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(54) **CUTTING BALLOON CATHETER**

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A61F 2/82 (2013.01)

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USPC 128/898; 606/159, 167, 180, 168–179, 606/190–200; 604/92–106
See application file for complete search history.

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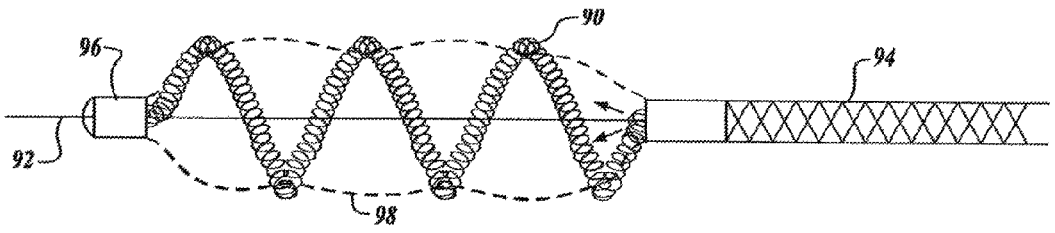
(57) **ABSTRACT**

A system for removing matter from a partially or totally occluded stent includes a cutter that is urged radially outward toward the inner surface of the stent. Preferably, the cutter has a hardness that is less than or equal to the hardness of the material used to make the stent. Aspiration may be provided to remove portions of the occluding material from the vessel.

12 Claims, 6 Drawing Sheets



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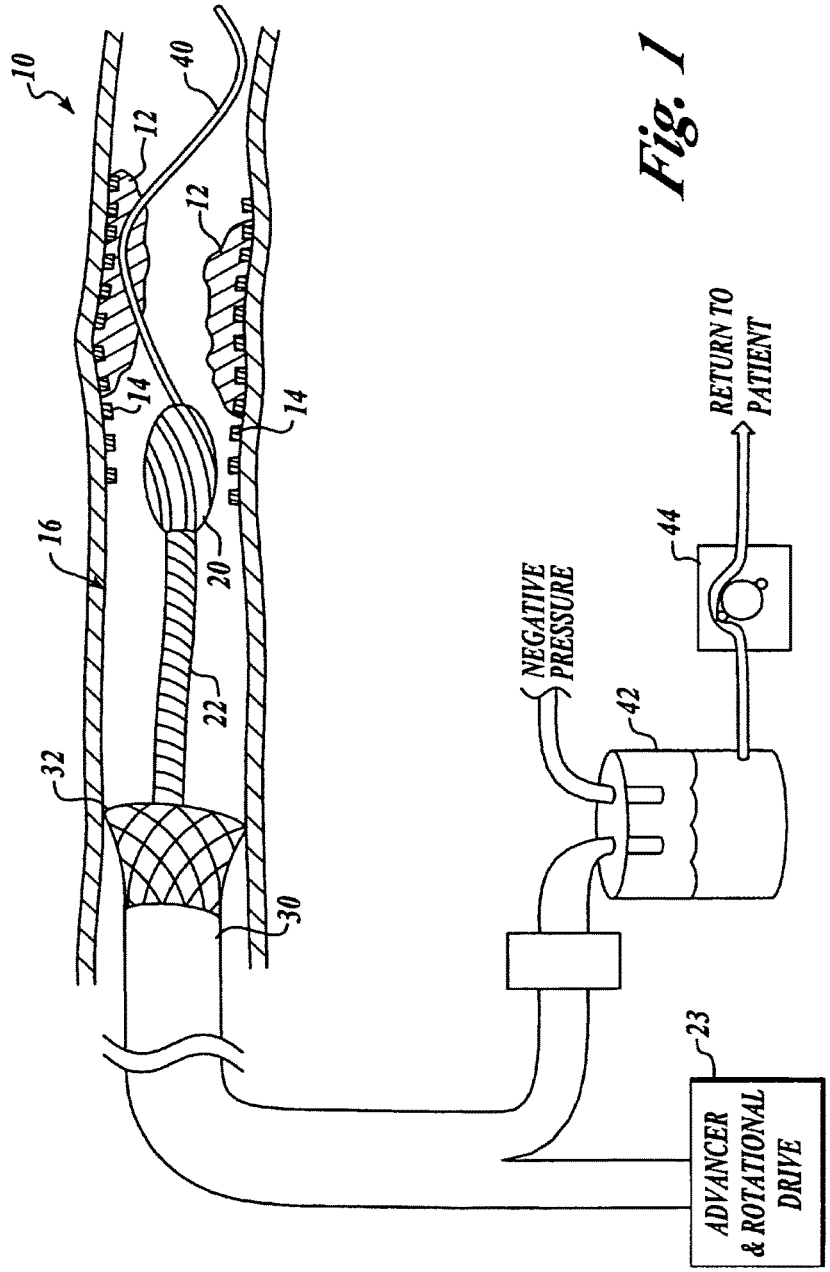
10
12
40
12
14
14
16
20
22
32
30
NEGATIVE PRESSURE
42
44
RETURN TO PATIENT
23
ADVANCER & ROTATIONAL DRIVE

Fig. 1

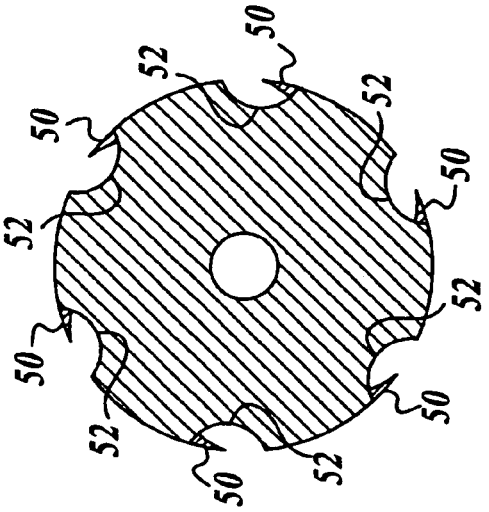

Fig. 3

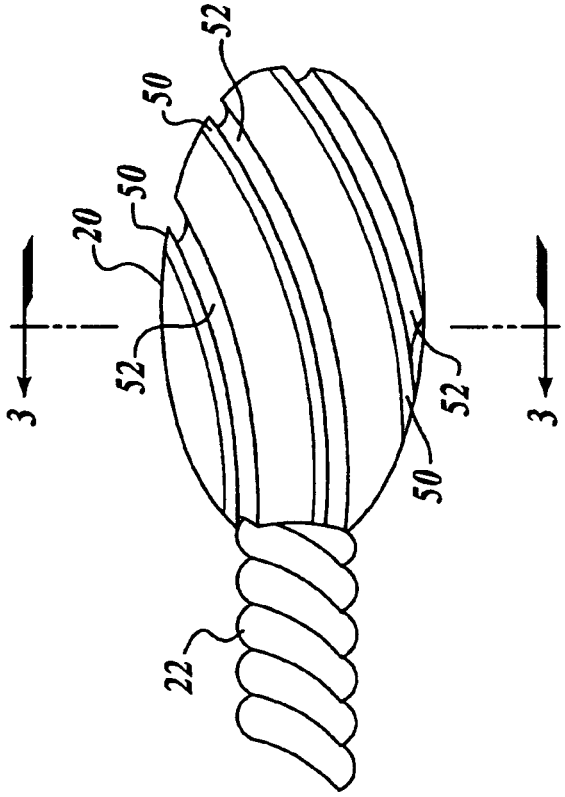

Fig. 2

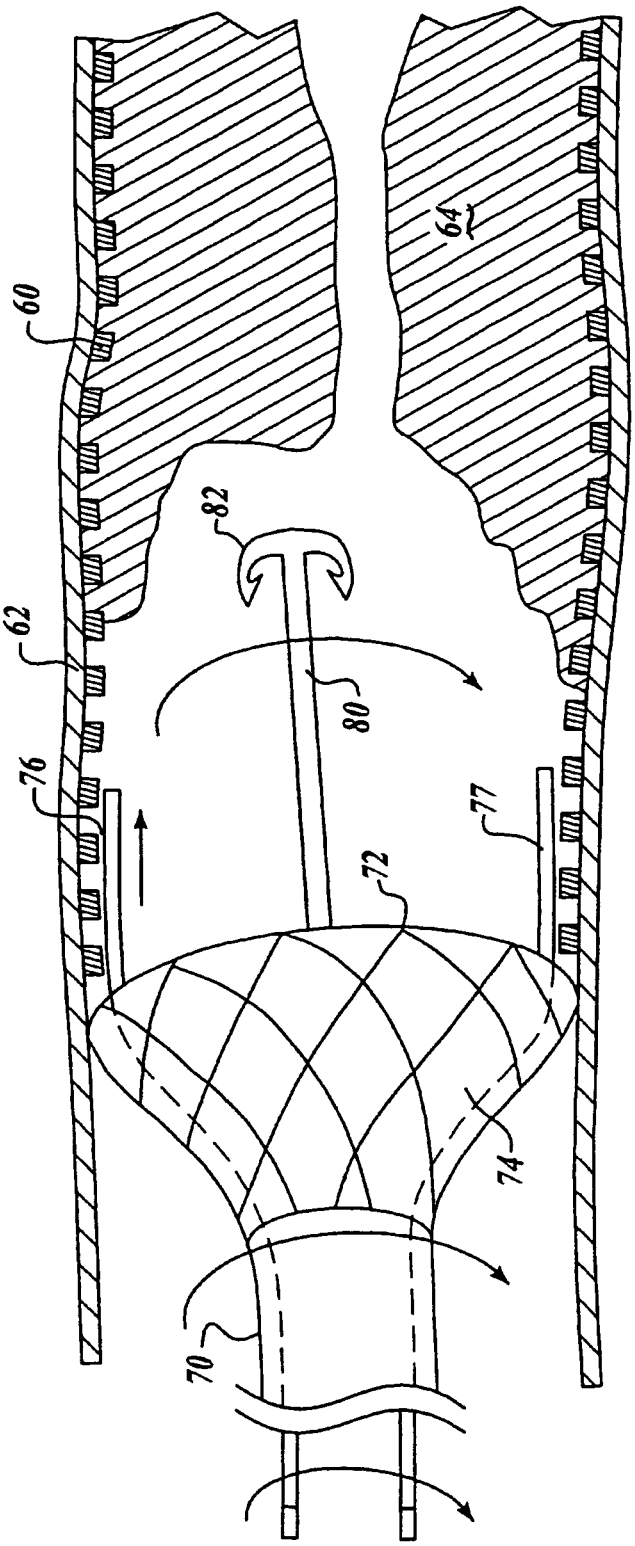

Fig. 4

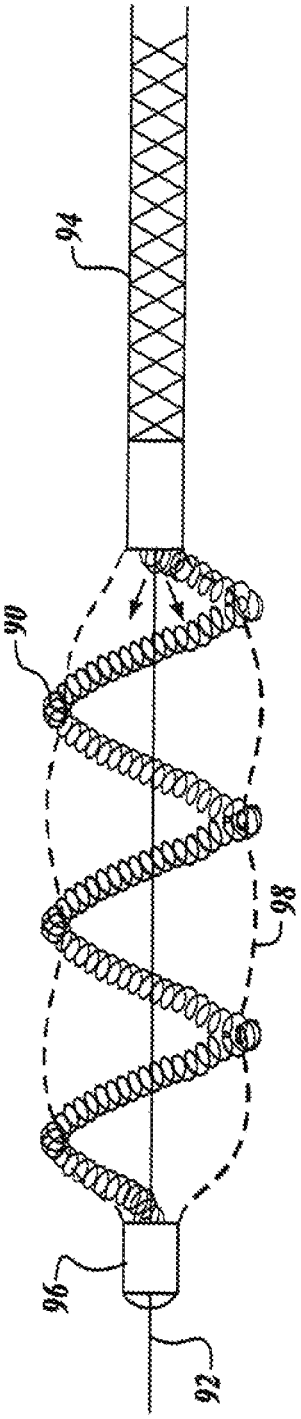

Fig. 5
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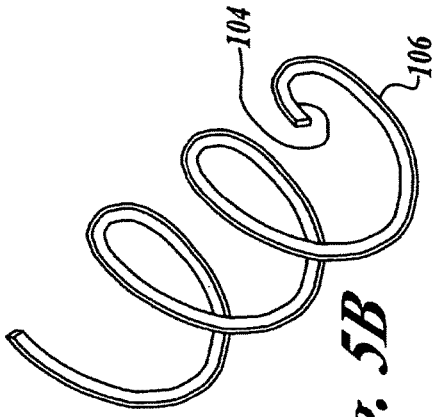

Fig. 5B

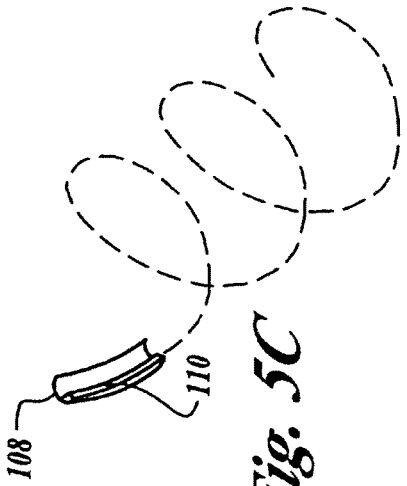

Fig. 5C

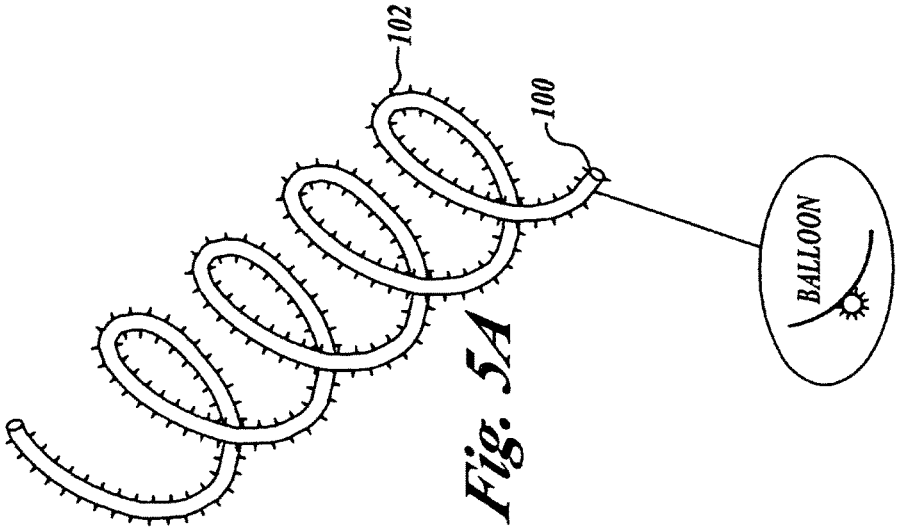

Fig. 5A

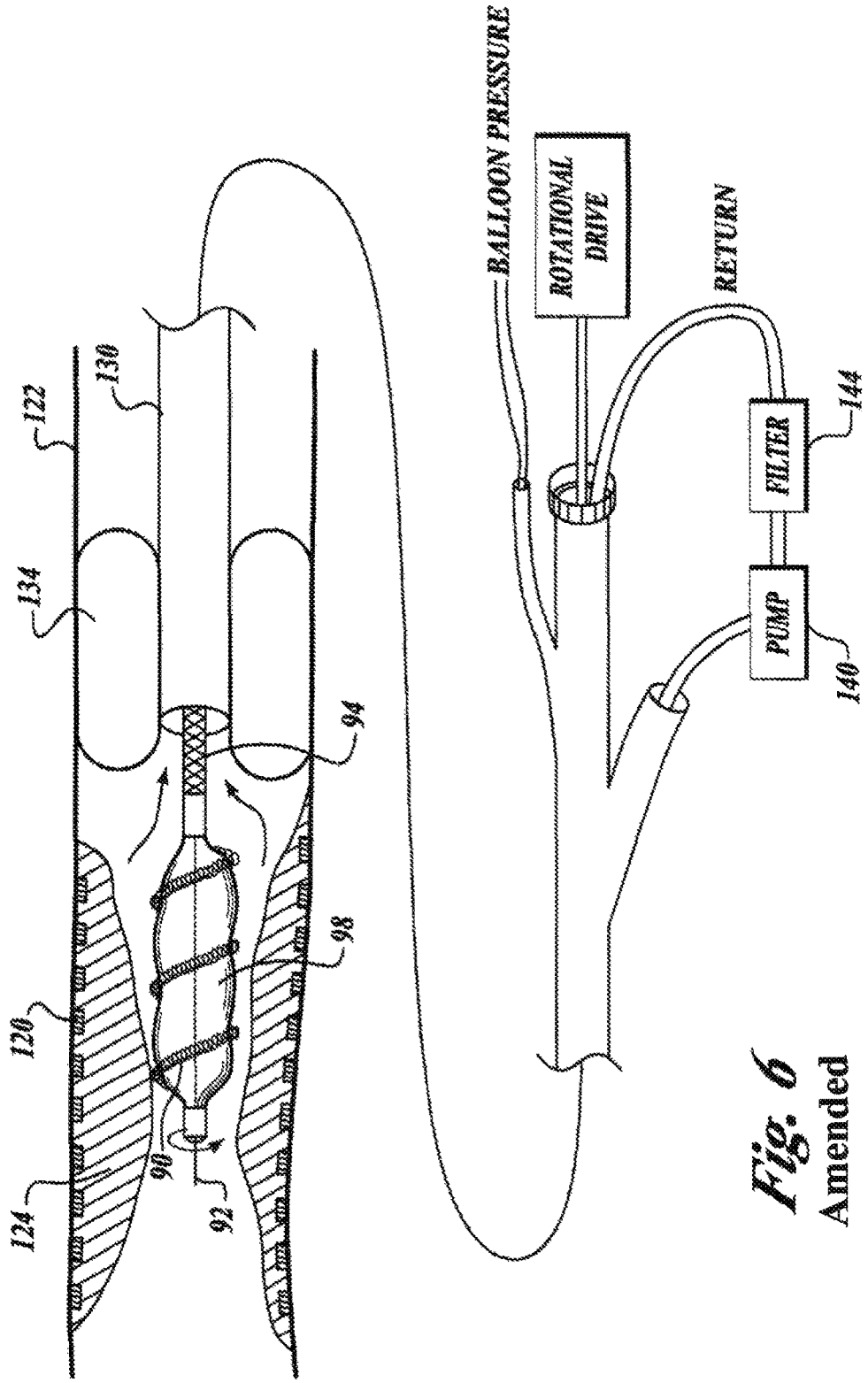

Fig. 6
Amended

CUTTING BALLOON CATHETER

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

Notice: More than one reissue application has been filed for the reissue of U.S. Pat. No. 6,500,186. The reissue applications are application Ser. No. 11/027,583 (the present application) and Ser. No. 13/368,116, each of which are divisional reissues of U.S. Pat. No. 6,500,186.

FIELD OF THE INVENTION

The present invention relates to medical devices in general, and in particular, to rotational atherectomy devices.

BACKGROUND OF THE INVENTION

One of the most common types of vascular diseases afflicting Americans today involves the narrowing of blood vessels by plaque or other materials. Left untreated, such narrowed vessels can contribute to high blood pressure, strokes, or cardiac arrest.

One of the most common techniques for treating a fully or partially blocked vessel is to bypass the blockage with a healthy vessel obtained from elsewhere in the body. A less traumatic approach involves the insertion of a balloon angioplasty device into the vessel and expanding the balloon to compress the occlusion against the vessel wall. Another minimally invasive technique is an atherectomy procedure, where a high-speed cutting device such as the Rotoblator™, produced by SCIMED Life Systems, Inc., the U.S. assignee of the present invention, is inserted into the vessel and advances against the occlusion in order to grind it into small particles that are passed by the body.

In many instances, a physician will place a stent in the area of the treated occlusion. In the case of balloon angioplasty, stents operate to prevent the compressed occlusion from springing back to its former size. For vessels that have undergone an atherectomy procedure, the stent helps maintain an open passage or lumen through the vessel.

Regardless of the procedure used, a fair percentage of stents become re-occluded within a relatively short period of time. However, the material that occludes the stent is somewhat different from the occluding material that blocked the vessel in the first instance. Therefore, techniques used to treat an original occlusion are not believed to be as effective when treating a re-occluded stent. Therefore, there is a need for a device and method of effectively treating re-occluded stents in a manner that does minimal or no damage to the stent itself.

SUMMARY OF THE INVENTION

The present invention is a system and method for removing occluding material from a stent that is positioned within a vessel. In one embodiment of the invention, a rotational cutter is made of a material having a hardness less than or equal to the hardness of the material used to make the stent. The cutter has a number of recessed blades such that the outer surface of the cutter is relatively smooth and cutting is limited to tissue that enters channels in which the blades are placed. The cutter is preferably routed on a guide wire that is shaped such that the cutter is pressed radially outward against the inner surface of the stent. To aid in the removal of ablated material that is cut from the stent, an aspiration system including a catheter coupled to a source of negative pressure operates to aspirate ablated particles.

In another embodiment of the invention, a cutting mechanism includes a catheter with a self-expanding stent on the distal end thereof. One or more knives are secured to the stent such that the knives are pushed radially outward by the stent. Once the expanding stent is positioned in an occluded stent, the one or more knives are extended and rotated to remove occluding material. Ablated material from the occluded stent is preferably aspirated from the vessel.

In another embodiment of the invention, a cutting mechanism includes a helically-wound cutter that surrounds an inflatable balloon. The balloon is inflated to urge the cutter radially outward against the inner wall of the stent. Ablated particles removed from the stent are preferably aspirated from the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIG. **1** shows a system for removing material from an occluded stent in accordance with one embodiment of the present invention;

FIGS. **2** and **3** illustrate a cutter in accordance with another aspect of the present invention;

FIG. **4** illustrates a cutter for removing material from an occluded stent in accordance with yet another embodiment of the present invention;

FIG. **5** illustrates a helical cutter in accordance with another aspect of the present invention;

FIGS. **5**A-**5**C illustrate various embodiments of helical cutters in accordance with other aspects of the present invention; and

FIG. **6** illustrates a system for operating the helical cutter in accordance with another aspect of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** illustrates one embodiment of a system **10** for removing occluding matter **12** from a stent **14** that is positioned within a vessel **16** according to the present invention. As indicated above, the occluding material **12** is typically different from the occluding material generally associated with arteriosclerosis or other vascular diseases. Once the stent **14** is positioned in the vessel **12**, the material **12** that re-occludes the stent is typically a smooth-celled growth that may continue to grow until the lumen or passage through the stent **14** is totally blocked.

To remove the occluding material **12** from the stent, the present invention includes a cutter **20** that is rotated by a drive shaft **22**. The drive shaft **22** is advanced and rotated by an advancer/rotational drive **23** at the maximal end of the drive shaft **22**. The cutter **20** and the drive shaft **22** are routed within a catheter **30** that is coupled to a source of negative pressure to provide a corresponding negative pressure or slight vacuum within the vessel **16** at the location of the stent. The catheter **30** may have a mechanism for sealing the

catheter within the vessel such as a self-expanding stent **32** that is covered with an elastomeric coating such that when the stent **32** expands, the vessel is sealed. Alternatively, inflatable balloons at the end of the catheter **30** or other mechanisms may be used to seal the vessel in order to provide proper aspiration of the ablated particles.

To ensure that the cutter **20** clears a passage with a fairly large diameter, the cutter **20** is preferably routed over a guide wire **40** that is helical or otherwise shaped to force the cutter **20** toward the inner surface of the stent **14** when the cutter is advanced over the guide wire.

In some instances, it may be desirable to deliver a saline solution or other liquid through the drive shaft **22** and/or the cutter **20** to provide additional liquid volume in the vessel so that the vessel **16** doesn't collapse during aspiration. Saline and blood aspirated from the vessel are received in a collecting jar **42** and returned by a pump **44** to the patient via an intravenous drip or other mechanism.

In order to prevent damage to the stent, the cutter **20** as shown in FIG. **2** is preferably made of a material that is soft or softer than the material from which the stent is made. Typically, the stent **14** is made is made of Nitinol™ or stainless steel. Therefore, the cutter **20** is preferably made of a material having a hardness less than or equal to Nitinol™ or stainless steel. As shown in FIG. **3**, the cutter **20** has a number of recessed blades **50** that lie within corresponding channels **52**. The blades **50** are positioned such that the outer surface of the cutter **20** is relatively smooth and will not catch or cut the inner surface of the stent **14**. However, any occluding matter **12** that enters or is forced into the channels **52** is cut by the one or more blades **50** as the cutter **20** is rotated by the drive shaft **22**. The channels **52** may be spiralled around the outer surface of the cutter **20** in order to force ablated material proximally as the burr is rotated in order to aid aspiration of the ablated tissue.

FIG. **4** shows an alternative embodiment of a system for removing occluding matter from a stent. Here, a stent **60** is positioned within a vessel **62**. The stent is shown as being fully blocked by occluding material **64**. To remove the occluding material **64**, a catheter **70** is inserted into the vessel. The catheter **70** has a self-expanding stent **72** at its distal end that is preferably covered with an elastomeric or other non-porous material **74** to seal the vessel when the stent **72** expands. One or more extendable cutting knives or blades **76**, **77** are secured to the stent **72** such that when the stent is expanded, the one or more knives **76** are urged radially outward toward the vessel wall. In operation, the catheter **70** can be placed within or adjacent to the occluded stent **60**. The self-expanding stent **72** is allowed to expand such that the one or more knives **76**, **77** are positioned within the stent **60**. Thereafter, the catheter **70**, self-expanding stent **72**, and one or more cutting knives **76**, **77** are rotated within the stent to remove portions of the occluding matter **64**. Aspiration can be applied to the catheter **70** to remove portions of the occluding material that are cut by the one or more cutting knives **76**, **77**.

To further hold the catheter **70** in position within the stent, a guide wire **80** has one or more hooks **82** (that may or may not be barbed) at its distal end that can be implanted into the occluding matter **64**. The guide wire **80** serves an anchor against which the catheter **70** can be pulled in order to advance the one or more cutting knives **76**, **77** within the occluded stent **60**. Once the one or more cutting knives **76**, **77** are rotated 360° in the stent **60**, the guide wire **80** can be further advanced into the occluding material **64** and the process repeated.

FIG. **5** shows yet another alternative embodiment of a system for removing occluding matter from a stent in accordance with the present invention. In this embodiment, a helical cutter **90** extends around a guide wire **92** that is routed within a catheter **94**. The cutter **90** extends from the end of the catheter **94** to a distal bearing **96** that is positioned on the guide wire **92**. Within the helical cutter **90** is a balloon **98** (*shown in phantom lines*). The balloon **98** can be inflated with the saline or other material that is delivered through the catheter **94** (*shown by arrows*). Preferably, the catheter **94** is sealed along its length to prevent loss of the material used to inflate the balloon. Inflating the balloon **98** urges the helical cutter **90** radially outward toward the inner surface of a stent.

FIGS. **5**A-**5**C show three of many possible embodiments of the helical cutter **90**. The helical cutter **90** can comprise a generally round wire **100** that is selectively coated with an abrasive material such as diamond grit **102** as shown in FIG. **5**A. The diamond grit is plated to a wire selectively such that the grit is not exposed on the surfaces that contact the stent itself, if the plated wire momentarily engages the stent, but only cuts deformable restenosis tissue that deforms in the abrasive.

Alternatively, as shown in FIG. **5**B, the helical cutter **90** can comprise a relatively flat spring **104** having an outer edge **106** that is sharpened to provide a cutting surface. The material used to make the flat spring **104** preferably has a hardness that is less than or equal to the hardness of the material used to make the stent to be cleared.

Alternatively, as shown in FIG. **5**C, the helical cutter **90** can comprise a cutaway tube, such as a hypotube, having a sharpened outer edge **110**. The tube is wound into a helical coil around the guide wire. The material used to make the tube should have a hardness less or equal to the hardness of the material used to make the stent.

FIG. **6** shows how a helical cutter **90** of a type shown in FIG. **5** is used within a vessel. The helical cutter **90** is positioned within a partially or totally occluded stent **120** that is within a vessel **122**. A catheter **130** is advanced into the vessel **122** and a sealing mechanism such as one or more balloons **134** at the distal end of the catheter is used to seal the vessel. A catheter **94** that contains the helical cutter **90** is then advanced through the catheter **94**. The helical cutter **90** is expanded radially outward once it is within the stent **120** by inflating the balloon **98**. The catheter **94** is then rotated by a prime mover such as gas turbine or an electric motor (not shown) at the proximal end of the catheters **94** and **130**. Rotation of the helical cutter **90** removes the occluding material **124** from the stent **120**. In addition, aspiration can be provided to the catheter **130** and/or **94** to remove portions of the ablated, occluding material **124**. The aspirated material can be removed from the vessel using a pump **140** and a filter **144** before the aspirated liquid is returned to the patient.

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention. It is therefore intended that the scope of the invention be determined from the following claims and equivalents thereto.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A **[**system for removing deposits from a partially or totally occluded stent**]** *balloon catheter*, comprising:

a catheter shaft configured to be routed over a guidewire;

an expandable cutter **[**disposed over a guide wire**]** *coupled to the catheter shaft*, the cutter including a coiled member *having a proximal end directly affixed to a*

distal end of the catheter shaft and a distal end directly affixed to a distal bearing through which the guidewire is routed; and

a balloon disposed within the coiled member that expands to urge the cutter radially outward, *the balloon being a separate component from the expandable cutter, a proximal end of the balloon directly affixed to the distal end of the catheter shaft proximate the proximal end of the coiled member and a distal end of the balloon directly affixed to the distal bearing proximate the distal end of the coiled member,* wherein the balloon is inflated **[**when the cutter is within the occluded stent to urge the cutter toward an inner wall of the occluded stent, the expandable cutter being rotatable in the occluded stent to remove occluding matter**]** *with a fluid delivered through the catheter shaft.*

2. The **[**system**]** *balloon catheter* of claim **1**, wherein the coiled member is a **[**diamond coated**]** helical wire.

3. The **[**system**]** *balloon catheter* of claim **1**, wherein the coiled member is a flat spring **[**having a sharpened outer edge**]**.

4. The **[**system**]** *balloon catheter* of claim **1**, wherein the coiled member is a semi-cylindrical wire **[**having a sharpened edge**]**.

[5. A method for removing restenotic tissue from within a stent, comprising:

advancing a cutter into the stent, the cutter being secured to a drive shaft and including an expandable coil having a cutting surface, wherein the cutting surface is positioned on the coil such that the cutting surface does not contact the stent when removing restenotic tissue from within the stent;

rotating the cutter; and

aspirating ablated particles of the restenotic tissue.**]**

6. The balloon catheter of claim 1, wherein the cutter is rotatable to remove occluding matter during use.

7. A medical device, comprising:

a catheter shaft having a proximal and a distal end, the catheter shaft being configured to be routed over a guidewire;

an inflatable balloon having a proximal end directly affixed to the distal end of the catheter shaft and a distal end directly affixed to a distal member through which the guidewire is routed; and

a helical cutter disposed over a portion of the inflatable balloon such that the balloon is disposed within the helical cutter, the helical cutter being a separate component from the inflatable balloon, a proximal end of the helical cutter being directly affixed to the distal end of the catheter shaft proximate the proximal end of the inflatable balloon and a distal end of the helical cutter being directly affixed to the distal member proximate the distal end of the inflatable balloon;

wherein the inflatable balloon is inflated with a fluid delivered through the catheter shaft to move the helical cutter radially outward.

8. The medical device of claim 7, wherein the helical cutter includes an abrasive.

9. The medical device of claim 8, wherein the abrasive is a diamond coating.

10. The medical device of claim 7, wherein the helical cutter is a flat spring.

11. The medical device of claim 7, wherein the helical cutter is a wire.

12. The medical device of claim 7, wherein the helical cutter is rotatable to remove occluding matter during use.

13. The medical device of claim 7, wherein the distal member is a distal bearing.

* * * * *