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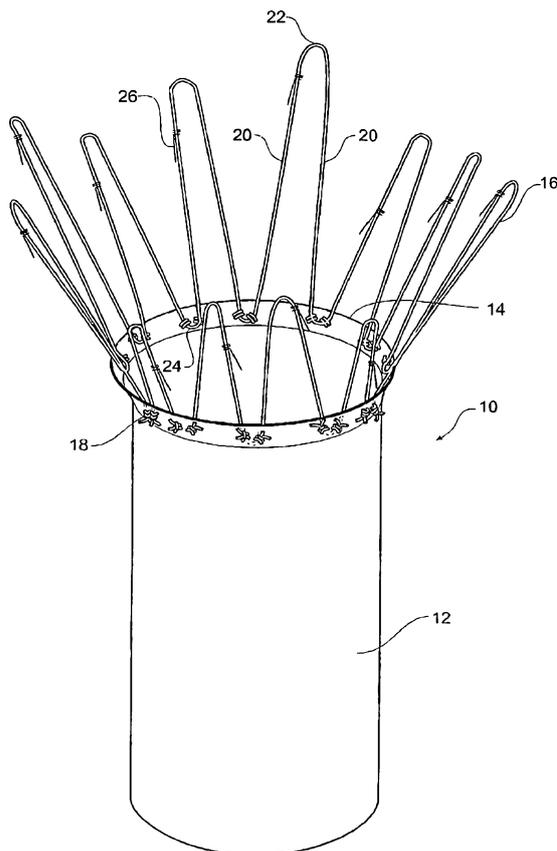
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(54) Title: RETENTION OF STENTS



(57) Abstract: A stent member (10) is retained on an introducer (38) by retention of an exposed stent (16) of the stent member to the introducer with trigger wires (44). The introducer has a trigger wire catheter (40) and four trigger wires with each trigger wire extending in a loop from the trigger wire catheter. The stent member has a tubular body (12) of a graft material and an exposed stent joined to and extending from one end of the tubular body. The exposed stent is a self expanding Z stent with struts (20) and bends (22, 28, 30) between them. A pair of struts and a bend between them define an apex a selected apex distance away from the tubular body. Adjacent apices of the exposed stent are different apex distances from the tubular body so that they stack under the trigger wires in a neat fashion. Distally extending barbs (26) on alternate struts of the exposed stent are spaced selected distances from the tubular body.



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- 1 -

RETENTION OF STENTS

DescriptionTechnical Field

This invention relates to stents and stent grafts, and more particularly to their retention on an introducer.

Background of the Invention

5 For the endovascular introduction of stent grafts into the human or animal body, there have been proposed introducers or deployment devices which hold such stent grafts in a radially compressed or constrained condition on the introducer. Normally upon withdrawal of a sheath, an activation of a suitable release mechanism causes such a stent graft to be released into a body lumen.

10 Some stent grafts include an exposed proximally extended zigzag stent comprised of struts and bends between the struts. Retention of such a stent graft onto an introducer can be by retention of the bends of the zigzag exposed stent to the introducer via a release mechanism. It is important, however, that the bends and struts of the exposed stent are retained onto the introducer in a neat
15 manner to enable the stent graft to be radially compressed or constrained into as small as possible region and to allow for release without tangling of the bends and struts of the exposed stent.

Aspects of the present invention seek to overcome or reduce one or more of the above problems. Aspects of the present invention also seek to provide the
20 physician with a useful alternative construction.

Throughout this specification the term distal with respect to a portion of the aorta, a deployment device or a stent graft refers to the end of the aorta, deployment device or stent graft further away in the direction of blood flow away from the heart and the term proximal refers to the portion of the aorta,
25 deployment device or end of the stent graft nearer to the heart. When applied to other vessels similar terms such as caudal and cranial should be understood.

Summary of the Invention

According to a first aspect of the present invention, there is provided a stent member comprising a tubular body portion and, extending from an end thereof, a

- 2 -

plurality of struts with bends therebetween, a pair of struts and a bend between the pair of struts defining an apex a selected apex distance away from the tubular body portion, characterised in that adjacent apices are different apex distances from the tubular body portion.

5 The reference to a "pair" of struts does not necessarily imply that the struts of a pair are identical.

 Preferably there are three apex distances being a shorter distance, a medium distance and a longer distance and that the three apex distances are consecutively placed around the exposed stent.

10 In a preferred embodiment the exposed stent can have twelve apices comprising four sets of the three apex distances consecutively spaced around the exposed stent.

 There may be further included barbs on alternate struts of the exposed stent. The barbs are preferably distally extending.

15 To facilitate packing on an introducer and to prevent tangling of the barbs upon release, the barbs on alternate struts of the exposed stent may be spaced selected distances from their respective apices such that adjacent barbs are different distances from the tubular body portion.

 According to a second aspect of the present invention there is provided a
20 combination of a stent introducer and a stent member releasably retained thereon, the introducer comprising a trigger wire catheter and at least one trigger wire, the or each trigger wire extending in a loop from the trigger wire catheter, the stent member comprising a tubular body portion and, extending from one end of the tubular body portion, a plurality of struts with bends therebetween, a pair of struts
25 and a bend between the pair of struts defining an apex a selected apex distance away from the tubular body portion, characterised in that adjacent apices are different apex distances from the tubular body portion, the stent member being retained on the introducer by the or each trigger wire passing through a plurality of apices at different apex distances from the tubular body portion.

30 Preferably the introducer has four trigger wires so that three bends of a twelve bend stent are retained by each trigger wire. There can be used a stent member with

- 3 -

different numbers of proximal bends on the stent member and the introducer can have different numbers of trigger wires to retain the proximal end of the stent member to the introducer. For instance a stent with nine proximal bends can be retained on a delivery device using three trigger wires with three bends each retained
5 by each wire. A stent with ten proximal bends can be retained on a delivery device using four trigger wires with two bends each retained by two of the wires and three bends each retained by the other two wires.

An advantage is thus provided by an arrangement for retaining the bends of a stent on an introducer by the use of trigger wires, in which adjacent bends stack
10 up one next to the other, preferably three bends to a trigger wire, and thereby are retained in as small a volume as possible and can be released without problem.

Similarly, by placing the barbs spaced distances along alternate struts, the barbs have less tendency to engage with each other and cause problems. Furthermore, a more secure attachment to the surrounding body lumen is provided
15 by such an arrangement.

Brief Description of the Drawing

Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, of which:

Figure 1 shows a stent graft suitable for endovascular deployment and including an exposed zigzag stent at its proximal end according to one
20 embodiment of the present invention;

Figure 2 shows a view of the proximal end of the stent of Figure 1 with the stent graft laid out flat;

Figure 3 shows the stent graft of Figures 1 and 2 in detail retained onto a stent graft introducer; and
25

Figures 4A, 4B and 4C show strut lengths and barb spacings for stent with different numbers of bends or points according to modifications of the embodiment of the invention.

Detailed Description

Referring to the drawings, and in particular Figure 1, it will be seen that a stent graft 10 has a tubular body 12 of a biocompatible graft material. At the
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- 4 -

proximal end 14 of the stent graft an exposed zigzag stent 16 is fastened to the tubular body 12 by stitching 18 and extends away from the tubular body. The exposed self expanding stent 16 is formed from struts 20 of a resilient wire such as stainless steel with proximal bends 22 and distal bends 24 between adjacent struts. The stitching 18 retaining the exposed stent to the proximal end of the stent graft is placed in the region of the distal bends 24. Barbs 26 are mounted onto alternate struts 20 with the point 27 of the barbs 26 extending distally. Further zig zag stents would normally be placed along the length of the stent graft but they have been omitted for clarity.

The proximal end 14 of the tubular body 12 of the stent graft 10 is shown in a laid out flat format (or developed view) in Figure 2.

It can be seen in Figure 2 that the bend 22 is the longest apex distance 22a from the tubular body 12, the adjacent bend 28 is a medium apex distance 28a from the tubular body 12 and the next adjacent bend 30 is the shortest apex distance 30a from the proximal end 14 of the tubular body 12. These three apex distances 22a, 28a and 30a are used consecutively around the proximal end of the tubular body.

It will also be noted that the barbs 26 on alternate struts 20 are spaced at different distances 26a, 26b and 26c from the proximal end 14 of the tubular body on adjacent alternate struts so as to assist in preventing adjacent barbs tangling or engaging with each other during introduction and release of the stent graft.

Figure 3 shows the stent graft of Figures 1 and 2 in detail retained onto a stent graft introducer before it is radially compressed within a sheath for delivery. Only part of the introducer is shown in Figure 3.

To retain the stent graft 10 onto an introducer 38 the exposed self expanding stent 16 is retained by trigger wires to the introducer. The introducer comprises a trigger wire catheter 40 extending to a nose cone dilator 42 with trigger wires 44 extending out of apertures 43 in the trigger wire catheter 40. In this embodiment there are four trigger wires 44. Each trigger wire 44 retains three proximal bends 22, 28 and 30 of the exposed stent 16.

- 5 -

It will be noted that adjacent individual bends 22, 28 and 30 of the exposed self expanding stent 16 are retained under a single trigger wire 44 with the bends being at different apex distances from the tubular body 12.

Accordingly, they position neatly under the trigger wire and assist with stacking
5 of the proximal end of the exposed stent 16 onto the introducer.

In a preferred embodiment of the invention the exposed self expanding stent 16 has adjacent pairs of struts with lengths of 26, 25 and 24 millimetres from the proximal end 14 of the tubular body 12, and the barbs are placed onto
10 the alternate struts at distances of 4 to 7mm, 7 to 10 mm and 10 to 13 mm from the respective bends of the exposed self expanding stent. Hence in one embodiment the barbs are spaced from the proximal end 14 of the tubular body 12 by distances of from 19 to 22 mm on the longest strut, 15 to 18 mm on the medium length strut and 11 to 14 mm on the shortest strut. All of these
15 dimensions are measured along the struts and hence are at a slight angle to the longitudinal direction of the stent graft.

Various modifications may be made to the above-described embodiment. For example there may be only two apex distances. In other embodiments there may be four or more apex distances.

Barbs may be provided on every strut. In other embodiments, barbs are
20 provided on fewer than half the struts. More than one barb may be provided on some or all of the struts.

A single trigger wire may extend through the loops of all the struts. Alternatively there may be two trigger wires, three trigger wires or more than four trigger wires. In general, a stent has c loops with d loops being arranged in each of
25 b sets. Thus $c = b \times d$ and in general there will be b trigger wires, unless each trigger wire passes through the loops of more than one set.

The stent graft may comprise a plurality of stents arranged along its axis.

In a modification, a stent may be provided and deployed without graft material. The stent may be an end or exposed stent located at the end of any medical implant
30 or prosthesis device.

- 6 -

Figures 4A, 4B and 4C show strut lengths and barb spacings for stents with different numbers of bends or points according to further modifications of the invention. Figure 4A shows a stretched out stent with 9 proximal and 9 distal points or bends. Figure 4B shows a stretched out stent with 10 proximal and 10 distal points or bends. Figure 4C shows a stretched out stent with 12 proximal and 12 distal points or bends. The table accompanying each of Figures 4A, 4B and 4C show strut lengths and barb spacings for each point. All the dimensions are in millimetres. The length (a) in each of Figures 4A, 4B and 4C indicates the length of a strut of the stent and the length (b) in each of Figures 4A, 4B and 4C indicates the spacing of the barbs on alternate struts from the proximal point or bend. It will be noted that each strut is a different length than the strut on either side of it and that the barb spacing of adjacent barbs is different so that the barbs occupy as small a space as possible when the stent graft is compressed within a delivery sheath and are less likely to engage or tangle with each other.

CLAIMS:

1. A stent graft introducer in combination with a stent graft, the stent graft releasably retained on the stent graft introducer, the introducer comprising a trigger wire catheter and a plurality of trigger wires and each trigger wire extending in a loop of a trigger wire from the trigger wire catheter, the stent graft comprising a tubular body of a graft material and an exposed stent joined to and extending from one end of the tubular body, the exposed stent comprising including a plurality of struts and proximal and distal bends therebetween, the distal bends being joined to a proximal end of the tubular body, a pair of struts and a proximal bend defining an apex which is a selected distance to the proximal bend away from the tubular body, wherein adjacent apices of the exposed stent comprise different strut lengths thereby defining different distances to the respective proximal bend from the tubular body, the stent graft being retained onto the introducer by the trigger wires, the loop of a trigger wire of the plurality of trigger wires passing through at least two adjacent apices of different distances to the bends from the tubular body whereby the at least two adjacent apices are retained by the trigger wire and stacked thereunder.

2. A stent graft introducer and a stent graft releasably retained thereon as in Claim 1 wherein there are three distances to the respective proximal bend being a shorter distance, a medium distance and a longer distance.

3. A stent graft introducer and a stent graft releasably retained thereon as in Claim 2 wherein the three distances to the respective proximal bend are consecutively around the exposed stent.

4. A stent graft introducer and a stent graft releasably retained thereon as in Claim 2 wherein the exposed stent has twelve apices comprising four sets of the three distances to the respective proximal bend consecutively around the exposed stent.

5. A stent graft introducer and a stent graft releasably retained thereon as in Claim 1 wherein the exposed stent is a self expanding Z stent.

6. A stent graft introducer and a stent graft releasably retained thereon as in Claim 1 further including distally extending barbs on at least some of the struts of the exposed stent.

7. A stent graft introducer and a stent graft releasably retained thereon as in Claim 1 further including distally extending barbs on alternate struts of the exposed stent.

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5 8. A stent graft introducer and a stent graft releasably retained thereon as in Claim 7 wherein the barbs on alternate struts of the exposed stent are spaced selected distances from their respective apices such that adjacent barbs are different distance from the apices such that adjacent barbs are different distance from the tubular body whereby to assist in preventing adjacent barbs tangling or engaging with each other during introduction and release of the stent graft.

9. A stent graft introducer in combination with a stent graft, the stent graft releasably retained on the stent graft introducer;

0 the introducer comprising a trigger wire catheter and a plurality of trigger wires and each trigger wire extending in a loop of a trigger wire from the trigger wire catheter, the stent graft comprising a tubular body of a graft material and an exposed stent;

the exposed stent being joined to and extending from one end of the tubular body;

the exposed stent comprising a plurality of struts and bends therebetween thereby defining a substantially cylindrical body with a first end, a second end and a cylindrical axis;

5 a first set of pairs of struts and bends between the pairs of struts defining a first set of apices at the first end of the cylindrical body and a second set of pairs of struts and bend between them defining a second set of apices at the second end of the cylindrical body;

the first set of apices being co-planar in a plane at right angles to the cylindrical axis;

0 the second set of apices being at a selected apex distances away from the first ends of the cylindrical body, characterised that adjacent second apices of the stent member are different apex distances from the tubular body and wherein there are three apex distances being a shorter distance, a medium distance and a longer distance, the three apex distances being consecutively placed around the stent member;

25 the stent graft being retained onto the introducer by the trigger wires, the loop of a trigger wire of the plurality of trigger wires passing through at least two adjacent of the second set of apices of different distances to the bends from the tubular body whereby the at least two adjacent apices are retained by the trigger wire and stacked thereunder.

30 10. A stent graft introducer and a stent graft releasably retained thereon as in Claim 9 wherein the three distances to the respective proximal bend are consecutively around the exposed stent.

35 11. A stent graft introducer and a stent graft releasably retained thereon as in Claim 10 wherein the exposed stent has twelve apices comprising four sets of the three distances to the respective proximal bend consecutively around the exposed stent.

12. A stent graft introducer and a stent graft releasably retained thereon as in Claim 9 wherein the exposed stent is a self expanding Z stent.

13. A stent graft as in Claim 9 further including distally extending barbs on at least some of the struts of the exposed stent.

14. A stent graft as in Claim 9 further including distally extending barbs on alternate struts of the exposed stent.

15. A stent graft as in Claim 14 wherein the barbs on alternate struts of the exposed stent are spaced selected distances from their respective apices such that adjacent barbs are different distance from the apices such that adjacent barbs are different distance from the tubular body whereby to assist in preventing adjacent barbs tangling or engaging with each other during introduction and release of the stent graft.

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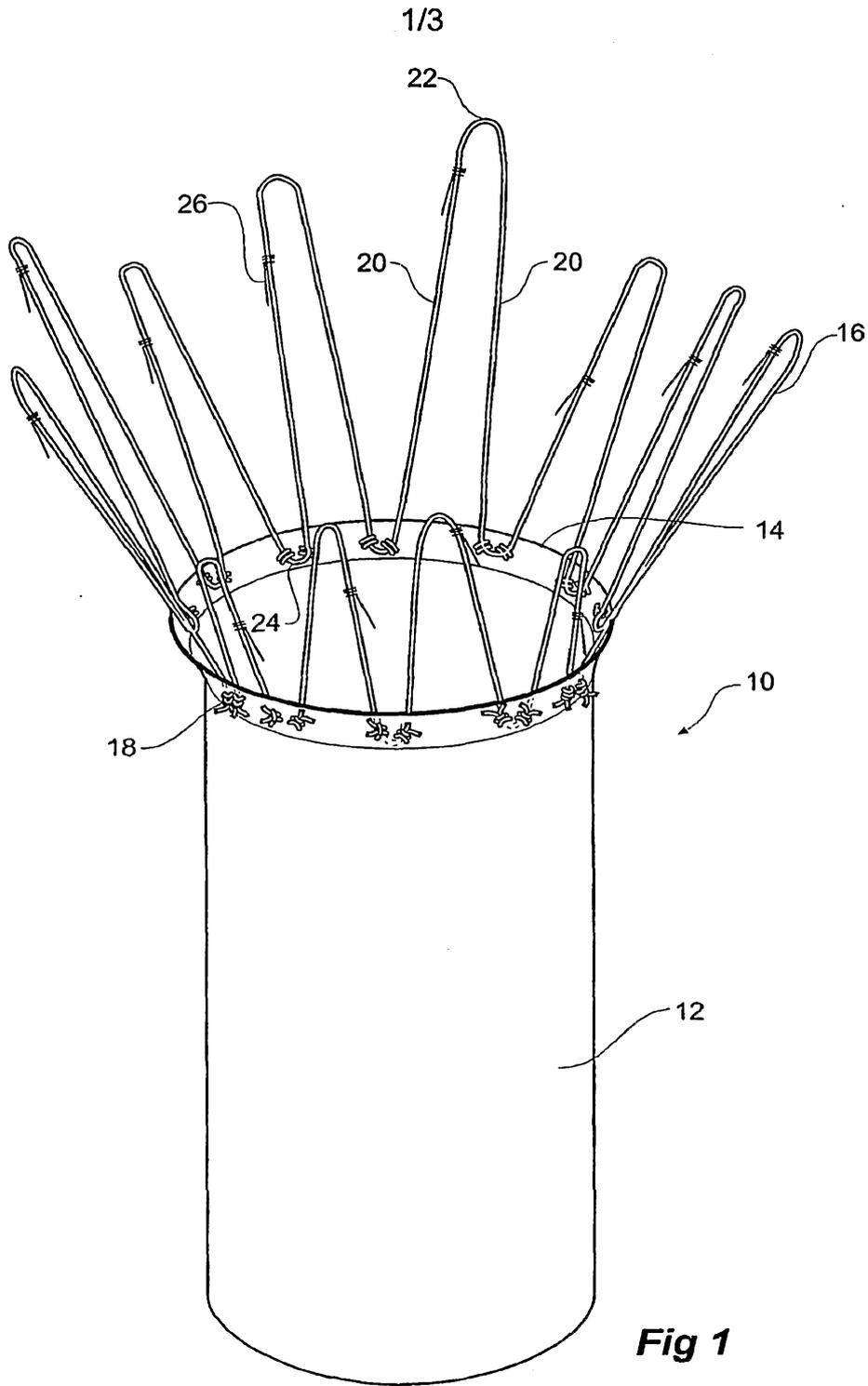


Fig 1

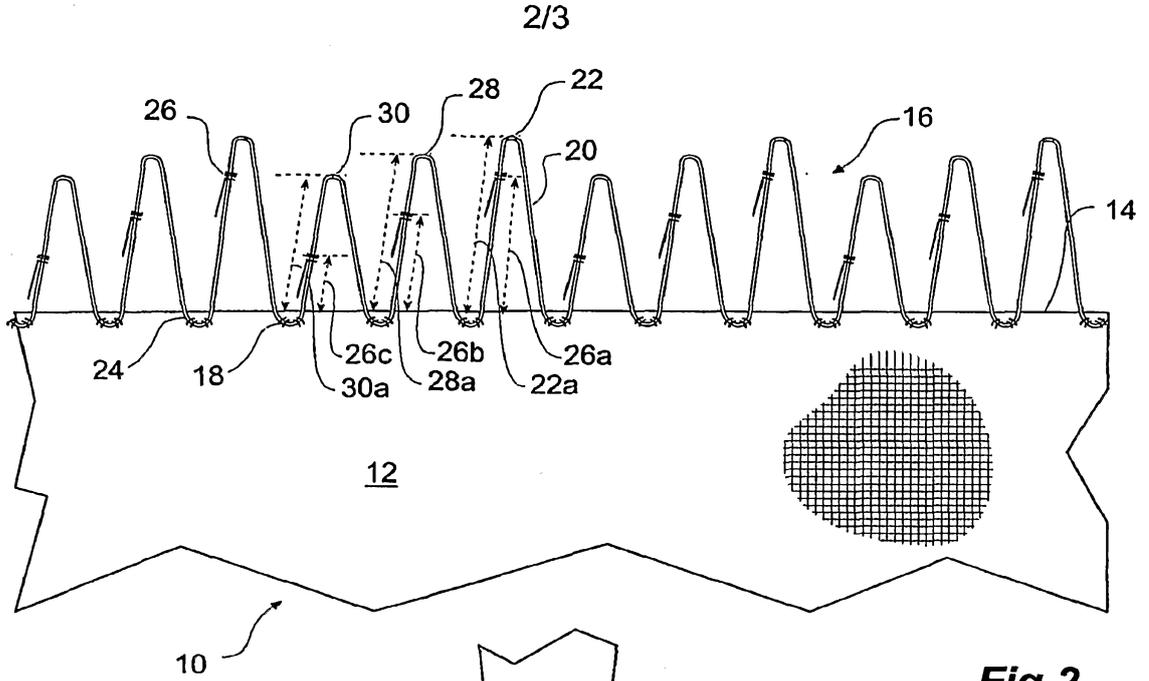


Fig 2

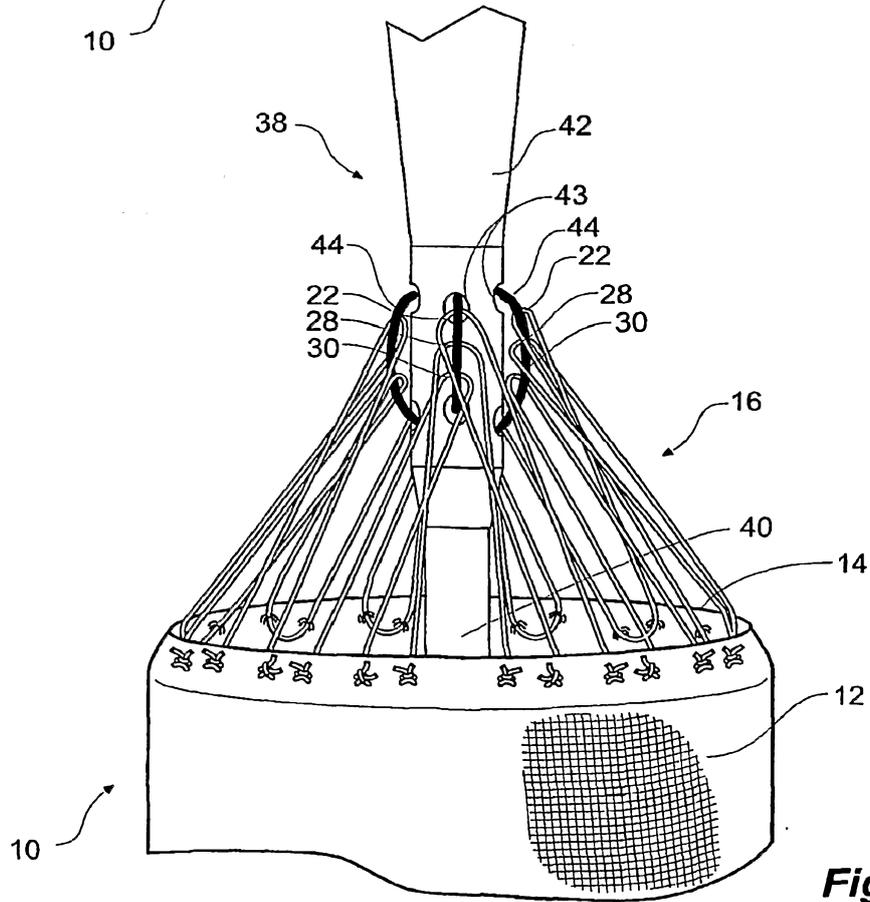


Fig 3

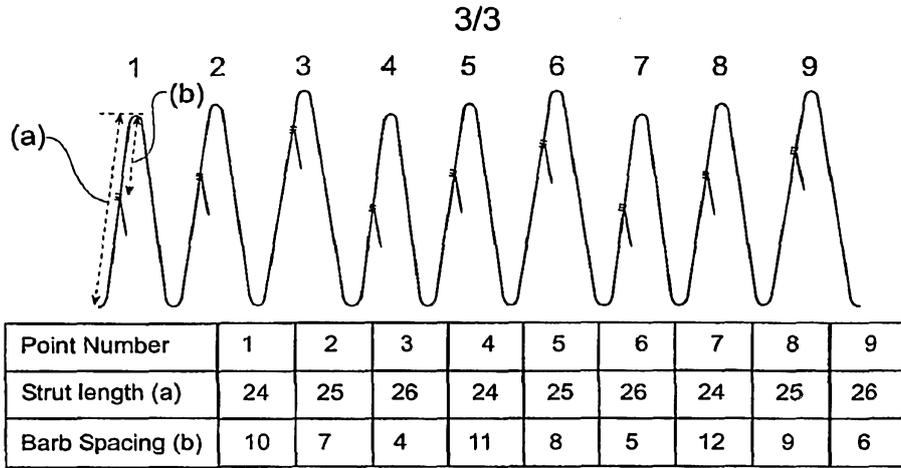


Fig 4A

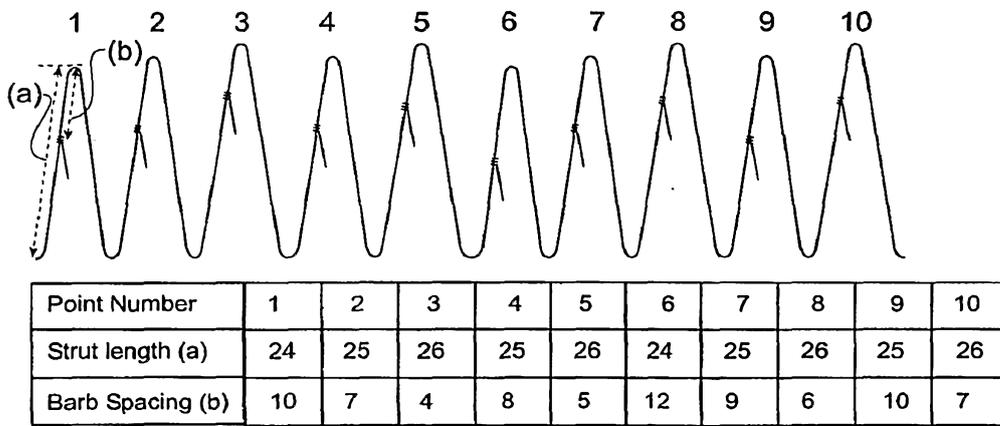


Fig 4B

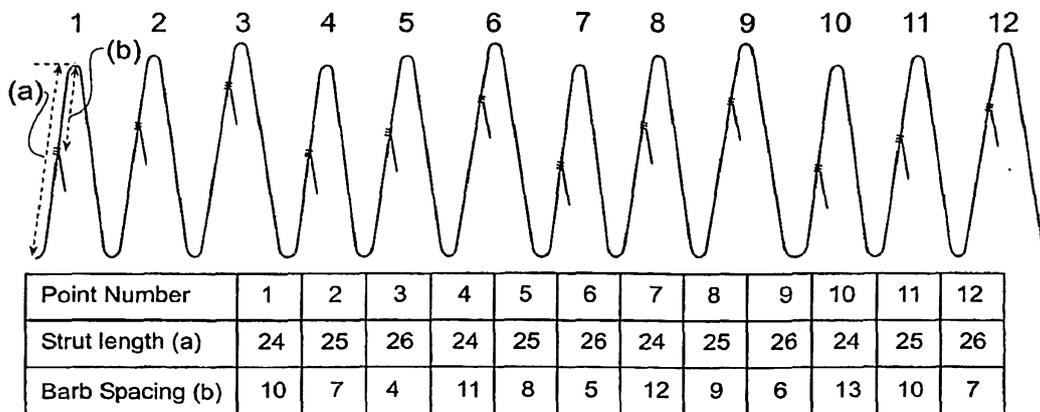


Fig 4C