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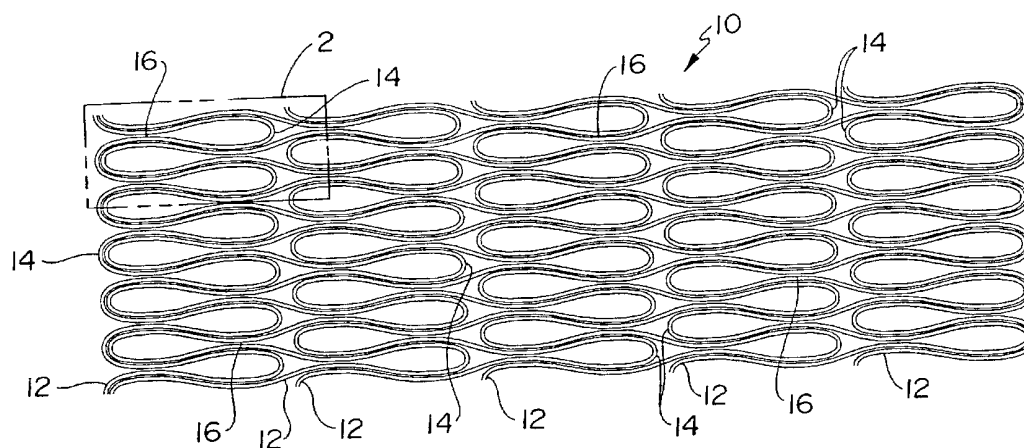
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(54) Title: FLEXIBLE STENT



(57) Abstract: A flexible tubular stent including loosely interlocked annular elements without intersections or cross-over points.



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## FLEXIBLE STENT

### BACKGROUND OF THE INVENTION

This invention relates to stents which are implanted in the body.

5               Stents are used in body lumens, such as blood vessels to maintain them in an open condition. Typically, the stent is delivered into the lumen by a catheter that supports the stent in a compact form during percutaneous insertion and transport through a lumen, such as a vessel, to the desired implantation site. Upon reaching the site the stent is expanded so that it engages the interior wall of the vessel. The catheter  
10 is then removed, leaving the stent in the body.

              The expansion of the stent may involve forcing it to expand radially outwardly as by inflation of a balloon carried by the catheter or the stent may be of a self-expanding type, several of which are known in the art. For example, the stent may be made of a memory metal such as NITINOL which self-expands in selected  
15 temperature ranges.

              It can be readily seen that the more flexible the stent is during percutaneous insertion the more easily it can negotiate bends and curves in the lumen or vessel to reach the implantation site.

### 20 SUMMARY OF THE INVENTION

              This invention provides a stent design of individual annular elements shaped so as to loosely interfit or interlock together with or without intersection and without cross-over points whereby the stent exhibits unusual flexibility.

              Preferably, the annular elements are multiple independent serpentine-like  
25 rings adjacent to each other having laterally spaced segments 180° out of phase with each other to provide a stepped sequence around each ring, each segment having a wide and a narrow intermediate portion with one set of segments on one side being fitted into an adjacent set of segments on one side of an adjacent serpentine ring to interlock the rings together against longitudinal separation thus forming a flexible cylindrical or  
30 tubular structure.

              In another aspect of the invention, the edges of the annular rings may be formed at an angle with respect to the center line of the tubular stent configuration

rather than aligned therewith as in the prior art. By fabricating the stent with such angular side walls "off center" the rings will interlock with one another against radial separation if moved radially in or out with respect to the stent centerline.

## 5 BRIEF DESCRIPTION OF THE DRAWING

Figure 1 is an unrolled flattened plan of a stent according to a preferred form of the invention;

Figure 2 is an enlarged portion of Figure 1 showing in detail the loosely interlocked serpentine rings;

10 Figure 3 is an enlarged fragmentary showing of a form of the invention having segments with angular side walls;

Figures 4 and 5 are end views of a stent showing their cylindrical construction and the unique cross-sectional shapes of the struts;

Figure 6 shows overlap in stent struts, and

15 Figures 7 and 8 show portions of stents of different embodiments according to this invention.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figures 1 and 2, an embodiment of a stent according to the  
20 invention is shown and generally designated at 10. Stent 10 is of cylindrical or tubular configuration as can be seen in end view Figures 4 and 5 and includes a plurality of annular serpentine segments 12 interfitted with each other over the length of the stent body.

Each annular segment 12 is of a generally serpentine configuration  
25 having wide lateral end portions 14 and narrow lateral portions 16 spaced from ends 14, the wide portions of one ring being interfitted into the wide portion of an adjacent ring as shown to prevent longitudinal separation of the serpentine rings. Radial separation of the rings is prevented during handling and delivery by carrying the interfitted rings on a shaft (not shown) as may be provided by the delivery catheter *per se*.

30 The stents of the invention may be made of wire or the like. More preferably, they are laser cut from a metal cylinder to a desired configuration.

Historically stents have been constructed of struts with either round, square, trapezoidal, oblong, or other cross-sections. The cross-section of the strut has remained relatively constant throughout the stent. The shape of the strut has been dictated by the starting material, the cutting or shaping process, and the surface finish process. Stent designers can select from a variety of shapes to give the stent unique mechanical properties, but the stent contains the same general cross-section throughout, i.e., if the strut is oblong in shape it remains oblong, if the strut is wider on the OD than the ID it retains this profile throughout the stent. This remains true even if the cross-sectional area of the strut varies in regions of the stent.

A further improvement is shown in Figures 3, 4 and 5 in which segments 18 may be formed from a tube or sheet having the side walls "off center" with respect to the center line of the stent so that the segments interlock with one another if moved radially in or out. Two options are shown. Figure 4 shows the struts laser cut off axis of the center of the stent all in the same direction. Figure 5 shows a second option in which the off-axis direction of cut alternates around the stent.

The result is a stent which contains elements having multiple varied strut cross-sectional shapes in a predetermined manner. This attribute is desirable because each cross-sectional shape is selected to give the stent unique mechanical properties at that specific location within the stent. By either using a means to selectively remove material or mechanically deform the material, the stent struts can be formed into a tailored shape at selected locations. These tailored shapes can cause the struts to be stronger, weaker, remain flat during expansion, twist during expansion, etc.

Also, varying the cross-section of the stent struts can improve the nesting or the compaction of the struts in the compressed state. By improving the compaction properties of the stent, the stent can achieve lower profiles. There can even be overlapping regions of the various struts without actually causing struts to be deformed into the ID or OD of the stent. This helps to maintain a low profile. Additionally, the overlapping of the struts creates a securement means. Each row of struts will help to contain an adjacent row. This is shown in Figure 6.

Referring now to Figure 7, there is shown an example of a stent 10 in fragment to illustrate that a stent according to the invention may be made of a single elongated piece of wire or the like.

In Figure 8, interconnections 20 are shown between rings 12 in a stent 10, showing in plan.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and  
5 alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

## WHAT IS CLAIMED IS:

1. A flexible expandable stent comprised of a plurality of serpentine-like rings loosely interfitted in mated relationship with adjacent serpentine rings to form a mesh-like cylindrical stent body.
- 5 2. The stent of claim 1 wherein each ring is comprised of a plurality of segments, each having alternating wide and narrow portions to facilitate interfitting thereof.
3. The stent of claim 1 in which the rings are unconnected with each other.
4. The stent of claim 1 in which the rings are interconnected to each other.
- 10 5. The stent of claim 1 in which the serpentine rings are formed of wire.
6. The stent of claim 5 in which the wire is a continuous length of wire extending through the entire stent body.
7. The stent of claim 1 in which the serpentine rings are formed of material having substantially flat sides.
- 15 8. The stent of claim 1 in which the rings are cut from a metal tube whereby a plurality of substantially flat sided struts in cross-section are provided.
9. The stent of claim 8 in which edges of at least some of the struts are angled with respect to the edges of adjacent struts whereby radial separation is prevented.
- 20 10. The stent of claim 1 in which the cross-section of the rings are varied in a predetermined manner to provide selected properties to various portions of the stent.
11. A stent comprised of structural elements in which at least some of the elements have certain predetermined cross-sectional configurations, the cross-sectional shapes of the elements varying at different locations of the stent.

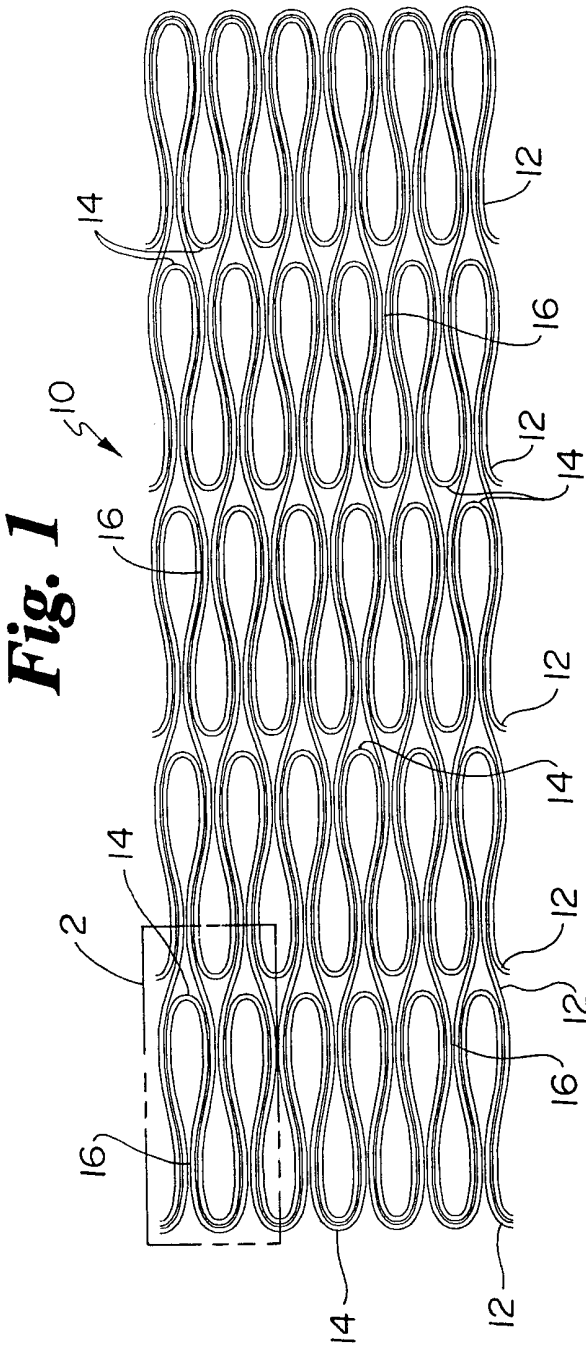
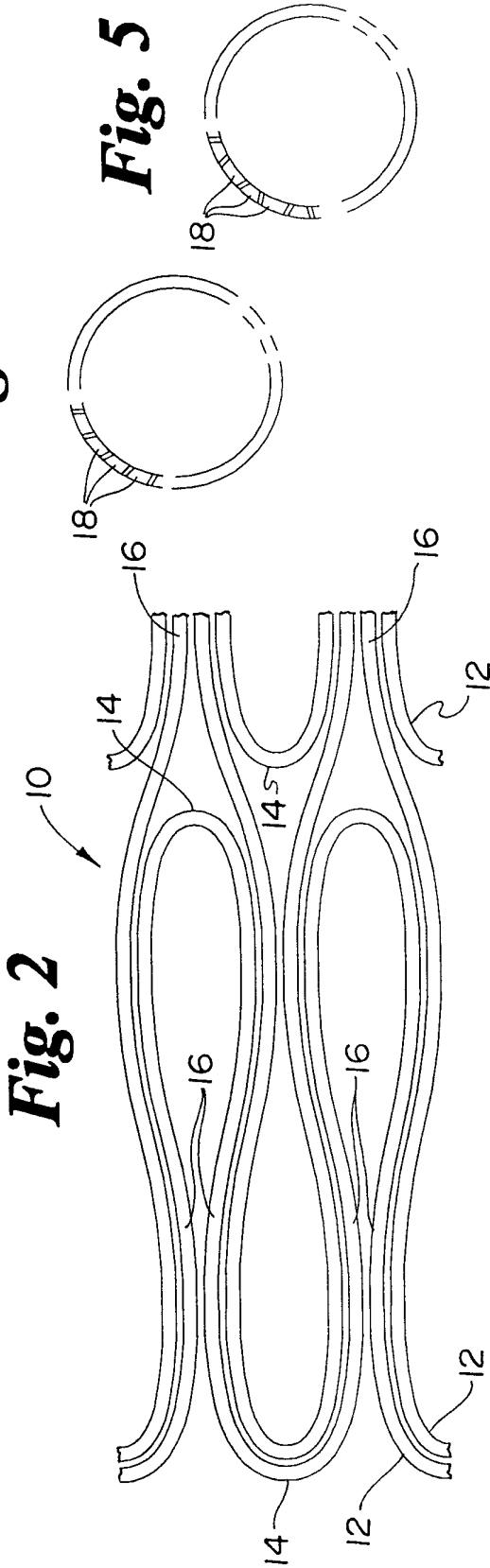


**Fig. 4**



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**Fig. 3**

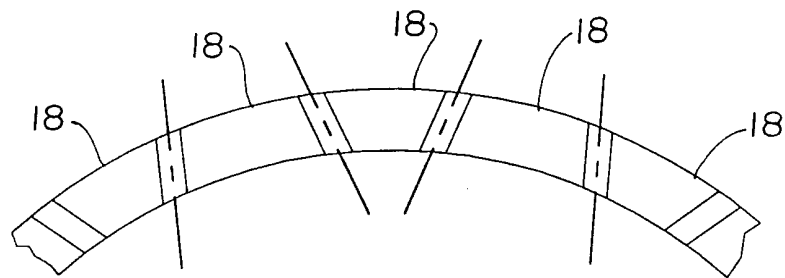
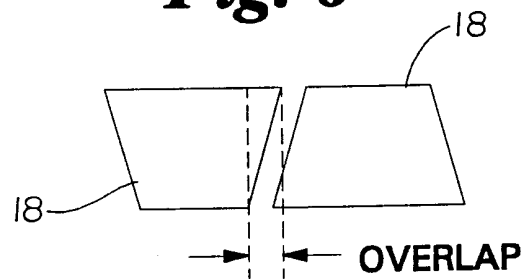


**Fig. 6**



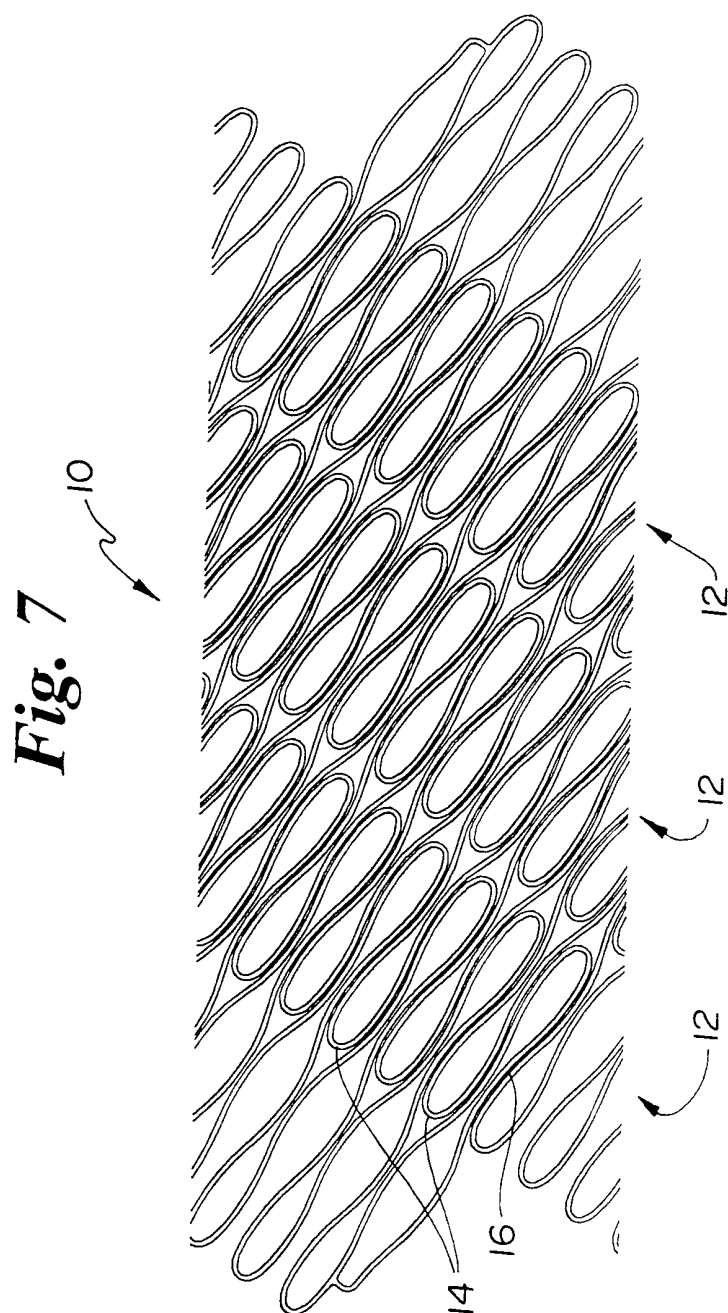


Fig. 8

