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Boyle et al.

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(54) **SCORING BALLOON WITH TRANSLATING SCORING WIRES**

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A61B 17/22 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/320725*** (2013.01); ***A61B 17/22012*** (2013.01); ***A61M 25/09*** (2013.01);
(Continued)

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(Continued)

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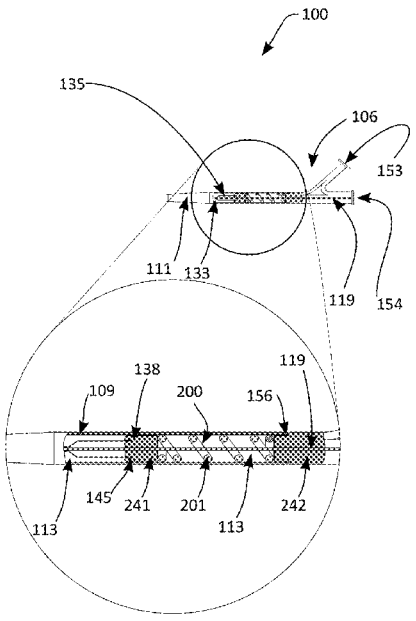
(57) **ABSTRACT**

A device for introduction into a body vessel includes a shaft, a balloon positioned at the distal end of the shaft, a guidewire disposed longitudinally within the shaft to receive a guidewire during use, a balloon disposed at the distal end of the shaft, and longitudinal scoring wires to score a vascular lesion attached to the distal end of the shaft, disposed over the balloon and disposed within the shaft. The proximal ends are welded or otherwise affixed to a spring mounted in the handle. The balloon expands when fluid is delivered to the balloon through the inflation lumen. This expansion pushes the scoring wires against the vascular lesion.

13 Claims, 9 Drawing Sheets



Related U.S. Application Data

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A61M 25/09	(2006.01)
A61M 25/10	(2013.01)
A61B 17/00	(2006.01)

(52) **U.S. Cl.**

CPC . ***A61M 25/104*** (2013.01); *A61B 2017/00477* (2013.01); *A61B 2017/00778* (2013.01); *A61B 2017/22014* (2013.01); *A61B 2017/22061* (2013.01); *A61M 2025/1086* (2013.01); *A61M 2025/1093* (2013.01)

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See application file for complete search history.

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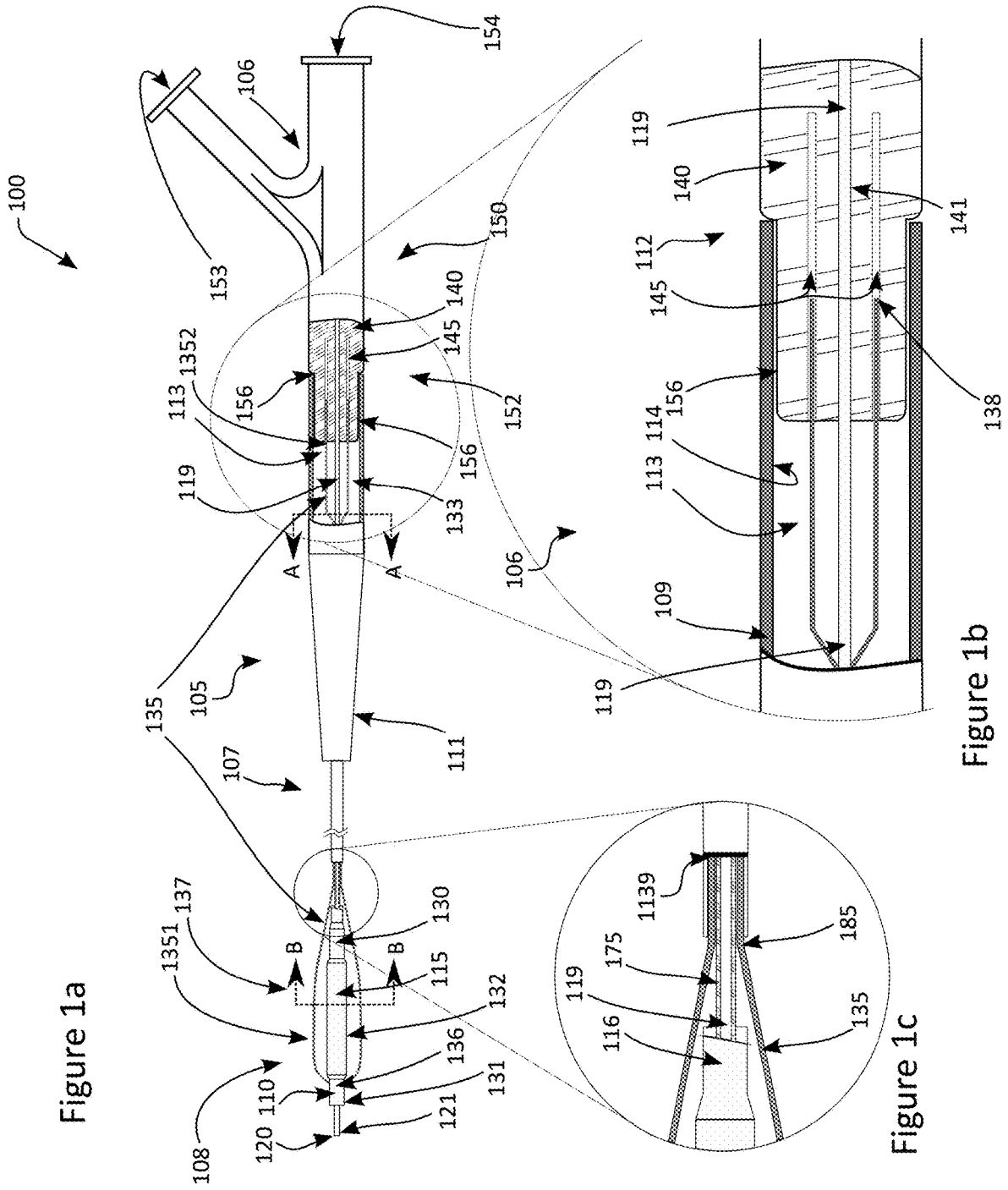


Figure 1a

Figure 1b

Figure 1c

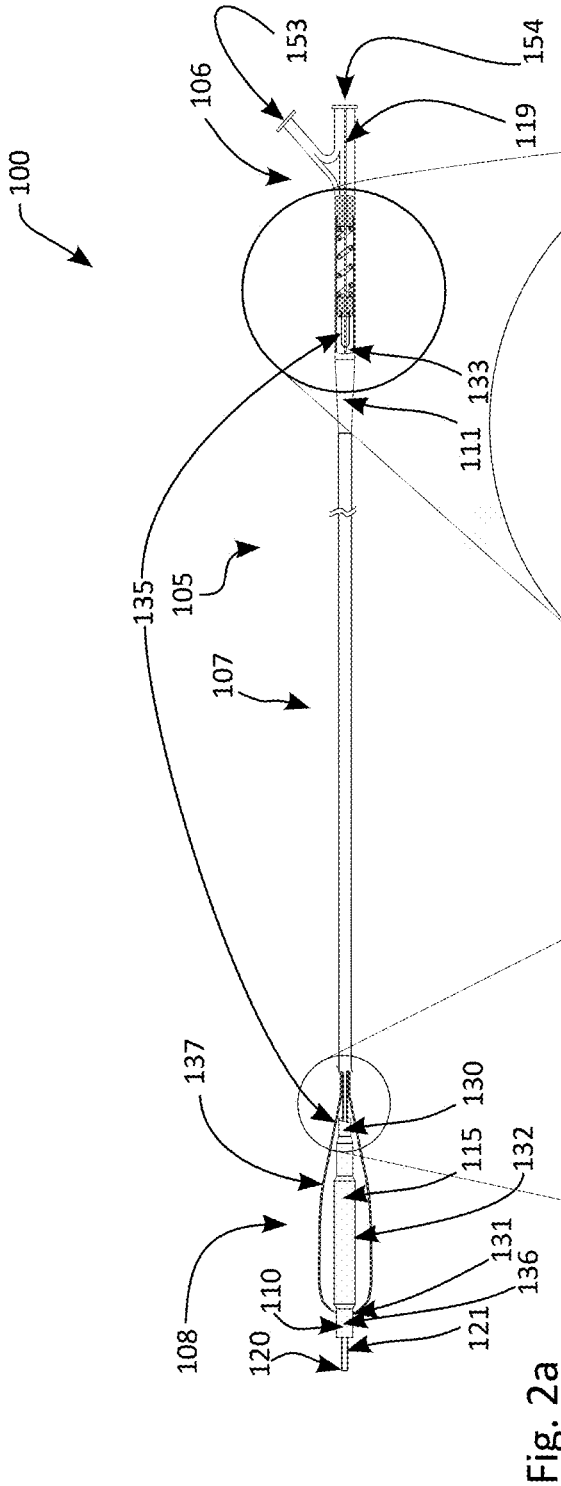


Fig. 2a

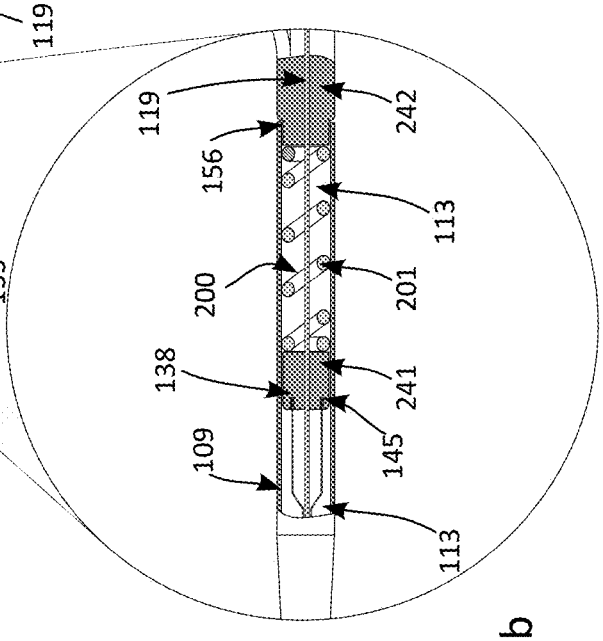


Fig. 2b

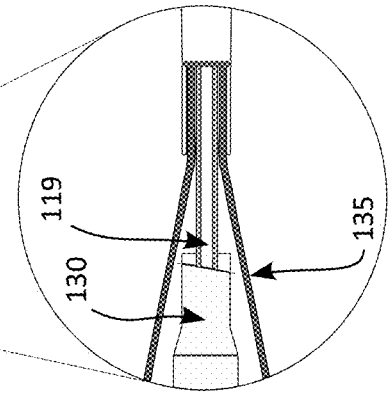


Fig. 2c

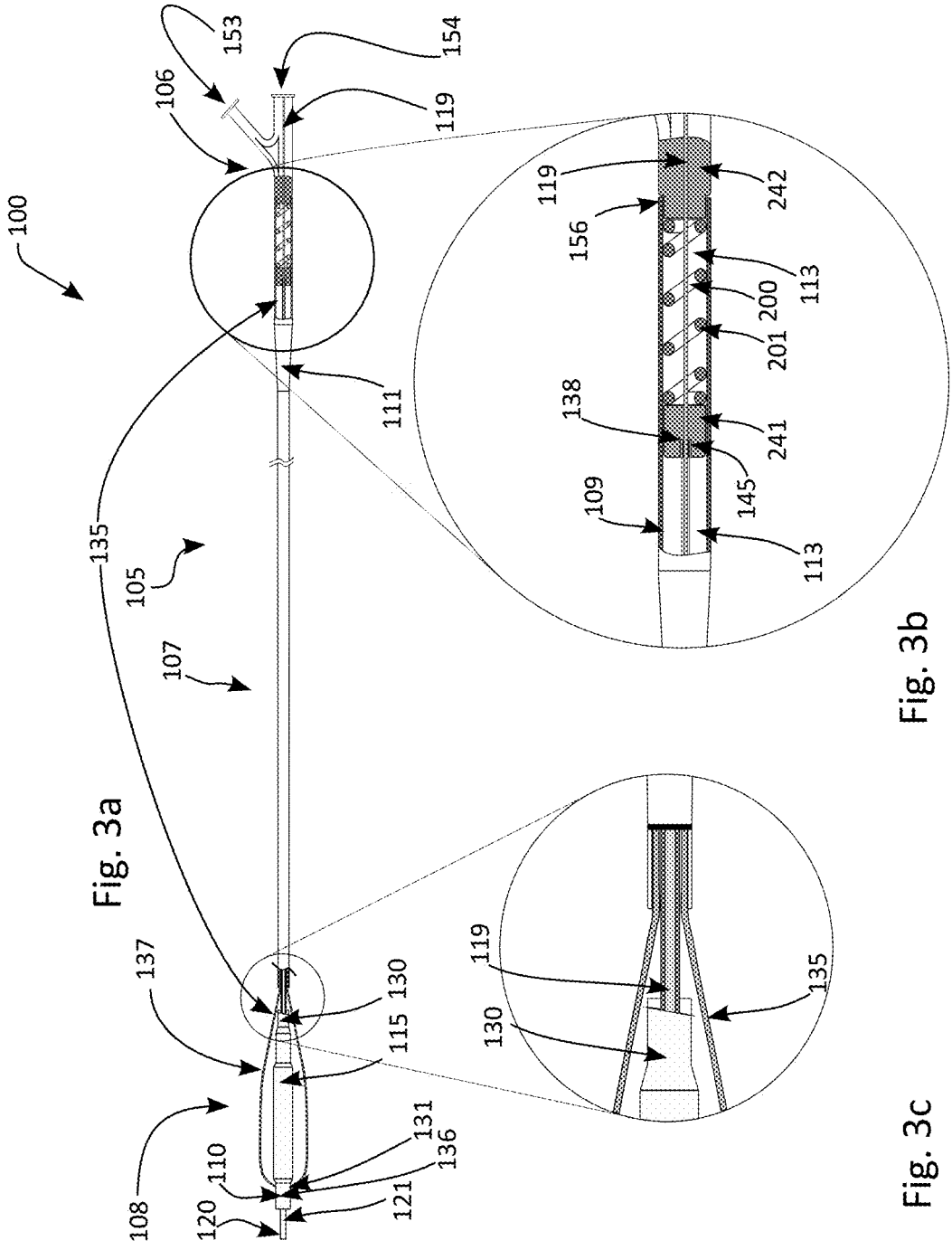


Fig. 3a

Fig. 3b

Fig. 3c

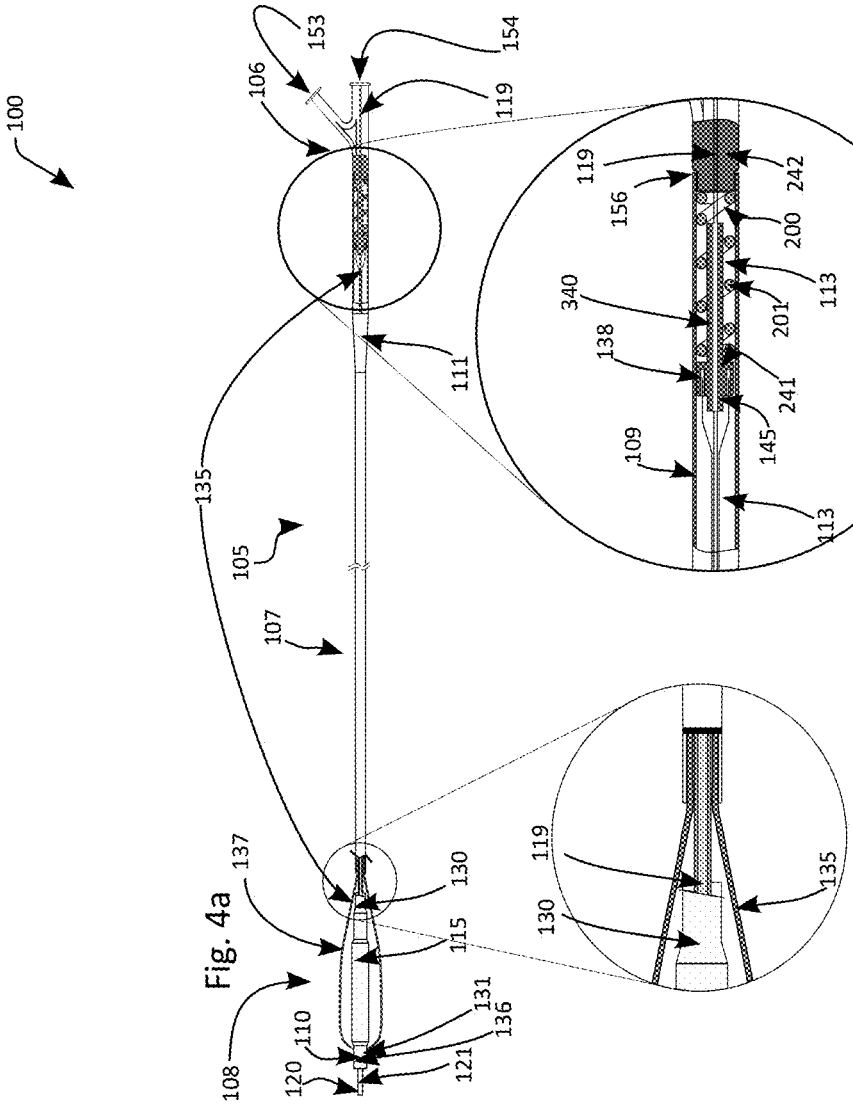
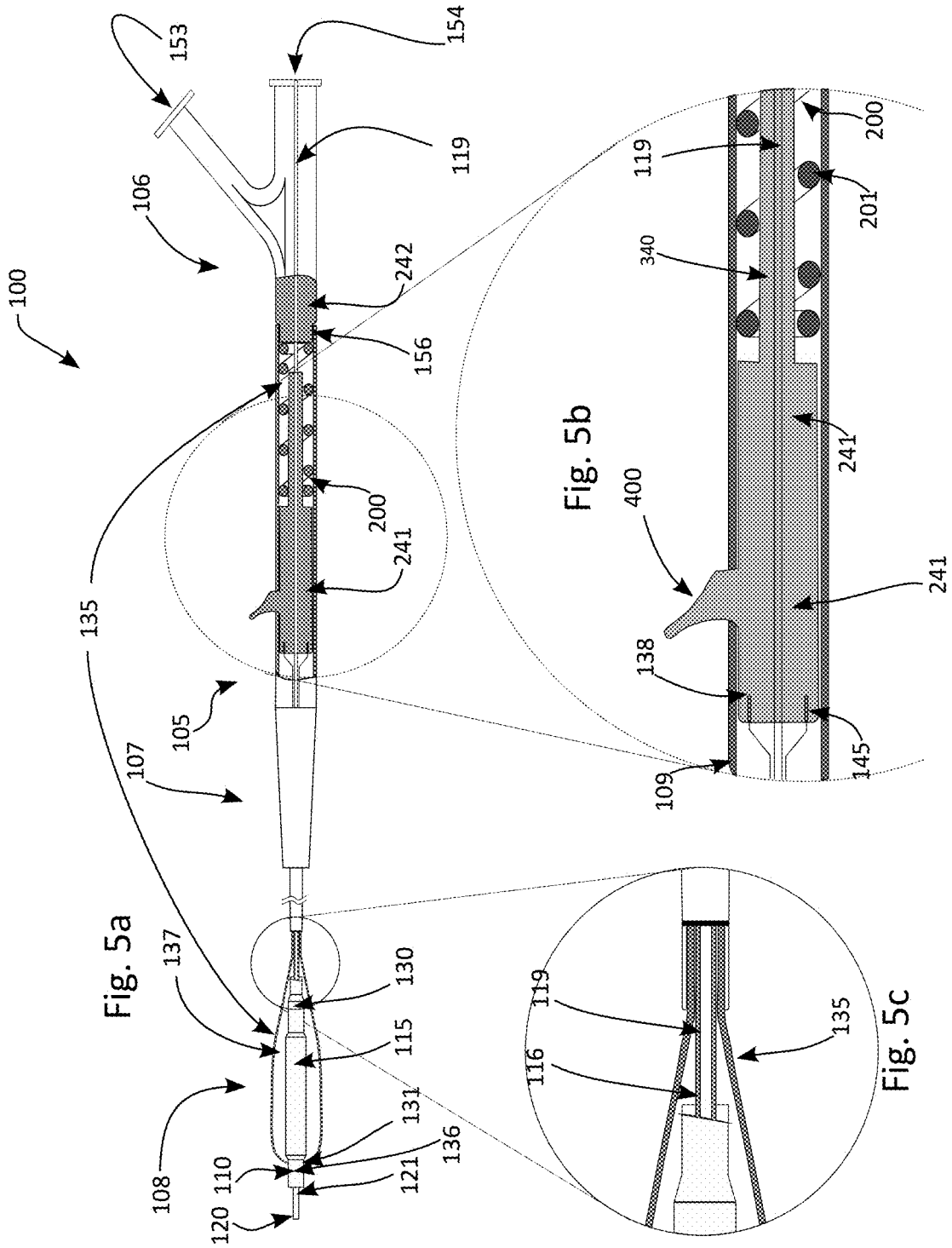


Fig. 4a

Fig. 4b

Fig. 4c


100
153
154
106
119
242
156
200
241
135
105
107
137
130
115
131
136
121
108
110
120
Fig. 5a
119
200
201
340
241
400
241
138
145
109
Fig. 5b
119
135
116
Fig. 5c

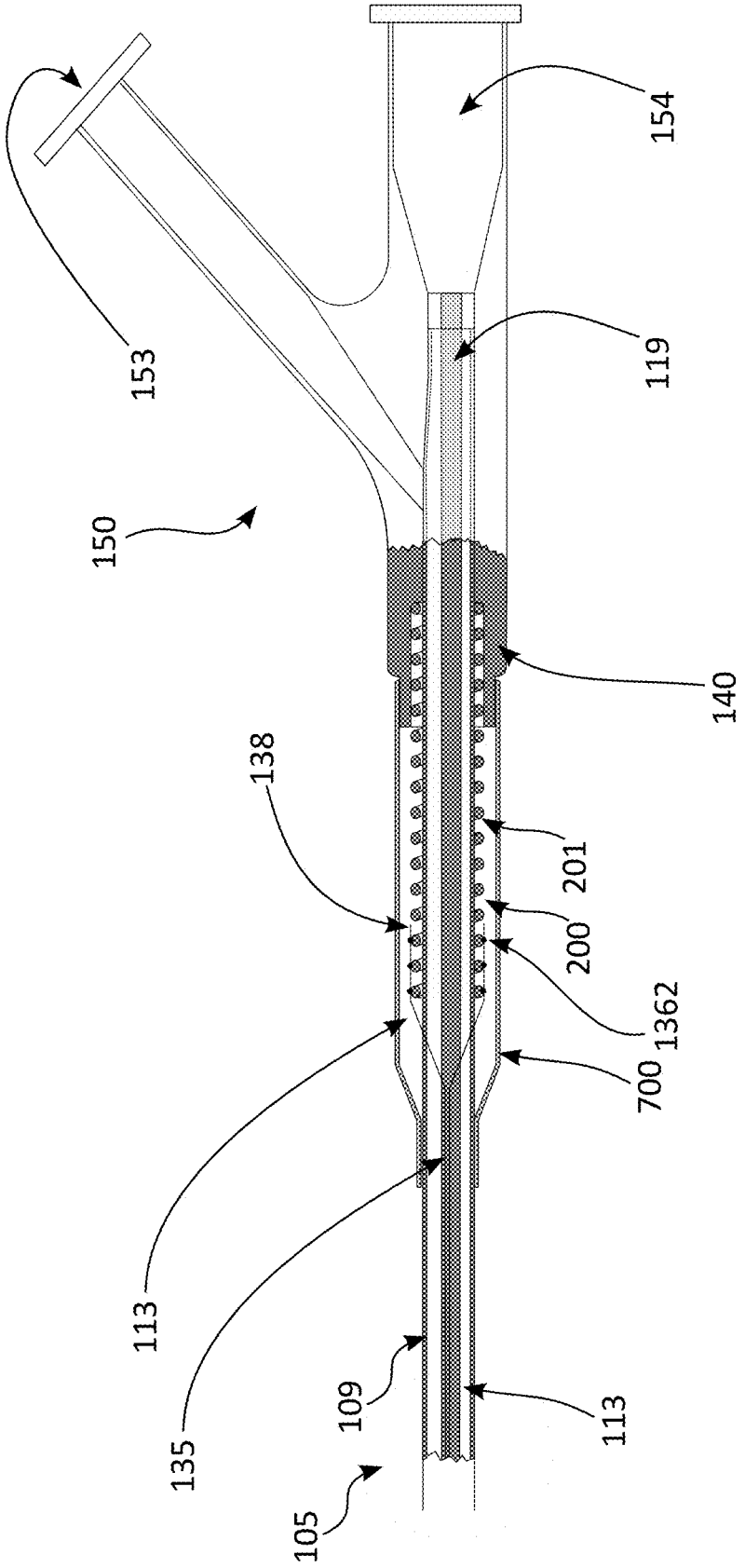


Fig. 6

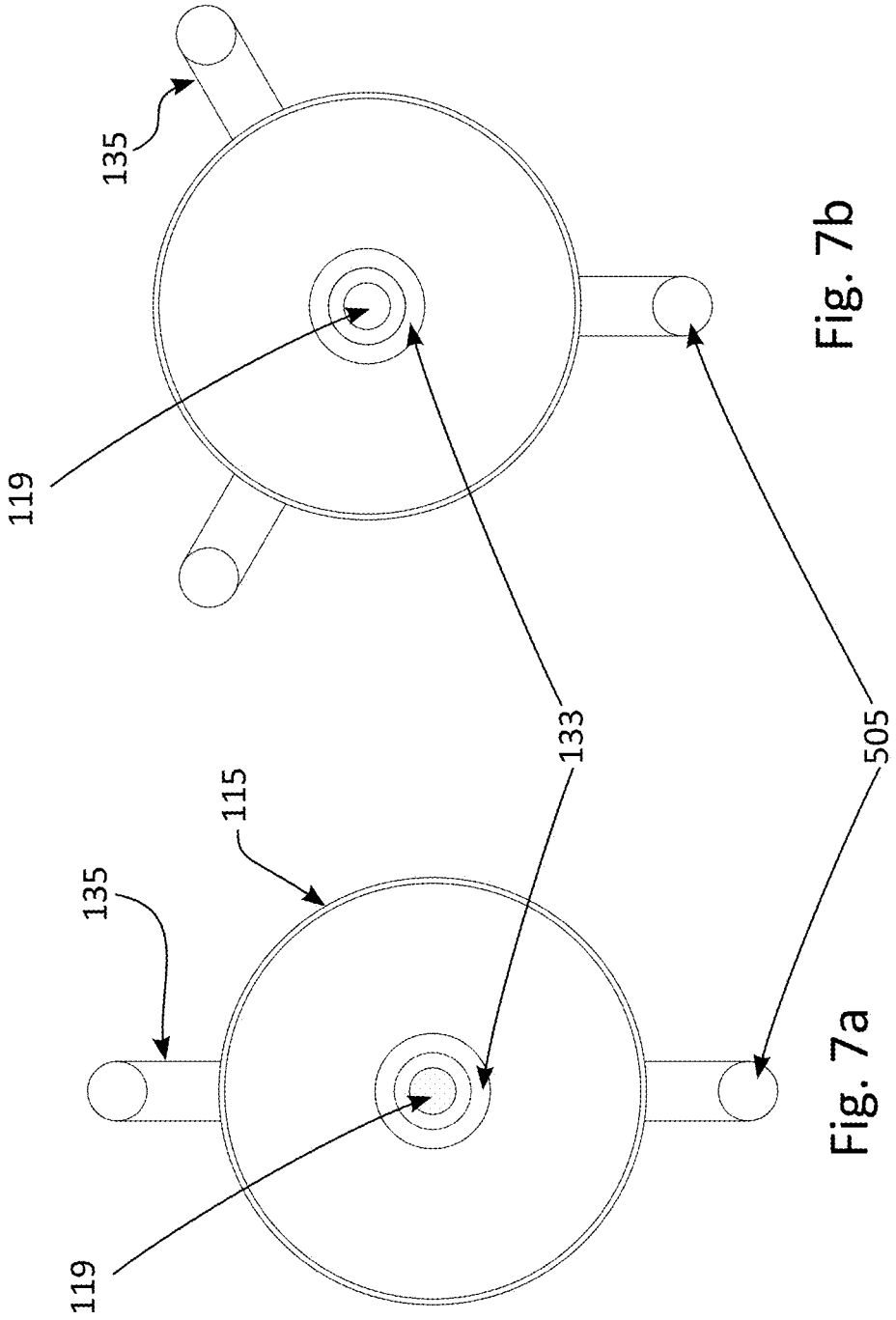


Fig. 7b

Fig. 7a

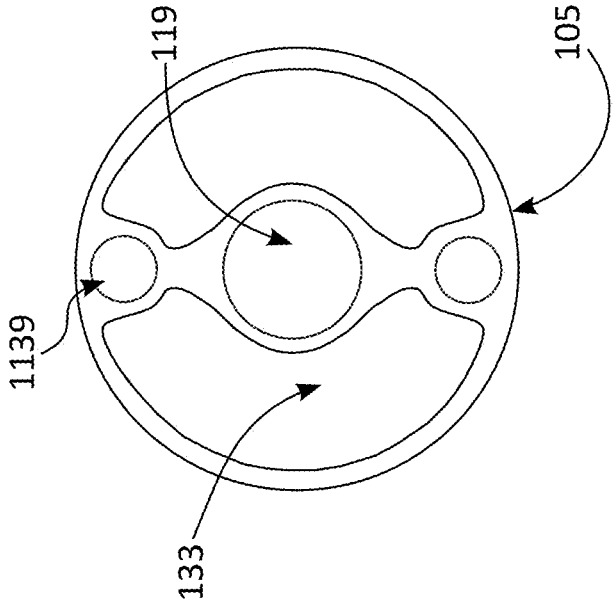


Fig. 8b

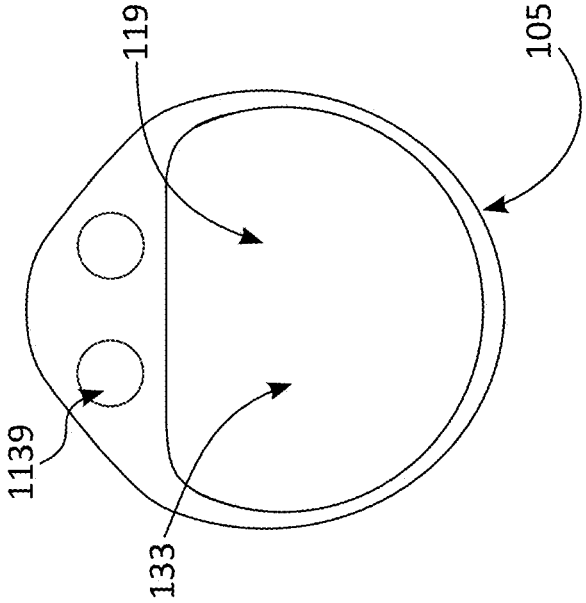


Fig. 8a

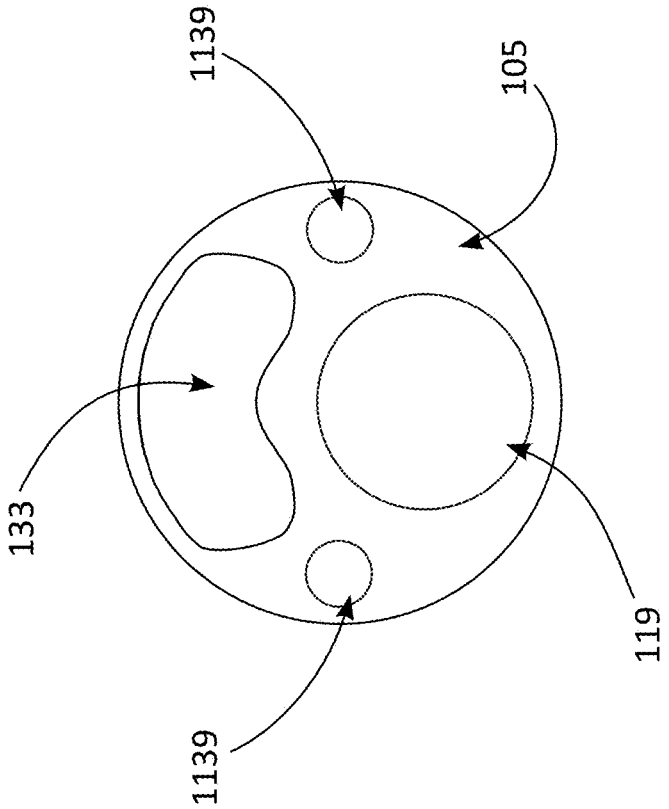


Fig. 9

SCORING BALLOON WITH TRANSLATING SCORING WIRES

This application is a continuation of U.S. application Ser. No. 15/210,603 filed on Jul. 14, 2016 which claims priority to U.S. provisional App. No. 62/249,119 filed on Oct. 30, 2015, which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Balloon dilatation catheters are used to treat lesions in vessels. However, difficulties are encountered in navigating tortuous anatomy and safely crossing very tight lesions. Moreover, some lesions are difficult to dilate using just a balloon, and require a focused force to dilate the lesion at safe inflation pressures.

U.S. Pat. No. 6,394,995 to Solar et al. describes a system used to provide enhanced force to treat a lesion. This system has a flexible advancement member with a tracking member slidable over a guidewire, and a balloon having a distal end attached to the tracking member. But this type of system provides limited focused force and lacks pushability and maneuverability.

SUMMARY OF THE INVENTION

The present invention provides a scoring balloon catheter that can be used for treating vascular lesions. In use, the balloon presses scoring wires into the lesion. The catheter includes a shaft; an inflatable balloon mounted on the shaft's distal section; a member or spring associated with the shaft, proximal to the balloon; and at least one scoring wire. In some embodiments the scoring wire has a fixed end mounted on the shaft between the shaft's distal end and the balloon. The scoring wire has a longitudinally movable end associated with the member or spring; and an intermediate portion disposed outside of the balloon.

In some embodiments the movable scoring-wire ends are the proximal ends of the wires. These ends extend into lumens in the member. In some of these embodiments, the member comprises or interacts with a longitudinally resilient member such as an elastic polymer or rubber or a spring. In some embodiments, the device further comprises a second member in which the spring sits between the member and the second member.

In some embodiments, the device comprises scoring wire lumens inside or outside of the shaft. These scoring wire lumens contain one or more scoring wires. In some embodiments, the device comprises two lumens inside of the shaft and two scoring wires inside of the lumens.

In other embodiments, the scoring balloon catheter uses a spring mounted within a hub on a handle assembly. The shaft passes through the spring and extends into the handle assembly. A hub cover sits over the shaft and over the hub. In some cases, the hub cover provides strain relieve to the hub-spring connection. The scoring wires are welded or otherwise attached to the spring.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and further advantages of the present invention may be better understood by referring to the following description in conjunction with the accompanying drawings in which:

FIG. **1***a* is a front view of an example of an invention device.

FIG. **1***b* is a magnified view of the indicated portion of FIG. **1***a*.

FIG. **1***c* is a magnified view of the indicated portion of FIG. **1***a*.

FIG. **2***a* is a front view of another example of an invention device.

FIG. **2***b* is a magnified view of the indicated portion of FIG. **2***a*.

FIG. **2***c* is a magnified view of the indicated portion of FIG. **2***a*.

FIG. **3***a* is a front view of another example of an invention device.

FIG. **3***b* is a magnified view of the indicated portion of FIG. **3***a*.

FIG. **3***c* is a magnified view of the indicated portion of FIG. **3***a*.

FIG. **4***a* is a front view of another example of an invention device.

FIG. **4***b* is a magnified view of the indicated portion of FIG. **4***a*.

FIG. **4***c* is a magnified view of the indicated portion of FIG. **4***a*.

FIG. **5***a* is a front view of another example of an invention device.

FIG. **5***b* is a magnified view of the indicated portion of FIG. **5***a*.

FIG. **5***c* is a magnified view of the indicated portion of FIG. **5***a*.

FIG. **6** is a front view of another embodiment of an invention device.

FIG. **7***a* is an end view showing the embodiment of FIG. **1** at section plane AA.

FIG. **7***b* is similar to FIG. **7***a* viewing section plane AA on a different invention embodiment.

FIG. **8***a* is an end view showing an embodiment of the device taken along a section plane similar to section plane BB.

FIG. **8***b* is similar to FIG. **8***a* viewing section plane AA on a different invention embodiment.

FIG. **9** is an end view of the device of FIG. **6**.

The drawings are not necessarily drawn proportionally or to scale. For example, the dimensions of some of the elements may be exaggerated relative to other elements for clarity or several physical components may be included in one functional block or element. Further, sometimes reference numerals may be repeated among the drawings to indicate corresponding or analogous elements. Moreover, some of the blocks depicted in the drawings may be combined into a single function.

DETAILED DESCRIPTION

In the following detailed description, numerous specific details are set forth to provide a thorough understanding of the present invention. Those of ordinary skill in the art will know that the present invention may be practiced without these specific details. In other instances, well-known methods, procedures, components, or structures may not have been described in detail so as not to obscure the present invention.

The present invention is directed to systems and methods for treatment of a vessel. The principles and operation of systems and methods of the present invention may be better understood with reference to the drawings and accompanying descriptions.

The invention is not limited in its application to the details of construction and the arrangement of the components set

forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting.

Certain features of the invention that are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention that are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable sub-combination.

Table of components.

100	scoring balloon (SCB) catheter
105	shaft
106	shaft proximal section
107	shaft middle section
108	shaft distal section
109	shaft wall
110	shaft distal end
111	shaft tapered section
112	shaft proximal end
113	shaft lumen
115	inflatable balloon (IB)
119	guidewire lumen (GWL)
120	GWL distal end
121	GWL outer surface
130	IB proximal end
131	IB distal end
132	IB outer surface
133	IB lumen
135	scoring wire (SCW)
1351	SCW distal section
1352	SCW proximal section
136	fixed SCW end
1361	SCW lumen section
1362	weld joint
137	SCW IB section
138	moveable SCW end
1139	SCW lumen
140	Hub
141	GWL passage
145	Hub lumen
150	handle assembly (HA)
153	HA IB lumen port
154	HA GW port
155	HA distal end point
156	HA stepped-down portion
200	spring
201	spring wire
241	Hub distal section
242	hub proximal section
340	narrowed region
400	fingergrip
451	extension
505	SCW cross-section
610	see IBL
700	Hub cover

Definitions

"fixed"—inseparable within the operational environment of the device.

"operational environment"—any environment in which the device would conceivably operate as an intravascular balloon catheter.

"longitudinally resilient"—the ability to repeatedly move longitudinally.

"definition of mechanically communicating"—describes the ability of one object to connect sufficiently such that its movement causes another object to move and vice versa.

"rail"—A substantially longitudinal object that supports and guides the movement of another object.

A "slidably engaged" component is a component that fits into a passageway or around a rail such that the component is largely or substantially constrained in two dimensions. Instead of the third dimension constraining the component, the component is unconstrained to some degree allowing the component to move longitudinally a substantial distance within the passageway or along the rail. If the system has stops or other components that curtail longitudinal movement, but still permit substantial longitudinal motion, the component is considered slidably engaged.

"effectively engaged"—a scoring wire is effectively engaged when it engages the lesion well enough for the treatment to substantially affect the lesion.

Invention catheters can be over-the-wire, short rapid exchange, or rapid exchange platform. If the catheter is a short rapid exchange platform, an inner member may traverse the entire length of the catheter.

Turning to the invention embodiments, FIG. **1***a* depicts an embodiment of the invention device. In this invention embodiment, a scoring balloon (SCB) catheter **100** is shown in a front view with selected sections shown in a magnified view. SCB catheter **100** comprises components as discussed below. For instance, catheter **100** comprises shaft **105**. Shaft **105** has shaft proximal section **106** connected to shaft middle section **107** and shaft middle section **107** connected to shaft distal section **108**. Shaft tapered section **111** joins shaft proximal section **106** to shaft middle section **107**. Shaft **105** also comprises shaft wall **109**, which provides a degree of rigidity to shaft **105** such that shaft **105** is suitable (as judged by those of ordinary skill in the art) for tracking into vasculature or tortuous vasculature being neither too rigid or too flexible. In some embodiments, the rigidity or flexibility is modified by adding a longitudinal member (not shown) to SCB catheter **100**. Shaft **105** comprises Pebax, in some embodiments.

In some embodiments, shaft tapered section **111** is fixed to shaft middle section **107**. In some embodiments, shaft wall **109** ends before shaft distal end **110** ends.

For purposes of this document, shaft distal end **110** is the end of shaft **105** that enters the patient first. Similarly, any other "distal"-characterized component means the component portion closer to shaft distal end **110** then is any other component portion. Likewise, any "proximal"-characterized component means the component portion further from shaft distal end **110** then is any other component portion.

SCB catheter **100** further comprises inflatable balloon (IB) **115**. Inflatable balloon **115** mounts to shaft **105** within shaft distal section **108**. In some embodiments, inflatable balloon **115** ends at shaft distal end **110**. In these or other embodiments, inflatable balloon **115** is fixed to shaft **105**.

Inflatable balloon **115** comprises IB proximal end **130** and IB distal end **131**. A typical embodiment has a flexible, polymeric film serving as inflatable balloon **115**. IB outer surface **132** ends up facing abluminally after inflatable balloon **115** mounts to shaft **105**. For this disclosure, IB proximal end **130** is the portion of inflatable balloon **115** that attaches or fixes the proximal end of inflatable balloon **115** to shaft **105**. IB proximal end **130** is defined as the proximal portion of inflatable balloon **115** that remains contacting shaft **105** after inflatable balloon **115** is inflated.

For this disclosure, IB distal end **131** is the portion of inflatable balloon **115** that distally attaches or fixes inflatable balloon **115** to shaft **105**. IB distal end **131** is defined as the distal portion of inflatable balloon **115** that remains contacting shaft **105** after inflatable balloon **115** in inflated.

IB lumen **133** fluidly communicates with inflatable balloon **115**, which allows inflatable balloon **115** to be inflated by fluid passing through IB lumen **133**.

SCB catheter **100** further comprises guidewire lumen (GWL) **119**, which longitudinally extends at least from shaft proximal end **112** to beyond shaft distal end **110**. GW lumen **119** ends at GWL distal end **120**.

In some embodiments, IB proximal end **130** and IB distal end **131** connect to GWL outer surface **121** or shaft **105** using any method known to those of ordinary skill in the art.

SCB catheter **100** further comprises scoring wire (SCW) **135**. Scoring wire **135** comprises fixed SCW end **136**, SCW IB section **137**, and movable SCW end **138**. Fixed SCW end **136** connects within shaft distal section **108** distal of IB distal end **131**. In some embodiments, fixed SCW end **136** attaches to GWL outer surface **121**. In other embodiments, fixed SCW end **136** attaches to the outer side of shaft wall **109**. Fixed SCW end **136** attaches using any method known to those of ordinary skill in the art.

This configuration provides for a focused force element (scoring wire **135**) alongside inflatable balloon **115**.

The distance between scoring wire **135** and IB outer surface **132** can be any value recognized as useful by those of ordinary skill in the art. Once past inflatable balloon **115**, scoring wire **135** dives below shaft wall **109**, extending proximally inside of shaft **105**. Movable SCW end **138** sits inside of shaft **105** within shaft proximal section **106**. In some embodiments, scoring wire **135** occupies at least part of SCW lumen **1139** (shown in FIGS. **8***a* and **8***b*).

FIG. **1***a*-FIG. **5***b* depicts SCB catheter **100** as having two scoring wires. In some embodiments, SCB catheter **100** has 1-15, 3-10, or 2-5 scoring wires. In some embodiments the diameter of SCW **135** is between 0.003 inches and 0.040 inches, or 0.005 inches and 0.015 inches, 0.008 inches and 0.012 inches. In some embodiments, SCW **135** is 0.10 inches. SCW **135** need not have a uniform diameter. In some embodiments SCW distal section **1351** has a diameter larger than SCW proximal section **1352**. In some embodiments SCW distal section **1351** has a diameter smaller than SCW proximal section **1352**. In some embodiments, SCW **135** comprises metals, metal alloys, polymers, and shape memory materials that are metal- or polymer-based.

SCB catheter **100** further comprises hub **140**. Hub **140** resides inside of shaft **105** within shaft proximal section **106**. Hub **140** comprises a GWL passage **141** for guidewire lumen **119** to pass through. Hub **140** further comprises one or more hub lumens **145** that interact with movable SCW end **138**.

In some embodiments, the interaction encompasses movable SCW end **138** connected in or to hub lumen **145**. In some embodiments, movable SCW end **138** is fixed to hub lumen **145**. In other embodiments, the interaction encompasses movable SCW end **138** being slidably engaged inside of hub lumen **145**. In some embodiments hub **140** comprises any biocompatible material such as metals, metal alloys, and polymers. In some embodiments hub **140** comprises nylon, Pebax, or any other suitable material known to those of ordinary skill in the art.

In some embodiments hub **140** is substantially fixed inside shaft proximal section **106** with movable SCW end **138** slidably engaged or disposed within hub lumen **145**. In some embodiments, hub **140** is longitudinally movable or elastic, allowing movable SCW end **138** to move longitudinally by pulling hub **140** distally, by moving hub **140** or by stretching material of hub **140**. For instance, in some embodiments, hub **140** is elastic. When movable SCW end **138** is subjected to a distally directed force that causes it to move distally and when movable SCW end **138** is fixed to or within hub lumen **145**, the movement stretches hub **140**. The restoring force or force counter to that distal stretching (counterforce) tends to move movable SCW end **138** substantially back into place when the distally directed force is removed.

In some embodiments, hub **140** is biased by a spring **200**. In some embodiments, spring **200** mounts distal to hub **140** and in some embodiments, spring **200** mounts proximal to hub **140**.

SCW catheter **100** further comprises handle assembly **150**. Handle assembly **150** associates with shaft proximal end **109**. Handle assembly **150** comprises HA port sub-assembly and HA transition sub-assembly. HA port sub-assembly occupies at least part of the proximal end of handle assembly **150**. And HA transition sub-assembly occupies at least part of the distal end of handle assembly **150**. HA port sub-assembly relates to HA transition sub-assembly. In some embodiments, HA port sub-assembly connects to or is fixed to HA transition sub-assembly. In some embodiments, HA port sub-assembly and HA transition sub-assembly together form a monolithic object or a number of objects or monolithic objects split by a plane containing SCW catheter **100**'s longitudinal axis.

HA transition sub-assembly comprises HA stepped-down portion **156** located at the distal end of HA transition sub-assembly. In some embodiments the distal end of HA transition sub-assembly and the distal end of handle assembly **150** are the same object.

HA stepped-down portion **156** is a portion of HA transition sub-assembly in which the overall outside dimension has a step transition decreasing to a smaller diameter, sized to engage shaft proximal end **112**.

In some embodiments, transition subassembly **152** does not have HA stepped-down portion **156**.

Shaft **105** relates to handle assembly **150** through shaft proximal end **112** and HA stepped-down portion **156**. In some embodiments, shaft **105** connects to handle assembly **150**. For example, shaft proximal end **112** can slide over HA stepped-down portion **156** and the components can be fixed such as by welding, fusing, gluing, etc. Or the friction fit between shaft proximal end **112** and HA transition sub-assembly can be strong enough to fix the components together. In some embodiments lacking HA stepped-down portion **156**, shaft proximal end **112** can connect to handle assembly **150** through a butt joint between shaft proximal end **112** and HA transition subassembly **152**.

HA port sub-assembly comprises HA GW port **154**, which occupies the proximal end of HA port sub-assembly. In some versions of handle assembly **150**, HA GW port **154** points away or directly away from shaft distal end **110**. HA GW port **154** allows access from outside of SCB catheter **100** into guidewire lumen **119**. In some versions of handle assembly **150**, HA port subassembly also comprises HA IB lumen port **153**, which angles out from the longitudinal axis of SCB catheter **100** at any of a variety of angles recognized as useful to those of ordinary skill in the art. In some versions, HA IB lumen port **153** flows into the guidewire-port-guidewire-lumen region and in other embodiments flows to a separate lumen inside or outside (not shown) of guidewire lumen **119**. HA IB lumen port **153** also allows access from outside of SCB catheter **100** into a passageway (guidewire lumen **119** or IB lumen **133** (IBL)) that carries gas or inflation fluid into inflatable balloon **115** to inflate it or carries gas or inflation fluid out of inflatable balloon **115** to deflate it.

Operationally, in the devices taught by the FIG. **1***a* embodiment, for treatment of calcified lesions, for example, a physician cuts through the patient's tissue until an appropriately sized vessel is revealed. The vessel must lead to the lesion site following a path that SCB catheter **100** can follow. In some embodiments, the location of the lesion site causes those of ordinary skill in the art to select a more or less flexible shaft **105** or SCB catheter **100**.

The physician opens the vessel, inserts a guidewire into the vessel, and advances the guidewire through the patient's vasculature under ultrasound, magnetic resonance, fluoroscopic, or some other type of guidance. Once the physician places the guidewire at a satisfactory site, the physician threads the proximal end of the guidewire into GWL distal end **120**, through guidewire lumen **119**, and ultimately out of SCB catheter **100**—through HA GW port **154**. With the guidewire in place and installed in SCB catheter **100**, the physician maneuvers SCB catheter **100** along the guidewire until inflatable balloon **115** reaches the desired position near the lesion site. Typically, this position will allow at least one scoring wire **135** to effectively engage the lesion. After that, the physician inflates inflatable balloon **115** until scoring wire **135** firmly presses into or cracks the lesion. Once lesion treatment with SCB catheter **100** is complete, the physician deflates inflatable balloon **115**, which allows scoring wire **135** to relax away from the lesion and from the vessel wall.

Scoring wire **135** contacts the lesion as long as inflatable balloon **115** remains inflated. The inflation time corresponds to the time the physician chooses for scoring wire **135** to contact the lesion. Those of ordinary skill in the art use inflation times of 5 seconds to 5 minutes. Those of ordinary skill in the art look to the nature of the lesion in determining the appropriate inflation time and inflation speed.

An aspect of this invention includes the behavior of scoring wire **135** during balloon inflation and specifically includes the behavior of movable SCW end **138**.

As inflatable balloon **115** inflates, scoring wire (or wires) **135** expands outwardly, placing scoring wire **135** under longitudinal tension. A component of the force vector caused by that longitudinal tension points proximally from fixed SCW end **136** and distally from movable SCW end **138**. But fixed SCW end **136** is fixed to shaft **105** or GWL outer surface **121**. Therefore, any movement of scoring wire **135** occurs at movable SCW end **138**. Hub **140** constrains the movement of movable SCW end **138** allowing it to move longitudinally. This movement decreases the strain on inflatable balloon **115** helping to maintain its engineered shape and helping to avoid any kinking in the balloon's net, which was sometimes seen in prior art devices having scoring wires substantially fixed at both ends.

When the physician deflates the balloon, the forces previously causing scoring wire **135** to expand disappear, allowing scoring wire **135** (and movable SCW end **138**) to relax. Hub **140** constrains the relaxation of movable SCW end **138**. Specifically, hub **140** guides movable SCW end **138** into an arrangement similar to the initial arrangement of movable SCW end **138** before balloon inflation. Hub **140**'s action helps regularize the inflation and deflation steps increasing their predictability.

Returning to FIG. **1***a*, FIG. **1***a* depicts the catheter as described above. The specific shaft **105** can be made by a variety of methods as known to those of ordinary skill in the art. The embodiment shown in FIG. **1***a* comprises shaft **105** coupled (attached, connected, joined) to handle assembly **150** through HA distal end portion **155** and HA stepped-down portion **156**. HA stepped-down portion **156** occupies shaft lumen **113** and substantially seals shaft proximal end **112** from the atmosphere. In some embodiments, shaft proximal end **112** and HA distal end portion **155** are glued together with an adhesive. In other embodiments, an adhesive is not used. Those of ordinary skill in the art know of other joining methods. These are considered to be within the scope of the current invention.

In FIG. **1***a*, HA stepped-down portion **156** sits midway along HA distal end portion **155**'s length. Moreover, in this embodiment HA distal end portion **155** also serves as hub **140**. The reference numbers refer to the same component because the component serves both as HA distal end **155** and as hub **140**.

FIG. **1***b* is magnified view of shaft proximal section **106**. Shaft **105** ends at shaft proximal end **112** and receives hub **140**, which is either part of HA distal end **155** or not. Hub **140** can have one or more hub lumens **145**—FIG. **1***b* shows two hub lumens **145**. These hub lumens **145** extend into hub **140** longitudinally in this embodiment. But SCB catheter **100** does not need lengthwise hub lumens **145** to function correctly. Hub lumens **145** need only function to slidably and reversibly receive movable SCW end **138**. FIG. **1***b* shows hub lumens **145** extending into hub **140** approximately three quarters of hub **140**'s length, but this is not critical. In some embodiments, hub lumens **145** extend completely through hub **140**. Hub lumens **145** extend into hub **140** as far as or further than movable SCW end **138** extends into hub lumen **145**. FIG. **1***b* also shows scoring wire **135** and movable SCW end **138**. In this embodiment, scoring wire **135** tapers or flares outwardly after proximally exiting SCW lumen **1139**. Movable SCW end **138** occupies a portion of hub lumen **145**. In this embodiment, SCB catheter **100** comprises one hub lumen **145** per movable SCW end **138**. But other embodiments exist in which a hub lumen can interact with more than one movable SCW end **138**.

Finally, FIG. **1***b* shows guidewire lumen **119** passing through hub **140** and continuing into shaft **105**. FIG. **1***c* depicts a magnified view of the region where scoring wire **135** distally exits SCW lumen **1139**.

Scoring wire **135** has a path through part of SCB catheter **100**. SCW lumen **1139** is a lumen that receives scoring wire **135** along some or all of shaft middle section **107**. We refer to the portion of scoring wire **135** within SCW lumen **1139** as SCW lumen section **1361**. And we refer to the section of scoring wire **135** near inflatable balloon **115** as SCW IB section **137**.

For discussion purposes, we begin the path at movable SCW end **138**. Movable SCW end **138** resides within hub lumen **145**. As we move distally along scoring wire **135**, we come to the proximal end of SCW lumen **1139**, which scoring wire **135** occupies. In some embodiments, scoring wire **135** tapers inwardly proximally of SCW lumen **1139**. Scoring wire **135** distally exits SCW lumen **1139** at the lumen's distal end. We refer to the section of scoring wire **135** that begins at this exit as SCW IB section **137**. After exiting, scoring wire **135** flares outward as it progresses distally, extending in a substantially longitudinal direction until the wire is past IB distal end **131**. At that point scoring wire **135** turns inwardly until it reaches shaft distal section **108** or GWL outer surface **121**. Fixed SCW end **136** attaches to SCB catheter **100** distally of inflatable balloon **115** or at or near the point where IB distal end **131** attaches to SCB catheter **100**. The portion of scoring wire **135** within SCW IB section **137** has a longitudinal region along inflatable balloon **115**. The distance this longitudinal section extends from SCB catheter **100**'s central axis (wire distance) can have a variety of values. The distance that IB outer surface

132 extends from the central axis when inflatable balloon 115 inflates is the balloon inflation distance. Typically, (wired distance)/(balloon inflation distance) is within the following ranges 0.99-1.01; 0.90-1.1; 0.8-1.2; and 0.5-1.5.

In the operation of the group of embodiments represented by the device in FIG. 1*a*, a physician places inflatable balloon 115 as described above. The physician inflates inflatable balloon 115 through HA IB lumen port 153. Balloon inflation first applies outward pressure on scoring wires 135 and then onto the lesion. Without wishing to be bound by any particular theory of operation, we believe that because movable SCW end 138 is moveably connected, scoring wire 135 does not contribute to balloon or balloon deformation caused by inflation or overinflation. Since the wire can move outwardly, it does not significantly cage the balloon. The caging effect will prevent the balloon from expanding past the wires. But if inflation continues, some other portion of the balloon will deform from the pressure exerted by the inflation fluid. In some cases balloon deformation leads to problems with later deflating the balloon. Instead, the outwardly directed inflation pressure on scoring wire 135 causes movable SCW end 138 to move distally, which lowers the counterforce that scoring wire 135 exerts against inflatable balloon 115. As movable SCW end 138 moves distally, it recedes from hub lumen 145. In some embodiments, inflation pressure causes movable SCW end 138 to pull out of hub lumen 145. In other embodiments, movable SCW end 138 remains inside of hub lumen 145.

The physician maintains pressure in inflatable balloon 115 long enough for scoring wire 135 to have the effect the physician desires. Afterward, the physician releases pressure, inflatable balloon 115 deflates, and movable SCW end 138 re-extends into hub lumen 145.

FIGS. 2*a* through 2*c* depict different embodiments of SCB catheter 100. These embodiments are similar to those shown in FIGS. 1*a* through 1*c*. The main difference between the sets of embodiments lies in the hub and the proximal scoring wire geometry.

FIG. 2*b* depicts a hub 140 that has hub distal section 241 and hub proximal section 242. Hub proximal section 242 through HA stepped-down portion 156 serves to connect shaft 105 with handle assembly 150. Additionally, hub proximal section 242 serves as a stop for spring 200. Spring 200 comprises spring wire 201—the figure depicts spring wire 201 in cross-section. Spring 200 adds resilience to the mechanism of scoring wire 135.

Hub distal section 241 lies next to the distal end of spring 200. Hub distal section 241 connects (attaches) to movable SCW end 138. In some embodiments, hub distal section 241 is fixed to movable SCW end 138. In other embodiments, hub distal section 241 comprises hub lumens 145, which in some cases are fixed to movable SCW end 138. Movable SCW end 138 flares outwardly as it reaches hub distal section 241. In this embodiment, on the other hand, the embodiment shown in FIG. 3*a* through 3*c* comprise movable SCW ends 138 that do not flare as it reaches hub distal section 241.

In the operation of the group of embodiments represented by the devices disclosed in FIGS. 1*a*-6, a physician places inflatable balloon 115 as described above. The physician inflates inflatable balloon 115 through HA IB lumen port 153, which first applies outer pressure on scoring wires 135 and then on the lesion. The difference in operation between the above embodiments and the group of embodiments represented by FIGS. 1*a*-3*c* is in the mechanism that that allows movement by movable SCW end 138. As in the above embodiments, in these embodiments, as inflatable balloon 115 inflates, the counterforce that scoring wire 135 would otherwise apply, is moderated by movable SCW end 138. In this group, movable SCW end 138 recedes distally as before, but hub distal section 241 also moves distally. The arrangement of hub distal section 241, spring 200, and hub proximal section 242 imparts force, through hub distal section 241, to movable SCW end 138. This force tends to proximally bias movable SCW end 138. And when the physician deflates the balloon as before, movable SCW end 138 moves proximally, substantially back to its initial position, aided by the force of spring 200.

FIGS. 4*a*-4*b* depict another embodiment of SCB catheter 100. The device of this embodiment is substantially similar to the embodiments described above. The main difference is that this version of hub distal section 241, although similar to hub distal sections described above, has narrowed region 340 that extends proximally from hub distal section 241. Narrowed region 340 sits inside of spring 200.

Similarly, FIG. 5*a* has narrowed region 340 and additionally has extension 451 sitting between hub distal section 241 and narrowed region 340. Finger grip 400 sits on extension 451, extending through the side of shaft proximal section 106. Finger grip 400 provides the physician some control of distal hub 450, which enables more direct control of movable SCW end 138 in these types of embodiments.

FIG. 6 discloses an embodiment of the proximal section of the device. In this embodiment a spring 200 sits within the distal end of HA 150 and extends distally from HA 150. Hub 140 connects to HA 150 and forms a monolithic structure with HA 150. Spring 200 receives shaft proximal section 106. Movable SCW end 138 exits scoring wire lumen 1139 near the distal end of shaft proximal section 106. Movable SCW end 138 connects directly to spring 200 through any suitable method, such as soldering, welding, overmolding, gluing, or press fitting using plastic tubing. In some embodiments, movable SCW end 138 connects directly to spring 200 through a weld joint 1362. In this or other embodiments, hub cover 700 sits over hub 140 and shaft 105. In some cases, hub cover 700 provides strain relieve for the connection between HA 150 and shaft 105.

The spring 200 provides longitudinal movement and a biasing force to movable SCW end 138. When movable SCW end 138 experiences a distally directed force that moves it distally, the movement holds that away from HA 150. The restoring force or force counter to that distal stretching (counterforce) tends to move movable SCW end 138 substantially back into place once the distally directed force disappears.

FIG. 7*a* depicts section AA of FIG. 1*a*. It shows two scoring wires 135, inflatable balloon 115, IB lumen 133, and guidewire lumen 119. As can be seen, section plane AA cuts through SCB catheter 100 at shaft distal section 108. The plane also cuts inflatable balloon 115; cuts scoring wire 135 at SCW IB section 137 showing SCW cross-section 505; and cuts guidewire lumen 119. FIG. 7*b* depicts a similar embodiment, but with three scoring wires 135.

FIG. 8*a* depicts section BB of FIG. 1*a*. It shows two SCW lumens 1139 sitting side-by-side. It also shows IB lumen 133 and GW lumen 119. SCW lumen 1139 need not adopt a side-by-side configuration, as shown in this figure, but can adopt a configuration distributed around the perimeter of shaft 105.

FIG. 8*b* shows a different embodiment similar to FIG. 1*a* in cross-section. Shaft proximal section 106 is cut proximally of shaft tapered section 111. Shaft tapered section 111 tapers from shaft proximal section 106 to shaft middle section 107. Shaft 105 has shaft wall 109. For example, FIG.

8*b* depicts two SCW lumens **1139** distributed across from each other in shaft **105**. This distribution need not be symmetric. Also in this figure, guidewire lumen **119** lies within shaft **105**, and it shows SCW lumen **1139** extending longitudinally inside of shaft **105**. In some embodiments, SCW lumens sit outside of the guidewire lumen.

FIG. **9** shows the embodiment of FIG. **6** in cross-section. In this figure, guidewire lumen **119** lies within shaft **105**. In some embodiments, shaft **105** is an extrusion providing guidewire lumen **119**, two SCW lumen **1139**, and one lumen **133**.

In any of the embodiments set out above, inflatable balloon **115** can have any of a variety of diameters ranging from 1.25-40 mm or 2.0-8.0 mm. In any of the embodiments set out above, inflatable balloon **115** can have any of a variety of lengths such as 10-300 mm or 20-300 mm. Long balloons may be particularly useful for treating peripheral lesions, which often have long diseased portions.

In all of the systems described above, a coating such as a hydrophobic or hydrophilic coating may be added externally to provide ease of insertion.

Suitable drugs or therapeutic agents include the following substances.

Antimicrobial agents may be selected, for example, from triclosan from triclosan, chlorhexidine, nitrofurazone, benzalkonium chlorides, silver salts and antibiotics such as rifampin, gentamycin and minocyclin and combinations thereof, among others.

In certain embodiments, antimicrobial agents may include triclosan, chlorhexidine and salts or combinations thereof. Anti-inflammatory agents include steroidal and non-steroidal anti-inflammatory agents. Examples of nonsteroidal anti-inflammatory drugs include aminoarylcarboxylic acid derivatives such as enfenamic acid, etofenamate, flufenamic acid, isonixin, meclofenamic acid, mefanamic acid, niflumic acid, talniflumate, terofenamate and tolfenamic acid; arylacetic acid derivatives such as acemetacin, alclofenac, amfenac, bufexamac, cinmetacin, clopirac, diclofenac sodium, etodolac, felbinac, fenclofenac, fenclorac, fenclozic acid, fentiazac, glucametacin, ibufenac, indomethacin, isofezolac, isoxepac, lonazolac, metiazinic acid, oxametacine, proglumetacin, sulindac, tiaramide, tolmetin and zomepirac; arylbutyric acid derivatives such as bumadizon, butibufen, fenbufen and xenbucin; arylcarboxylic acids such as clidanac, ketorolac and tinoridine; arylpropionic acid derivatives such as alminoprofen, benoxaprofen, bucloxic acid, carprofen, fenoprofen, flunoxaprofen, flurbiprofen, ibuprofen, ibuproxam, indoprofen, ketoprofen, loxoprofen, miroprofen, naproxen, oxaprozin, piketoprofen, pirprofen, pranoprofen, protizinic acid, suprofen and tiaprofenic acid; pyrazoles such as difenamizole and epirizole; pyrazolones such as apazone, benzpiperylon, feprazone, mofebutazone, morazone, oxyphenbutazone, phenybutazone, pipebuzone, propyphenazone, ramifenazone, suxibuzone and thiazolinobutazone; salicylic acid and its derivatives such as acetaminosalol, aspirin, benorylate, bromosaligenin, calcium acetylsalicylate, diflunisal, etersalate, fendosal, gentisic acid, glycol salicylate, imidazole salicylate, lysine acetylsalicylate, mesalamine, morpholine salicylate, 1-naphthyl salicylate, olsalazine, parsalmide, phenyl acetylsalicylate, phenyl salicylate, salacetamide, salicylamine a-acetic acid, salicylsulfuric acid, salsalate and sulfasalazine; thiazinecarboxamides such as droxicam, isoxicam, piroxicam and tenoxicam; others such as Eacetamidocaproic acid, s-adenosylmethionine, 3-amino-4-hydroxybutyric acid, amixetrine, bendazac, benzydamine, bucolome, difenpiramide, ditazol, emorfazone, guaiazulene, nabumetone, nimesulide, orgotein, oxaceprol, paranyline, perisoxal, pifoxime, proquazone, proxazole and tenidap; and pharmaceutically acceptable salts thereof.

Examples of steroidal anti-inflammatory agents (glucocorticoids) include 21-acetoxyprefnenolone, alclometasone, algestone, amicinonide, beclomethasone, betamethasone, budesonide, chloroprednisone, clobetasol, clobetasone, clocortolone, cloprednol, corticosterone, cortisone, cortivazol, deflazacort, desonide, desoximetasone, dexamethasone, diflorasone, diflucortolone, difluprednate, enoxolone, fluazacort, flucloronide, flumehtasone, flunisolide, fluocinolone acetonide, fluocinonide, fluocortin butyl, fluocortolone, fluorometholone, fluperolone acetate, fluprednidene acetate, fluprednisolone, flurandrenolide, fluticasone propionate, formocortal, halcinonide, halobetasol priopionate, halometasone, halopredone acetate, hydrocortamate, hydrocortisone, loteprednol etabonate, mazipredone, medrysone, meprednisone, methyolprednisolone, mometasone furoate, paramethasone, prednicarbate, prednisolone, prednisolone 25-diethylaminoacetate, prednisone sodium phosphate, prednisone, prednival, prednylidene, rimexolone, tixocortal, triamcinolone, triamcinolone acetonide, triamcinolone benetonide, triamcinolone hexacetonide, and pharmaceutically acceptable salts thereof.

Analgesic agents include narcotic and non-narcotic analgesics. Narcotic analgesic agents include alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, codeine methyl bromide, codeine phosphate, codeine sulfate, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydrocodeinone enol acetate, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine, ethoheptazine, ethylmethlythiambutene, ethylmorphine, etonitazene, fentanyl, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levorphanol, lofentanil, meperidine, meptazinol, metazocine, methadone hydrochloride, metopon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, normorphine, norpipanone, opium, oxycodone, oxymorphone, papaveretum, pentazocine, phenadoxone, phenazocine, pheoperidine, piminodine, piritramide, proheptazine, promedol, properidine, propiram, propoxyphene, rumifentanil, sufentanil, tilidine, and pharmaceutically acceptable salts thereof. Non-narcotic analgesics include aceclofenac, acetaminophen, acetaminosalol, acetanilide, acetylsalicylsalicylic acid, alclofenac, alminoprofen, aloxiprin, aluminum bis(acetylsalicylate), aminochlorthenoxazin, 2-amino-4-picoline, aminopropylon, aminopyrine, ammonium salicylate, amtolmetin guacil, antipyrine, antipyrine salicylate, antrafenine, apazone, aspirin, benorylate, benoxaprofen, benzpiperylon, benzydamine, bermoprofen, brofenac, p-bromoacetanilide, 5-bromosalicylic acid acetate, bucetin, bufexamac, bumadizon, butacetin, calcium acetylsalicylate, carbamazepine, carbiphene, carsalam, chloralantipyrine, chlorthenoxazin(e), choline salicylate, cinchophen, ciramadol, clometacin, cropropamide, crotethamide, dexoxadrol, difenamizole, diflunisal, dihydroxyaluminum acetylsalicylate, dipyrocetyl, dipyrone, emorfazone, enfenamic acid, epirizole, etersalate, ethenzamide, ethoxazene, etodolac, felbinac, fenoprofen, floctafenine, flufenamic acid, fluoresone, flupirtine, fluproquazone, flurbiprofen, fosfosal, gentisic acid, glafenine, ibufenac, imidazole salicylate, indomethacin, indoprofen, isofezolac, isoladol, isonixin, ketoprofen, ketorolac, plactophenetide, lefetamine, loxoprofen, lysine acetylsalicylate, magnesium acetylsalicylate, methotrimeprazine, metofoline, miropro-

fen, morazone, morpholine salicylate, naproxen, nefopam, nifenazone, 5' nitro-2' propoxyacetanilide, parsalmide, perisoxal, phenacetin, phenazopyridine hydrochloride, phenocoll, phenopyrazone, phenyl acetylsalicylate, phenyl salicylate, phenyramidol, pipebuzone, piperylone, prodilidine, propacetamol, propyphenazone, proxazole, quinine salicylate, ramifenazone, rimazolium metilsulfate, salacetamide, salicin, salicylamide, salicylamide a-acetic acid, salicylsulfuric acid, salsalte, salverine, simetride, sodium salicylate, sulfamipyrine, suprofen, talniflumate, tenoxicam, terofenamate, tetradrine, tinoridine, tolfenamic acid, tolpronine, tramadol, viminol, xenbucin, zomepirac, and pharmaceutically acceptable salts thereof.

Local anesthetic agents include amucaine, amolanone, amylocaine hydrochloride, benoxinate, benzocaine, betoxycaine, biphenamine, bupivacaine, butacaine, butaben, butanilicaine, butethamine, butoxycaine, carticaine, chloroprocaine hydrochloride, cocaethylene, cocaine, cyclomethycaine, dibucaine hydrochloride, dimethisoquin, dimethocaine, diperadon hydrochloride, dyclonine, ecgonidine, ecgonine, ethyl chloride, betaeucaine, euprocin, fenalcomine, fomocaine, hexylcaine hydrochloride, hydroxytetracaine, isobutyl p-aminobenzoate, leucinocaine mesylate, levoxadrol, lidocaine, mepivacaine, meprylcaine, metabutoxycaine, methyl chloride, myrtecaine, naepaine, octacaine, orthocaine, oxethazaine, parethoxycaine, phenacaine hydrochloride, phenol, piperocaine, piridocaine, polidocanol, pramoxine, prilocaine, procaine, propanocaine, proparacaine, propipocaine, propoxycaine hydrochloride, pseudococaine, pyrrocaine, ropavacaine, salicyl alcohol, tetracaine hydrochloride, tolycaine, trimecaine, zolamine, and pharmaceutically acceptable salts thereof.

Antispasmodic agents include alibendol, ambucetamide, aminopromazine, apoatropine, bevonium methyl sulfate, bietamiverine, butaverine, butropium bromide, nbutylscopolammonium bromide, caroverine, cimetropium bromide, cinnamedrine, clebopride, coniine hydrobromide, coniine hydrochloride, cyclonium iodide, difemerine, diisopromine, dioxaphetyl butyrate, diponium bromide, drofenine, emepronium bromide, ethaverine, feclemine, fenalamide, fenoverine, fenpiprane, fenpiverinium bromide, fentonium bromide, flavoxate, flopropione, gluconic acid, guaiactamine, hydramitrazine, hymecromone, leiopyrrole, mebeverine, moxaverine, nafiverine, octamylamine, octaverine, oxybutynin chloride, pentapiperide, phenamacide hydrochloride, phloroglucinol, pinaverium bromide, piperilate, pipoxolan hydrochloride, pramiverin, prifinium bromide, properidine, propivane, propyromazine, prozapine, racefemine, rociverine, spasmolytol, stilonium iodide, sultroponium, tiemonium iodide, tiquizium bromide, tiropramide, trepibutone, tricromyl, trifolium, trimebutine, n,n-1 trimethyl-3,3-diphenyl-propylamine, tropenzile, trospium chloride, xenytropium bromide, and pharmaceutically acceptable salts thereof.

In certain embodiments, therapeutic agents for reducing pain or discomfort may be selected from ketorolac and pharmaceutically acceptable salts thereof (e.g., the tromethamine salt thereof, sold under the commercial name Torado®), 4-diethylamino-2-butynylphenylcyclohexylglycolate and pharmaceutically acceptable salts thereof (e.g., 4-diethylamino-2-butynylphenylcyclohexylglycolate hydrochloride, also known as oxybutynin chloride, sold under the commercial name Ditropang®), and combinations thereof. The amount of therapeutic agent present, will depend, for example, upon the efficacy of the therapeutic agent employed, the release rate, and so forth. One skilled in the art can readily determine an appropriate therapeutic agent loading to achieve the desired outcome.

In some embodiments, the surface of IB **115** is embossed with any of a variety of patterns. For example, in some embodiments the surface of IB **115** is embossed with a checkered pattern. Additionally, in some embodiments, inflatable balloon **115** tapers along its longitudinal direction.

In some embodiments, scoring wire **135** sits within SCW lumen **1139**. And in some embodiments, SCW lumen **1139** sits outside of shaft **105**.

Although the invention has been described in conjunction with specific embodiments, many alternatives, modifications, and variations will be apparent to those skilled in the art. Accordingly, it embraces all such alternatives, modifications, and variations that fall within the appended claims' spirit and scope. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

The invention claimed is:

1. A scoring balloon catheter comprising: a shaft; an inflatable balloon mounted at a distal region of the shaft;

a handle mounted at a proximal region of the shaft;

a hub including a spring, said hub mounted at the distal end of the handle with said spring coaxial with the shaft;

at least one scoring wire having: a fixed distal end mounted on the shaft between a distal end of the shaft and the inflatable balloon;

intermediate portions longitudinally tracing the outside of the balloon; and a proximal end welded to the spring; and

a hub cover circumferentially surrounding at least a portion of the hub and the spring, said hub cover connected at a distal end to the shaft and at a proximal end to the handle.

2. The catheter of claim **1**, wherein the proximal end of the scoring wire is welded to a distal portion of the spring such that the spring exerts a proximal force on the scoring wire.

3. The catheter of claim **1**, wherein the hub at least partially surrounds the shaft.

4. The catheter of claim **1**, wherein the hub at least partially surrounds the spring.

5. The catheter of claim **1**, wherein the spring is biased against the hub.

6. The catheter of claim **1**, wherein the hub connects to the handle and forms a monolithic structure.

7. The catheter of claim **1**, wherein the spring at least partially surrounds the shaft.

8. The catheter of claim **1**, further including an inflation lumen at least partially inside the shaft, the inflation lumen including a distal end inside the balloon.

9. The catheter of claim **1**, further including a guidewire lumen at least partially inside the shaft.

10. The catheter of claim **9**, wherein the handle includes a guidewire port connecting to a proximal end of the guidewire lumen.

11. The catheter of claim **8**, wherein the handle includes a balloon inflation port connected to a proximal end of the inflation lumen.

12. A scoring balloon catheter comprising:

a shaft;

an inflatable balloon mounted at a distal region of the shaft;

a hub mounted at a proximal region of the shaft;

a spring mounted to the hub with said spring coaxial with the shaft;

at least one scoring wire having: a fixed distal end mounted on the shaft between a distal end of the shaft and the inflatable balloon;

intermediate portions longitudinally tracing the outside of the balloon; and

a proximal end welded to the spring; and

a hub cover circumferentially surrounding at least a portion of the hub and the spring, said hub cover connected at a distal end to the shaft and at a proximal end to the hub.

13. The catheter of claim **12**, wherein the spring is mounted at least partially within a recess in the hub.

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