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(56) Documents Cited:
EP 0419154 A1 **WO 2005/107615 A1**
WO 1999/044513 A2 **WO 1993/001753 A2**
US 6451037 B1 **US 20080077164 A1**

(58) Field of Search:
INT CL **A61B, A61M**
Other: **WPI, EPODOC**

(54) Title of the Invention: **Minimally invasive device and method for treating vascular disorders**
Abstract Title: **Medical device for treating vascular disorders.**

(57) A minimally invasive medical device 100 for treating vascular disorders such as varicose veins comprises a flexible sheath 102 having a central bore through which a guide wire 110 passes. An expansible member 104 that expands when the sheath is inserted in a vein is coupled to the sheath and has a roughened outer surface which may be formed from diamond chips. The expansible member may comprise one or more inflatable members and the sheath may include one or more lumens through which inflation fluid may pass. The expansible member may form part of an exterior surface of the sheath. A minimally invasive method of treating vascular disorders is also claimed, and comprises the step of moving the device and guide wire through the vein with the expansible member in contact with the wall of the vein 106. The device may be introduced into the vein under ultrasonic guidance.

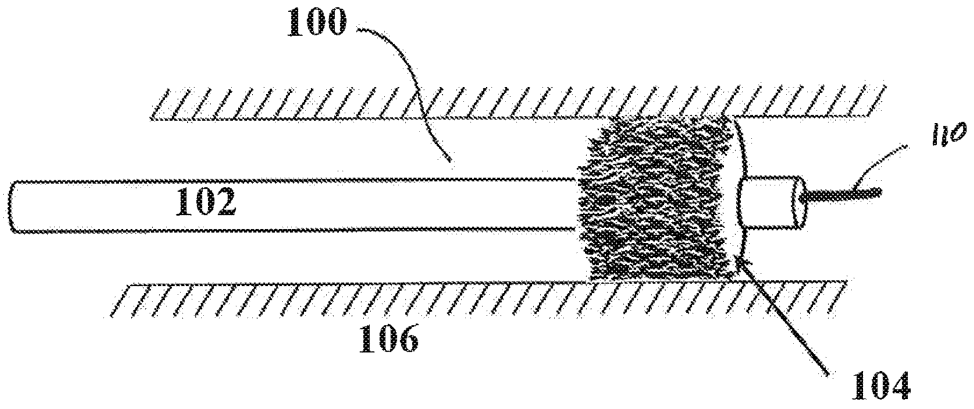

FIG. 1

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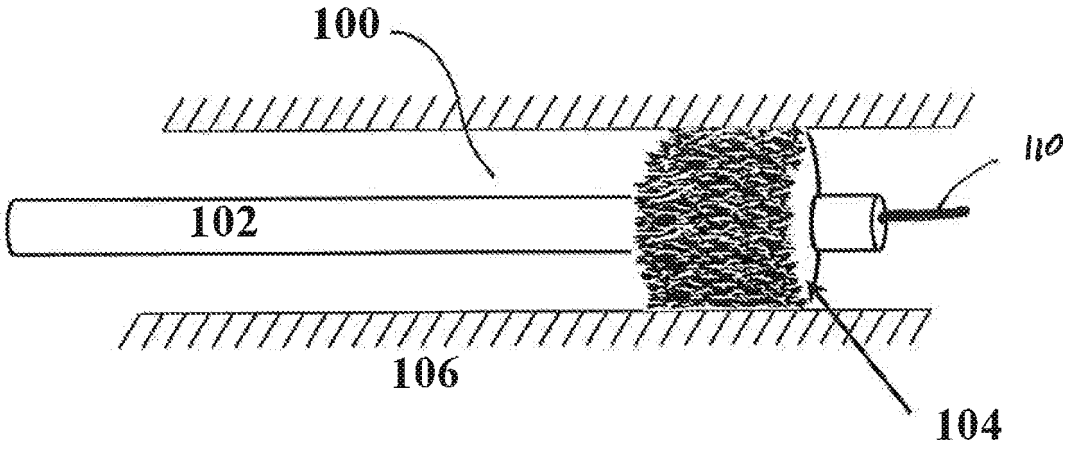

FIG. 1

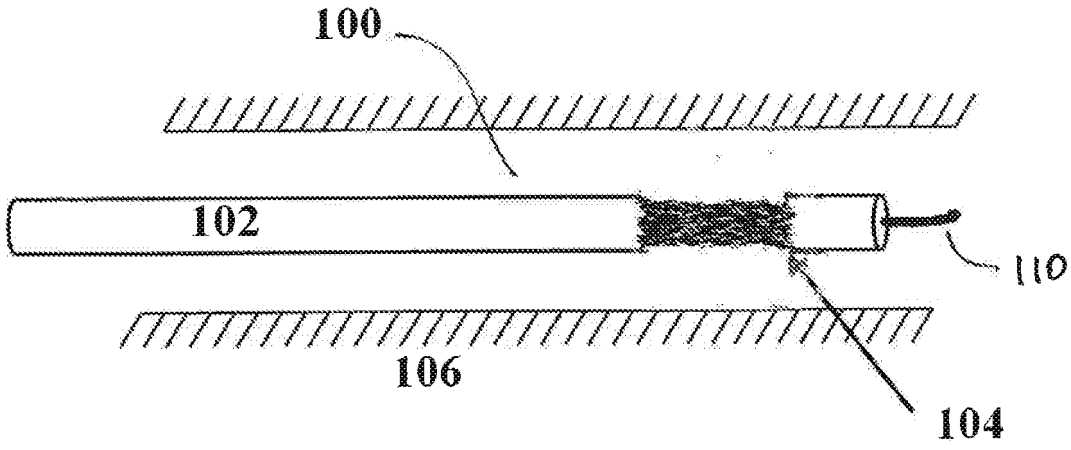

FIG. 2

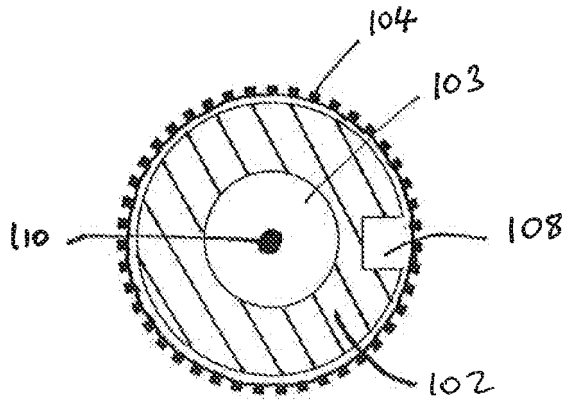

FIG. 3

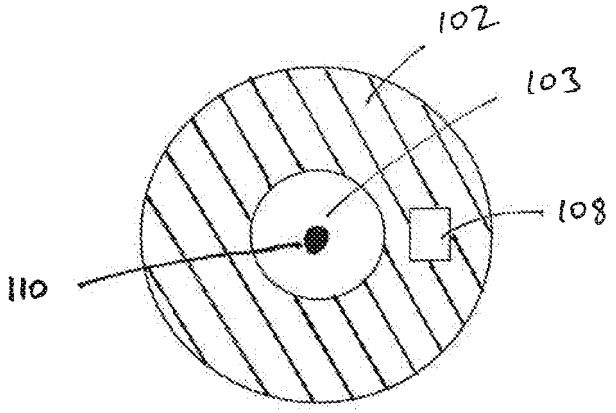

FIG. 4

MINIMALLY INVASIVE DEVICE AND METHOD FOR TREATING VASCULAR DISORDERS

Field of the Invention

The present invention relates to devices and methods for treating vascular disorders. More particularly, present invention provides minimally invasive methods and medical devices for endoluminally treating blood vessels of a mammal.

Background to the Invention

Varicose veins are blood vessels with deficient valves, which cause retrograde blood flow and enlarge the vessel walls, affecting both women and men. This vein disorder is most common in the superficial veins of the legs, which are subject to high pressure when standing. Varicose veins are not only a cosmetic problem, but also a medical condition. They are often painful, especially when standing or walking, which can lead to ulcers.

Common methods for treating vascular disorders such as varicose veins include surgical and non-surgical methods such as vein stripping, phlebectomy, endovenous laser treatments, radiofrequency ablation and foam sclerotherapy. There are many disadvantages associated with these methods, including the requirement for costly equipment, drug side-effects, long recovery periods, and high recurrence rates. Additionally, general anesthesia is required for some of these treatments, particularly for larger veins, and with it board-certified medical professionals and precautionary measures need to be taken in case serious complications arise, such as heart attacks, strokes, brain damage or even death. Other complications such as deep vein thrombosis, pulmonary embolism and infections due to the wounds generated are also possible. Moreover, there are risks connected with sclerotherapy procedures including allergic reaction to the injected fluid or its side-effects.

Thus, there is a need to provide minimally invasive methods and medical devices for treating vascular disorders, such as varicose veins, reducing the potential complications and costs associated with commonly used therapies, reducing the cost of the equipment required, eliminating the administration of drugs, as well as avoiding or reducing the need of general anesthesia. The cost of the equipment significantly affects the number of patients that can receive the treatment, as the equipment can be used only once. If the cost of the equipment

could be reduced from the order of hundreds of dollars to the order of tens of dollars, then the treatment can reach many more patients. Clearly, avoiding general anesthesia also significantly reduces cost, time and complications and would increase the appeal of the treatment.

In US 2011/0066142 A1 a vascular treatment device for ablating varicose veins is disclosed. The ablation is achieved with a rotating wire that perturbs the vessel to cause vasospasm and may cause damage to vessel wall to promote sclerosis. One of the main disadvantages with this is the need of a complex and costly device to perform the procedure.

In another attempt to treat varicose veins, U.S. Patent No. 5,047,013 discloses a probe comprising a flexible plastic tube with a tip portion, and at least one opening in the region of the tip portion for injecting a sclerosing agent. Risks associated with injecting a sclerosing agent include allergic reaction to the injected fluid and its potential drug side-effects. If the use of sclerosing agent can be reduced or avoided altogether it would also reduce costs associated with the treatment and recovery from the treatment.

Summary of the Invention

The present invention is defined in the appended independent claims, to which reference should be made. Advantageous features are set out in the dependent claims.

In one aspect, the invention provides a medical device for treating vascular disorders comprising:

a flexible sheath suitable for insertion into a vein, the flexible sheath having an open ended central bore through which a guide wire may pass; and

an expansible member coupled to, or forming part of, the sheath, the expansible member having a roughened outer surface and configured to expand from a first configuration to a second configuration when the sheath is inserted in a vein.

A device in accordance with the invention has the advantage of being simple and inexpensive to manufacture and simple to use. It does not require a catheter for placement within a vessel to be treated and has few components. In general, the fewer component parts to a device the less susceptible to defects and failure it is.

Due to the roughened surface of the expansible member, a preselected section of the vessel wall can be damaged by moving the roughened surface across that section of the vessel. As a result of the damage, the vessel collapses.

The expansible member advantageously comprises one or more inflatable members. The inflatable member or members may be a polymeric balloon. The roughened outer surface maybe formed using a number of different materials. For example, diamond chips may be fixed to an outer surface of the expansible member. The diamond chips may of the order of 1- 30 microns in diameter. The diamond chips may be applied to the expansible member in a slurry using a electroplating or electroless plating. Alternatively, the diamond chips may be fixed to the expansible member using an adhesive. As an alternative metal wire or metal filings may be fixed to an outer surface of the expansible member to form the roughened surface.

The sheath may include one or more inflation lumens through which inflation fluid may pass to inflate the one or more inflatable members. The inflation fluid may be saline or may be air, for example. If a plurality of inflation lumens are provided, each inflation lumen may supply a different inflatable member so that the length of the roughened surface in contact with a vessel wall can be selected by selecting which inflatable members to inflate.

The expansible member may form a part of an exterior surface of the sheath. In an unexpanded state, the roughened surface preferably does not extend proud of the surrounding exterior surface of the sheath. For example, for an inflatable member, in an uninflated state, the roughened surface may be positioned below the level of the exterior surface of the adjacent portions of the sheath. This reduces the possibility of damage to the areas of the vessel that are not to be treated, as the device is inserted or withdrawn from the vessel.

Advantageously, the sheath has a rounded end to reduce the possibility of damage to vessels as the device is inserted and positioned within the vessel.

The central bore may be dimensioned such that a thermal treatment device may be inserted through it and positioned within the vessel. For example, a fibre optic cable may be passed through the central bore to the treatment site so that laser treatment can be applied to the

vessel. This may complement the mechanical treatment provided by the roughened surface and may be useful for larger vessels in particular. The additional mechanical treatment may allow thermal treatment to be effective at lower power, meaning less pain for the patient and avoiding the need for general anesthesia. Similarly, a radio frequency treatment device may be passed through the central bore to allow radio frequency treatment to be carried out together with the mechanical treatment.

If required a sclerosing agent may be delivered to the treatment site through the central bore.

In another aspect of the invention, there is provided a method for treating vascular disorders comprising the steps of:

introducing a guide wire inside a vein to be treated;

introducing a device in accordance with any one of claims 1 to 6 into the vein, wherein the flexible sheath is positioned around the guide wire so that the guide wire extends through the central bore;

positioning a distal end of the device at a preselected treatment site inside the vein;

expanding the expansible member to the second configuration so that the roughened surface contacts a wall of the vein; and

moving the device and the guide wire through the vein with the expansible member in contact with the wall.

The method does not require the use of catheter. The device simply fits around the guide wire. This simplifies the procedure when compared to prior treatment methods. As explained, a section of the vessel wall is damaged by moving the roughened surface across that section of the vessel. As a result of the damage, the vessel collapses. The medical practitioner performing the procedure may simply withdraw the device through the vein with the expansible member in contact with the wall. However, the practitioner may use other movements, such as rotation and movement back and forth.

The medical practitioner is given direct tactile feedback as the method is performed, providing an indication of the abrasive force being applied to the vein wall. The practitioner may alter the degree of expansion of the expansible member to increase or reduce the abrasive force and so suit different vessels and different sections of a single vessel. For example, if the expansible member comprises an inflatable member, the pressure of the inflation fluid may be altered to adjust the diameter of the inflatable member. The ability to adjust the diameter means that only a single device need be manufactured and supplied to treat different sized vessels. This in turn allows production costs to be reduced.

As explained, the method may further comprise a complementary vessel treatment, such as thermal treatment. In one example, the method may further comprise passing a fibre optic cable through the central bore to the treatment site and apply laser light through the fibre optic cable to the treatment site. In another example, a radio frequency treatment device may be passed through the central bore and radio frequency radiation applied to the treatment site.

Alternatively, or in addition, a sclerosing agent may be passed through the central bore and applied to the treatment site. The expansible member may be moved back and forth across the treatment site to massage the sclerosing agent into the vessel wall.

The guide wire and device may be introduced into the vein under ultrasound guidance.

Brief Description of the Drawings

Embodiments of the invention will now be described by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 shows an embodiment of present invention, comprising a medical device for minimally invasive treatments of varicose veins;

Fig. 2 shows the device of Figure 1, with the inflatable member in an uninflated condition;

Figure 3 is a cross-section through the device of Figure 1 in the region of the inflatable member; and

Figure 4 is a cross-section through the device of Figure 1 remote from the inflatable member.

Detailed Description

Figure 1 illustrates a medical device 100 for treating vascular disorders. The device 100 comprises a hollow sheath 102 and an inflatable member 104 close to its proximal tip. The sheath is at least as long as the length of a vessel to be treated and typically is longer, allowing insertion into the vascular system remote from the section of a vessel to be treated. In this example, the sheath is approximately 50 centimetres long. The sheath defines a central bore 103, running along its length. In this example, the diameter of the sheath is 3mm, with the central bore having a diameter of 1.5 mm. However, it should be clear that the sheath may be made with larger or smaller diameter to suit a particular application. The sheath is formed from a flexible material, such as silicone elastomer.

The inflatable member 104 in this embodiment is a balloon formed from an elastic material such as latex, polyurethane, nylon elastomer, or other thermoplastic elastomer. However, non-elestomeric materials may be used, such as polyethylene terephthalate (PET). The inflatable member has a roughened surface formed from diamond chips, which have been electroplated to the inflatable member 104 in a nickel slurry. Other abrasive materials may be used such as steel wire or filings. Alternatively hooks or bristles may be adhered to the inflatable member. The inflatable member may be of variable length, but in this embodiment is 2cm long. The inflatable member extends around the circumference of a reduced diameter portion of the sheath 102, as shown in Figures 2 and 3 and described below. The inflatable member may be fixed to the sheath using adhesive or by welding or heat sealing.

In Figure 1, the inflatable member 104 is shown in an inflated condition, within a vessel 106 that is being treated. The roughened surface is in contact with a wall of the vessel. In Figure 2, the device is shown with the inflatable member in an uninflated condition.

Figure 3 is a cross-section through the device shown in Figures 1 and 2, in the region of the inflatable member, with the inflatable member in an uninflated condition. The sheath has a reduced diameter in the region covered by the inflatable member. This allows the roughened surface of the inflatable member to have a diameter smaller than the diameter of the surrounding portions of the sheath, as shown in Figure 2. This reduces the likelihood of the

roughened surface contacting and damaging the vessel walls when in an uninflated condition.

The inflatable member can be inflated with a fluid such as air or saline water, that is supplied through an inflation lumen 108, shown in Figure 3. The inflation lumen 108 extends from a distal end of the sheath 102 to the inflatable member 104.

Figure 4 is a cross section through the sheath at a position distal of the inflatable member. The inflation lumen 108 is shown within the body of the sheath.

To use the device to treat a section of varicose vein, a proximal end of a guide wire 110 is first inserted into the vein to be treated up to the selected treatment site. The device is then threaded onto a distal end of the guide wire so that the guide wire passes through the central bore 103. The device is then inserted into the vessel along the guide wire. The guide wire 110 is introduced inside the vein to be treated with the aid of an introducer needle or similar. For guiding the device to the desired position inside the blood vessel, the treatment is advantageously performed with the aid of a viewing or imaging scope, preferably under ultrasound guidance. Preferably, the procedure is carried out entirely under ultrasound guidance in order to monitor progress inside the blood vessel and check appropriate positioning inside blood vessel lumen.

When the tip of the sheath 102 is positioned in the section of the vein to be treated, inflatable member 104 is inflated by supplying pressurized inflation fluid through the inflation lumen 108 until its surface reaches vein wall 106, as shown in Figure 1. Once inflatable member 104 is in contact with vessel wall 106, the medical practitioner withdraws sheath 102. Due to the roughened surface of the inflatable member, a preselected section of the vessel wall is damaged and the vessel collapses. In order to enhance the damaging effect to the vessel wall, the hollow tube may be moved back and forth, rotated or moved in other manners while it is withdrawn. The tip of the sheath may have a round tip that cannot damage the vessel wall while it enters and follows the blood vessel up to the preselected treatment site.

Once treatment is complete, the pressure of the inflation fluid is reduced so that the inflatable member returns to an uninflated state, as shown in Figure 2. The device and guide wire can then be completely withdrawn from the patient.

As a result of the treatment, the endothelium of the surrounding annular portion of the vessel wall in contact with the inflatable member is damaged, achieving an efficient lumen diameter reduction and/or closure of the blood vessel. The terms "lumen closure", "close the blood vessel", "occlude the vessel", or like terms, are used herein to mean closure and/or shrinkage of the blood vessel lumen that is sufficient to substantially prevent or reduce significantly the pathological blood reflux. A significant advantage is that neither tumescent anesthesia nor general anesthesia is required; only a small amount of local anesthesia may be applied at the access site.

The present invention provides minimally invasive methods and medical devices for safe and efficient endoluminal treatment of veins in mammals. A key feature of present invention is the possibility of endoluminally treating blood vessels in a simple manner avoiding the complexity and possible undesired side effects of prior art devices and techniques. One of the main advantages of present invention is that the treatment can be performed as an outpatient procedure without needing general anesthesia, significantly diminishing the risks associated with prior art procedures. With this invention, the lumens of blood vessels are endoluminally damaged, reducing its diameter sufficiently to avoid the pathological reflux in the diseased veins. While the treatment is performed, the damaged blood vessel collapses due to a vasospasm producing the desired permanent diameter reduction and/or closure of the vessels.

The described treatment may be carried out in conjunction with other treatments. For example, if the central bore is made sufficiently large, a fibre optic cable may be passed through the central bore to the treatment site so that laser treatment can be applied to the vessel. This may complement the mechanical treatment provided by the roughened surface and may be useful for larger vessels in particular. The additional mechanical treatment may allow thermal treatment to be effective at lower power, meaning less pain for the patient and avoiding the need for general anesthesia. Similarly, a radio frequency treatment device may be passed through the central bore to allow radio frequency treatment to be carried out together with the mechanical treatment.

Having described preferred embodiments of the invention with reference to the accompanying drawings, it is to be understood that the invention is not limited to the precise embodiments, and that various changes and modifications may be effected therein by skilled

in the art without departing from the scope or spirit of the invention as defined in the appended claims.

Claims

1. A medical device for treating vascular disorders comprising:

a flexible sheath suitable for insertion into a vein, the flexible sheath having an open ended central bore through which a guide wire may pass; and

an expansible member coupled to, or forming part of, the sheath, the expansible member having a roughened outer surface and configured to expand from a first configuration to a second configuration when the sheath is inserted in a vein.

2. A medical device according to claim 1, wherein the expansible member comprises one or more inflatable members.

3. A medical device according to claim 2, wherein the sheath includes one or more inflation lumens through which inflation fluid may pass to inflate the one or more inflatable members.

4. A medical device according to claim 1, 2 or 3, wherein the expansible member forms a part of an exterior surface of the sheath.

5. A medical device according to any preceding claim, wherein the roughened outer surface comprises diamond chips fixed to an outer surface of the expansible member.

6. A medical device according to any preceding claim, wherein the sheath has a rounded end.

7. A method for treating vascular disorders comprising the steps of:

a) introducing a guide wire inside a vein to be treated;

b) introducing a device in accordance with any one of claims 1 to 6 into the vein, wherein the flexible sheath is positioned around the guide wire so that the guide wire extends through the central bore;

c) positioning a distal end of the device at a preselected treatment site inside the vein;

d) expanding the expansible member to the second configuration so that the roughened surface contacts a wall of the vein; and

e) moving the device and the guide wire through the vein with the expansible member in contact with the wall.

8. A method according to claim 8, wherein the guide wire and device are introduced into the vein under ultrasound guidance.

9. A medical device for treating vascular disorders substantially as described herein with reference to the accompanying drawings.

Intellectual Property Office

Application No:	GB1313843.3	**Examiner:**	Mr William Crowe
Claims searched:	1-6	**Date of search:**	4 February 2015

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-5	WO99/44513 A2 (SCIMED LIFE SYSTEMS INC) See Figures, noting sheath 24, guide wire 26 and expandable burr 40 with abrasive diamond coating 36.
X	1-4	US2008/077164 A1 (NATIONAL UNIVERSITY OF IRELAND) See Figures, noting sheath 8, guide wire 16 and balloon 4 with surface blades 50.
X	1-4	WO2005/107615 A1 (BOSTON SCIENTIFIC SCIMED INC) See Figure 8 in particular, noting sheath 18, guide wire 22, balloon 16 and cutting members 620.
X	1 and 4-6	US6451037 B1 (SCIMED LIFE SYSTEMS INC) See Figures 2 and 3 especially, noting sheath 24, guide wire 26 and expandable burr 28 with abrasive surface 36.
X	1, 4 and 5	EP0419154 A1 (FISCHELL) See Figures, noting sheath 22, guide wire 32 and expandable member 24 with abrasive diamond coating 24d.
X	1, 4 and 5	WO93/01753 A2 (ZACCA ET AL.) See Figures and paragraph 2 of page 17, noting sheath 160, guide wire 12 and diamond coated coil 20.

Categories:

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.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[X] :

Worldwide search of patent documents classified in the following areas of the IPC

A61B; A61M

The following online and other databases have been used in the preparation of this search report

WPI, EPODOC

Intellectual Property Office

International Classification:

Subclass	Subgroup	Valid From
A61B	0017/3207	01/01/2006
A61B	0017/00	01/01/2006
A61M	0025/09	01/01/2006
A61M	0025/10	01/01/2013