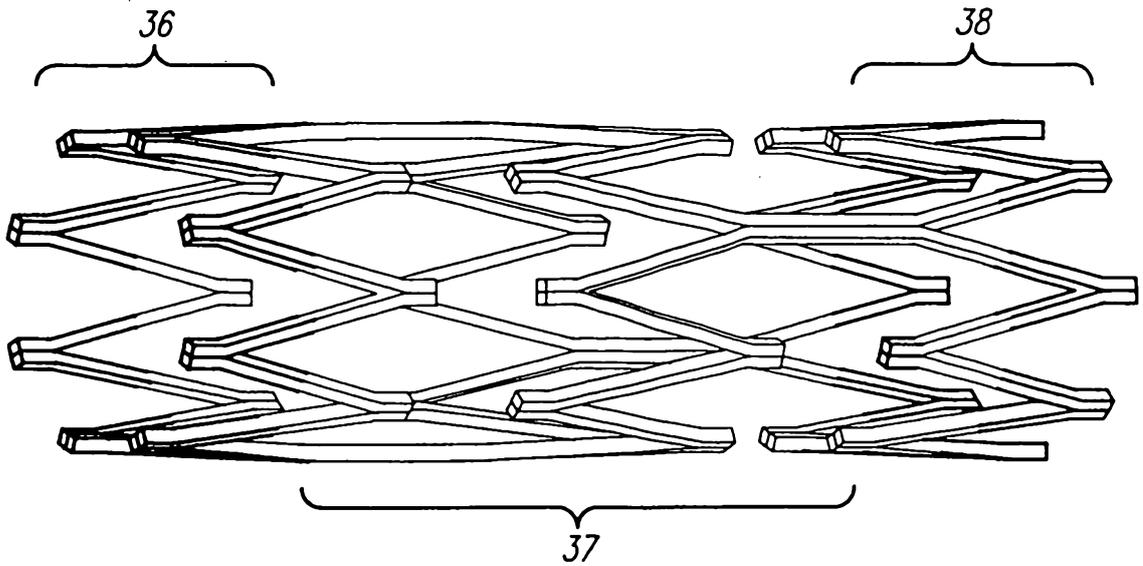


FIG. 10

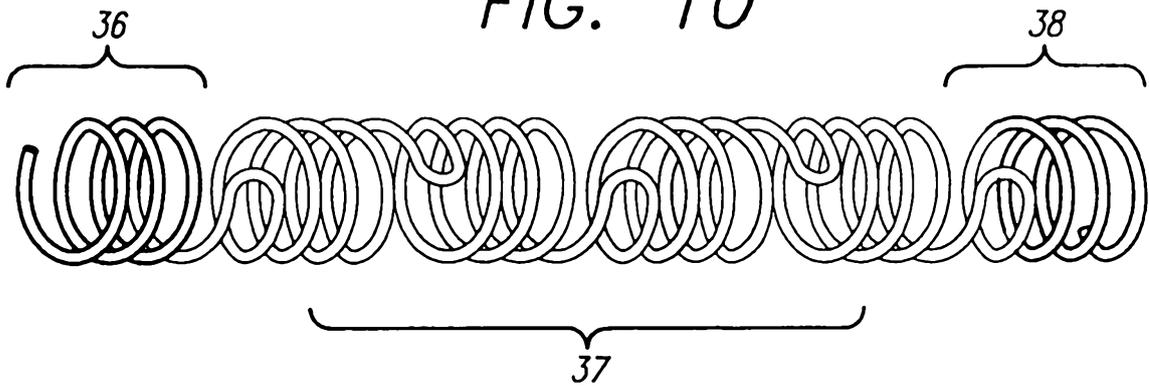
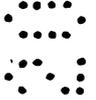
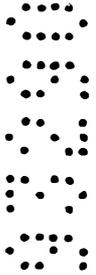
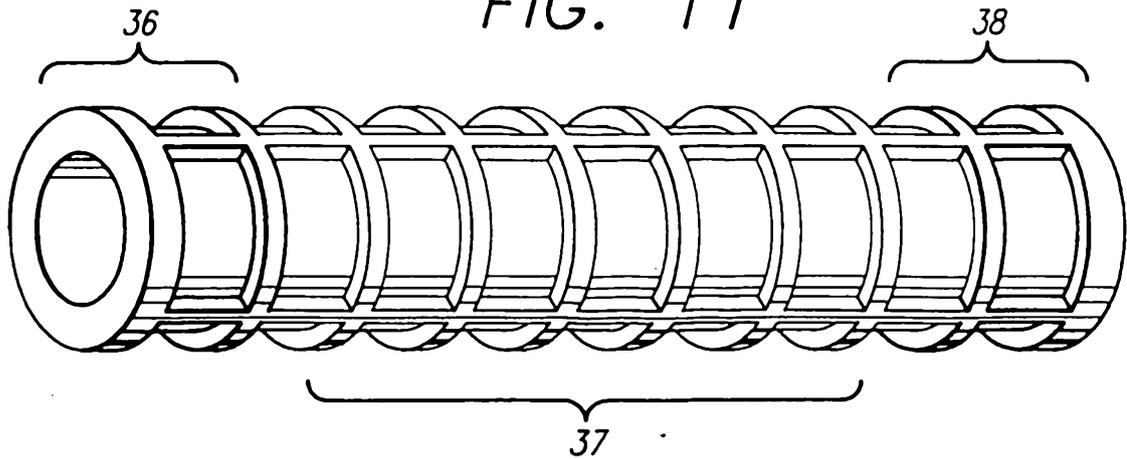


FIG. 11



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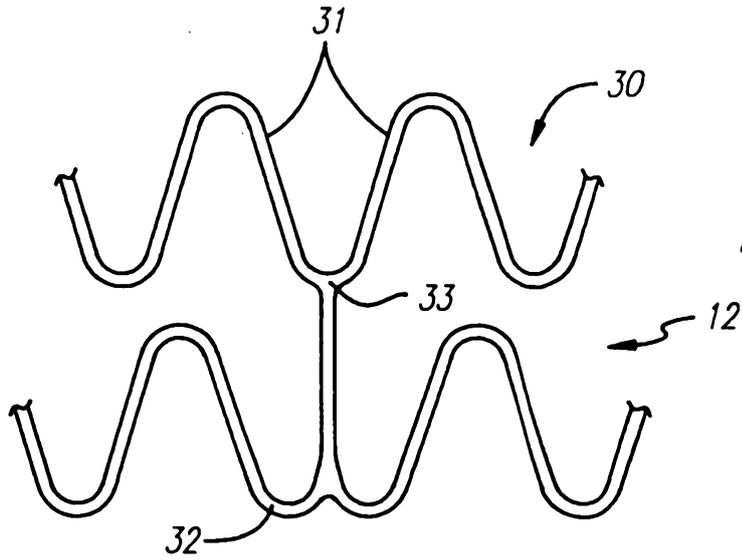


FIG. 12

FIG. 13

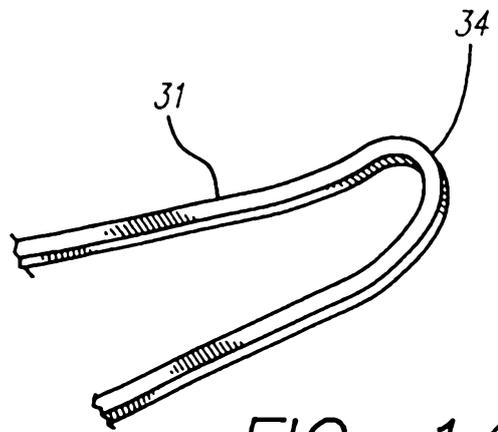
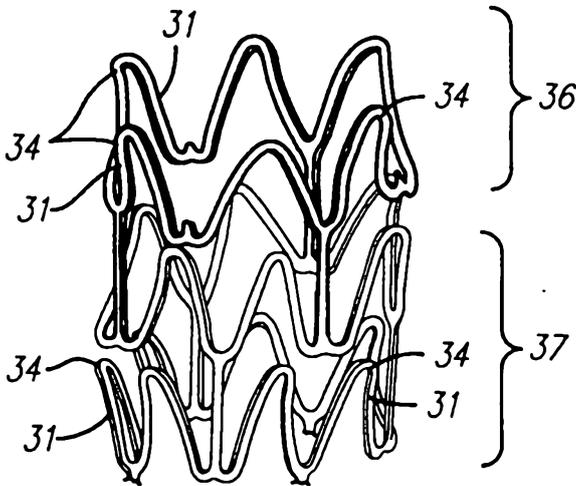


FIG. 14

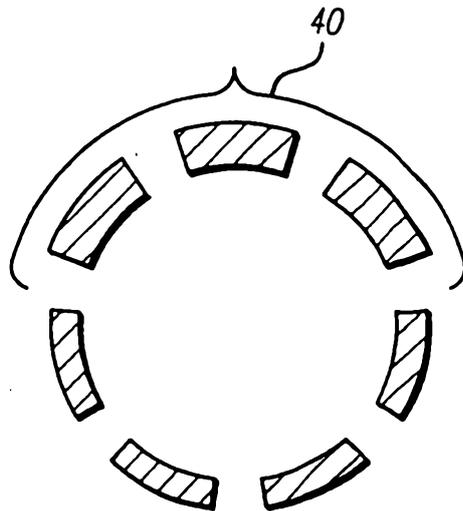


FIG. 19

