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AUSTRALIA

PATENTS ACT 1990

PATENT REQUEST : STANDARD PATENT

I/We being the person(s) identified below as the Applicant(s), request the grant of a patent to the person(s) identified below as the Nominated Person(s), for an invention described in the accompanying standard complete specification.

Full application details follow:

[71/70] Applicant(s)/Nominated Person(s):

Meadox Medicals, Inc.

of

112 Bauer Drive, Oakland, New Jersey, 07436, United States of America

[54] Invention Title:

High strength and high density intraluminal wire stent

[72] Name(s) of actual inventor(s):

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Basic Convention Application(s) Details:

[31] Application Number	[33] Country	Code	[32] Date of Application
289,791	United States of America	US	12 August 1994

DATED this TWENTY EIGHTH day of APRIL 1995

.....
a member of the firm of
DAVIES COLLISON CAVE for
and on behalf of the
applicant(s)

MO67753 280495

AUSTRALIA
PATENTS ACT 1990
NOTICE OF ENTITLEMENT

We, **Meadox Medicals, Inc.**, the applicant/Nominated Person named in the accompanying Patent Request state the following:-

The Nominated Person is entitled to the grant of the patent because the Nominated Person derives title to the invention from the inventors by assignment.

The Nominated Person is entitled to claim priority from the basic application listed on the patent request because the Nominated Person is the assignee of the applicants in respect of the basic application.

DATED this TWENTY EIGHTH day of APRIL 1995



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a member of the firm of
DAVIES COLLISON
CAVE for and on behalf
of the applicant(s)

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(12) PATENT ABRIDGMENT (11) Document No. AU-B-17720/95
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- (54) Title
HIGH STRENGTH AND HIGH DENSITY INTRALUMINAL WIRE STENT
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- (56) Prior Art Documents
US 4886062
US 5314472
US 4913141
- (57) Claim

8. A radially expandable generally tubular endoluminal implantable prosthesis comprising:

a wire which is wound in a helical configuration to define a generally elongate tubular body, the wire including successively formed waves along the length of said wire, each wire wave being non-overlappingly nested within the wave formed longitudinally thereadjacent.

AUSTRALIA
PATENTS ACT 1990
COMPLETE SPECIFICATION

NAME OF APPLICANT(S):

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ADDRESS FOR SERVICE:

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Patent Attorneys
1 Little Collins Street, Melbourne, 3000.

INVENTION TITLE:

High strength and high density intraluminal wire stent

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

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1 FIELD OF THE INVENTION:

 The present invention relates generally to implantable intraluminal stents and more particularly, the present invention relates to an improved high strength intraluminal stent having increased wire density.

BACKGROUND OF THE INVENTION:

 It is well known to employ endoprotheses for the treatment of diseases of various body vessels. Intraluminal devices of this type are commonly referred to as stents. These devices are typically intraluminally implanted by use of a catheter into various body organs such as the vascular system, the bile tract and the urogenital tract. Many of the stents are radially compressible and expandable so that they may be easily inserted through the lumen in a collapsed or unexpanded state. Some stent designs are generally flexible so they can be easily maneuvered through the various body vessels for deployment. Once in position, the stent may be deployed by allowing the stent to expand to its uncompressed state or by expanding the stent by use of a catheter balloon.

 As stents are normally employed to hold open an otherwise blocked, constricted or occluded lumen, a stent must exhibit a relatively high degree of radial or hoop strength in its expanded state. The need for such high strength stents is especially seen in stents used in the urogenital or bile tracts where disease or growth adjacent the lumen may exert an external compressive force thereon which would tend to close the lumen.

 One particular form of stent currently being used is a wire stent. Stents of this type are formed by single or multiple strands of wire which may be formed into a shape such as a mesh coil, helix or the like which is flexible and readily expandable. The spaces between the coiled wire permit such flexibility and expansion. However, in certain

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situations, such as when the stent is employed in the urogenital or bile tract, it is also desirable to inhibit tissue ingrowth through the stent. Such ingrowth through the stent could have a tendency to reclose or occlude the open lumen. The open spaces between the wires forming the stent, while facilitating flexibility and expansion, have a tendency to allow such undesirable tissue ingrowth.

Attempts have been made to provide a stent which has less open space and more solid wire. U.S. Patent No. 5,133,732 shows a wire stent where the wire forming the stent is overlapped during formation to provide less open space. However such overlapping wire increases the diameter of the stent and has a tendency to reduce flexibility and make implantation more difficult. It is therefore desirable to provide a wire stent which exhibits high compressive strength and full flexibility without allowing extensive ingrowth therethrough.

SUMMARY OF THE INVENTION

Advantageously, the present invention provides an intraluminal stent which exhibits high compressive strength and is resistive to tissue ingrowth.

The present invention also advantageously provides a flexible wire stent having high compressive strength and maximum wire density to inhibit tissue ingrowth.

According to one aspect of the present invention, there is provided an intraluminal stent comprising:

a generally elongate tubular body formed of an elongate helically wound wire, the wire being formed into successive waves along the length of the wire, the waves being arranged in non-overlapping longitudinally spaced succession along the length of said tube, the longitudinal spacing of the helical windings being less than twice the amplitude of the wave.

According to another aspect of the present invention, there is provided a radially expandable generally tubular endoluminal implantable prosthesis comprising:

a wire which is wound in a helical configuration to define



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a generally elongate tubular body, the wire including successively formed waves along the length of said wire, each wire wave being non-overlappingly nested within the wave formed longitudinally thereadjacent.

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1 As more particularly shown by way of the preferred
embodiment herein, an intraluminal wire stent includes
longitudinally adjacent waves being nested along the length
of the tubular body. The peaks or apices of the
5 longitudinally nested waves are linerally aligned. Further,
the intraluminal stent so constructed would have a
percentage of open surface area in relationship to the total
surface area of the stent which is less than 30% in the
closed state, resulting in less open area upon expansion
10 which would inhibit tissue ingrowth.

BRIEF DESCRIPTION OF THE DRAWINGS:

Figure 1 is a perspective view of a conventional
helical coil formed of a single wound wire.

15 Figure 2 is a perspective view of the stent of the
present invention.

Figure 3 is a perspective view of the stent of
Figure 1 exhibiting longitudinal flexibility.

20 Figure 4 is a schematic showing of one wave of the
wire forming the stent of Figure 2.

Figure 5 is a schematic showing of nested
longitudinally adjacent waves of the stent of Figure 2.

Figure 6 is a perspective view of the stent of
Figure 2 shown in the open or exposed condition.

25 Figure 7 shows a portion of a further embodiment
of a wire used to form a stent in accordance with the
present invention.

Figure 8 shows a still further embodiment of a
wire used to form a stent of the present invention,
30 partially wound around a forming mandrel.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS:

A simple helically formed coil spring 10 is shown
in Figure 1. Coil spring 10 is formed of a single metallic
35 wire 12 which for stent purposes may be formed of a suitably
flexible biocompatible metal. The wire coil spring 10
defines generally a cylindrical tubular shape which is

1 radially expandable upon application of outward radial pressure from the interior thereof.

5 The present invention shown in Figure 2, improves upon the simple coil spring 10 shown in Figure 1. However with reference to Figure 1, certain terminology used hereinthroughout may be defined. As mentioned, the spring defines a generally elongate cylindrically tubular shape lying along a central axis χ . Wire 12 is helically wound, for example against a constant diameter mandrel (not shown),
 10 to form a longitudinally extending structure consisting of wire 12 and spaces or pitch 16 therebetween. Each individual winding 14 may be defined as the wire segment traversing one complete revolution around axis χ . As the wire is helically coiled about axis χ , each winding is successively longitudinally spaced from the next adjacent
 15 winding by a given distance.

For present purposes, the axial spacing between any point on the wire coil spring 10 to the point defining the next successive winding may be thought of as the pitch 16 of the wire coil spring 10. As so defined, the pitch of the coil spring 10 defines the spacing between windings and therefore the degree of compactness or compression of the wire coil spring 10.
 20

Also with reference to Figure 1, as the wire coil
 25 spring 10 has a generally cylindrical tubular shape, it defines an outside diameter d_1 and an inside diameter d_2 , which would typically differ by twice the diameter d_3 of wire 12. Further, wire coil spring 10 generally defines an outer cylindrical surface area along its length which may be
 30 thought of as being composed of solid surface portions defined by the outward facing surface of wire 12 itself and open surface portions defined by the spaces or pitch 16 multiplied by the number of wire windings 14. The ratio of open surface space to solid surface space may be varied by
 35 varying the so-defined pitch 16 of the wire coil spring 10. A smaller pitch coil, where the windings are more compacted or compressed, would result in an outer surface area having

1 less open space than a coil formed to have greater spacing
or pitch between the wire windings.

Having set forth the definitional convention used
hereinthroughout, the present invention may be described
5 with reference specifically to Figures 2-6. A wire stent 20
of the present invention is shown in Figure 2. Wire stent
20 is generally in the form of an elongate cylindrically
shaped tubular member defining a central open passage 21
therethrough. Stent 20 is formed of multiple windings 24 of
10 a single wire 22 which in the present invention is metallic,
preferably tantalum, as such wire exhibits sufficient spring
elasticity for purposes which will be described in further
detail hereinbelow.

While stent 20 may be formed by helically winding
15 wire 22 much in a manner shown with respect to Figure 1 to
form wire coil spring 10, the present invention contemplates
preshaping the wire 22 itself along its length prior to
helically coiling the wire.

Referring now to Figure 4, wire 22 in an elongate
20 pre-helically coiled configuration may be shaped in a manner
having a longitudinally extending wave-like pattern. Wave
pattern 25 is defined by a plurality of continuously
repeating wave lengths 27 therealong. It has been found
advantageously that the waves may take the form specifically
25 shown in Figure 4 and 5 for optimum results as a wire stent.
However, for explanation purposes, the wave-like pattern 25
generally functions mathematically as sinusoidal wave,
having a given amplitude A as measured from a central axis
y and a peak-to-peak amplitude of 2A. The wave pattern 25
30 has a uniform preselected period λ equal to the transverse
extent of a single wave length. The geometry of each wave
length 27 is shown in Figure 4.

The wave-like configuration imparted to wire 22
may be accomplished in a variety of forming techniques. One
35 such technique is to pass wire 22 between the teeth of
intermeshed gears (not shown) which would place a generally
uniform sinusoidal wave-like crimp along the length of the

1 wire. Other techniques may be used to form the specific
 shape shown in Figure 4. Wire 22 may be passed through a
 pair of gear-like overlapping wheels (not shown) having
 depending interdigitating pins. By arranging the size,
 5 position and spacing of the pins, various wave-like
 configurations may be achieved. The particular shape shown
 with reference to Figures 4 and 5 has been selected as each
 wave length 27 includes a pair of non-curved linear sections
 29 between curved peaks 31. As will be described with
 10 respect to Figure 5, this configuration allows the waves to
 be stacked or nested with maximum compactness when the wire
 is helically wound around a forming mandrel (Figure 8) into
 the shape shown in Figure 2.

Referring now to Figure 5, schematically shown is
 15 a portion of stent 20 of Figure 2 which has been cut once,
 parallel to the x axis and flattened after being wound in a
 helical fashion such as that described with respect to the
 wire coil spring 10 of Figure 1. Wire 22 formed in the
 manner shown and described with respect to Figure 4, may be
 20 helically wound around an appropriately shaped mandrel
 (Figure 8). The width of the mandrel is selected in
 combination with the frequency and period of the waves
 forming wire 22 so that upon helical coiling therearound the
 waves forming each winding 24 are longitudinally stacked or
 25 nested within the waves formed by the longitudinally
 adjacent winding successively spaced therefrom.

As can be seen with respect to Figure 5, the peaks
 31 of the waves of longitudinally adjacent windings 24 are
 each linearly aligned so that each wave is stacked or nested
 30 within the next adjacent wave. In optimum configuration,
 the spacing or pitch 26 between each longitudinally
 successive winding 24 is constructed to be minimal.
 However, nesting or stacking does occur where the pitch or
 spacing between longitudinally adjacent windings 24 is less
 35 than $2A$ i.e. the peak-to-peak amplitude. As long as the
 pitch remains less than $2A$ each longitudinally adjacent
 winding 24 will be nested within the wave formed by the

1 previously formed winding 24. By minimizing the pitch or
 spacing 26 between adjacent windings 24, the open space
 between windings may be minimized. The particular wave-like
 pattern imparted to wire 22 as shown in Figure 4 allows
 5 particularly tight stacking of longitudinally adjacent
 windings.

The particular configuration of the stent 20 shown
 in Figure 2, provides significant advantages in medical
 applications. The stent 20 of the present invention is
 10 typically implanted by means of a balloon catheter (not
 shown). The stent 20 in a closed form is held around a
 deflatable catheter balloon. The stent is then inserted
 into the lumen and located at the desired position. The
 shape of the closed stent shown in Figure 2 permits ease of
 15 insertability. As shown in Figure 3, the stent may be
 easily bent or flexed along its longitudinal extent. The
 spacing or pitch 26 of windings 24 facilitate such bending.
 This helps in the insertion and deployment of the stent
 through a lumen, as typically body lumens traverse a
 20 tortuous path through the body which must be followed by
 the stent which is being deployed therein. Once properly
 located, the balloon is inflated and the stent is radially
 expanded for deployment. The balloon is then deflated, and
 the catheter is removed leaving the expanded stent in place.

25 The windings of stent 20 in closed condition are
 tightly nested. The cylindrical surface area formed by the
 coiled wire has greater wire density, i.e. more of the
 surface area is composed of solid wire while less of the
 surface area is composed by open space between the wire
 30 windings than in previous non-nested single wire stents.
 The wire surface area in the closed condition equals the
 wire surface area in an expanded condition. By maximizing
 the closed condition wire surface area, even when the stent
 is expanded such as shown in Figure 6, the expanded wire
 35 surface area is also maximized reducing tissue ingrowth
 between the expanded windings of the stent. Contrary to a
 simple coil spring such as that shown in Figure 1, the stent

1 20 of the present invention expands without significant
foreshortening of the stent or rotation of the ends of the
coil. Rather, expansion is achieved by a flattening or
5 elongation of the individual waves of the stent 20. Once
the stent is expanded after deployment to a shape shown in
Figure 6, the increased wire surface area as well as the
particular shape of the wire provides sufficient radial
strength to resist the compressive forces of a blocked,
constricted or impinged upon lumen.

10 Additionally, the above-described benefits of the
stent of the present invention are achieved without the
necessity of longitudinally overlapping adjacent wire
windings. In many prior art stents, the stents include
portions of wire windings which are longitudinally
15 overlapped. This increases the wall thickness of the stent
thereat and results in a stent which is more difficult to
implant in the body lumen by means of a balloon catheter.
Also, such stents create an undesirable, more turbulent
fluid flow therethrough. The stent of the present invention
20 maximizes wire density, maintains a high degree of
flexibility and radial compressive strength without
increasing the stent wall thickness beyond the single wire
diameter.

25 EXAMPLE:

Mathematically, the geometric analysis of the
preferred embodiment of the stent of the present invention
may be described as follows with reference to Figures 4 and
5.

30 Each wave length 27 of the wave pattern 25 forming
stent 20 is formed to include a straight leg segment 29 with
a bend radius at peak 31. The angle at which the helix
coils around the center line χ (Figure 1) is assumed to be
close to 90° , so that the successive windings 24 are
35 positioned to be as close to concentric as possible while
still maintaining a helical pattern.

The integer number of waves N per single circumference or single winding follows the equation:

$$N = \frac{\pi D}{\lambda} ;$$

where D is the diameter of the closed stent and λ is the period of a single wave.

The number of helical windings M per stent is defined by the equation:

$$M = \frac{L \sin \theta}{d_3} ;$$

where L is the overall stent length; θ is the angle of the straight leg segments with respect to the line of amplitude of the wave pattern; and d_3 is the wire diameter.

The exterior exposed surface area of the stent is equivalent to the amount of wire packed within a fixed stent length. The total length L_w of wire employed to form the stent follows the equation:

$$L_w = MN \left(4 \ell + 4 \left(r + \frac{d_3}{2} \right) \frac{\pi}{180} (90 - \theta) \right)$$

where r is the radius defining the peak curvature; and ℓ is the length of the straight line segment of the wire.

It follows that the projected solid wire area is $L_w d_3$, and the percentage of open space coverage (% open) is given by the equation:

$$\% \text{ OPEN} = 100 \left(1 - \frac{L_w d_3}{\pi D L} \right)$$

In a specific example, a stent having the parameters listed in Table I and formed in accordance with the present invention yields a percentage of open space (% open) equivalent to 28.959%.

TABLE I

L	Length of Stent	1.000 in
D	Diameter of Closed Stent	0.157 in
d_w	Wire Diameter	0.010 in
r	Radius of Curvature of Peak	0.020 in
N	Number of Waves per Winding	3
M	Number of Windings per Stent	22.47
ℓ	Length of Straight Portion of Stent	0.097 in

Further, it is found that an expanded stent constructed in accordance with the example set forth above, exhibits superior resistance to pressure P acting upon the stent in a radially compressive manner (Figure 6). In the present and illustrative example, P has been determined, both mathematically and empirically, to be 10 psi.

It is further contemplated that the stent of the present invention may be modified in various known manners to provide for increased strength and support. For example the end of wire 22 may be looped around an adjacent wave or extended to run along the length of the stent. The wire may be welded to each winding to add structural support such as is shown in U.S. Patent No. 5,133,732. Also, each windings may be directly welded to the adjacent winding to form a support spine such as shown in U.S. Patent No. 5,019,090.

Further, as mentioned above, wire 22 is helically wound around a mandrel to form the helical pattern shown in Figure 1. While the angle at which the helix coils around the mandrel is quite small, a certain angle must be imparted to the uniform windings to form a coil. It is further contemplated that a helix-like winding may be formed by concentrically wrapping a wave pattern around the mandrel

1 where the length of the sides of each wave are unequal. As
 shown in Figure 7 a wave pattern 125 may be formed having
 leg segments 129 of uneven length. Wave pattern 125
 includes individual wave lengths 127 having a first leg
 5 segment 129a and a second leg segment 129b. Leg segment
 129a is constructed to be shorter than leg segment 129b.
 Thus wave pattern 125 has a step-type shape so that upon
 winding around a mandrel, the windings 124 coil in a
 helical-like fashion therearound. This provides a
 10 lengthwise extent to the coil without having to impart a
 helical wrap thereto. Forming the stent length in this
 manner may tend to result in better flow characteristics
 through the stent in use.

Other modifications which are within the
 15 contemplation of the present invention may be further
 described. Figure 8 shows a wire 222 which has been
 preformed to have a wave pattern 225 which is generally
 triangular in shape. This wave pattern 225 includes
 individual wave lengths 227 having straight leg segments
 20 229a and 229b which meet at an apex 231. Wire 222 so
 formed, may be wound around a mandrel 200. As the
 individual wave lengths 227 nest in a manner above
 described, the apices 231 of the wave length 227 are
 longitudinally aligned.

25 The winding of wire 222 around mandrel 200 takes
 place in the following manner. The formed wire 222 is held
 in position while the mandrel is rotated in the direction of
 arrow A, thereby coiling the wire 222 around mandrel 200.
 The spacing or pitch 216 is created by subsequent vertical
 30 movement of the of the formed wire 222 along mandrel 200
 while rotation thereof is taking place. When the winding is
 complete, the ends 233 of the wire 222 may be "tied off" by
 looping the end 233 around the next longitudinally adjacent
 winding.

35 While in the embodiment shown above, the amplitude
 of each wave is relatively uniform, it is contemplated that
 the wire could be formed to have waves of varied amplitude.

1 For example, the wire could be formed so that at the ends of
the wound stent the amplitude of the waves is relatively
small while in the central portion of the stent the
amplitude is relatively large. This provides a stent with
5 a more flexible central section and more crush-resistant
ends.

In certain situations the stent of the present
invention may include a membrane covering (not shown) which
would cover the entire stent. The wire surface of the stent
10 would serve as a support surface for the membrane covering.
The membrane covering would act as a further barrier to
tissue ingrowth. Any membrane covering may be employed with
the present invention such as a fabric or elastic film.
Further, this membrane covering may be completely solid or
15 may be porous. In addition, as above described, employing
a formed wire having varied amplitude where the amplitude of
the wire is smaller at the ends of the stent would help
support the membrane covering as the crush-resistant ends
would serve as anchors to support the membrane covering with
20 little support necessary at the more flexible central
section of the stent.

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

Various changes to the foregoing described and
shown structures would not be evident to those skilled in
the art. Accordingly, the particularly disclosed scope of
the invention is set forth in the following claims.



THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

- 1 1. An intraluminal stent comprising:
a generally elongate tubular body formed of an
elongate helically wound wire, the wire being formed into
successive waves along the length of the wire, the waves
5 being arranged in non-overlapping longitudinally spaced
succession along the length of said tube, the longitudinal
spacing of the helical windings being less than twice the
8 amplitude of the wave.
- 1 2. An intraluminal stent of claim 1 wherein
longitudinally adjacent ones of said waves are
3 longitudinally nested along the length of said tubular body.
- 1 3. An intraluminal stent of claim 2 wherein said
longitudinally nested waves define peaks which are linerally
3 aligned.
- 1 4. An intraluminal stent of claim 1 wherein said
longitudinal spacing of the helical windings is less than
3 the amplitude of the wave.
- 1 5. An intraluminal stent of claim 1 wherein said
stent includes said wire being helically wound in non-
overlapping disposition and wherein said wire defines an
open area between said helically wound wire and wherein said
5 percentage of open surface area of said stent in
relationship to the total surface area of said stent is less
7 than 30% in the closed condition.
- 1 6. An intraluminal stent of claim 1 wherein said
2 tubular body is uniformly flexible along the length thereof.
- 1 7. An intraluminal stent of claim 6 wherein said
stent is radially expandable after intraluminal
3 implantation.

1 8. A radially expandable generally tubular
endoluminal implantable prosthesis comprising:

5 a wire which is wound in a helical configuration
to define a generally elongate tubular body, the wire
including successively formed waves along the length of said
7 wire, each wire wave being non-overlappingly nested within
the wave formed longitudinally thereadjacent.

1 9. A prosthesis of claim 8 wherein said wire waves
are of generally uniform configuration defining a peak-to-
3 peak amplitude of a preselected first dimension.

1 10. A prosthesis of claim 9 wherein said
longitudinally adjacent wire waves are spaced apart a
preselected second dimension which is less than the
4 preselected first dimension.

1 11. A prosthesis of claim 10 wherein said wire has a
given wire diameter and wherein said wound wire defines a
generally cylindrical outer surface having solid portions
5 formed by said wire and open portions formed between said
wound wire.

1 12. A prosthesis of claim 11 wherein said generally
cylindrical outer surface defines a total surface area
including an open surface and a wire surface and wherein
said non-expanded wire surface substantially exceeds said
5 open surface.

1 13. A prosthesis of claim 12 wherein said open surface
2 area is less than 30% of said total surface area.



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14. An intraluminal stent according to claim 1 and substantially as hereinbefore described with reference to the drawings and/or Examples.

5 15. A prosthesis according to claim 8 and substantially as hereinbefore described with reference to the drawings and/or Examples.

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Dated this 12th day of October 1998.

MEADOX MEDICALS, INC.

by their Patent Attorneys

15 DAVIES COLLISON CAVE

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HIGH STRENGTH AND HIGH DENSITY INTRALUMINAL WIRE STENT

1 ABSTRACT OF THE DISCLOSURE:

 An intraluminally implantable stent is formed of
helically wound wire. The stent has a generally elongate
tubular configuration and is radially expandable after
5 implantation in a body vessel. The wire includes
successively formed waves along the length of the wire.
When helically wound into a tube, the waves are
longitudinally nested along the longitudinal extent of the
stent so as to form a densely compacted wire configuration.
10 After radial expansion the stent maintains high radial
compressive strength and wire density to retard tissue
ingrowth.

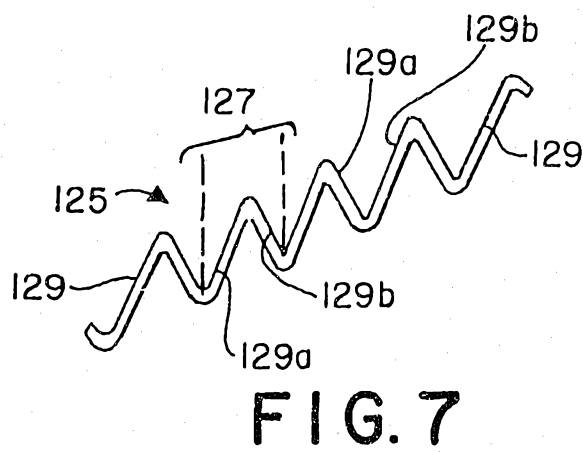
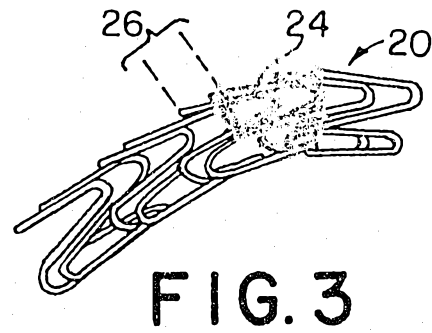
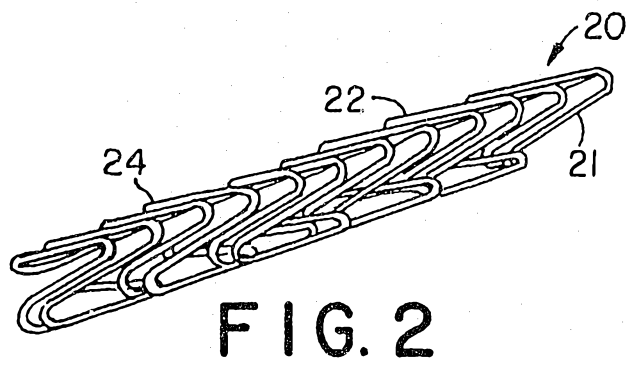
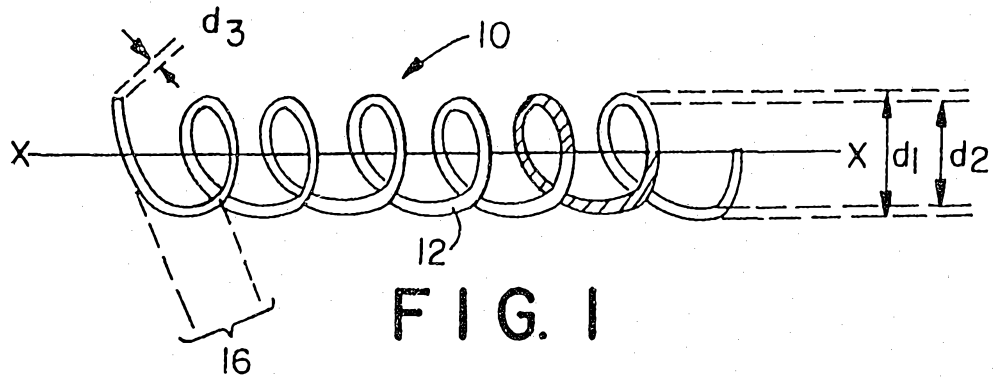
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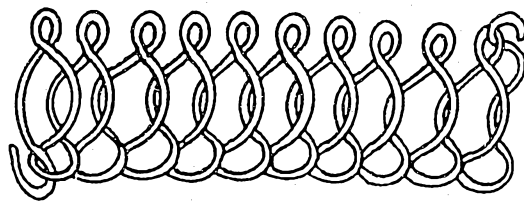
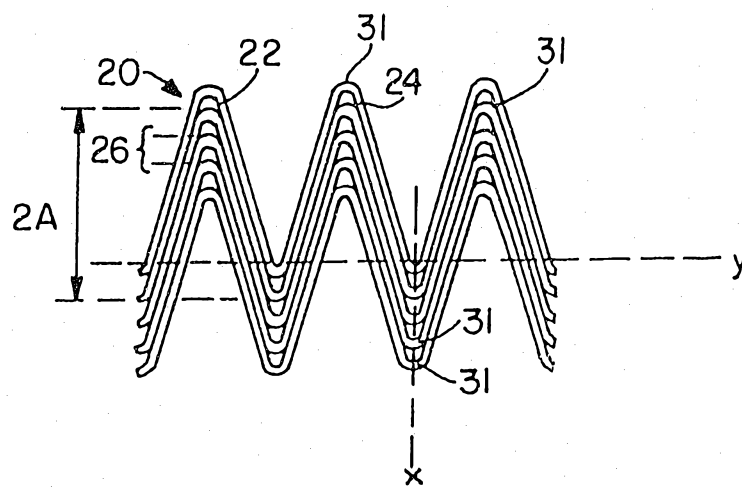
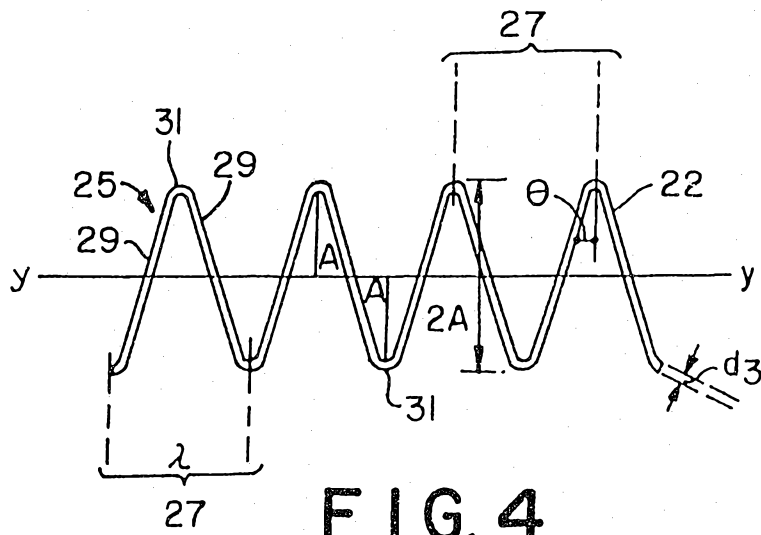
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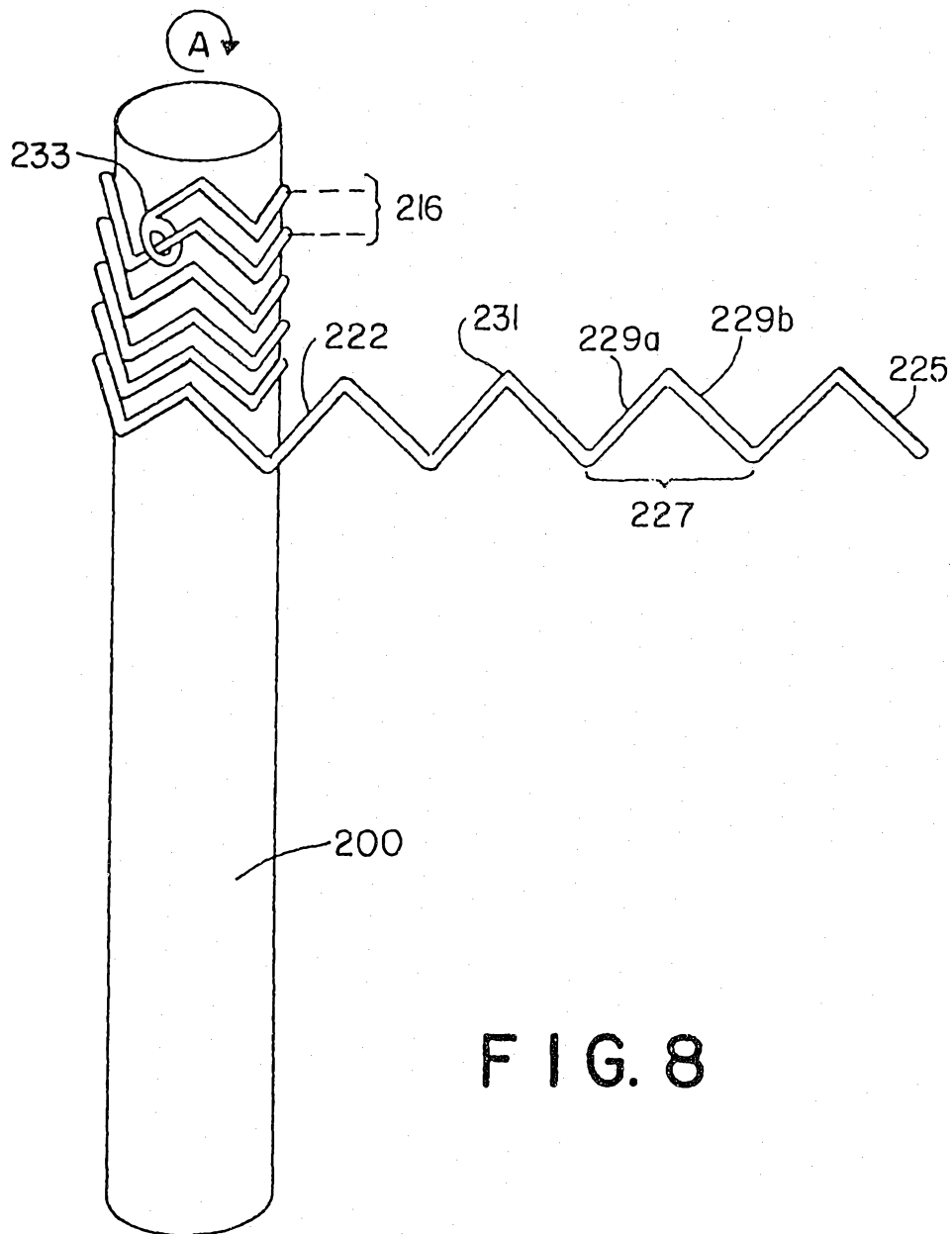


FIG. 8

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