(12) UK Patent Application (19) GB (11) 2 355 728 (13) A

(43) Date of A Publication 02.05.2001

(21) Application No 9925447.6

(22) Date of Filing 27.10.1999

(71) Applicant(s)
Anson Medical Limited
(Incorporated in the United Kingdom)
The Innovation Centre, 68 Milton Park, Abingdon, OXFORD, OX14 4RX, United Kingdom

(72) Inventor(s)
Peter William Phillips
Gail Beaton

(74) Agent and/or Address for Service
Williams, Powell & Associates
4 St Paul's Churchyard, LONDON, EC4M 8AY, United Kingdom

(51) INT CL[7]
A61F 2/06

(52) UK CL (Edition S)
D1G GE GF
A5R RAR
U1S S1036

(56) Documents Cited
GB 2322637 A **GB 2165559 A** **WO 99/37242 A1**
WO 90/15895 A1 **US 5676671 A** **US 5413601 A**
US 4502159 A

(58) Field of Search
UK CL (Edition R) **A5R RAR , D1G GAH GE GF GHX GMA GS**
INT CL[7] **A61F , D05B , D05C**
Online: EPODOC, JAPIO, WPI

(54) Abstract Title
Tubular medical implants and methods of manufacture

(57) A method for stitching thread to the wall of a tubular graft, comprising the steps of feeding thread from the outside of the graft through the graft wall to form a loop of thread inside the graft, passing thread through said loop, and pulling said loop closed to form a stitch. The thread which is passed through said loop may be a second loop of the same thread which has been fed through the wall of the graft, said second loop subsequently having a third loop of the same thread passed through it, in order to form a chain stitch in the graft wall. Alternatively, it may be a length of a second thread, which is subsequently passed through subsequent loops of the first thread which have been fed through the wall of the graft, in order to form a lock stitch in the graft wall.

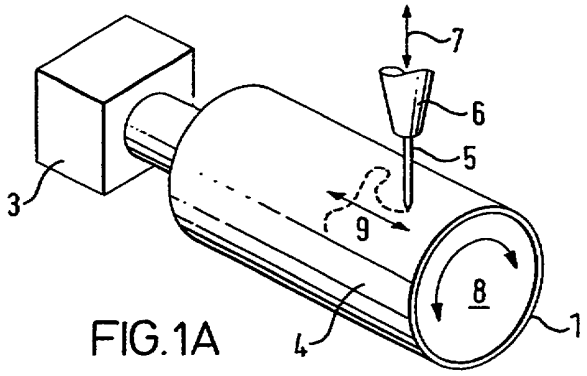

FIG.1A

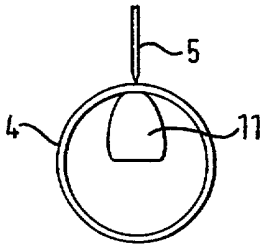

FIG. 1B

GB 2 355 728 A

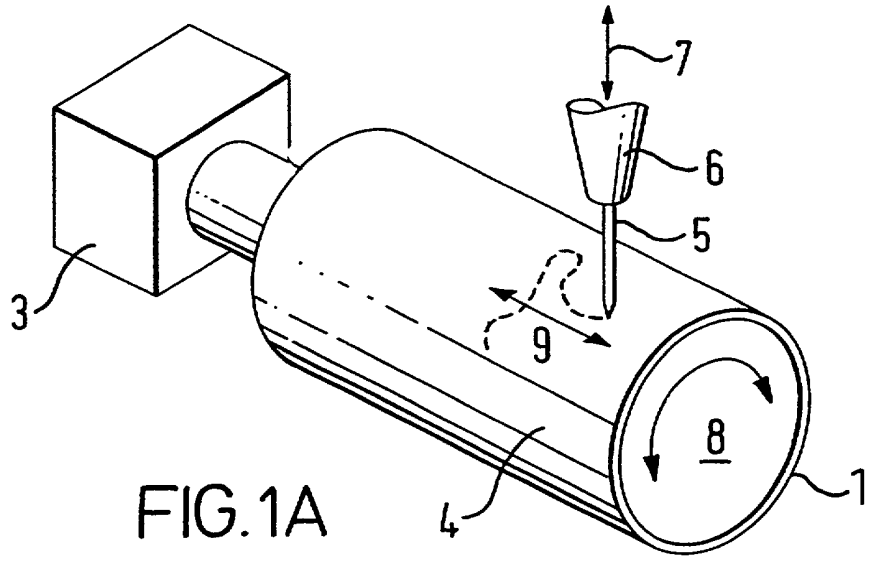

FIG.1A

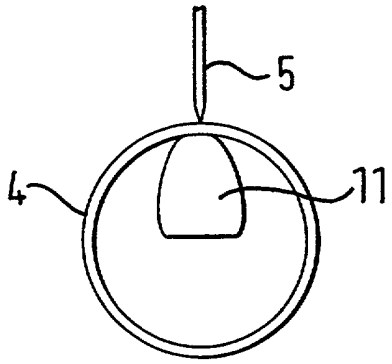

FIG. 1B

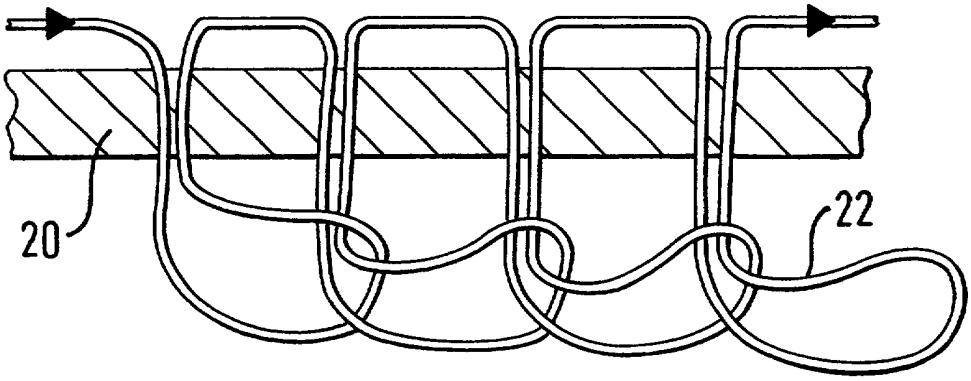

FIG. 2

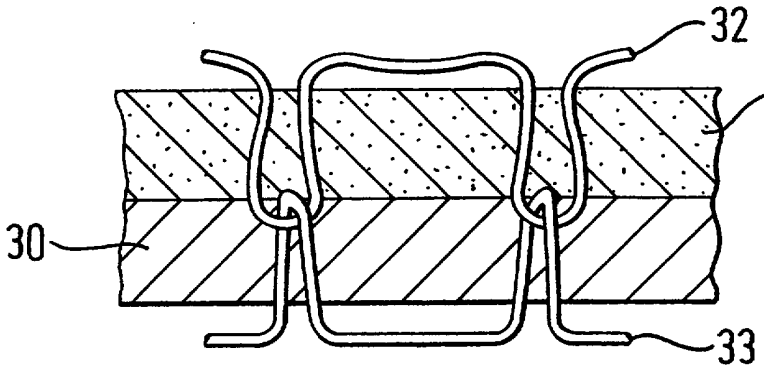

FIG. 3

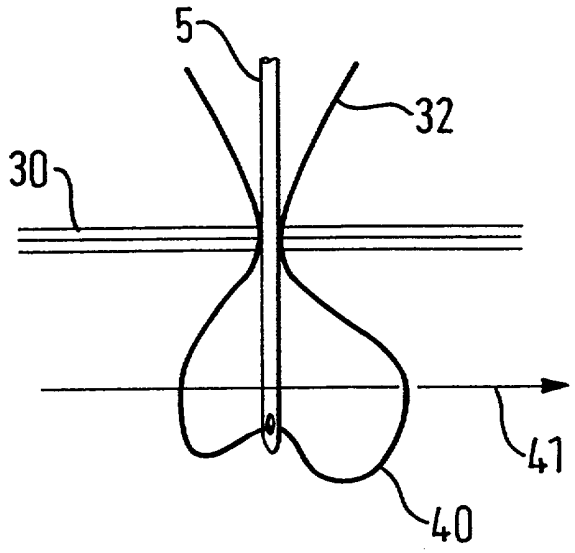

FIG. 4

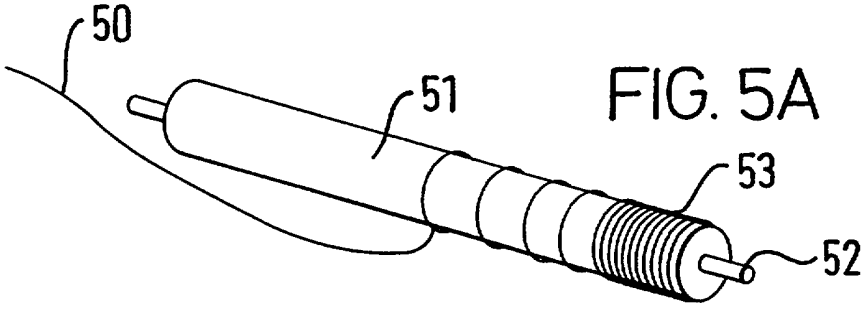

FIG. 5A

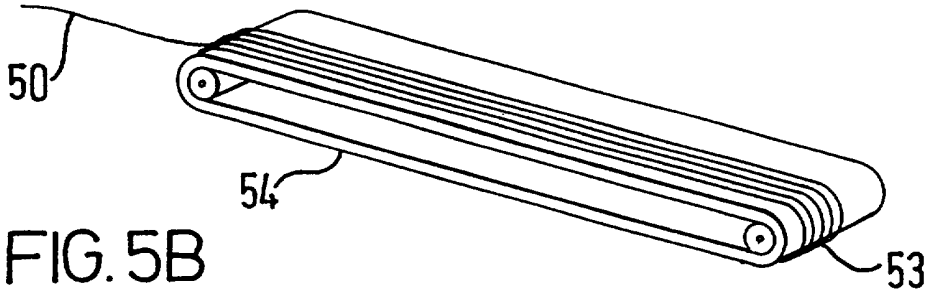

FIG. 5B

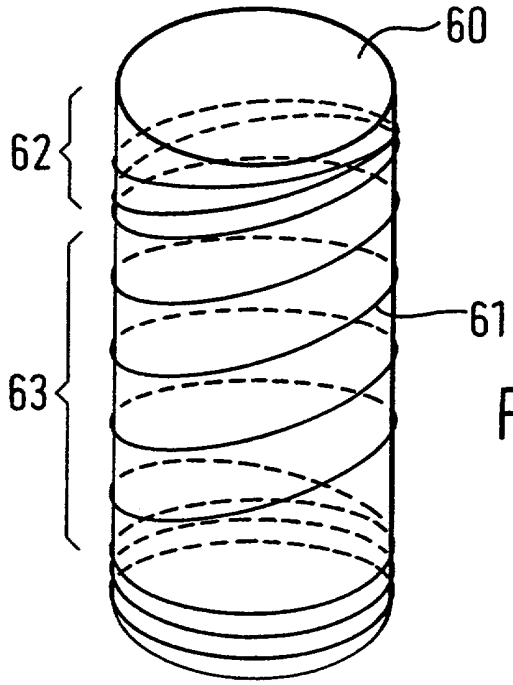

FIG. 6

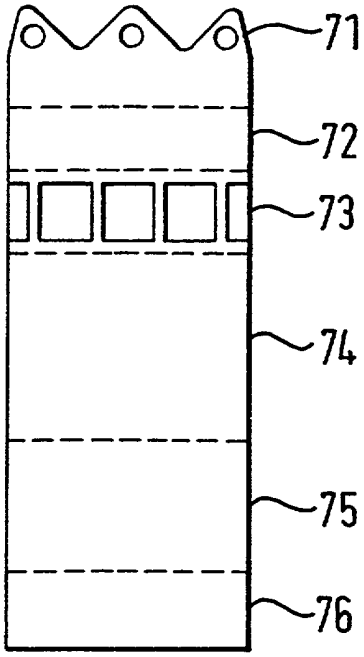

FIG. 7

TUBULAR MEDICAL IMPLANTS AND METHOD FOR MANUFACTURE

This disclosure describes tubular medical implants, particularly those fabricated from textiles, polymer membranes or sheets to which is applied filamentous material which is used to alter the properties of the device at different locations on its surface.

An example of such a device in current use is the so-called graft stent in which a tubular, flexible graft is attached by sewing with needle and thread to a metallic reinforcing skeleton commonly known as a stent. Other medical structures, such as tubular fixation devices and heart valve seating rings are also included.

In manufacturing graft stents, devices are limited in their characteristics by the manufacturing techniques which are available. Typically, tubular grafts are stitched by hand to metallic stent structures and this process can take a long time. Other problems with the process include difficulties in controlling and assuring the quality and the cost of the final product.

An alternative solution has been described in WO 99/37242 in which computerised embroidery is used to manufacture a flat-form device which is subsequently rolled into a tube. This approach solves many of the issues associated with hand manufacture but results in a seam and prevent some continuous structures from being designed.

This invention describes a specialised machine which is capable of sewing on the surface of a cylinder under numeric or computer control and which allows a number of devices to be constructed which have hitherto been impossible to make with adequate quality, reliability and cost constraints.

The process involves a machine with the principal components shown in Figure 1. These comprise:

- A hollow drum assembly which supports the tubular implant at either end.

- Two drive mechanisms which control the angular position of the drum and its axial position.
- A sewing machine head which has been adapted to sew from the outside to the inside of a narrow tube.

Thus the mechanism is capable, by means of axial translation or rotation of the cylinder which supports the implant, of placing the sewing machine head at any desired position over the surface of the implant. The implant is likely to be frustro-conical i.e. it will have different diameters at either end but parallel sided implants will be possible.

Normal sewing machines are not suitable for use in this application because the internal diameter and length of the implants are too small to allow a conventional bobbin mechanism to pass through the lumen of the implant so as to lie opposite the needle of the sewing machine. Implants may be as small as 4mm in diameter and as large as 35mm in diameter. Preferred sizes are in the range 10mm to 30mm in diameter. Implants are up to 500mm long with a preferred length of 250mm. Two solutions to this limitation are identified:

- A chain stitch (Figure 2) sewing machine is employed in which a small simple mechanism is used beneath the fabric to hook the single thread, which passes through the needle. The hooked thread is then pulled through with the subsequent stitch so that a continuous run of stitches is formed from a single thread. Chain stitch is associated with a tendency to fray or to come apart. As part of the sewing algorithm, the machine can be made to back-stitch or otherwise over stitched to lock the stitch into place. Glues may also be used to stabilise the thread.

- A lock stitch (Figure 3 and 4) sewing machine is employed in which a special design of bobbin is incorporated. In this case the bobbin is long and thin (Figure 5) and carried the second thread used in the lock stitch. The bobbin can be wound circumferentially or end-over-end and an appropriate shell is used to draw the yarn off the bobbin. Such designs are feasible in this application of machine because the bulk of stitching used in any single device will be small by comparison with sewing machines used for industrial processes in the

clothing industry. Moreover, the stitching speed of the machine is not required to be high because of the small size of the implants and this allows longer bobbins and bobbins of higher mass to be used than would be possible with conventional machines. The mechanism used to traverse the bobbin through the loop formed in the needle thread (Figure 4) requires that the bobbin is fired by means of compressed air, spring energy, magnetic repulsion or similar means along the axis of the implant.

Either design of tubular sewing machine will yield a machine in which stitches can be placed on the surface of a cylinder under the complete control of a computer or similar numerical control device. This will permit a number of textile processes to take place:

- Tubes can be joined end to end by stitching.
- Tubes can be formed by stitching the seam formed by the edges of a single sheet of material rolled to form a tube.
- Stitches of filamentous material can be stitched with any orientation over the surface of the tube.
- Material can be attached to the surface of the tube by stitching over it. Such material can include robust filamentous material such as wires which are attached with single or groups of stitches placed on either side of the wire. Larger pieces of material can include tubes which can conduct fluids to other parts of the device or which can be rigidised by pressurisation.
- Pseudo-lacework can be created in a tubular form by stitch yarn onto a substrate which is subsequently removed by dissolving or other disintegration process. After said process, the stitched yarn remains in place.

Considering the example of the graft stent, wire can be stitched to the surface of a textile tube to reinforce the tube. In its simplest form, wire can be wrapped around the tube following a helical path (Figure 6) without any prior forming of the wire having taken place other than it being nominally straight or curved with a large radius of curvature. In this case, once the wire is attached by stitching around the tubular implant, the wire will be pre-stressed. The resultant implant has the characteristics of the textile tube but with

significantly higher radial stiffness, radial expansion after compression such as occurs after passing through a catheter and the ability for the entire implant to be bent back on itself without kinking or collapse.

Wire can be formed in situ by applying a large current or similar heating means across a short section of wire just prior to stitching it to the device. This will locally anneal it to allow the sewing process to form the shape of the wire.

Preferred wires for use in such a machine include nickel/titanium shape memory alloy, stainless steels, Elgiloy and similar highly durable alloys.

Alternatively, pre-shaped wire can be stitch to the surface of the implant. Zig-zags of the form described in WO 99/37242 can be applied to a tubular implant, providing the benefits described above coupled with resistance to axial compression.

When the sewing machine is designed to take more than one needle thread, yarns with different characteristics can be used. Elastic properties can be applied locally by applying yarns made from elastomers, polymers & co-polymers such as polysiloxane. Similarly, tissue adhesives can be drawn into yarns and applied to the surface of the implant. This provides a zone of highly effective sealing to the intimal surface of the vessel in which the device has been implanted.

A method of producing pseudo-lace is to stitch the lace pattern onto a substrate material. This substrate can be either a light-weight fabric such as a gauze, or it can be soluble. In either case, the cylindrical sewing machine described above will create a tubular implant in which the textile fibres have been distributed to match the mechanical and physiological needs of the implant. Thus fenestrations can be left to allow blood to escape through the walls of the implant into side arteries. These fenestrations can be made without risk of fraying at their edges. Similarly, reinforcing sections can be built up without separate components being added to the device. Wire reinforcements can be included in the wall of the device and can be hidden from either the intimal or visceral surfaces of the device if

required. Using the materials suggested above, the implant can be fabricated to have elastic sections, tissue gluing sections, reinforced sections, fenestrated sections (Figure 7). Yarns can be incorporated which release drugs or other pharmaceutical agents over the surface of the implant.

Tubular devices which can be constructed using this technology include:

Grafts
Stents
Graft-stents
Graft fixation devices
Opthalmic orbital reinforcement devices
Annuli for heart valve supports
Vein implants
Vein valve supports.

UK Patent Application No. GB 9925447.6

KEY FOR DRAWINGS

FIGURE 1A

1. Drum assembly
3. Drive assembly
4. Tubular part - moves in x-direction and rotates
5. Needle - moves up/down
6. Sewing machine head
7. Up/down movement of needle
8. Rotational movement of tubular part
9. x-direction movement of tubular part

FIGURE 1B

4. Tubular part
5. Needle
6. Bobbin element

FIGURE 2

20. Base fabric of material
22. Chain stitch

FIGURE 3

30/31. Materials in cross section
32. Top thread
33. Bottom thread

FIGURE 4

5. Needle
30. Fabric or other material
32. Top thread
40. Loop pushed through fabric or other material
41. Path of bobbin for bottom thread

FIGURE 5A

50. Wire/thread winding off bobbin
51. Bobbin
52. Axis of bobbin
53. Wire/thread wound onto diameter of bobbin

FIGURE 5B

50. Wire/thread winding off bobbin
53. Wire/thread wound onto diameter of bobbin
54. Belt - moves on rollers

FIGURE 6

60. Base tube
61. Spiral formed around tube
62. More dense region
63. Less dense region

FIGURE 7

71. Fixation region
72. Dense region
73. Fenestrated region
74. Less dense region
75. Different support element region
76. Barbed region

CLAIMS

1. A method for stitching thread to the wall of a tubular graft, comprising the steps of feeding thread from the outside of the graft through the graft wall to form a loop of thread inside the graft, passing thread through said loop, and pulling said loop closed to form a stitch.

2. A method as claimed in claim 1, in which the thread which is passed through said loop is a second loop of the same thread which has been fed through the wall of the graft, said second loop subsequently having a third loop of the same thread passed through it, in order to form a chain stitch in the graft wall.

3. A method as claimed in claim 1, in which the thread which is passed through said loop is a second length of thread which is subsequently passed through subsequent loops of the first thread which have been fed through the wall of the graft, in order to form a lock stitch in the graft wall.

4. Apparatus for stitching thread to the wall of a tubular graft, comprising a support for the graft, means for rotating the graft about its longitudinal axis and for translating the graft along said axis, means for feeding thread from the outside of the graft through the graft wall to form a loop of thread inside the graft, and means for passing thread through said loop from within the graft.

5. Apparatus as claimed in claim 4, wherein the means for passing thread through said loop from within the graft is an elongated bobbin with thread wound thereon which is adapted to fit inside the graft.

6. Apparatus as claimed in claim 4 or 5, wherein the graft support is a hollow drum assembly for supporting the graft at either end.

7. A method for forming a graft, comprising the steps of stitching thread onto a soluble substrate which is in the shape of a graft or of a precursor which can be formed into a graft, dissolving the substrate to leave a graft or precursor formed from said thread, and forming the precursor into a graft.

8. A method as claimed in claim 7, wherein the step of stitching thread onto a soluble substrate is carried out by means of a method as claimed in any of claims 1 to 3 or by employing apparatus as claimed in any of claims 4 to 6.

9. A method for stitching thread to the wall of a tubular graft substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

10. Apparatus for stitching thread to the wall of a tubular graft substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

Application No: GB 9925447.6
Claims searched: 7,8

Examiner: Alex Littlejohn
Date of search: 14 September 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): A5R (RAR); D1G (GE, GS)

Int Cl (Ed.7): A61F; D05B; D05C

Other: On;ine: EPODOC, JAPIO, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	GB 2322637 A	(Jung-Tang Hung) see whole document	7
Y	WO 99/37242 A1	(Anson) see whole document	7
Y	WO 90/15895 A1	(Garzone) see whole document, e.g. page 5 lines 21-23	7

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Application No:	GB 9925447.6	**Examiner:**	Alex Littlejohn
Claims searched:	1-6,9,10	**Date of search:**	14 September 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): A5R (RAR); D1G (GAH, GMA, GHX, GF)

Int Cl (Ed.7): A61F; D05B; D05C

Other: Online: EPODOC, JAPIO, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2165559 A	(University College) see whole document	-
A	WO 99/37242 A1	(Anson) see whole document	-
A	US 5676671	(Inoue Kanji) see whole document	-
A	US 5413601	(Keshelava) see whole document	-
A	US 4502159	(Woodroof) see whole document	-

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.