

(21) Application No 9202852.1

(22) Date of filing 11.02.1992

(71) Applicant
Martin Terry Rothman
Flat 5, Free Trade Wharf, 340 The Highway, London,
E1 9ES, United Kingdom

(72) Inventor
Martin Terry Rothman

(74) Agent and/or Address for Service
Beresford & Co
2-5 Warwick Court, High Holborn, London, WC1R 5DJ,
United Kingdom

(51) INT CL⁵
A61M 29/00

(52) UK CL (Edition L)
A5R REP

(56) Documents cited
GB 2238245 A GB 2189150 A EP 0321912 A
EP 0312852 A EP 0119688 A WO 87/04935 A
WO 83/03752 A US 5015253 A

(58) Field of search
UK CL (Edition K) A5R RAR REP
INT CL⁵ A61F 2/06, A61M 29/00

(54) Catheter and stent used therewith

(57) A temporary "stent" for use in conjunction with a balloon-type or other catheter, in order to shore-up tissue within e.g. an artery, comprises a multi-coil member 9a etc. which is contained in a substantially linear stressed condition within the catheter for transport to the diseased area and which when released from the catheter adopts an expanded coiled configuration to hold the damaged tissue in place whilst at the same time allowing blood flow through the artery. The stent may consist of stainless steel wire 8 which at its distal end comprises a plurality of coils 9a, 9b, 9c running parallel to one another. The distal ends of these coils may terminate together at 11 to form a lead wire for the stent.

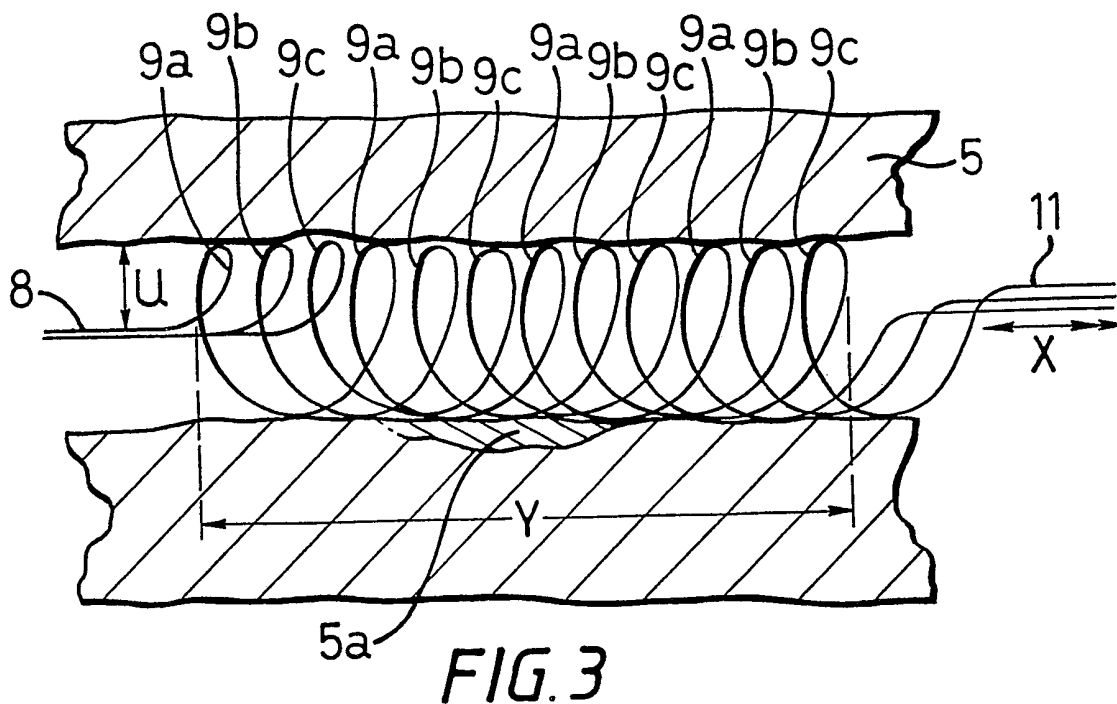


FIG. 3

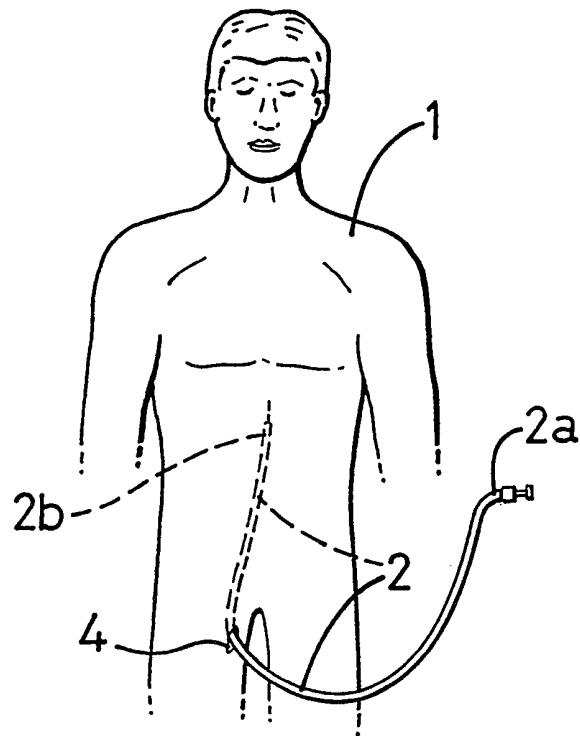


FIG. 1

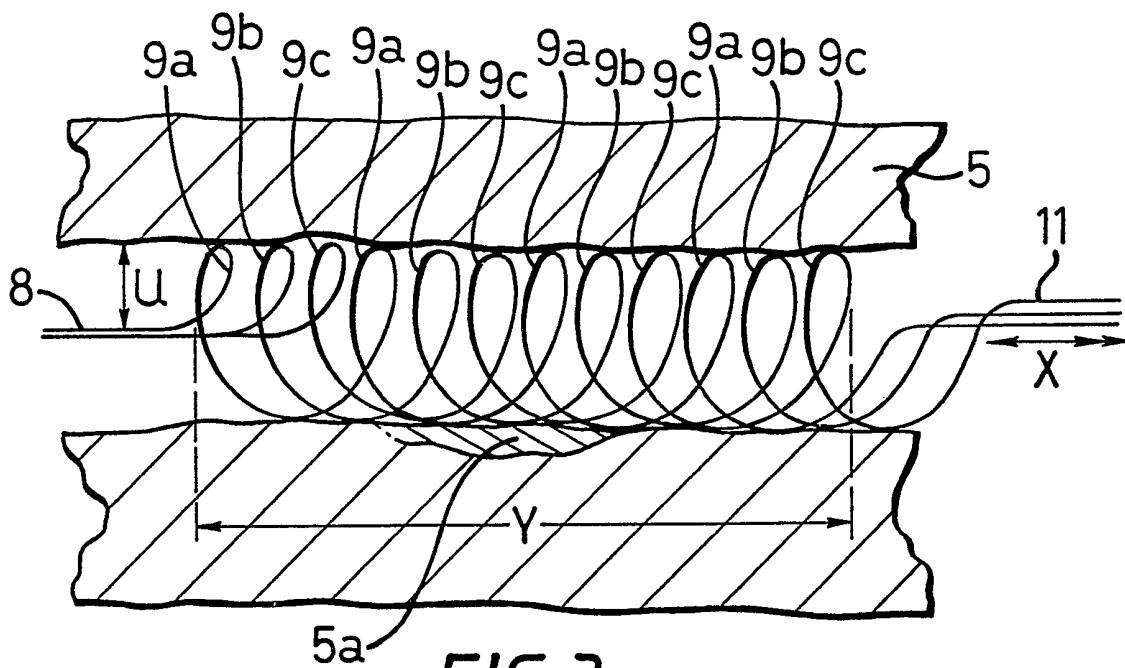


FIG. 3

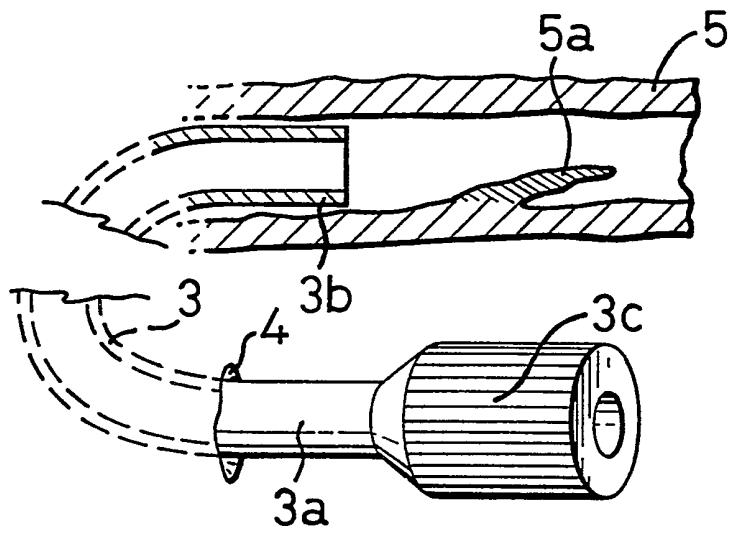


FIG. 2A

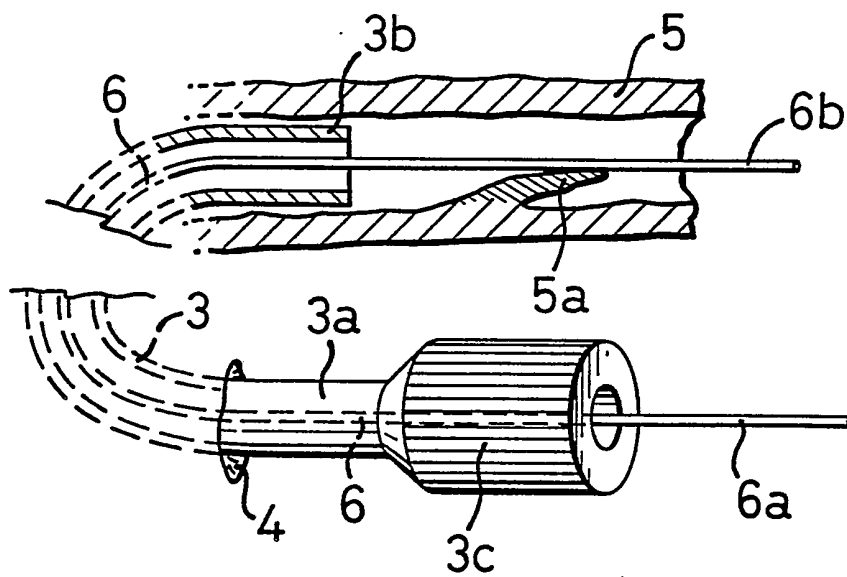


FIG. 2B

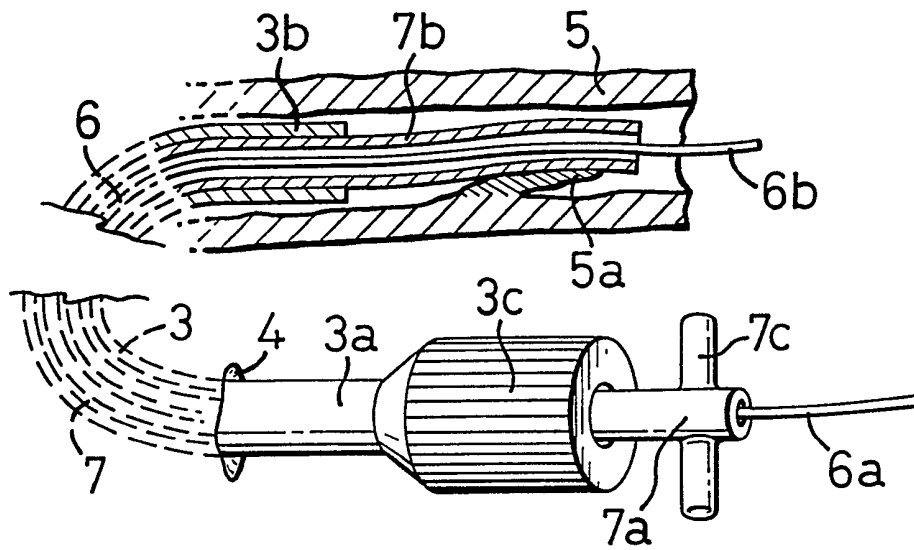


FIG. 2C

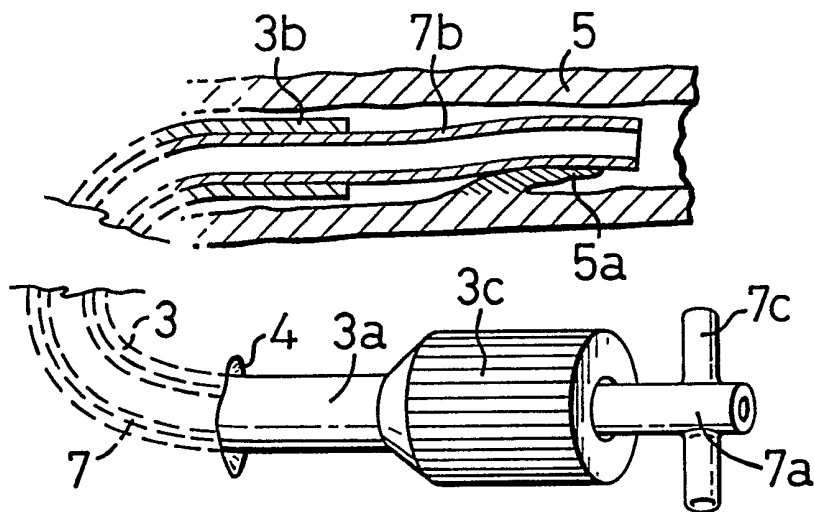


FIG. 2D

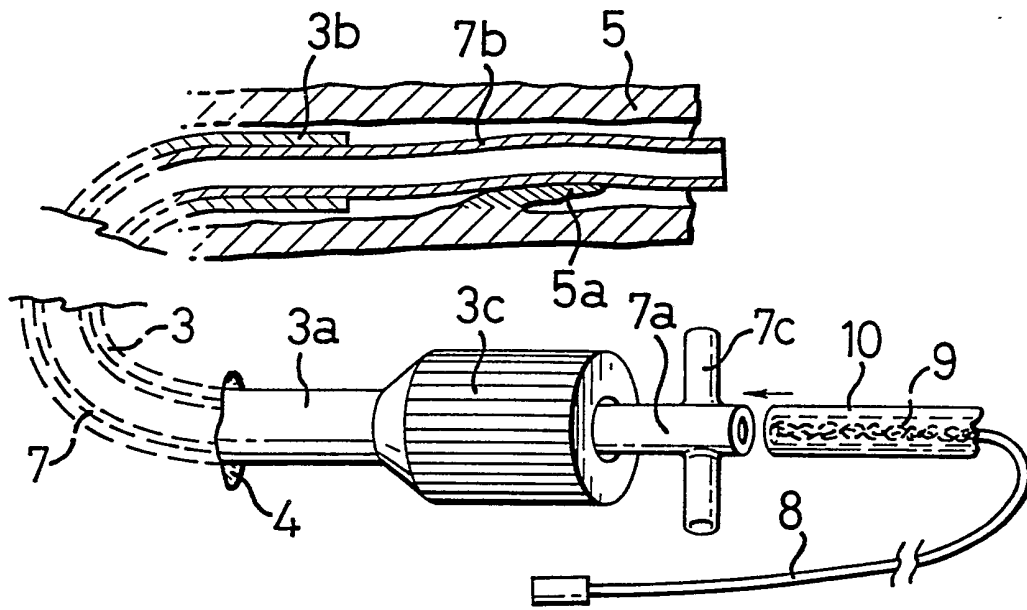


FIG. 2E

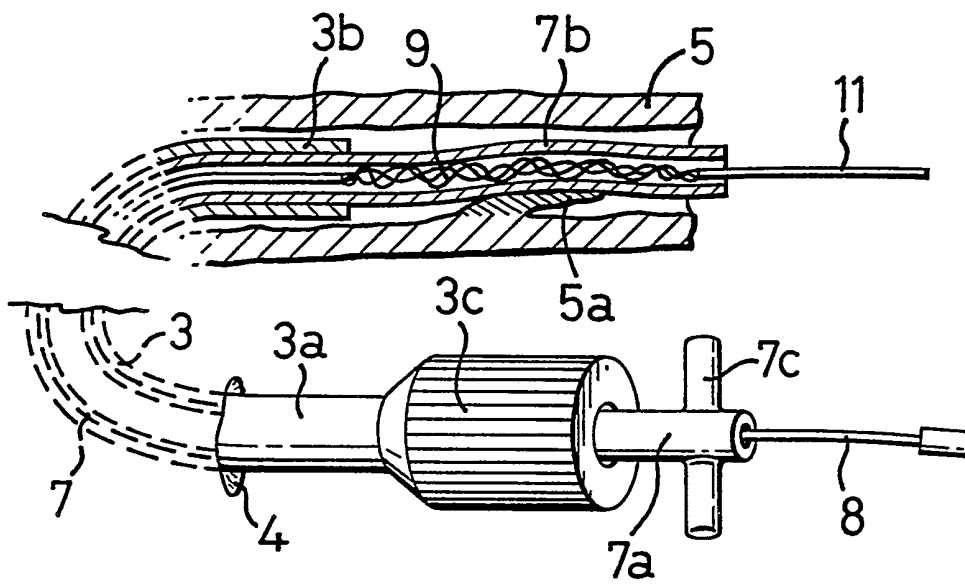


FIG. 2F

- 1 -

CATHETERS

The present invention relates to catheters for insertion into the human body.

5

There are many designs of catheters for different medical purposes and the present invention is particularly concerned with the use of so-called balloon-type catheters which are used to flatten the interior of a diseased artery in order to increase the internal cross-section of the artery at the point where it would otherwise be constructed by a diseased area or plaque. The present invention could however be used in conjunction with catheters other than balloon-type catheters.

15

A known treatment involves inserting a balloon catheter in the artery, expanding the balloon at the point of the diseased area to thus compress that diseased area into the wall of the artery and then deflating the balloon and withdrawing the catheter from within the patient.

20

Whilst in many cases the compressed diseased area will remain compressed and thus leave the artery relatively open for the flow of blood, there are occasions when upon extraction of the deflated balloon portions of the diseased area fall back into the passageway of the artery to thereby continue to obstruct it whilst still being connected to the internal wall of the artery.

There are a number of known approaches to dealing with this particular problem. One approach is to use a so-called "stent" which consists essentially of a fine wire element, made of stainless steel or the like, which is used to, as it were, shore-up the above-mentioned projecting diseased portions.

There are a number of known ways in which the so-called "stent" can be inserted into the artery and brought into an operative position in relation to the diseased portion.

Clearly, the "stent" has to be in a collapsed state in order to enable it to be inserted into the artery. There are different ways in which the collapsed "stent" is then expanded once it is in the desired

position in order to shore-up the aforesaid diseased portion.

5 One way of expanding the "stent" is to mount it on a balloon which can be inflated by remote control from the end of the catheter which is outside the patient's body, i.e. the "proximal" end. Such a "stent" is sometimes referred to as being "balloon expandable".

10 An alternative method employs a so-called "self-expanding stent". In this arrangement, the "stent" is collapsed onto a centre tube under tension and held in the collapsed state by a sleeve. The sleeve containing the collapsed "stent" is inserted
15 into the patient's artery to bring the "stent" into the vicinity of the diseased area. The sleeve is then withdrawn to expose the collapsed "stent" which can thus expand as a result of its having been collapsed under tension and contained by the sleeve.

20 With these known arrangements, the expanded "stent" pushes the aforementioned diseased portions back into the wall of the artery and holds them there. The "stent" remains permanently in the patient's artery.
25 In other words, the purpose behind these prior art

arrangements is to provide a permanent repair. An example of such prior art arrangements is to be found in European Patent Application No. 0119688 (Balko).

5 In a known angioplasty operation using a balloon catheter, a problem may arise which necessitates the withdrawal of the balloon and the preparation of a new catheter or treatment. Delay in preparing the new catheter or treatment can be fatal for the
10 patient, for example, in a situation where the diseased portion of a blood vessel is within the patient's heart.

The present invention is concerned with providing a
15 means to enable the surgeon to hold the diseased artery open while the new treatment is being prepared. By this means more time is available for the latter without exposing the patient to a high risk of blood flow being impeded.

20 The Applicant's UK Patent Application No. 8926551 and International Patent Application GB 90/01805 discloses a "stent" designed to be used primarily as a temporary expedient in the kind of situation described
25 immediately above. This contrasts with prior art

devices which are all concerned with providing a permanent treatment and are thus designed to be left within the patient's body having once been inserted.

5 The present invention is an improvement or variation on the construction of "stent" disclosed in the Applicant's aforementioned co-pending applications.

10 According to the present invention a catheter for flattening the interior wall of an artery or other organ of the kind which includes the following combination of features:

- 15 a) a balloon catheter or simple catheter tube;
- b) a "stent" contained within a) in a stressed collapsed condition, the tube a) and "stent" being movable axially with respect to one another to progressively bring the "stent" outside the
- 20 tube, the "stent" then being radially expandable;

 is characterised in that the "stent" comprises a multi-coil element which in its contracted state is

25 substantially linear to fit in the catheter tube but

which when free of the catheter tube adopts an expanded hollow configuration whereby it can press against the interior surface of an artery but still allow blood flow through the artery.

5

How the invention may be carried out will now be described, by way of example only, and with reference to the accompanying drawings, in which:

10 Figure 1 shows a patient into whom a catheter has been inserted;

Figures 2A to 2F show, on a larger scale, the sequence of steps involved in an operation utilising a catheter incorporating the present invention; and

15

Figure 3 is an even more enlarged view showing the operative part of a stent constructed according to the present invention.

20

A patient 1, lying on an operating table (not shown), has inserted into them a catheter 2. The insertion is made through an incision 4 in the groin of the patient to enable the catheter 2 to be inserted into an artery of the patient in known manner. The proximal end 2a of

25

the catheter is held by the operator and by movement of it the distal end 2b is moved to the vicinity of the diseased or damaged area which it is desired to treat or repair. This could, for example be a flap of tissue partially blanking the lumen of an artery within the heart of the patient. The distal end could typically be provided with a dilator such as an expandable balloon of known type.

After the dilator, e.g. balloon has been removed and it has been found that, unfortunately, the balloon catheter treatment has not been entirely successful in pressing the flap of tissue 1 back into the wall of the artery, the "stent" according to the present invention is brought into play.

As indicated earlier, the delay involved in preparing a further balloon catheter can literally prove fatal for the patient in certain circumstances.

The purpose of the present invention is to enable the surgeon to easily temporarily treat the protruding flap of tissue sufficient to keep the patient's blood flowing while the new balloon catheter, or other treatment, is being prepared.

Figure 2 shows the various stages by which the catheter 2 is inserted into the patient 1 and the device of the present invention brought into an operative position at the distal end of the catheter.

In Figure 2A a first hollow plastic tube 3 is inserted into the patient's artery through the incision 4 in the patient's skin and threaded so that the distal end 3b of the tube 3 arrives at the (vessel) artery with disease, which in this case is in an artery in the heart of the patient. In order to enable the operator to thread the tube 3 into the desired position, the surgeon is provided with an X-ray picture, in known manner, which defines the position where the problem exists, in this case a flap of tissue 5 obstructing the blood flow. The operator threads the tube by gripping the proximal end 3a of the tube which is appropriately shaped to facilitate gripping and to prevent the distal end from passing through the incision 4. In this case an enlarged knurled end 3c is provided.

A known standard guide wire 6 is then passed through the tube 3 so that its distal end 6b has been moved past the flap of tissue 5, as shown in Figure 2B.

5 Referring to Figure 2C, a second hollow plastic tube 7, having an external diameter less than the internal diameter of the first plastic tube 3, is then threaded over the guide wire 6 and moved until its distal end 7b has passed the flap of tissue 5. The second tube 7
10 may be provided with an inner former or mandril. It is also provided with a suitably shaped proximal end 7a to enable the operator to grip it and to prevent the proximal end from passing into the proximal end 3a of the tube 3. In this case wings 7c are provided for
15 these purposes.

Referring to Figure 2D, the inner former, (mandril) if any, is then removed along with the guide wire 6.

20

A "stent" constructed according to the present invention is then inserted into the second tube 7.

This temporary "stent" consists of a wire 8 having at its distal end a section consisting of a plurality of coils 9, when in the substantially unstressed state. However, in its supplied condition the section of coils 9 is contained within a further tube 10. The purpose of the tube 10 is to contain the coils in a substantially linear, unexpanded stressed condition. The wire 8 and coils 9 are made of stainless steel.

In order to deliver the "stent" to its operative position adjacent the diseased area 5a, the tube 10 is brought into end-to-end abutting contact with the proximal end 7a of the second tube 7, as indicated by the arrow in Figure 2E. The wire 8 is then pushed, in relation to the tube 10, to slide the multi-coiled section 9 out of the tube 11 and into the proximal end 7a of the second tube 7. The "stent" can then be threaded through the tube 7 until the section 9 reaches the diseased area 5a (see Fig. 2F). When it is in this position, the tube 7 is then withdrawn, by pulling on its proximal end 7a, to expose the multi-coiled section 9. As this section is thus no longer constrained by the tube 7 it expands radially to contact the inner wall of the artery 5 and in

particular to press the flap 5a against the artery wall (see Fig. 3).

5 The "stent" will now be described in more detail with reference to Figure 3.

10 The "stent" consists of a stainless steel wire 8 which at its distal end consists of a plurality of coils 9a, 9b, 9c running parallel to one another. The distal ends of these coils terminate together at 11 to form a lead wire for the "stent" as a whole, otherwise commonly referred to as a "tail". Alternatively, the distal ends could remain separate from one another. They could all be of the same or similar length or one
15 could be longer than the others.

As indicated earlier, at the time the temporary "stent" is initially inserted into the patient, the coils 9a, 9b and 9c are not in the expanded
20 configuration shown in Figure 3. Instead they all lie as a substantially linear extension of the wire 8, their expansion into the configuration shown in Figure 3 being prevented by the constraining tube 7.

In other words, the "stent" is manufactured so that in its unstressed condition it will adopt the configuration shown in Figure 3 but due to its elasticity it can be deformed to be contained within the relatively small diameter tubes 7 and 10, under stress.

As stated earlier in relation to Figure 2E, the temporary "stent" is inserted into the patient so that the distal end 9 of the "stent" is constrained by the distal end 7b of the tube 7. The tube 7 is then withdrawn by the operator to thus expose the multi-coiled end 9 of the "stent", thus releasing the constraint which had up to then held that coiled end 9 in a substantially linear configuration.

Upon release of this constraint the multiple coils 9a, 9b and 9c of the "stent" expand radially to press the flap of tissue 5a against the wall of the artery 5. However because, in this configuration, they form a hollow cage they still allow an acceptable level of blood flow through the patient's artery at this point.

The tube 7 is completely withdrawn from within the patient to thus leave the "stent" in the position shown in Figure 3.

5 In the context of the overall operation on the patient, it is a relatively quick and easy matter to insert the temporary "stent" of the present invention in the manner described above, while steps are taken to prepare a follow-up treatment, e.g. a second
10 balloon catheter, permanent stent, atherectomy device or other manoeuvre such as surgery.

In order to introduce this further treatment, the hollow tube 7 is re-introduced over the "stent" 8 thus
15 re-establishing access to the artery. The temporary "stent" is then removed and the new balloon angioplasty catheter (or indeed any other treatment) can then be inserted through the tube to bring the distal end of the catheter into the vicinity of the
20 diseased area. The balloon angioplasty, or other treatment, can then be effected in known manner. Alternatively, a second wire can be placed through the temporary "stent" to facilitate localisation of another treatment device.

Alternatively, depending upon the circumstances, the temporary "stent" may simply be removed without re-introduction of the tube such as where use of the temporary "stent" has itself effected a satisfactory treatment of the flap of tissue 5.

The advantage of a temporary "stent" constructed according to the present invention and utilising multiple coils 9, is that each of the coils needs to be less stressed than if only a single coil were used. The more coils that are incorporated in the "stent", the less each coil needs to be stressed in order to achieve the desired expanded configuration shown in Figure 3.

One possible practical disadvantage of the temporary "stent" disclosed in the Applicant's earlier International Application No. GB 90/01805 is that the stressed coiled stainless steel wire may not entirely return to its original unstressed coiled configuration when released from the constraints of the associated plastic tube.

The various dimensions of the "stent" will now be considered in relation to Figure 3.

5 The distance from the proximal end of the "stent" to the coiled portion 9 clearly depends upon the length of wire required to enable the operator to position the coiled portion at the diseased site in question whilst still retaining control. The length Y of the coiled portion will depend upon the length of the
10 damaged segment which the "stent" is intended to treat. The radius U of the unstressed coils 9 will depend on the size of the vessel, e.g. artery, into which the temporary "stent" is designed to fit. The length X of the tail of the "stent" (which facilitates
15 insertion of the "stent" into its operative position), will again depend on the particular area of application for which the "stent" is designed.

20 In some cases there may not be a long enough segment of artery into which to park a long tail 11 whilst in some cases a long tail 11 will be optimal.

The pitch of the turns of the coils 9a, 9b and 9c will depend, among other factors, on the number of coils
25 employed. The larger the number of coils the coarser

the pitch and the less stressed each coil will be when constrained by the tubes 7 or 10.

5 As indicated earlier in this specification, there have been prior proposals for "stents" which can expand when they are located in the operative position but such prior proposals were intended to be permanent treatments. Furthermore, such proposals have envisaged the "stent" being made from a material which
10 is referred to as a "shape memory metal alloy", the characteristic of which is that at a first temperature it will be in an unstressed substantially linear configuration but at a higher temperature it will move into an expanded configuration. Typically the higher
15 temperature could be the body temperature of the patient. European Patent Application No. 0119688 (Balko) discloses such an arrangement.

In contrast the "stent" of the present invention is
20 not only designed to be a temporary solution to a particular medical condition but it is made from a relatively ordinary material such as stainless steel which does not depend upon temperature variations to enable it to change from its substantially linear
25 configuration to its expanded configuration.

CLAIMS:

1. A catheter for flattening the interior wall of an
artery or other organ of the kind which includes the
5 following combination of features:

- a) a balloon catheter or simple catheter tube;
- b) a "stent" contained within a) in a stressed
10 collapsed condition, the tube a) and "stent"
being movable axially with respect to one another
to progressively bring the "stent" outside the
tube, the "stent" then being radially
expandable;

15

is characterized in that the "stent" comprises a
multi-coil element which in its contracted state is
substantially linear to fit in the catheter but which
when free of the catheter tube adopts an expanded
20 hollow configuration whereby it can press against the
interior surface of an artery but still allow blood
flow through the artery.

2. A catheter as claimed in claim 1, in which the "stent" has a substantially straight lead portion at its distal end to assist the insertion of the catheter into the artery.

5

3. A catheter as claimed in claim 2, in which the straight lead portion is formed by the distal ends of the plurality of coiled portions of the "stent".

10 4. The "stent" as defined in any one of claims 1 to 3 separate from the catheter.

5. A temporary method of maintaining blood flow in a diseased artery, which method includes the steps of:

15

a) inserting into the artery a catheter as claimed in any previous claim;

20 b) positioning the distal end of the catheter with the enclosed "stent" in the vicinity of the diseased part of the artery'

25 c) moving the catheter and enclosed "stent" axially with respect to one another to expose that portion of the "stent" which is adapted to expand

radially when not constrained by the catheter tube to cause the expanded "stent" to come into contact with the diseased portion of the artery in order to press it radially outwardly; and

5

d) withdrawing the catheter tube from within the artery.

6. A catheter substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

10

7. A "stent" substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

15

8. A temporary method of maintaining blood flow in a diseased artery substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

20

Patents Act 1977
Examiner's report to the Comptroller under
Section 17 (The Search Report)

Application number

9202852.1

Relevant Technical fields

(i) UK Cl (Edition K) A5R (RAR, REP)

(ii) Int Cl (Edition 5) A61M 29/00
A61F 2/06

Search Examiner

L V THOMAS

Databases (see over)

(i) UK Patent Office

(ii)

Date of Search

30 MARCH 1992

Documents considered relevant following a search in respect of claims 1-4, 6, 7

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	GB A 2238245 (ROTHMAN) See lines 4-24, page 4, line 15 page 7, line 24 page 8 and Figures 3, 4	1-4
X	GB A 2189150 (MEDINVENT) See lines 34-48, page 2 line 62 page 6 line 12 page 7 and Figure 8	4
X	EP A 0321912 (DELSANTI) See line 53 column 3 - line 41, column 4	1,4
X	EP A 0312852 (MEDTRONIC INC) See lines 34-52 column 2, lines 16-29 column 3 and Figure 6	1,4
X	EP A 0119688 (BALKO) See line 9, page 7 - line 24, page 8 and Figure 4	1,4
X	WO A 87/04935 (FISCHELL) See lines 16-25 page 6, lines 1-8 page 7, and lines 23-27 page 8	1,4
X	WO A 83/03752 (WALLSTEN) See lines 13-23, page 8, line 20 page 14, line 23, page 15 and Figure 1a and 11	1,4

Patents Act 1977
Examiner's report to the Comptroller under
Section 17 (The Search Report)

Application number

9202852.1

Relevant Technical fields

(i) UK CI (Edition) Contd. from page 1

(ii) Int CI (Edition)

Databases (see over)

(i) UK Patent Office

(ii)

Search Examiner

L V THOMAS

Date of Search

30 MARCH 1992

Documents considered relevant following a search in respect of claims

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	US 5015253 (MACGREGOR) See lines 14-19 column 4, and line 61 column 5 line 25 column 6	1,4

Category	Identity of document and relevant passages -21-	Relevant to claim

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).