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(54) **DIFFERENTIALLY COATED STENT**

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(57) **ABSTRACT**

The present invention provides a stent that is differentially coated to accommodate areas of high strain. A therapeutic coating is applied to only those areas of the stent that do not experience high strain. This allows a therapeutic coating to be chosen for its elution characteristics, for example, rather than for its ability to withstand high strain. An elastic coating may be applied to the areas of high strain. The elastic coating may or may not include a therapeutic agent.

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200

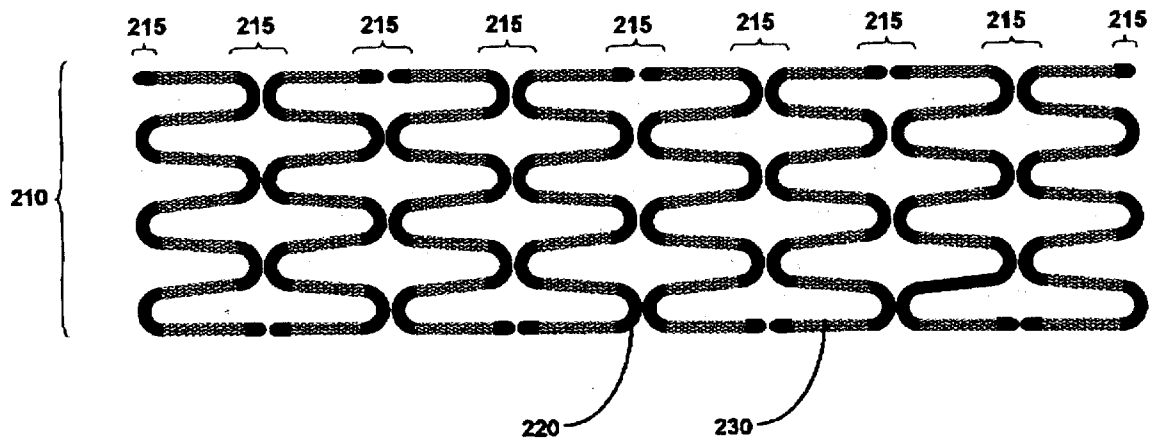


FIG. 1

100

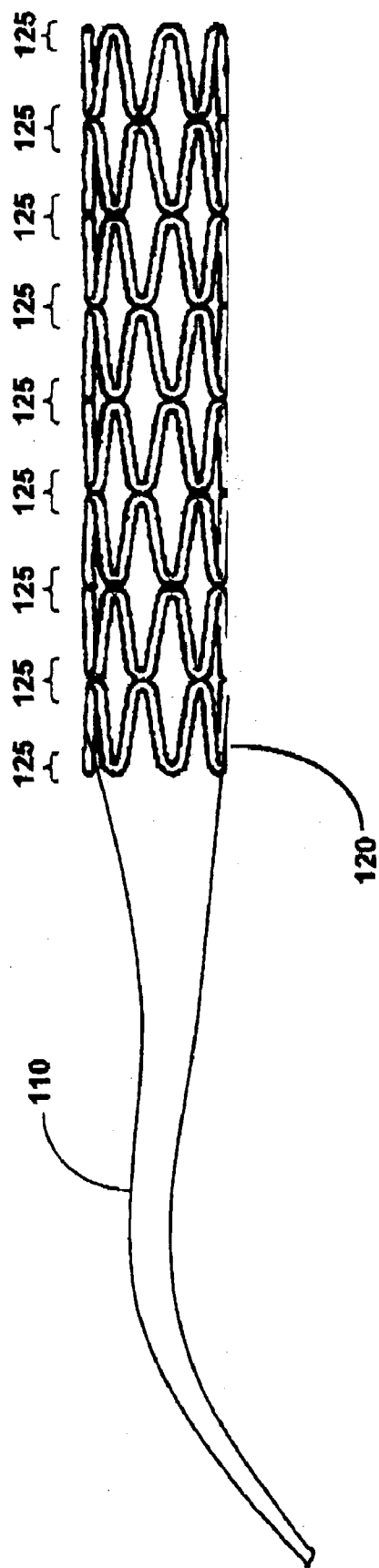


FIG. 2

200

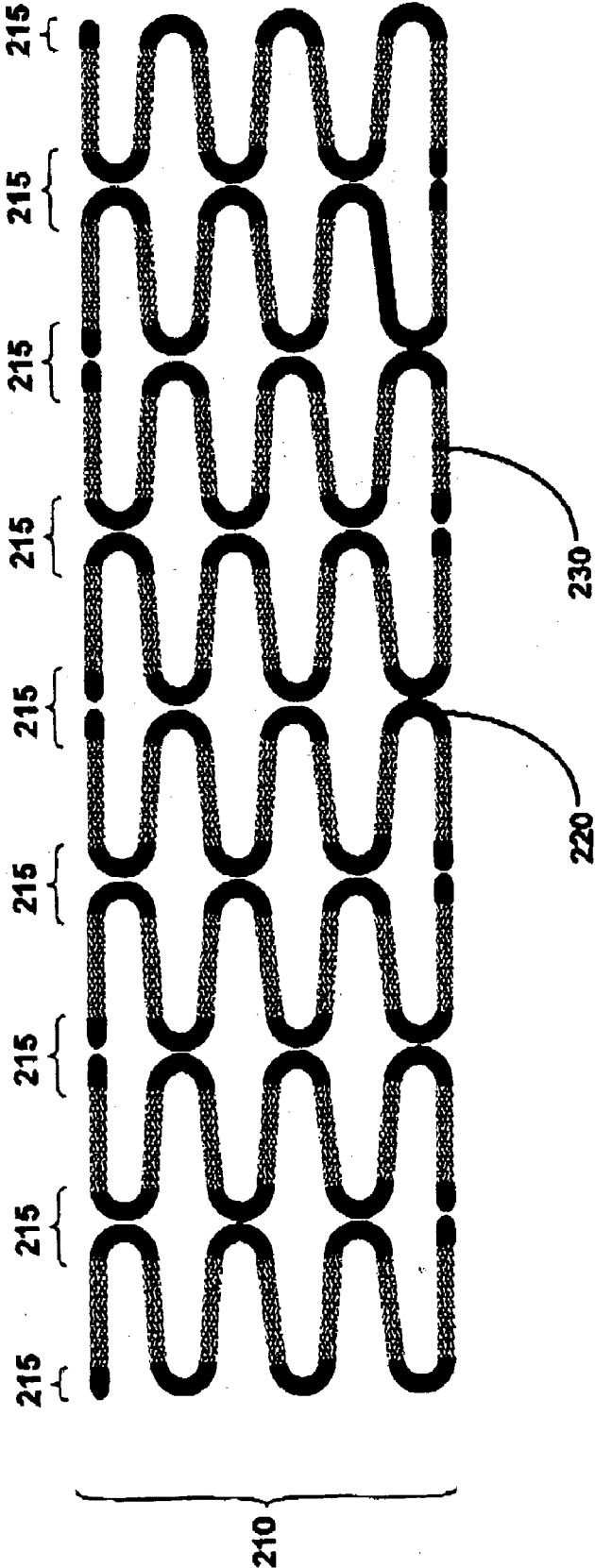


FIG. 3

300

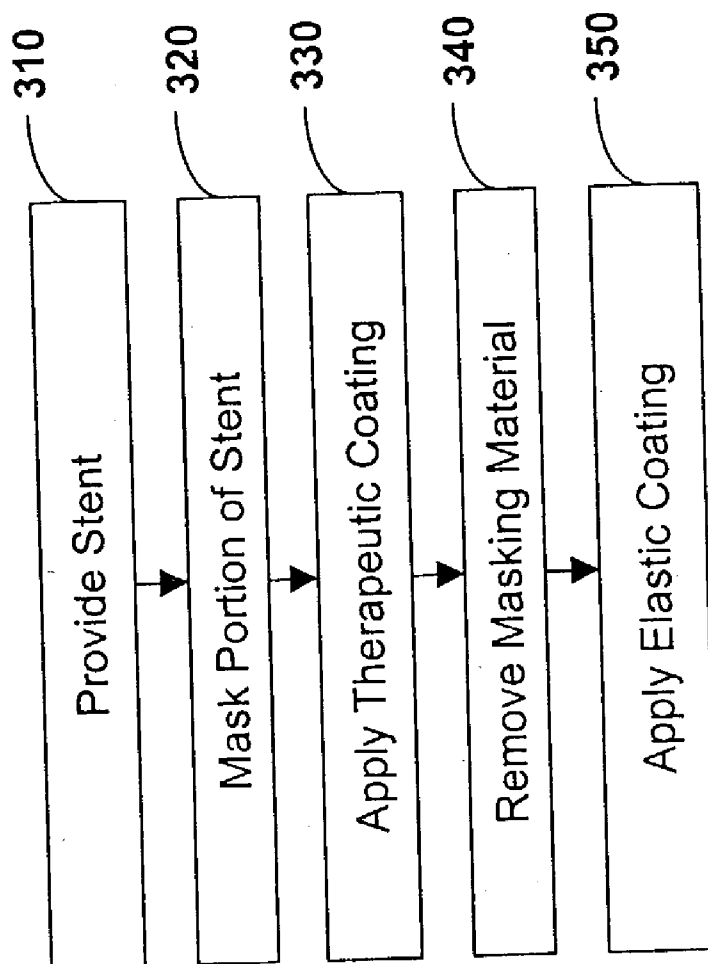


FIG. 4

400

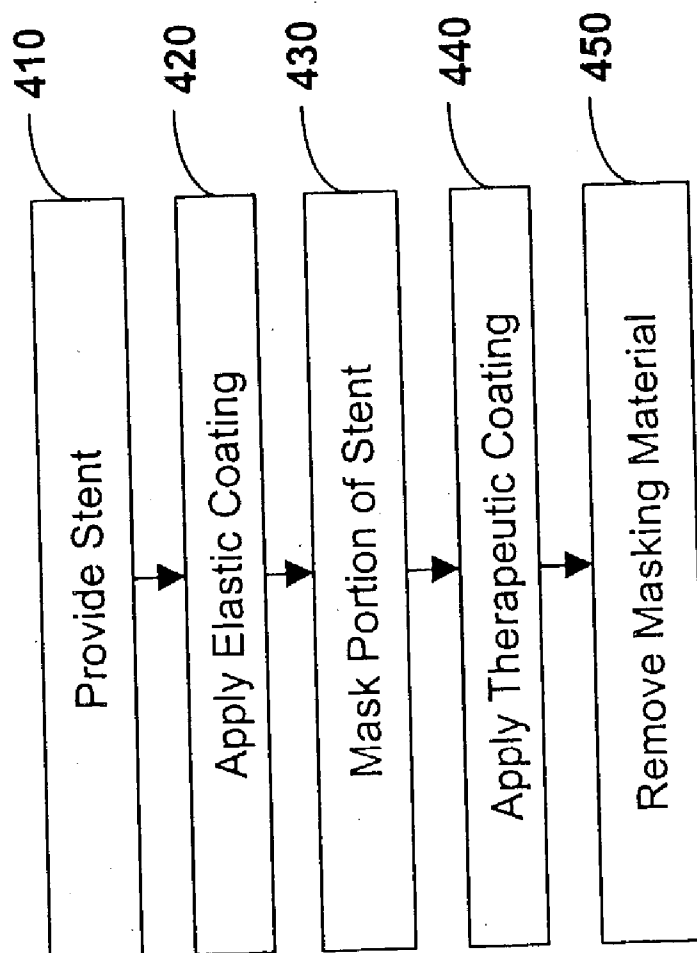
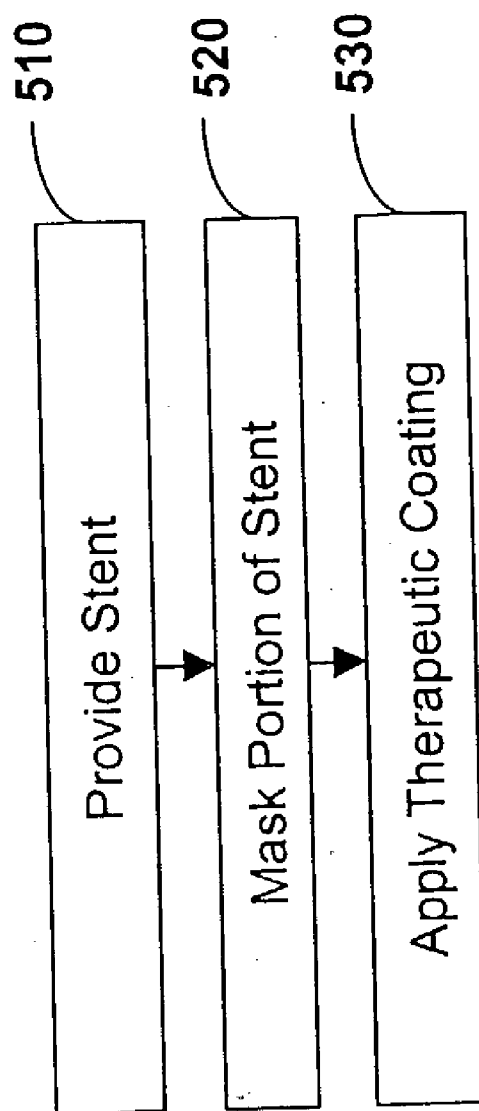


FIG. 5

500



DIFFERENTIALLY COATED STENT

TECHNICAL FIELD

[0001] This invention relates generally to biomedical stents. More specifically, the invention relates to stents that are differentially coated to accommodate areas of high strain.

BACKGROUND OF THE INVENTION

[0002] Stents are cylindrical-shaped devices that are radially expandable to hold open a segment of a vessel or other anatomical lumen after implantation into the body lumen. Various types of stents are in use, including expandable and self-expanding stents. Expandable stents generally are conveyed to the area to be treated on balloon catheters or other expandable devices. For insertion, the stent is positioned in a compressed configuration along the delivery device, for example crimped onto a balloon that is folded or otherwise wrapped about a guide wire that is part of the delivery device. After the stent is positioned across the lesion, it is expanded by the delivery device, causing the length of the stent to contract and the diameter to expand. For a self-expanding stent, commonly a sheath is retracted, allowing expansion of the stent.

[0003] Stents are used in conjunction with balloon catheters in a variety of medical therapeutic applications, including intravascular angioplasty. For example, a balloon catheter device is inflated during PTCA (percutaneous transluminal coronary angioplasty) to dilate a stenotic blood vessel. The stenosis may be the result of a lesion such as a plaque or thrombus. After inflation, the pressurized balloon exerts a compressive force on the lesion, thereby increasing the inner diameter of the affected vessel. The increased interior vessel diameter facilitates improved blood flow.

[0004] Soon after the procedure, however, a significant proportion of treated vessels restenose. To prevent restenosis, short flexible cylinders, or stents, constructed of metal or various polymers, are implanted within the vessel to maintain lumen size. The stents act as a scaffold to support the lumen in an open position. Various configurations of stents include a cylindrical tube defined by a mesh, interconnected stents or like segments. Some exemplary stents are disclosed in U.S. Pat. No. 5,292,331 to Boneau, U.S. Pat. No. 6,090,127 to Globerman, U.S. Pat. No. 5,133,732 to Wiktor, U.S. Pat. No. 4,739,762 to Palmaz and U.S. Pat. No. 5,421,955 to Lau.

[0005] Stent insertion may cause undesirable reactions such as inflammation, infection, thrombosis, and proliferation of cell growth that occludes the passageway. Stents have been used with coatings to deliver drugs or other therapeutic agents at the site of the stent that may assist in preventing these conditions. The coatings must be bioengineered to control the release of highly potent and potentially toxic drugs.

[0006] The choice of a coating may be limited by its mechanical attributes. For example, a polymer with a desired drug elution profile may be brittle and prone to cracking in areas of the stent that experience high strain while the stent is being compressed during manufacture or expanded during delivery into the target vessel. Alternatively, a coating that erodes at a desired rate, thereby

delivering drug at a known, controlled rate, may also be brittle or otherwise unable to withstand the strains of compression or expansion. Cracking of a coating in high-strain areas may cause extensive delamination of the coating from other areas of the stent, resulting in an unknown amount of drug being delivered.

[0007] Therefore it would be desirable to have an improved, differentially coated stent that accommodates these areas of high strain and overcomes the above and other disadvantages.

SUMMARY OF THE INVENTION

[0008] One aspect of the present invention is a system for treating a vascular condition, comprising a catheter; a stent coupled to the catheter, the stent including a stent framework, the stent framework including areas of high strain; and a therapeutic coating disposed on the stent framework and avoiding the areas of high strain. The system may further comprise an elastic coating disposed on at least the high strain areas of the stent framework.

[0009] Another aspect of the present invention is a coated stent having a stent framework, the stent framework including areas of high strain, and a therapeutic coating disposed on at least a portion of the stent framework and avoiding the areas of high strain. The stent may further comprise an elastic coating disposed on at least the areas of high strain.

[0010] Yet another aspect of the present invention is a method of manufacturing a differentially coated stent. A stent framework is provided, the stent framework including areas of high strain. A therapeutic coating is applied to at least a portion of the stent framework, avoiding the areas of high strain. An elastic coating may be applied to at least the high-strain areas of stent framework either before or after the therapeutic coating is applied.

[0011] An additional aspect of the present invention is a system for producing a differentially coated stent, comprising means for providing a stent framework, the stent framework including areas of high strain, and means for applying a therapeutic coating to at least a portion of the stent framework, avoiding the areas of high strain. The system may further comprise means for applying an elastic coating to at least the areas of high strain.

[0012] The aforementioned, and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is an illustration of one embodiment of a system for treating a vascular condition, in accordance with the present invention;

[0014] FIG. 2 is an illustration of one embodiment of a differentially coated stent, in accordance with the present invention;

[0015] FIG. 3 is a flow diagram of one embodiment of a method of manufacturing a differentially coated stent, in accordance with the present invention;

[0016] FIG. 4 is a flow diagram of another embodiment of a method of manufacturing a differentially coated stent, in accordance with the present invention;

[0017] FIG. 5 is a flow diagram of another embodiment of a method of manufacturing a differentially coated stent, in accordance with the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

[0018] One aspect of the present invention is a system for treating a vessel. One embodiment of the system, in accordance with the present invention, is illustrated in FIG. 1 at 100. System 100 comprises a catheter 110 and a stent 120 coupled to the catheter. Stent 120 includes a stent framework with areas of high strain 125. Stent 120 is differentially coated, with a therapeutic coating disposed on at least a portion of the stent framework and avoiding the areas of high strain. An elastic coating may be disposed on the areas that experience high strain.

[0019] Catheter 110 may include a balloon to expand the stent, or it may include a sheath that retracts to allow expansion of a self-expanding stent. Both types of catheter are well known in the art. Stent 120 is shown coupled to catheter 110 for delivery within a vessel.

[0020] The stent framework may be made of a wide variety of medical implantable materials, such as stainless steel, nitinol, tantalum, ceramic, nickel, titanium, aluminum, polymeric materials, MP35N, stainless steel, titanium ASTM F63-83 Grade 1, niobium, high carat gold K 19-22, or combinations of the above.

[0021] Areas of high strain 125 may be those areas of the stent framework that undergo deformation, for example when a stent is compressed onto a delivery catheter during manufacture or expanded during delivery. Coatings on high-strain areas of the stent framework may experience the same high strain as the stent framework. For this reason, these high-strain areas may be left uncoated or may be coated with an elastic coating that is capable of withstanding high strain without cracking, delaminating, or otherwise failing. Areas of the stent framework that do not experience high strain are coated with a therapeutic coating that may be selected for characteristics such as elution profile or durability rather than an ability to withstand high strain.

[0022] The therapeutic coating may include a therapeutic agent such as an antineoplastic agent, an antiproliferative agent, an antibiotic, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, an anti-inflammatory agent, combinations of the above, and the like. The coating may be a polymer, including, but not limited to, urethane, polylactide (PLA), poly-L-lactic acid (PLLA), polyglycolic acid (PGA) polymer, poly (ε-caprolactone) (PCL), polyacrylates, polymethacrylates, polycaprolactone (PCL), polymethylmethacrylate (PMMA), combinations and/or copolymers of the above, and the like. The specific polymer, polymer combinations or copolymers used may be adjusted as seen fit as required by the specific needs of the medical device and the drug used.

[0023] The elastic coating may be a polymer, including, but not limited to, urethane, polycaprolactone (PCL), polybutylmethacrylate (PBMA), polyethylenevinyl acetate (PEVA), combinations and/or copolymers of the above, and

the like. The specific polymer, polymer combinations or copolymers used may be adjusted as required by the specific needs of the medical device and the drug used. The elastic coating may comprise a different polymer than that comprising the therapeutic coating. The elastic coating may include no therapeutic agent, or it may include a therapeutic agent that is the same as or different from the agent carried in the therapeutic coating.

[0024] Using the same therapeutic agent in both coatings may offer the benefit of delivering the therapeutic agent at different rates or different times. For example, the two coatings may display different elution characteristics, resulting in a drug being delivered at two rates; or they may have different durability characteristics, allowing the drug to be delivered by elution from one coating and being released through erosion from another. If the coatings contain different therapeutic agents, a benefit may be realized from the ability to simultaneously deliver more than one therapeutic agent.

[0025] Another aspect of the present invention is a differentially coated stent. One embodiment of the stent, in accordance with the present invention, is illustrated in FIG. 2 at 200. Stent 200 includes a stent framework 210 with areas of high strain 215. Stent 200 is differentially coated, with an elastic coating 220 disposed on the areas that experience high strain and a therapeutic coating 230 disposed on areas that experience low or no strain. Alternatively, the stent may be uncoated in the areas that experience high strain.

[0026] Stent framework 210 may be made of a wide variety of medical implantable materials, such as stainless steel, nitinol, tantalum, ceramic, nickel, titanium, aluminum, polymeric materials, MP35N, stainless steel, titanium ASTM F63-83 Grade 1, niobium, high carat gold K 19-22, or combinations of the above.

[0027] Areas of high strain 215 may be those areas of the stent framework that undergo deformation, for example when the stent is compressed onto a delivery catheter during manufacture or expanded during delivery. Coatings on high-strain areas of the stent framework may experience the same high strain as the stent framework. For this reason, these high-strain areas may be left uncoated or may be coated with an elastic coating 220 that is capable of withstanding high strain without cracking, delaminating, or otherwise failing. Areas of the stent framework that do not experience high strain are coated with a therapeutic coating 230. Elastic coating 220 and therapeutic coating 230 may comprise different polymers with different material properties. Because the therapeutic coating is not exposed to high strain, it may be selected for characteristics such as elution profile or durability rather than the ability to withstand high strain.

[0028] Therapeutic coating 230 may include a therapeutic agent such as an antineoplastic agent, an antiproliferative agent, an antibiotic, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, an anti-inflammatory agent, combinations of the above, and the like. The coating may be a polymer, including, but not limited to, urethane, polycaprolactone (PCL), polymethylmethacrylate (PMMA), combinations of the above, and the like.

[0029] Elastic coating 220 may be a polymer, including, but not limited to, urethane, polycaprolactone (PCL), poly-

butylmethacrylate (PBMA), combinations of the above, and the like. The elastic coating may include no therapeutic agent, or it may include a therapeutic agent that is the same as or different from the agent carried in the therapeutic coating. Using the same therapeutic agent in both coatings may offer the benefit of delivering the therapeutic agent at different rates or different times. For example, the two coatings may display different elution characteristics, resulting in a drug being delivered at two rates; or they may have different durability characteristics, allowing the drug to be delivered by elution from one coating and being released through erosion from another. If the coatings contain different therapeutic agents, a benefit may be realized from the ability to simultaneously deliver more than one therapeutic agent.

[0030] A further aspect of the present invention is a method of manufacturing a differentially coated stent. **FIG. 3** shows a flow diagram of one embodiment, in accordance with the present invention at **300**.

[0031] In this embodiment, a stent framework is provided (Block **310**). High-strain areas of the stent framework are masked by, for example, applying a narrow tetrafluorethylene sleeve over each area (Block **320**). A therapeutic coating is then sprayed onto or otherwise applied to the stent framework (Block **330**). The masking material is removed (Block **340**). The areas carrying the therapeutic coating are then masked (Block **350**), and an elastic coating is sprayed onto or otherwise applied to the areas of high strain (Block **360**). Those skilled in the art will recognize that the high-strain areas may also be left uncoated.

[0032] **FIG. 4** shows a flow diagram of another embodiment of a method of manufacturing a differentially coated stent, in accordance with the present invention at **400**.

[0033] In this embodiment, a stent framework is provided (Block **410**). The stent framework is coated with an elastic coating (Block **420**). High-strain areas of the stent framework are then masked by, for example, applying a narrow tetrafluorethylene sleeve over each area (Block **430**). A therapeutic coating is then sprayed onto or otherwise applied to the stent framework (Block **440**). After coating, the masking material is removed (Block **450**).

[0034] **FIG. 5** shows a flow diagram of yet another embodiment of a method of manufacturing a differentially coated stent, in accordance with the present invention at **500**.

[0035] A stent framework is provided (Block **510**). High-strain areas of the stent framework are masked by coating with a protective polymer coating material such as Parylene (Block **520**). The stent framework is then dipped into or otherwise exposed to a therapeutic coating (Block **530**). The protective polymer coating material resists the therapeutic coating, resulting in the high-strain areas being coated with only the protective polymer.

[0036] While the embodiments of the invention disclosed herein are presently considered preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes and modifications that come within the meaning and range of equivalents are intended to be embraced therein.

What is claimed is:

1. A system for treating a vascular condition, comprising:
 - a catheter;
 - a stent coupled to the catheter, the stent including a stent framework, the stent framework including areas of high strain; and
 - a therapeutic coating disposed on at least a portion of the stent framework and avoiding the areas of high strain.
2. The system of claim 1 further comprising:
 - an elastic coating disposed on at least the high-strain areas of the stent framework.
3. The system of claim 2 wherein the therapeutic coating comprises a first polymer and the elastic coating comprises a second polymer.
4. The system of claim 1 wherein the therapeutic coating includes a therapeutic agent selected from a group consisting of an antineoplastic agent, an antiproliferative agent, an antibiotic, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, and an anti-inflammatory agent.
5. The system of claim 2 wherein the elastic coating includes a therapeutic agent selected from a group consisting of an antineoplastic agent, an antiproliferative agent, an antibiotic, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, and an anti-inflammatory agent.
6. The system of claim 2 wherein the therapeutic coating includes a first therapeutic agent and the elastic coating includes a second therapeutic agent.
7. The system of claim 2 wherein the therapeutic coating and the elastic coating display different elution characteristics.
8. The system of claim 2 wherein the therapeutic coating and the elastic coating display different durability characteristics.
9. The system of claim 1 wherein the catheter includes a balloon used to expand the stent.
10. The system of claim 1 wherein the catheter includes a sheath that retracts to allow expansion of the stent.
11. A differentially coated stent, comprising:
 - a stent framework, the stent framework including areas of high strain; and
 - a therapeutic coating disposed on at least a portion of the stent framework and avoiding the areas of high strain.
12. The stent of claim 11 further comprising:
 - an elastic coating disposed on at least the areas of high strain.
13. The stent of claim 11 wherein the therapeutic coating includes an agent selected from a group consisting of an antineoplastic agent, an antiproliferative agent, an antibiotic, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, and an anti-inflammatory agent.
14. The stent of claim 12 wherein the elastic coating includes a therapeutic agent selected from a group consisting of an antineoplastic agent, an antiproliferative agent, an antibiotic, an antithrombogenic agent, an anticoagulant, an antiplatelet agent, and an anti-inflammatory agent.
15. The stent of claim 12 wherein the therapeutic coating includes a first therapeutic agent and the elastic coating includes a second therapeutic agent.
16. The stent of claim 12 wherein the therapeutic coating and the elastic coating display different elution characteristics.

17. The stent of claim 12 wherein the therapeutic coating and the elastic coating display different durability characteristics.

18. A method of manufacturing a differentially coated stent, comprising:

providing a stent framework, the stent framework including areas of high strain; and

applying a therapeutic coating to at least a portion of the stent framework, avoiding the areas of high strain.

19. The method of claim 18 wherein avoiding the areas of high strain comprises applying a therapeutic coating to only those areas of the stent framework that do not experience high strain.

20. The method of claim 18 wherein avoiding the areas of high strain comprises removing the therapeutic coating from high-strain areas of the stent framework.

21. The method of claim 18 wherein avoiding the areas of high strain comprises masking high-strain areas of the stent framework prior to applying a therapeutic coating.

22. The method of claim 21 wherein the stent framework is masked by one or more materials selected from a group consisting of a tetrafluorethylene sleeve, an adhesive-backed material, and a removable coating.

23. The method of claim 21 further comprising:

removing the masking material from the stent framework after the therapeutic coating is applied.

24. The method of claim 21 wherein the masking material is a protective polymer coating material.

25. The method of claim 24 wherein the protective polymer coating material is Parylene.

26. The method of claim 18 further comprising:

applying an elastic coating to at least the high-strain areas of the stent framework after applying the therapeutic coating.

27. The method of claim 26 further comprising:

masking the portion of the stent framework to which the therapeutic coating has been applied prior to applying the elastic coating.

28. The method of claim 18 further comprising:

applying an elastic coating to at least the high-strain areas of the stent framework prior to applying a therapeutic coating.

29. The method of claim 28 further comprising:

masking high-strain areas of the stent framework prior to applying the therapeutic coating.

30. The method of claim 18 wherein the therapeutic coating is applied by a method selected from the group consisting of pad printing, inkjet printing, rolling, painting, spraying, micro-spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, and combinations thereof.

31. The methods of claims 26 and 28 wherein the elastic coating is applied by a method selected from the group consisting of pad printing, inkjet printing, rolling, painting, spraying, micro-spraying, dipping, wiping, electrostatic deposition, vapor deposition, epitaxial growth, and combinations thereof.

32. A system for producing a differentially coated stent, comprising:

means for providing a stent framework, the stent framework including areas of high strain; and

means for applying a therapeutic coating to at least a portion of the stent framework, avoiding the areas of high strain.

33. The system of claim 32 further comprising:

means for applying an elastic coating to at least the areas of high strain.

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