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(54) **STENTS AND CATHETERS HAVING IMPROVED STENT DEPLOYMENT**

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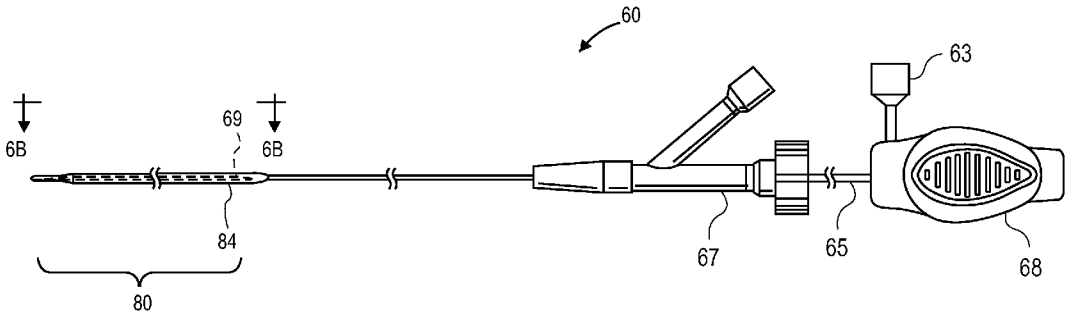
*A61F 2/82* (2006.01)

(52) **U.S. Cl.** ..... **623/1.11**; 623/1.42; 623/1.2

(57) **ABSTRACT**

An implant delivery system and method comprises an implant, for example, a stent, and a delivery catheter. The stent has a scaffold with a coating or a shell that retains the scaffold in a collapsed configuration. The coating or shell is made of a material that dissolves or biodegrades upon exposure to a dissolution or biodegradation media. The stent is used with an implant delivery system which has a catheter with a catheter, wherein the stent is mounted on the catheter shaft. The catheter shaft is configured to be withdrawn through the patient's vessel when the scaffold is in its expanded configuration. Advantageously, the implant is thereby prevented from changing length during implant delivery and implant deployment.



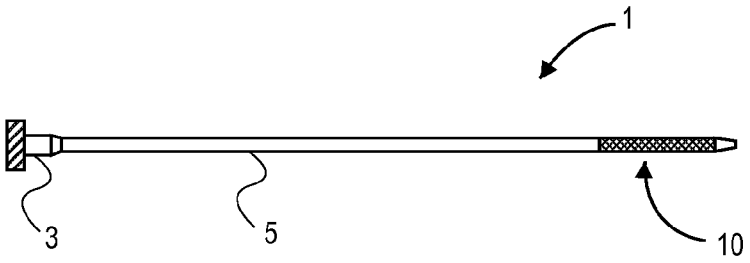



FIG. 1A

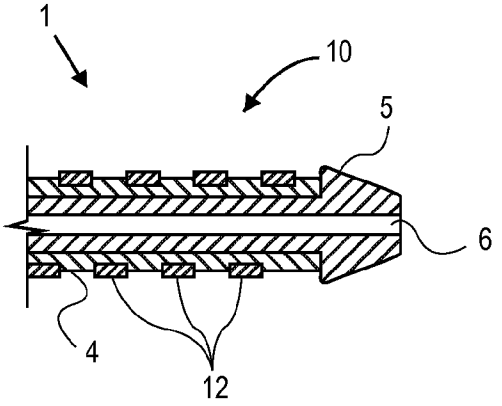



FIG. 1B

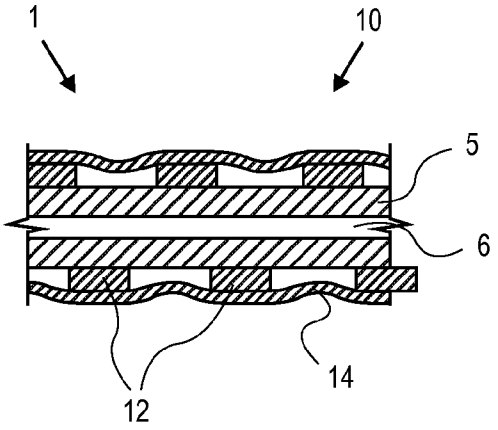



FIG. 1C

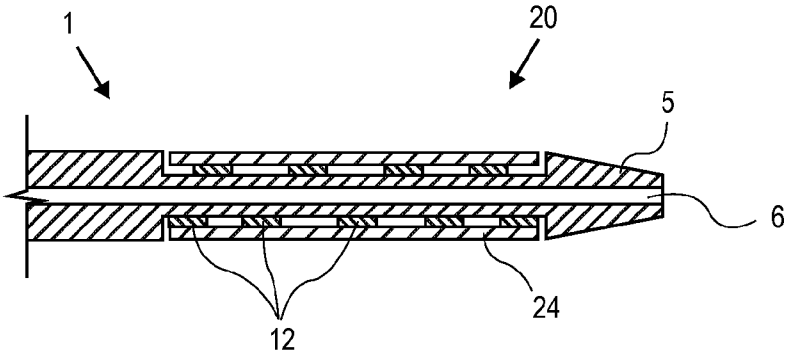



FIG. 1D


FIG. 3A

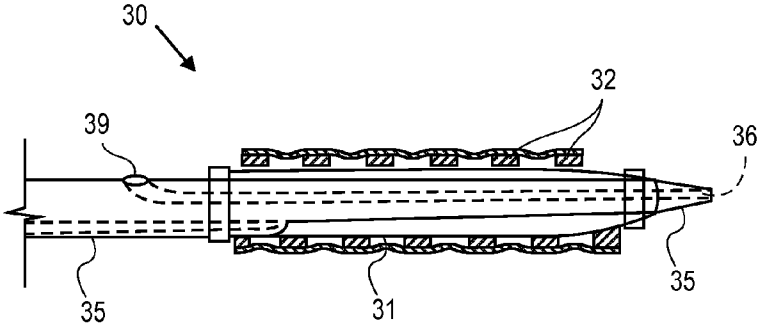



FIG. 3B

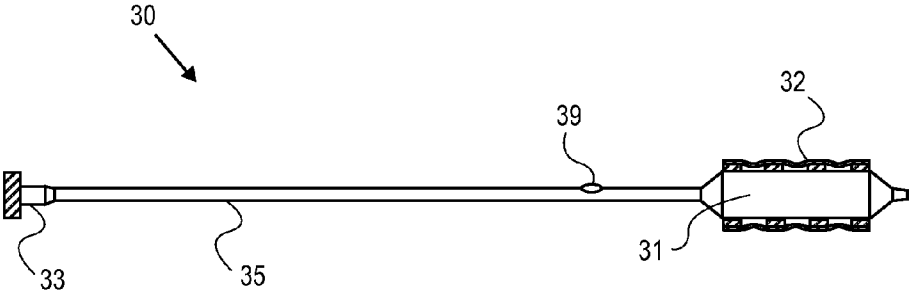



FIG. 3C

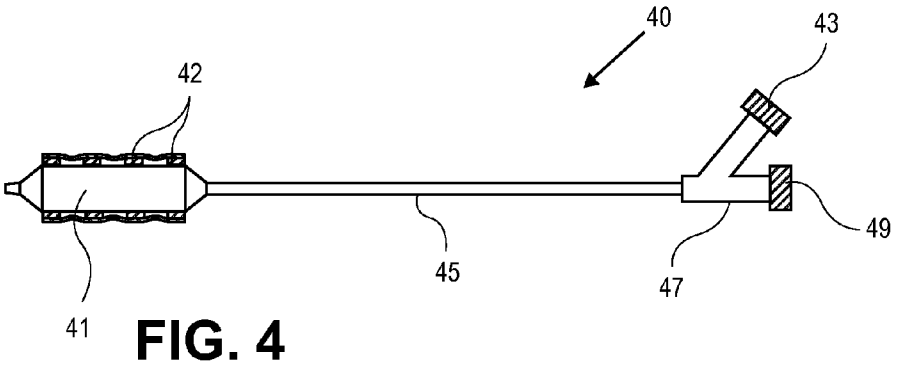



FIG. 4

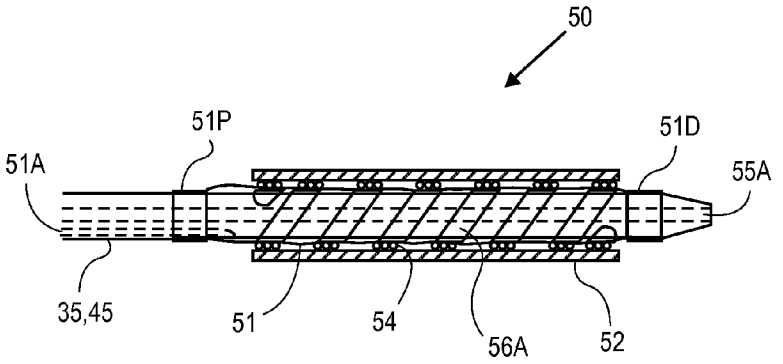



FIG. 5A

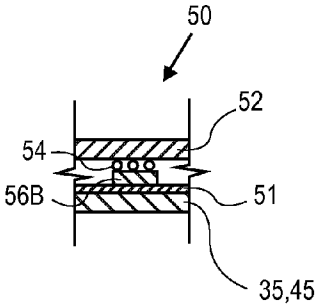



FIG. 5B


FIG. 5C

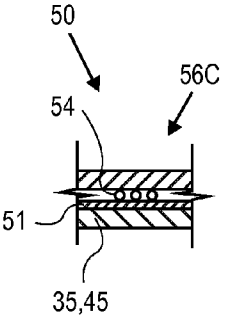



FIG. 5D

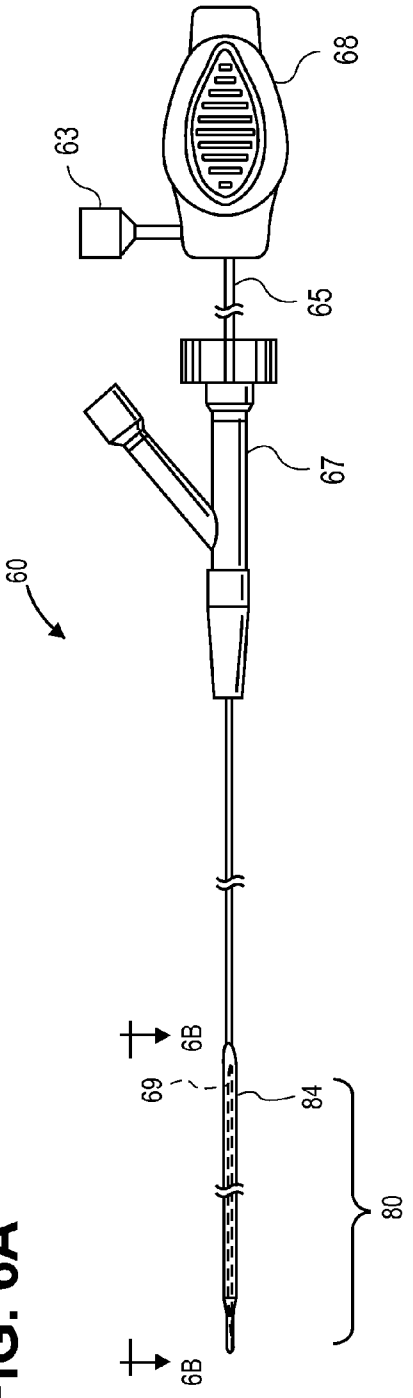



FIG. 6A

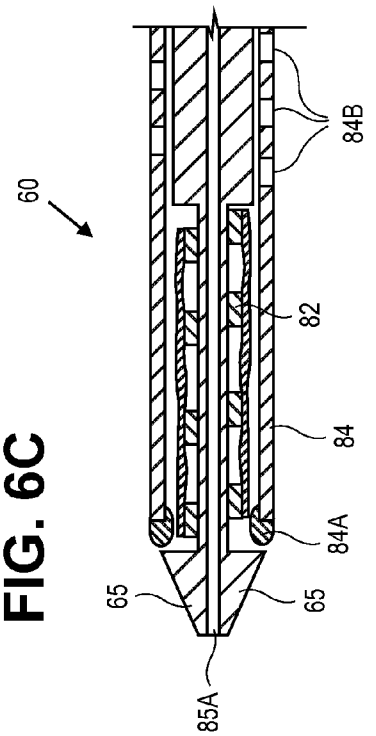



FIG. 6C

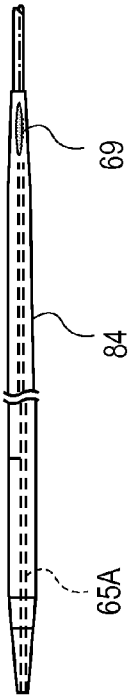



FIG. 6B

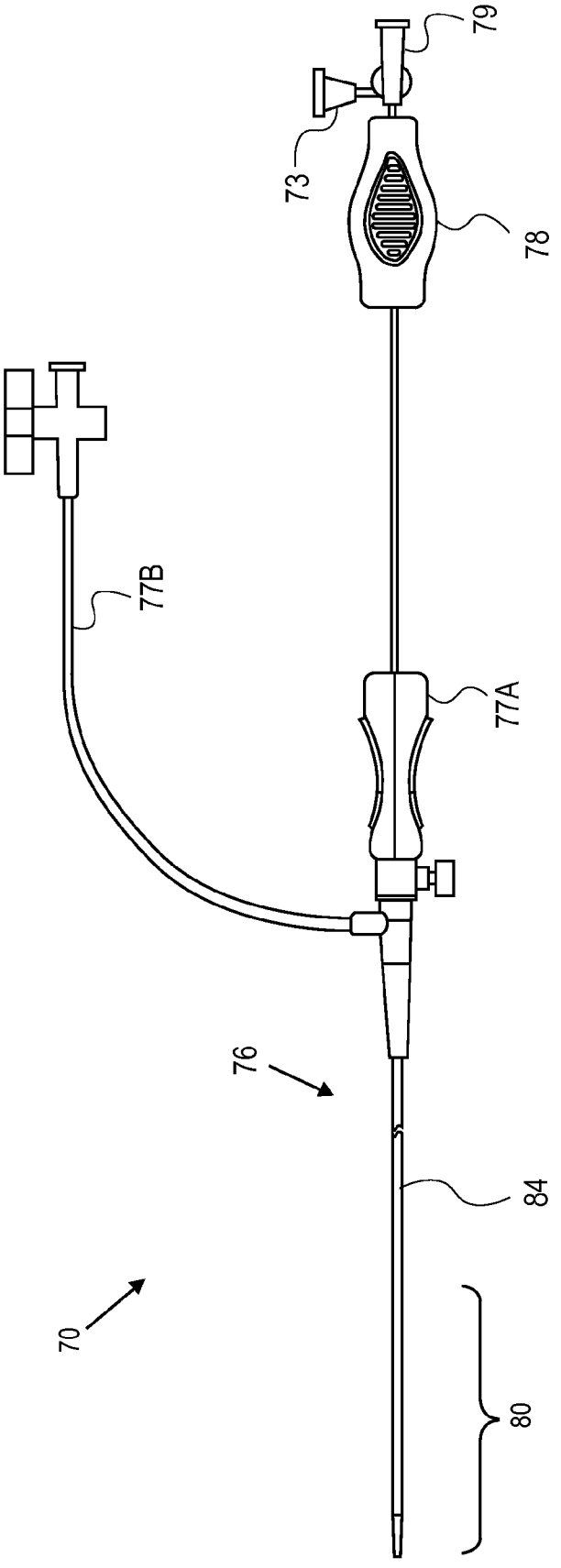



FIG. 7

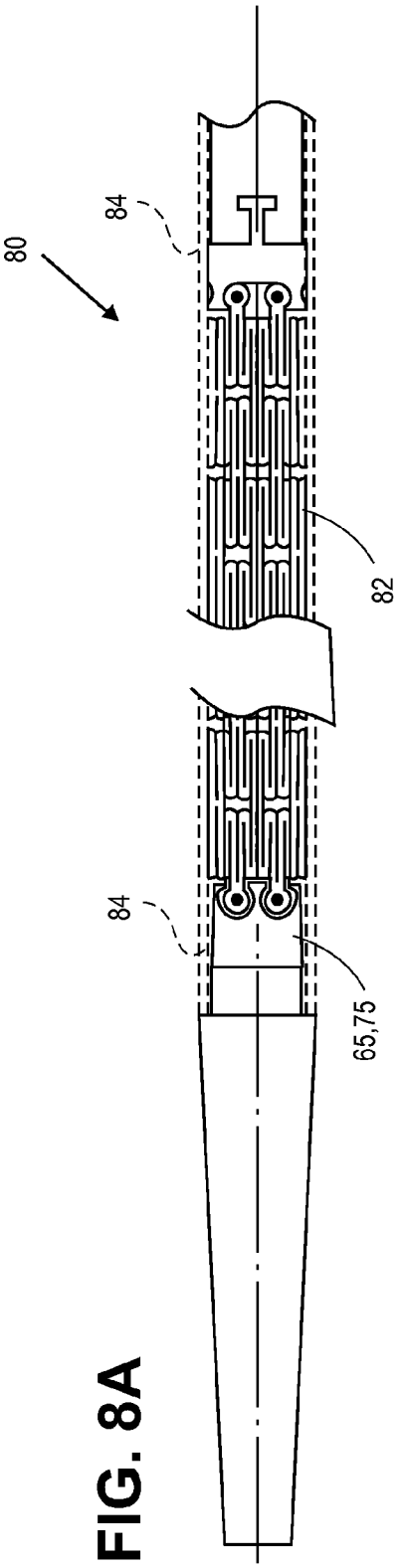



FIG. 8A

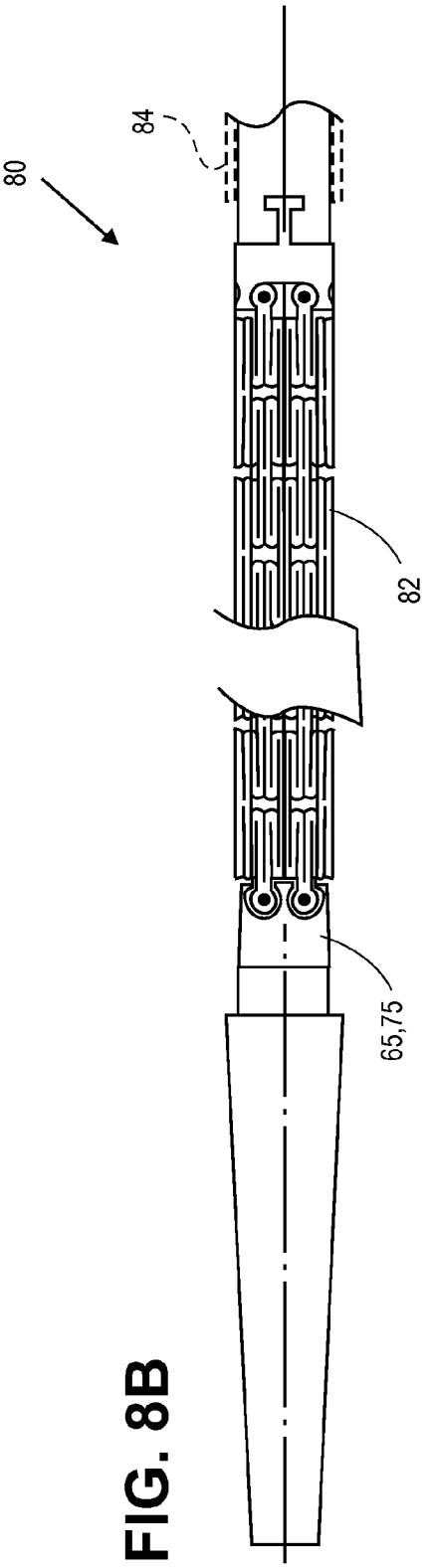



FIG. 8B

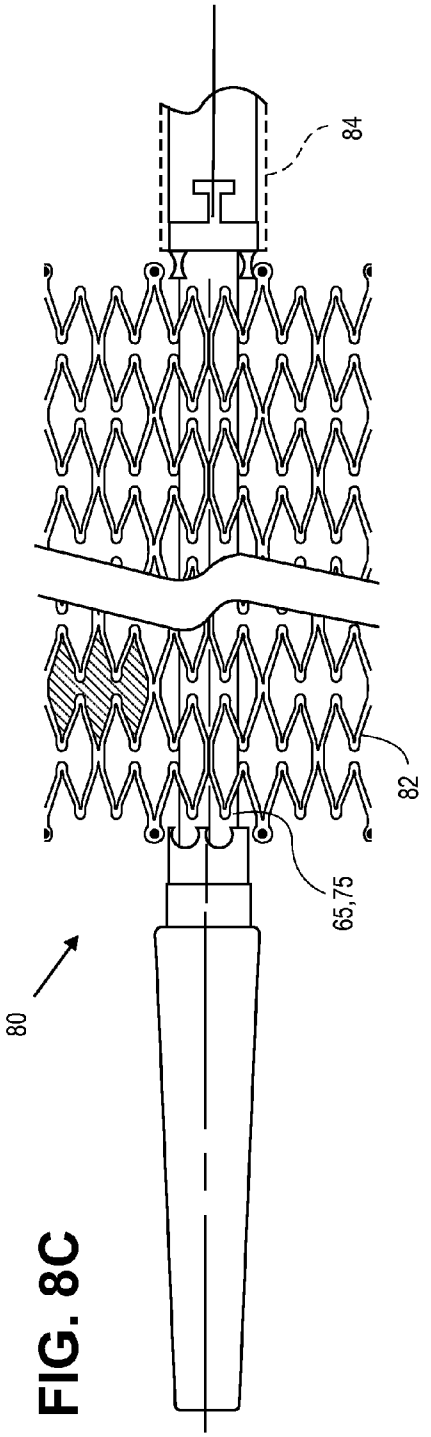



FIG. 8C

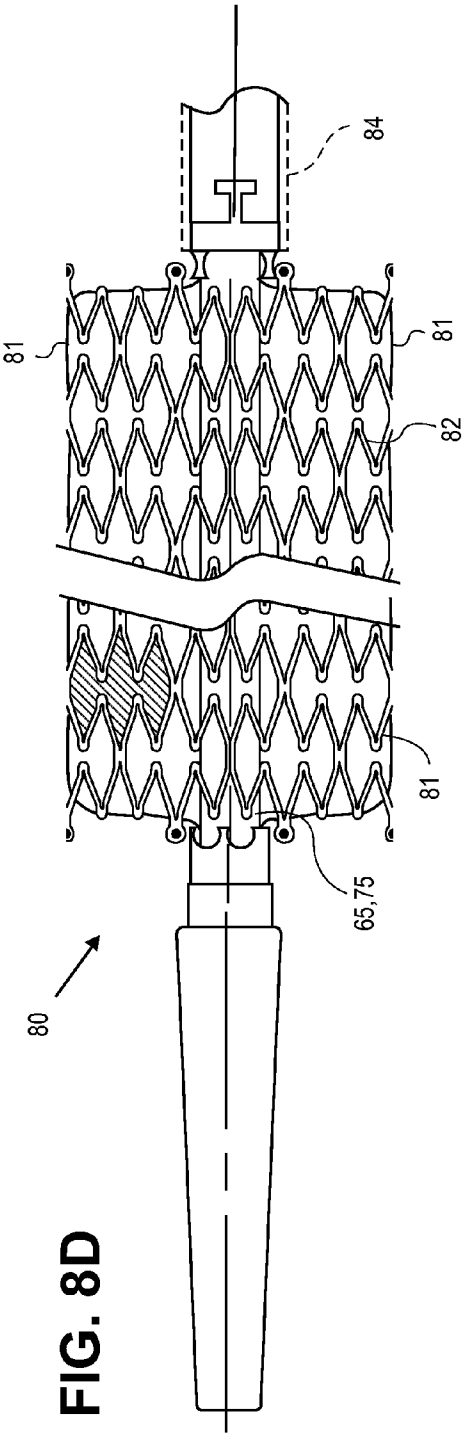



FIG. 8D

# STENTS AND CATHETERS HAVING IMPROVED STENT DEPLOYMENT

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. provisional application Ser. No. 61/095,766, filed Sep. 10, 2008, the entire content of which is incorporated herein by reference in its entirety.

## FIELD OF THE INVENTION

**[0002]** The present invention relates to systems for delivering an implant to a site in a body lumen. More particularly, this invention pertains to delivery systems for a vascular implant such as a self-expanding stent.

## BACKGROUND OF THE INVENTION

**[0003]** Stents are widely used for supporting a lumen structure in a patient's body. For example, stents may be used to maintain patency of a coronary artery, carotid artery, cerebral artery, femoral artery, other blood vessels including veins, or other body lumens such as the ureter, urethra, bronchus, esophagus, or other passage.

**[0004]** Stents are commonly metallic tubular structures made from stainless steel, Nitinol, Elgiloy, cobalt chrome alloys, tantalum, and other metals, although polymer stents are known. Stents can be permanent enduring implants, or can be bioabsorbable at least in part. Bioabsorbable stents can be polymeric, bio-polymeric, ceramic, bio-ceramic, or metallic, and may elute over time substances such as drugs. Non-bioabsorbable stents may also release drugs over time. Stents are passed through a body lumen in a collapsed state. At the point of an obstruction or other deployment site in the body lumen, the stent is expanded to an expanded diameter to support the lumen at the deployment site.

**[0005]** In certain designs, stents are comprised of tubes having multiple through holes or cells that are expanded by inflatable balloons at the deployment site. This type of stent is often referred to as a "balloon expandable" stent. Stent delivery systems for balloon expandable stents are typically comprised of an inflatable balloon mounted on a two lumen tube. The stent delivery system with stent compressed thereon can be advanced to a treatment site over a guidewire, and the balloon inflated to expand and deploy the stent.

**[0006]** Other stents are so-called "self expanding" stents and do not use balloons to cause the expansion of the stent. An example of a self-expanding stent is a tube (e.g., a coil of wire or a tube comprised of cells) made of an elastically deformable material (e.g., a superelastic material such a nitinol). Some self expanding stents are also comprised of tubes having multiple through holes or cells. This type of stent is secured in compression in a collapsed state to a stent delivery device. At the deployment site, stent compression is released and restoring forces within the stent cause the stent to self-expand to its enlarged diameter.

**[0007]** Other self-expanding stents are made of so-called shape-memory metals. Such shape-memory stents experience a phase change at the elevated temperature of the human body. The phase change results in expansion from a collapsed state to an enlarged state.

**[0008]** A very popular type of self expanding stent is a cellular tube made from self-expanding nitinol, for example, the EverFlex stent from ev3, Inc. of Plymouth, Minn. Cellular stents are commonly made by laser cutting of tubes, or cutting patterns into sheets followed by or preceded by welding the sheet into a tube shape, and other methods. Another delivery technique for a self expanding stent is to mount the collapsed stent on a distal end of a stent delivery system. Such a system can be comprised of an outer tubular member and an inner tubular member. The inner and outer tubular members are axially slideable relative to one another. The stent (in the collapsed state) is mounted surrounding the inner tubular member at its distal end. The outer tubular member (also called the outer sheath) surrounds the stent at the distal end.

**[0009]** Prior to advancing the stent delivery system through the body lumen, a guide wire is first passed through the body lumen to the deployment site. The inner tube of the delivery system is hollow throughout at least a portion of its length such that it can be advanced over the guide wire to the deployment site. The combined structure (i.e., stent mounted on stent delivery system) is passed through the patient's lumen until the distal end of the delivery system arrives at the deployment site within the body lumen. The deployment system and/or the stent may include radiopaque markers to permit a physician to visualize positioning of the stent under fluoroscopy prior to deployment. At the deployment site, the outer sheath is retracted to expose the stent. The exposed stent is free to self-expand within the body lumen. Following expansion of the stent, the inner tube is free to pass through the stent such that the delivery system can be removed through the body lumen leaving the stent in place at the deployment site.

**[0010]** In prior art devices, high forces may be required to retract the outer sheath so as to permit the stent to self expand. Delivery systems designed to withstand high retraction forces can be bulky, can have reduced flexibility and can have unacceptable failure rates. In addition, due to frictional forces between the stent and the outer sheath in prior art devices the stent may change in length during deployment, either in overall length or locally over regions of the stent. For example, long stents, thin stents, stents with high axial flexibility parallel to the central axis of the stent, or stents with a large amount of expansile force, when compressed in a sheath, tend to change in length as the outer sheath is withdrawn from the inner tubular member. Also, prior art delivery systems can be moved when the implant is partially deployed, resulting in undesirable regional length changes in the implanted device. Changes in stent length during stent deployment can prevent a stent from being properly deployed over the intended treatment area, can compromise stent fracture resistance and can compromise stent fatigue life.

**[0011]** What is needed is a stent delivery system that permits low force and precise delivery of stents without altering the intended length of the stent.

## SUMMARY OF THE INVENTION

**[0012]** According to one aspect of the present invention, a stent includes a scaffold and a coating that restrains diametrical expansion of the scaffold. Dissolution or biodegradation of the coating allows the stent to expand or be expanded.

**[0013]** According to another aspect of the present invention, a stent includes a scaffold and a shell that restrains diametrical expansion of the scaffold. Dissolution or biodegradation of the shell allows the stent to expand or be expanded.

**[0014]** According to other aspects of the present invention, an implant delivery system includes a stent with a scaffold

and a coating or shell that restrains diametrical expansion of the scaffold and a catheter on which the stent is mounted in a collapsed, restrained state. Upon exposure to dissolution fluid or biodegradation media, dissolution or biodegradation of the coating or shell allows the stent to expand or be expanded.

**[0015]** According to other aspects of the present invention, an implant delivery system includes a stent with a scaffold and a coating that restrains diametrical expansion of the scaffold and an inflatable balloon mounted on the catheter beneath the stent. Upon inflating the balloon the coating or shell is compromised or fractured and the stent self-expands or is further expanded by further inflation of the balloon. Exposure to dissolution fluid or biodegradation media causes fragments of the coating or shell to dissolve or biodegrade.

**[0016]** According to other aspects of the present invention, an implant delivery system includes a stent with a scaffold and a coating that restrains diametrical expansion of the scaffold and a slidable tubular sheath surrounding the catheter and restrained stent. Upon proximal withdrawal of the sheath the coating or shell is exposed to dissolution fluid or biodegradation media and dissolution or biodegradation of the coating or shell allows the stent to expand or be expanded. Exposure to dissolution fluid or biodegradation media causes fragments of the coating or shell to dissolve or biodegrade.

**[0017]** According to yet other aspects of the present invention, an implant delivery system includes a stent with a scaffold and a coating that restrains diametrical expansion of the scaffold, and a slidable tubular sheath surrounding the catheter, an inflatable balloon and a restrained stent. The stent is deployed by proximal withdrawal of the sheath followed by inflation of the balloon to compromise or fracture the coating or shell. The stent then self-expands or is further expanded by further inflation of the balloon. Exposure to dissolution fluid or biodegradation media causes fragments of the coating or shell to dissolve or biodegrade.

**[0018]** In yet another aspect of the present invention, an implant delivery system having a stent with a scaffold and a coating that restrains diametrical expansion of the scaffold is delivered to a treatment site, a slidable tubular sheath surrounding the catheter, an inflatable balloon and a restrained stent, is delivered to a treatment site. At the treatment site, the balloon is inflated until the sliding friction of the stent against the balloon is greater than the sliding friction of the stent against the outer sheath. The outer sheath is then retracted to expose the stent which self expands upon exposure. The stent may be further expanded by further inflation of the balloon.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0019]** The above and further advantages of the invention may be better understood by referring to the following description in conjunction with the accompanying drawings in which:

**[0020]** FIG. **1**A illustrates a schematic side view of an implant delivery system having features in accordance with the principles of the present disclosure;

**[0021]** FIGS. **1**B, **1**C and **2** illustrate schematic cross sectional views of stent and stent implant system embodiments having features in accordance with the principles of the present disclosure;

**[0022]** FIGS. **3**A to **3**C, **4**, and **5**A to **5**D illustrate schematic cross sectional views of implant delivery systems having features in accordance with the principles of the present disclosure;

**[0023]** FIGS. **6**A, **6**B, **6**C, **7**, **8**A, **8**B, **8**C and **8**D illustrate schematic side views of implant delivery systems having features in accordance with the principles of the present disclosure.

## DETAILED DESCRIPTION

**[0024]** Embodiments that are examples of how inventive aspects in accordance with the principles of the present invention will now be described in more detail with reference to the drawings. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the broad inventive aspects disclosed herein. It will also be appreciated that the inventive concepts disclosed herein are not limited to the particular stent configurations disclosed herein, but are instead applicable to any number of different stent configurations.

**[0025]** FIGS. **1**A and **1**B illustrate implant delivery system **1** comprised of stent **10**, catheter shaft **5** with hub **3** and guidewire lumen **6** extending through catheter shaft and hub. Catheter shaft **5** is relatively flexible, may be comprised of a polymeric material such as nylon or PEBAX, and may range in length from 60 cm to 300 cm. Catheter outside diameter may range from about 2 Fr to about 10 Fr. Guidewire lumen **6** diameter may be large enough to allow passage of guidewires ranging in diameter from 0.009" to 0.038". Hub **3** is sealingly attached to catheter shaft **5**, is adapted to reversibly connect to other medical devices (for example by means of a luer fitting) and may be comprised of polycarbonate. Stent **10** is comprised of scaffold **12** and coating **14**. In various embodiments scaffold may be self expanding, balloon expandable, tubular, comprised of cells, comprised of coils, comprised of metals, polymer, ceramics, or other materials, or may have other characteristics. In one embodiment scaffold **12** includes Nitinol tubing having cellular openings and having suitable heat treatment to cause scaffold **12** to self-expand at human body temperatures. Scaffold **12** configurations suitable for the invention include but are not limited to tapered, flared, braided, bifurcated, fracturable, mesh covered, scaffolds comprised of radiopaque markers, and other scaffolds as are known in the art. Long scaffolds are especially suited to the invention. Implant delivery systems **1** for scaffolds having lengths of from 20-400 mm are contemplated. In one embodiment, implant delivery system **1** can deliver and deploy a 30 mm scaffold. In other embodiments, implant delivery system 1 can deliver and deploy a 40 mm, 60 mm, 80 mm, 100 mm, 120 mm, 150 mm, 180 mm, 200 mm, 250 mm, 300 mm or 350 mm scaffold. As shown in FIGS. **1**B and **1**C, coating **14** may optionally be applied to catheter shaft **5** outer diameter along some or all of the scaffold length and may be applied to at least one of outer surface, inner surface, or through thickness of scaffold **12**. In some embodiments coating **14** covers the exposed edges of stent **10** so as to form a smooth exterior coated stent surface. Coating **14**, when applied and hardened, maintains stent **10** at an unexpanded diameter and a fixed length prior to stent deployment. Coating **14** may cause stent to adhere directly to inner member. Coating **14** may be comprised of biodegradable materials, or may be comprised of materials that dissolve in the body or in the bloodstream. In some embodiments coating **14** includes sugar, carbowax, polyethylene oxide, poly vinyl alcohol or other materials. Coating **14** may be applied by spray, dip, or other processes to unexpanded stent and allowed to harden, may be applied to expanded stent and allowed to harden after

stent is compressed, may be applied to and hardened on expanded stent so as to maintain scaffold in an unexpanded diameter after subsequent stent compression, or may be applied and hardened by other methods.

**[0026]** In some embodiments coating **14** can dissolve or biodegrade over time so as to release the scaffold. In some embodiments coating **14** can dissolve or biodegrade when in contact with blood to allow expansion of scaffold **12**. Upon contact with dissolution or biodegradation causing media, scaffold release times of 0.5 to 300 seconds are contemplated. In one embodiment, scaffold release time is approximately 1 second. In other embodiments, scaffold release time is approximately 2, 5, 10, 20, 30, 45, 60, 90, 120, 150, 180 or 240 seconds. In some embodiments a change in scaffold **12** length of less than 10% upon expansion from a contracted to an expanded configuration is contemplated. In other embodiments, scaffold **12** length change upon expansion from a contracted to an expanded configuration is less than 9%, 8%, 7%, 6%, 5%, 4%, 3%, 2% or 1%.

**[0027]** Coating **14** may be comprised of bioactive materials such as antirestenotic agents, anti-inflammatory agents, antithrombotic agents, antiatheromatic (antiatheroma) agents, antioxidative agents, or other agents. Bioactive coating materials may be released from the coating into surrounding tissue or blood and may have a diagnostic or therapeutic action on tissue or blood.

**[0028]** An exemplary method of using a stent **10** with implant delivery system **1** is now described. A guidewire is advance into a patient's femoral artery using known techniques, through a patient's vessel and past a treatment site. Stent **10** is loaded onto implant delivery system **1** and introduced over the guidewire into the patient's vessel. Stent **10** is restrained from expanding by coating **14**. The stent and implant delivery system combination is advanced over the guidewire and through the patients vessel until stent **10** is located at a treatment site, for example within a stenosis in a femoral artery. Stent **10** is deployed by allowing coating **14** to dissolve or to biodegrade thereby allowing scaffold **12** to self-expand. Catheter shaft **5** is then withdrawn through the patient's vessel and out of the patient's body. Any of coating that is pinned between scaffold and the vessel, attached to scaffold, or which embolizes from the treatment site dissolves or biodegrades over time. Scaffold **10** does not change length upon deployment because the scaffold is immobilized on catheter shaft **5** by coating **14** during delivery to the treatment site and because there is no sheath to draw past the stent during deployment.

**[0029]** FIG. **2** illustrates implant delivery system **1** comprised of stent **20**, catheter shaft **5** with hub (not shown) and guidewire lumen **6** extending through catheter shaft and hub. Stent **20** includes scaffold **12** and shell **24**. Shell **24** surrounds scaffold **12** and may form a smooth exterior surface over stent **20**. Shell **24** maintains stent **20** at an unexpanded diameter prior to stent deployment and may be comprised of biodegradable materials, or may be comprised of materials that dissolve in the body or in the bloodstream. In some embodiments shell **24** includes sugar, carbowax, polyethylene oxide, poly vinyl alcohol, poly lactic acid (PLA), poly glycolic acid (PGA), poly lactic glycolic acid (PLGA), poly (c-caprolactone) copolymers, polydioxanone, poly(propylene fumarate) poly(trimethylene carbonate) copolymers, polyhydroxy alkanoates, polyphosphazenes, polyanhydrides, poly(ortho esters), poly(amino acids), or "pseudo"-poly(amino acids).

**[0030]** The resorption or dissolution time of shell **24** can be varied by varying the ratio of constituent materials or by other means. The shell material may be axially or biaxially oriented or may have other structure. Shell **24** may be comprised of tubing into which scaffold **12** is inserted, or of film which is wrapped around compressed scaffold, or other structures, and may be applied by other application methods. Shell may be slit, perforated, have a high ability to stretch, may soften abruptly or substantially when heated to near body temperature, or have other characteristics to aid with shell fracture during scaffold expansion.

**[0031]** In some embodiments shell **24** can dissolve or biodegrade over time so as to release scaffold. In some embodiments shell **24** can dissolve or biodegrade when in contact with blood to allow expansion of scaffold **12**. Upon contact with dissolution or biodegradation causing media, scaffold release times of 0.5 to 300 seconds are contemplated. In one embodiment, the scaffold release time is approximately 1 second. In other embodiments, the scaffold release time is approximately 2, 5, 10, 20, 30, 45, 60, 90, 120, 150, 180 or 240 seconds. In some embodiments a change in scaffold **12** length of less than 10% upon expansion from a contracted to an expanded configuration is contemplated. In other embodiments, scaffold **12** length change upon expansion from a contracted to an expanded configuration is less than 9%, 8%, 7%, 6%, 5%, 4%, 3%, 2% or 1%.

**[0032]** Shell **24** may be comprised of bioactive materials such as antirestenotic agents, anti-inflammatory agents, antithrombotic agents, antiatheromatic (antiatheroma) agents, antioxidative agents, or other agents. Bioactive coating materials may be released from the coating into surrounding tissue or blood and may have a diagnostic or therapeutic action on tissue or blood.

**[0033]** An exemplary method of using a stent **20** with implant delivery system **1** is now described. A guidewire is advance into a patient's femoral artery using known techniques, through a patient's vessel and past a treatment site. Stent **20** is loaded onto implant delivery system **1** and introduced over the guidewire into the patient's vessel. Stent **20** is restrained from expanding by shell **24**. The stent and implant delivery system combination is advanced over the guidewire and through the patients vessel until stent **20** is located at a treatment site, for example within a stenosis in a carotid artery. Stent **20** is deployed by allowing shell **24** to dissolve or to biodegrade thereby allowing scaffold to self-expand. Shell may fracture upon expansion of scaffold, and such fracture may be assisted by preplaced slits, slots, local thinning of wall thickness of shell, or other means. Catheter shaft **5** is then withdrawn through the patient's vessel and out of the patient's body. Any of shell **24** that is pinned between scaffold and the vessel, attached to scaffold, or which embolizes from the treatment site dissolves or biodegrades over time. Scaffold **12** does not change length on deployment because the scaffold is immobilized on catheter shaft **5** during delivery to the treatment site and because there is no sheath to draw past the stent during deployment

**[0034]** FIGS. **3**A to **3**C illustrate an example of a Rapid Exchange (RX) delivery system **30** comprised of stent **32**, catheter shaft **35** having balloon inflation lumen (not shown), guidewire lumen **36**, guidewire lumen exit skive **39** and inflation hub **33**, and balloon **31**. Catheter shaft **35** is relatively flexible, may be comprised of a polymeric material such as nylon or PEBAX, and may range in length from 60 cm to 300 cm. Catheter shaft **35** outside diameter may range from about

2 Fr to about 10 Fr. Guidewire lumen **36** diameter may be large enough to allow passage of guidewires ranging in diameter from 0.009" to 0.038". Hub **33** is sealingly attached to catheter shaft **35**, is adapted to reversibly connect to other medical devices (for example by means of a luer fitting) and may be comprised of polycarbonate. Balloon **31** is sealingly attached at both proximal and distal ends to catheter shaft **35** and may be comprised of biaxially oriented nylon, polyester, Pebax, polyolefin, or other materials. Stent **32** may be comprised of stents **10**, **20** or other stents, is shown in an unexpanded configuration in FIGS. **3**A and **3**B and in an expanded configuration in FIG. **3**C. Stent **32** is deployed by connecting an inflation device (not shown) to hub **33** and pressurizing balloon inflation lumen with fluid or gas so as to expand balloon **31** thereby expanding stent **32**. In some embodiments stent **32** is fully expanded into contact with vessel wall by expansion of balloon **31**.

**[0035]** When balloon **31** is expanded beneath stent **10**, the restraining force of coating **14** is overcome by balloon pressure and the coating fractures, allowing stent **10** to expand. When balloon **31** is expanded beneath stent **20**, the restraining force of shell **24** is overcome by balloon pressure and the shell fractures, allowing stent **20** to expand.

**[0036]** An exemplary method of using stent **32** with delivery system **30** is now described. A guidewire is advanced into a patient's femoral artery using known techniques, through a patient's vessel and past a treatment site. A stent **32** (for example stent **10**, **20**) is loaded onto implant delivery system **30** and introduced over the guidewire into the patient's vessel. The stent and implant delivery system combination is advanced over the guidewire and through the patient's vessel until the stent is located at a treatment site, for example within a stenosis in a carotid artery. Stent **10**, **20** is deployed by inflating balloon **31** thereby causing coating **14** or shell **24** to fracture and stent to expand. Catheter **35** is then withdrawn through the patient's vessel and out of the patient's body. Any of coating or shell that is pinned under scaffold, or which embolizes, dissolves/degrades over time. Stent **10**, **20** does not change length on deployment because the stent is immobilized on catheter shaft **35** during delivery to the treatment site and because there is no sheath to draw past the stent during deployment.

**[0037]** FIG. **4** illustrates an example of an Over The Wire (OTW) delivery system **40** comprised of stent **42**, catheter shaft **45** having balloon inflation lumen (not shown), guidewire lumen (not shown) and manifold **47**, and balloon **41**. Manifold **47** includes guidewire lumen exit port **49** and inflation hub **43**. Catheter shaft **45**, guidewire lumen, balloon **41**, and inflation hub **43** have substantially the same construction, dimensions, and function as catheter shaft **35**, guidewire lumen **36**, balloon **31**, and inflation hub **33** described above in conjunction with FIGS. **3**A to **3**C. Manifold **47** is sealingly attached to catheter shaft **45** and may be comprised of polycarbonate. Guidewire lumen exit port **49** and inflation hub **43** are adapted to reversibly connect to other medical devices (for example by means of a luer fitting). (for example stent **10**, **20**), Stent **42** may be comprised of stents **10**, **20** or other stents and is shown in an expanded configuration in

**[0038]** FIG. **4**. Stent **42** is deployed by connecting inflation device (not shown) to hub **43** and pressurizing balloon inflation lumen with fluid or gas so as to expand balloon **41** thereby expanding stent **42**. In some embodiments stent **42** is fully expanded into contact with vessel wall by expansion of balloon **41**.

**[0039]** The methods of using and the benefits of using Over The Wire (OTW) delivery system **40** are substantially the same as those described above for Rapid Exchange (RX) delivery system **30**.

**[0040]** FIGS. **5**A, **5**B, **5**C and **5**D illustrate further embodiments of implant delivery systems having features in accordance with the principles of the present disclosure. FIG. **5**A illustrates implant delivery system **50** comprised of implant delivery system **30**, **40** with modifications to the distal balloon containing portion of implant delivery system **30**, **40**. Proximal region of system **50** includes catheter shaft **35**, **45** having balloon inflation lumen **51***a* and guidewire lumen **55***a*, inflation hub **33**, **43** (not shown) and either guidewire lumen exit skive **39** (not shown) in catheter shaft **35** or manifold **47** (not shown) attached to catheter shaft **45** as described above for systems **30**, **40**. Distal region of system **50** includes catheter shaft **35**, **45**, balloon **51**, stent **52**, band **56***a* and adhesive **54**. Balloon **51** is sealingly attached to catheter shaft **35**, **45** at proximal and distal bonds **51***p*, **51***d* and may be comprised of compliant, semi compliant, non-compliant, or low pressure balloon materials and may be comprised of biaxially oriented nylon, polyester, Pebax, polyolefin, or other materials. In some embodiments balloon **51** includes highly elastic materials such as polyurethane elastomers.

**[0041]** Stent **52** may be comprised of stent **10**, stent **20**, or any stent to which adhesive **54** can bond. For example, stent **54** configurations suitable for the invention include but are not limited to cellular stents, fracturable stents, coil stents, covered stents, stent grafts, mesh covered stents, tapered stents, flared stents, braided stents, bifurcation stents, and other stents as are known in the art. Long stents are especially suited to the invention. Implant delivery systems **50** for stents having lengths of from 20 to 400 mm are contemplated. In one embodiment, a stent delivery system **50** can deliver and deploy a 30 mm stent. In other embodiments, a stent delivery system **50** can deliver and deploy a 40 mm, 60 mm, 80 mm, 100 mm, 120 mm, 150 mm, 180 mm, 200 mm, 250 mm, 300 mm or 350 mm stent.

**[0042]** Band **56***a* is attached to catheter shaft **35**, **45** by friction fit and may be comprised of materials such as metal, Elgiloy, platinum, platinum alloy, nickel-titanium alloy, engineering polymer, liquid crystal polymer, polyester, nylon, or other materials. Edges of band are rounded so as to not promote balloon burst upon balloon inflation. Band **56***a* sandwiches balloon **51** between band and catheter shaft. Band is configured to allow inflation of the portion of balloon **51** that does not underlie band **56***a*. In one embodiment band **56***a* takes the form of a coiled ribbon. In another embodiment, outer surface of catheter **35**, **45** has a groove therealong to receive band **56***a*. Adhesive **54** attaches stent **52** to band **56***a* and may be comprised of biodegradable or dissolvable materials such as poly lactic acid (PLA), poly glycolic acid (PGA), or poly lactic glycolic acid (PLGA), or may be comprised of EVA, polyurethane, nylon, or other materials. In some embodiments adhesive extends into openings through wall thickness of stent **52**.

**[0043]** In an alternate embodiment (FIGS. **5**B and **5**C), band **56***b* includes one or more patches or islands of material having circular, oval, irregular, or other shape and is further comprised of one or more of the materials used to construct band **56***a*. Band **56***b* is bonded to balloon **51**, and balloon **51** is locally bonded to catheter shaft **35**, **45** in the region underlying band **56***b* by means of heat, adhesive, or other means. Local bonds of balloon **51** to catheter shaft **35**, **45** are arranged

in a pattern that allows flow to inflate unbonded portion of balloon. In yet another embodiment (FIG. **5**D), balloon is locally bonded to catheter shaft **35**, **45** by means of heat, adhesive, or other means over a patch or island having circular, oval, irregular, or other shape and band **56***c* includes the bonded region or patch or island. Local bonds of balloon **51** to catheter shaft **35**, **45** are arranged in a pattern that allows flow to inflate unbonded portion of balloon. Adhesive **54** attaches stent **52** to band **56***b*, **56***c* and may be comprised of biodegradable or dissolvable materials such as poly lactic acid (PLA), poly glycolic acid (PGA), or poly lactic glycolic acid (PLGA), or may be comprised of EVA, polyurethane, nylon, or other materials. In some embodiments adhesive extends into openings through wall thickness of stent **52**.

**[0044]** An exemplary method of using a stent **52** with implant delivery system **50** is now described. A guidewire is advanced into a patient's femoral artery using known techniques, through a patient's vessel and past a treatment site. Stent **52** (for example stent **10**, **20**, or other stent) is loaded onto stent delivery system **50** and introduced over the guidewire into the patient's vessel. The stent and stent delivery system combination is advanced over the guidewire and through the patients vessel until the stent is located at a treatment site, for example within a stenosis in a popliteal artery. Stent **52** is deployed by inflating balloon **51** thereby fracturing adhesive **54** attachments between band(s) **56***a*, **56***b*, **56***c* and stent **52**, causing or allowing stent to expand. Catheter shaft **35**, **45** is then withdrawn through the patient's vessel and out of the patient's body. In the case of biodegradable or dissolvable adhesive **54**, any of adhesive that is pinned under stent **52**, or which embolizes, dissolves or degrades over time. Stent **52** does not change length on deployment because the stent is immobilized on catheter shaft **35** during delivery to the treatment site and because there is no sheath to draw past the stent during deployment.

**[0045]** FIGS. **6**A, **6**B, **8**A, **8**B, **8**C and **8**D illustrate RX delivery system **60** comprised of implant delivery catheter **66** having distal region **80** and stent **82**. Implant delivery catheter **66** includes catheter shaft **65**, guidewire lumen **65***a*, proximal guidewire exit skive **69**, proximal handle **68**, sheath **84** and distal manifold **67**. Proximal handle **68** is sealingly attached to catheter shaft **65** and may be comprised of polycarbonate. Catheter shaft **65** is relatively flexible, may be comprised of a polymeric material such as nylon or PEBAX, and may range in length from 60 cm to 300 cm. Catheter outside diameter may range from about 2 Fr to about 10 Fr. Guidewire lumen **65***a* diameter may be large enough to allow passage of guidewires ranging in diameter from 0.009" to 0.038". Distal manifold **67** is sealingly attached to sheath **84** and may be comprised of polycarbonate. Sheath **84** may be comprised of braid-reinforced polyester, non-reinforced polymers such as nylon or polyester, or other materials, and adapted to resist kinking and to transmit axial forces along its length. Sheath **84** may be constructed so as to have varying degrees of flexibility along its length. In one embodiment (FIG. **6**C) sheath **84** includes seal **84***a*, weep holes **84***b*, or both. Seal prevents liquids and body fluids from contacting stent **82** when sheath is fully advanced to cover stent **82**, and may be constructed of elastomeric materials such as low durometer PEBAX, polyurethane, or other materials. Weep holes **84***b* allow annular space between sheath **84** and catheter shaft **65** to be purged of air. Stent **82** may be comprised of stent **10**, **20**, or other stents. In some embodiments, coating **14** or shell **24** is substantially shielded from dissolution or biodegradation causing media due to barrier properties of sheath in combination with sheath seal.

**[0046]** Optionally, implant delivery catheter **66** is further comprised of balloon **81** (FIG. **8**D), balloon inflation lumen within catheter **65** (not shown), and balloon inflation hub **63**. Hub **63** is sealingly attached to proximal handle **88**, is adapted to reversibly connect to other medical devices (for example by means of a luer fitting) and may be comprised of polycarbonate. Balloon **81** is sealingly attached at both proximal and distal ends to catheter shaft **65** and may be comprised of biaxially oriented nylon, polyester, Pebax, polyolefin, or other materials. In one embodiment, balloon **81** is constructed such that the coefficient of friction of the balloon in contact with stent **82** is greater than the coefficient of friction of sheath **84** in contact with stent **82**.

**[0047]** FIGS. **7**, **8**A, **8**B, **8**C and **8**D illustrate OTW delivery system **70** comprised of implant delivery catheter **76** having distal region **80** and stent **82**. Implant delivery catheter **76** includes catheter shaft **75**, guidewire lumen (not shown), proximal guidewire exit port **79**, proximal handle **78**, sheath **84** and distal manifold **77***a*. Sheath **84** may optionally be comprised of seal **84***a*, weep holes **84***b*, or both and distal manifold **77***a* includes infusion tube with stopcock **77***b*. Catheter shaft **75**, guidewire lumen, proximal handle **78** and distal manifold have substantially the same construction, dimensions, and function as catheter shaft **65**, guidewire lumen **65***a*, proximal handle **68** and distal manifold **67** described above in conjunction with FIGS. **6**A to **6**D. Stent **82** may be comprised of stent **10**, **20**, or other stents. In some embodiments, coating **14** or shell **24** is substantially shielded from dissolution or biodegradation causing media due to barrier properties of sheath in combination with sheath seal.

**[0048]** Optionally, implant delivery catheter **76** is further comprised of balloon **81** (FIG. **8**D), balloon inflation lumen within catheter **75** (not shown), and balloon inflation hub **73**. Hub **73** is sealingly attached to proximal guidewire exit port **79**, is adapted to reversibly connect to other medical devices (for example by means of a luer fitting) and may be comprised of polycarbonate. Balloon **81** is sealingly attached at both proximal and distal ends to catheter shaft **75** and may be comprised of biaxially oriented nylon, polyester, Pebax, polyolefin, or other materials.

**[0049]** An exemplary method of using implant delivery system **60**, **70** with stent **82** is now described with the assistance of FIGS. **8**A to **8**C. A guidewire is advanced into a patient's femoral artery using known techniques, through a patient's vessel and past a treatment site. Stent **82** (for example stent **10**, **20**) is loaded onto stent delivery system **60**, **70** (FIG. **8**A) and introduced over the guidewire into the patient's vessel. The stent and stent delivery system combination is advanced over the guidewire and through the patients vessel until the stent is located at a treatment site, for example within a stenosis in an iliac artery. Stent **82** is deployed by sliding proximal handle **68**, **78** and distal manifold **67**, **77***a* closer together, thereby causing sheath **84** to withdraw proximally and uncover stent **82** (FIG. **8**B). Withdrawal of sheath from stent **10**, **20** allows blood and/or media to contact coating or shell thereby releasing stent restraint after dissolution or biodegradation of coating or shell, allowing stent to self-expand (FIG. **8**C). Catheter **66**, **76** is then withdrawn through the patient's vessel and out of the patient's body. Because the coating or shell restrains the stent from

expanding or changing length sheath withdrawal force is reduced and the stent does not change length on deployment.

**[0050]** In some methods, sheath **84** is partially withdrawn from stent **82** so as to allow uncovered portion of stent to expand into contact with the vessel wall, thereby providing frictional localization of the expanded portion of the stent against the vessel wall.

**[0051]** In some embodiments, before dissolution or biodegradation of coating or shell an operator can advance the sheath distally so as to recapture the stent. This is possible because the coating or shell provides a smooth covering over the structural portion of the stent such that the distal end of the sheath will not become mechanically entangled with the structural portion. Recapture of a stent is desirable when the operator wishes to change the eventual deployed position of the stent or for other reasons. In other embodiments, sheath seal **84***a* prevents blood and/or media to contact stent **82** during stent delivery in the patient, thereby preventing expansion of stent **82** secondary to premature dissolution or biodegradation of coating **14** or shell **24**. In still other embodiments, prior to introduction into a patient delivery system **60**, **70** is flushed with fluid to purge air by connecting a syringe filled with flushing solution (e.g. saline) to distal manifold **67**, **77***a* and forcing flushing solution through sheath **84** and out weep holes **84***b*, thereby preventing flushing fluid from contacting stent **82** and potentially causing premature dissolution or biodegradation of coating **14** or shell **24**.

**[0052]** In methods of using embodiments of implant delivery system **60**, **70** where balloon **81** is incorporated into the system, balloon **81** is inflated after withdrawal of sheath **84** (FIG. **8**D) by connecting inflation device (not shown) to hub **63**, **73** and pressurizing balloon inflation lumen with fluid or gas thereby causing stent **82** to expand after fracture or compromise of coating or shell. In some embodiments stent **82** is fully expanded into contact with vessel wall by expansion of balloon. Because the coating or shell restrains the stent from expanding or changing length and because the stent is expanded by balloon, sheath withdrawal force is reduced and the stent does not change length on deployment.

**[0053]** An alternate exemplary method of using embodiments of implant delivery system **60**, **70** where balloon **81** is incorporated into the system with stent **82** is now described with the assistance of FIGS. **8**A to **8**D. A guidewire is advanced into a patient's femoral artery using known techniques, through a patient's vessel and past a treatment site. Stent **82** (for example any stent that self expands when not restrained by another device or component) is loaded onto stent delivery system **60**, **70** (FIG. **8**A) and introduced over the guidewire into the patient's vessel. The stent and stent delivery system combination is advanced over the guidewire and through the patients vessel until the stent is located at a treatment site, for example within a stenosis in a carotid artery. Balloon **81** is inflated prior to withdrawal of sheath **84** (FIG. **8**A, balloon not shown) by connecting inflation device (not shown) to hub **63**, **73** and pressurizing balloon inflation lumen with fluid or gas until sliding friction of stent **82** against balloon **81** exceeds sliding friction of stent **82** against sheath **84**. Stent **82** is deployed by sliding proximal handle **68**, **78** and distal manifold **67**, **77***a* closer together, thereby causing sheath **84** to withdraw proximally and uncover stent **82** (FIG. **8**D). Catheter **66**, **76** is then withdrawn through the patient's vessel and out of the patient's body. Because the inflated balloon restrains the stent from changing length (for example buckling, stretching, kinking, or "bunching up") in the sheath, sheath withdrawal force is reduced and the stent does not change length on deployment.

**[0054]** While the various examples of the present invention have related to stents and stent delivery systems, the scope of the present invention is not so limited. For example, while particularly suited for stent delivery systems, it will be appreciated that the various aspects of the present invention are also applicable to systems for delivering other types of expandable implants. By way of non-limiting example, other types of expanding implants include anastomosis devices, blood filters, grafts, vena cava filters, percutaneous valves, aneurism treatment devices, or other devices.

**[0055]** It has been shown how certain objects of the invention have been attained in a preferred manner. Modifications and equivalents of the disclosed concepts are intended to be included within the scope of the claims. Alternate materials for many of the delivery system components are generally well known in the art can be substituted for any of the non-limiting examples listed above provided the functional requirements of the component are met. Further, while choices for materials and configurations may have been described above with respect to certain embodiments, one of ordinary skill in the art will understand that the materials and configurations described are applicable across the embodiments.

What is claimed is:

**1**. A stent for insertion into a body lumen, comprising:

a scaffold having a collapsed and a diametrically expanded configuration; and

a coating or a shell surrounding the scaffold that retains the scaffold in its collapsed configuration, said coating or shell made of a material that dissolves or biodegrades upon exposure to a dissolution or biodegradation media;

wherein the scaffold is expanded from its collapsed to its expanded configuration through exposure of the coating or shell to the dissolution or biodegradation media.

**2**. The stent of claim **1**, wherein the coating comprises a material selected from the group consisting of sugar, carbowax, polyethylene oxide, and poly vinyl alcohol.

**3**. The stent of claim **1**, wherein the coating or shell comprises a bioactive material selected from the group consisting of antirestenotic agents, anti-inflammatory agents, antithrombotic agents, antiatheromatic (antiatheroma) agents, and antioxidative agents.

**4**. The stent of claim **1**, wherein the shell comprises a material selected from the group consisting of sugar, carbowax, polyethylene oxide, poly vinyl alcohol, poly lactic acid (PLA), poly glycolic acid (PGA), poly lactic glycolic acid (PLGA), poly (ϵ-caprolactone) copolymers, polydioxanone, poly(propylene fumarate) poly(trimethylene carbonate) copolymers, polyhydroxy alkanoates, polyphosphazenes, polyanhydrides, poly(ortho esters), poly(amino acids), or "pseudo"-poly(amino acids).

**5**. The stent of claim **1**, wherein the shell comprises tubing into which the scaffold is inserted, or a film which is wrapped around the compressed scaffold.

**6**. The stent of claim **5**, wherein the shell comprises a longitudinal slit or is perforated.

**7**. The stent of claim **1**, wherein the scaffold is self-expanding.

**8**. The stent of claim **1**, wherein the scaffold is balloon-expandable.

**9**. An implant delivery system for deploying a stent in a patient's vessel, the system comprising:

a catheter having a catheter shaft;

a stent mounted on the catheter shaft, said stent comprising a scaffold having a collapsed configuration and a diametrically expanded configuration; and

a coating or a shell surrounding the scaffold and retaining the scaffold in its collapsed configuration, said coating or shell made of a material that dissolves or biodegrades upon exposure to a dissolution or biodegradation media;

wherein the scaffold is expanded from its collapsed to its expanded configuration through exposure of the coating or shell to the dissolution or biodegradation media and wherein the catheter shaft is configured to be withdrawn through the patient's vessel when the scaffold is in its expanded configuration.

**10**. The system of claim **9**, wherein the stent is self-expanding.

**11**. The system of claim **9**, further comprising a slidable tubular sheath surrounding the stent in the collapsed configuration on the catheter shaft, said tubular sheath protecting the coating or a shell from exposure to the dissolution or biodegradation media.

**12**. The system of claim **9**, further comprising an inflatable balloon disposed between the stent and the catheter shaft, said balloon fracturing the coating or shell upon inflation.

**13**. The system of claim **12**, wherein the balloon is sealingly attached to both a proximal end and a distal end of the catheter shaft.

**14**. The system of claim **12**, further comprising a slidable tubular sheath surrounding the stent in the collapsed configuration on the catheter shaft, wherein the balloon is constructed such that a force of friction of the balloon in contact with the stent is greater than a force of friction of the sheath in contact with the stent.

**15**. A method for delivering a stent to a treatment site, comprising the steps of:

providing an implant delivery system having a stent mounted on a catheter shaft, said stent having a scaffold with a coating or a shell surrounding the scaffold and retaining the scaffold in its collapsed configuration, and a tubular sheath surrounding the stent in the collapsed configuration on the catheter shaft;

advancing the implant delivery system to the treatment site;

withdrawing the tubular sheath to expose the coating or shell to a dissolution or biodegradation media; and

withdrawing the catheter shaft from the treatment site.

**16**. The method of claim **15**, wherein the stent is self-expanding.

**17**. The method of claim **15**, wherein the delivery system further comprises a balloon interposed between the stent and the catheter shaft, the method further comprising the step of inflating the balloon to cause expansion of the stent before withdrawing the catheter shaft.

**18**. The method of claim **17**, wherein inflating the balloon comprises pressurizing a balloon inflation lumen with fluid or gas until a force of sliding friction of the stent against the balloon exceeds a force of sliding friction of the stent against the tubular sheath.

**19**. A method for delivering a stent to a treatment site, comprising the steps of:

providing an implant delivery system having a stent mounted on a catheter shaft, a balloon interposed between the stent and the catheter shaft, and a tubular sheath surrounding the stent in the collapsed configuration on the catheter shaft;

advancing the implant delivery system to the treatment site;

inflating the balloon to cause expansion of the stent before withdrawing the tubular sheath;

withdrawing the tubular sheath; and

withdrawing the catheter shaft from the treatment site.

**20**. The method of claim **19**, wherein the stent is self-expanding.

**21**. The method of claim **19**, wherein inflating the balloon comprises pressurizing a balloon inflation lumen with fluid or gas until a force of sliding friction of the stent against the balloon exceeds a force of sliding friction of the stent against the tubular sheath.

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