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Radhakrishnan et al.

(54) **BIOERODIBLE ENDOPROSTHESIS**

(75) Inventors: **Rajesh Radhakrishnan**, Maple Grove, MN (US); **Chandru Chandrasekaran**, Mercer Island, WA (US); **Scott R. Schewe**, Eden Prairie, MN (US); **Ken Merdan**, Loretto, MN (US)

(73) Assignee: **Boston Scientific SciMed. Inc.**, Maple Grove, MN (US)

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(52) **U.S. Cl.** **623/1.46**

(57) **ABSTRACT**

An endoprosthesis includes a plurality of struts defining a flow passage. At least one strut includes (a) a body comprising a bioerodible material and having a thickness and (b) a coating overlying the body. The coating includes a plurality of regions that allow physiological fluids to contact a plurality of corresponding areas of the underlying body when the endoprosthesis is implanted in a physiological environment. The plurality of regions are sized and arranged so that the contacted areas of the body erode substantially through the body in the thickness direction while the coating remains on the body when the endoprosthesis is implanted in the physiological environment.

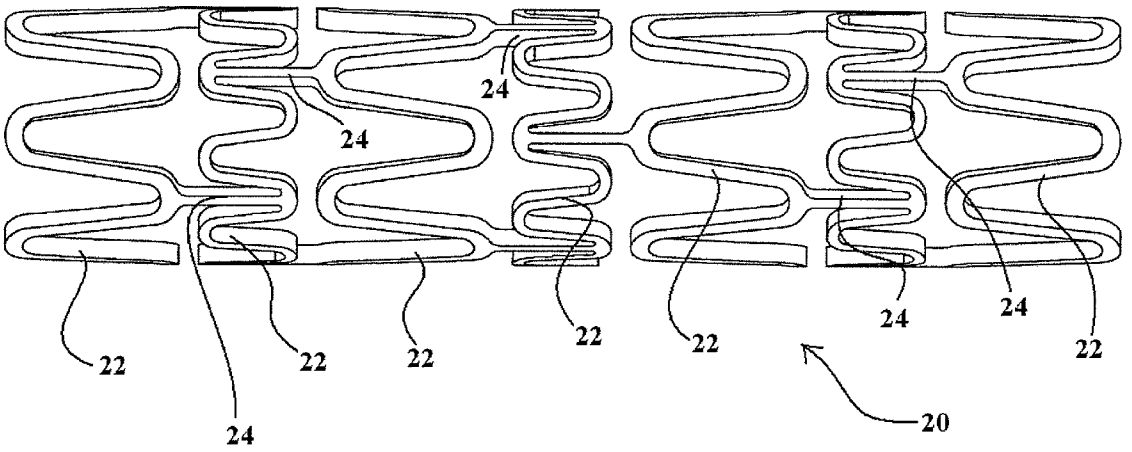
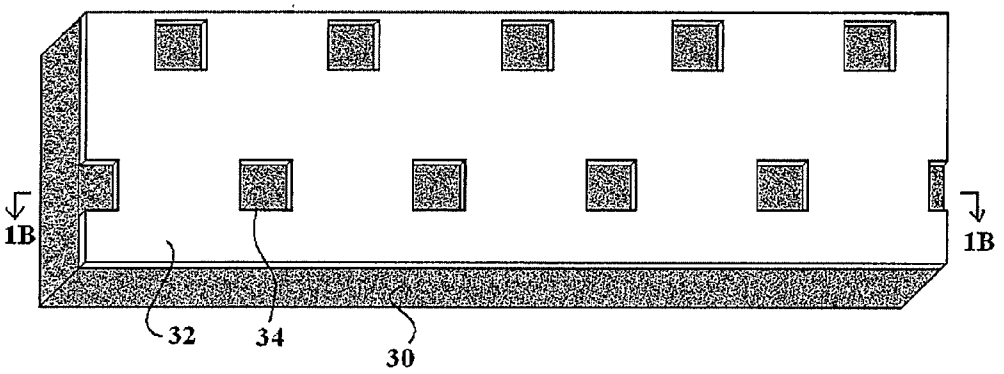


FIG. 1A



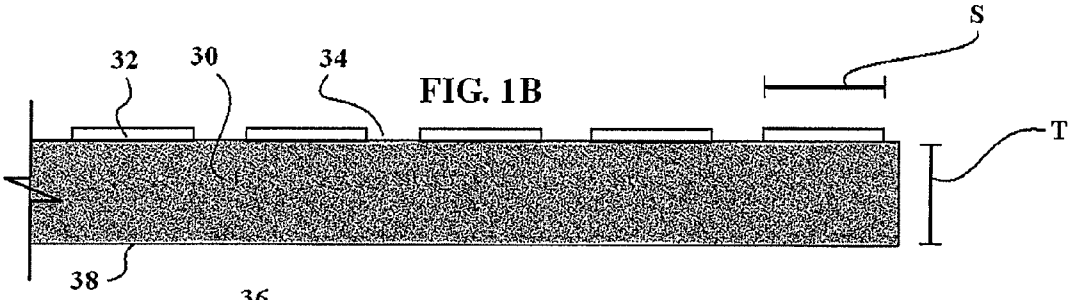


FIG. 1B

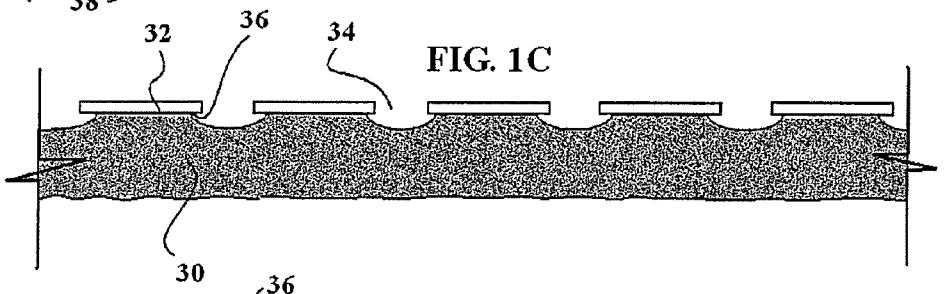


FIG. 1C

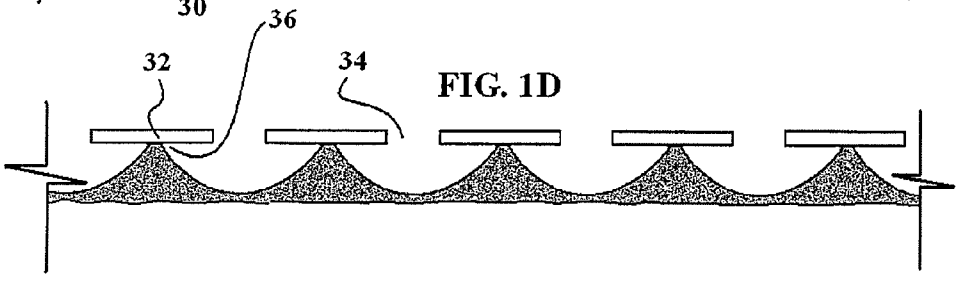
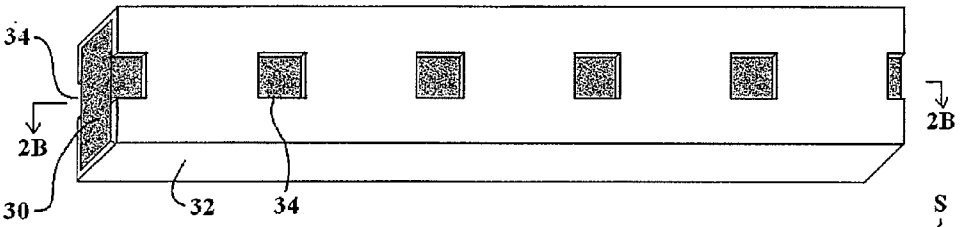


FIG. 1D

FIG. 2A



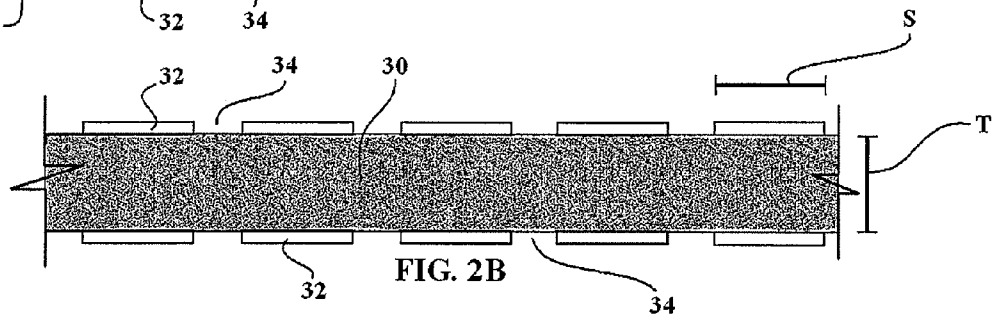


FIG. 2B

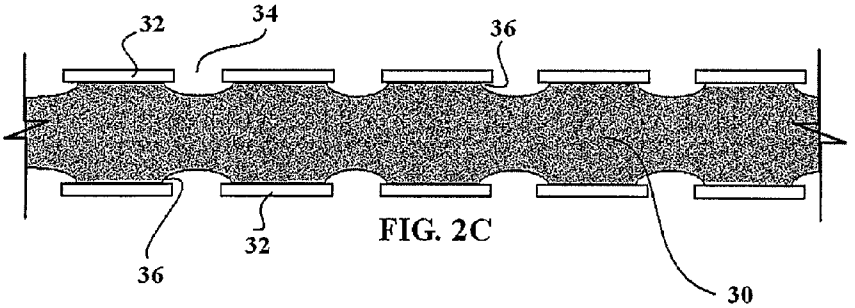


FIG. 2C

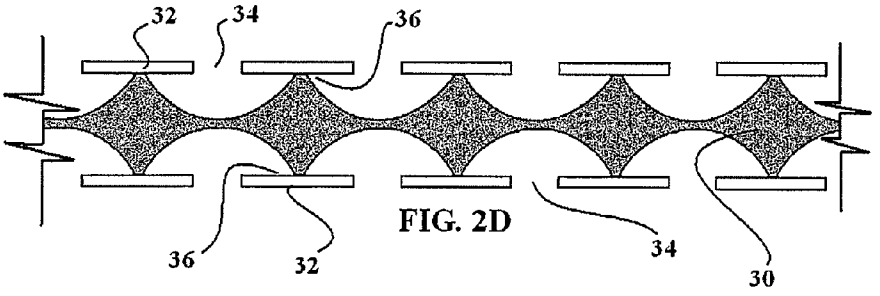
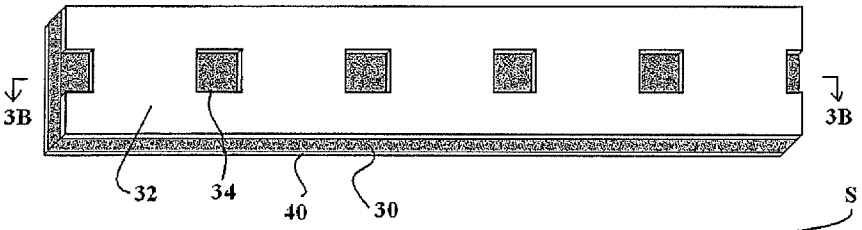


FIG. 2D

FIG. 3A



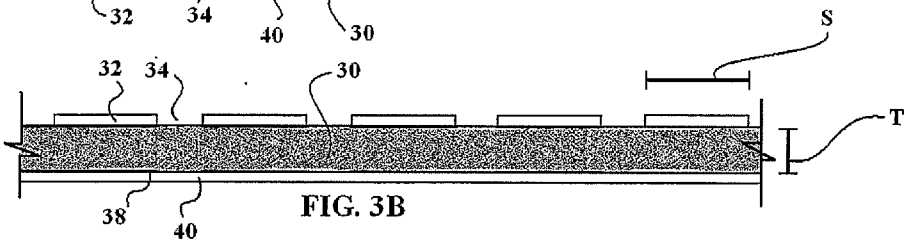


FIG. 3B

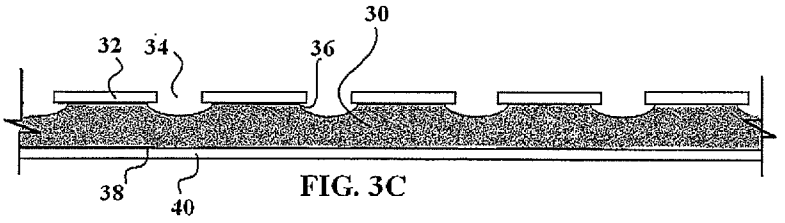


FIG. 3C

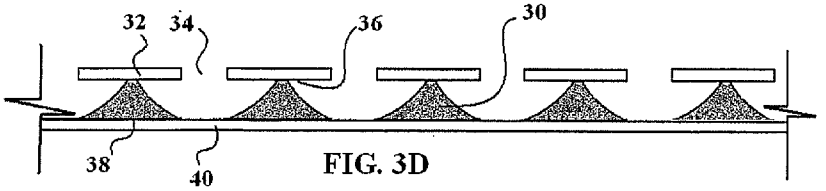


FIG. 3D

FIG. 4A

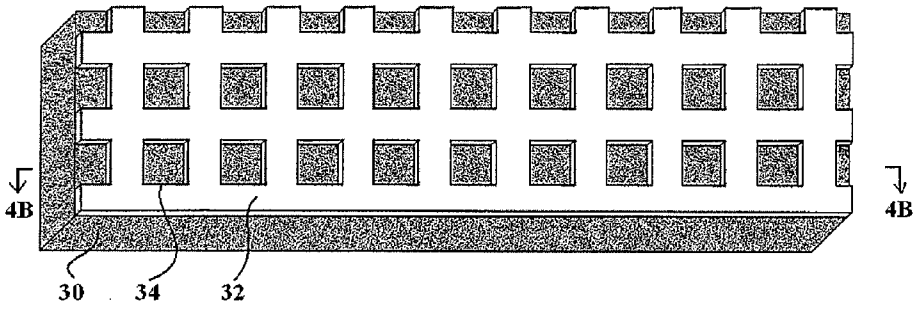
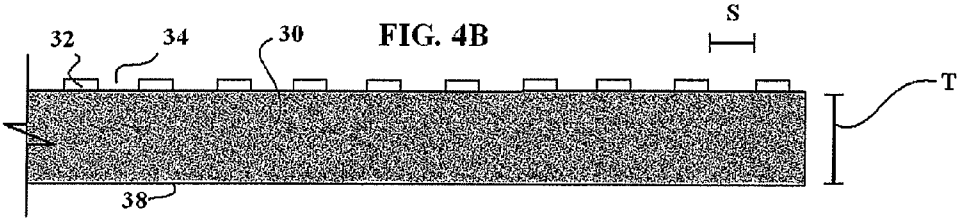


FIG. 4B



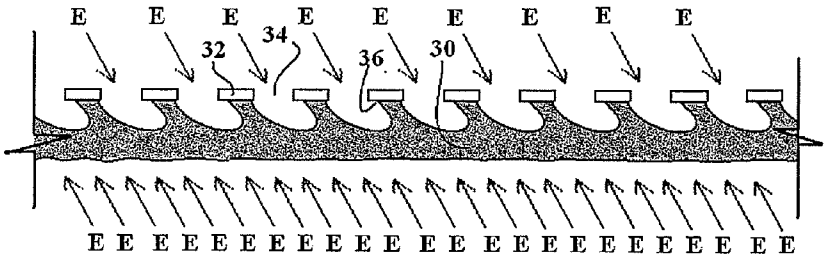


FIG. 4C

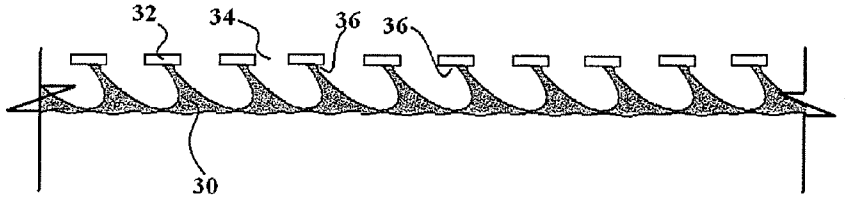


FIG. 4D

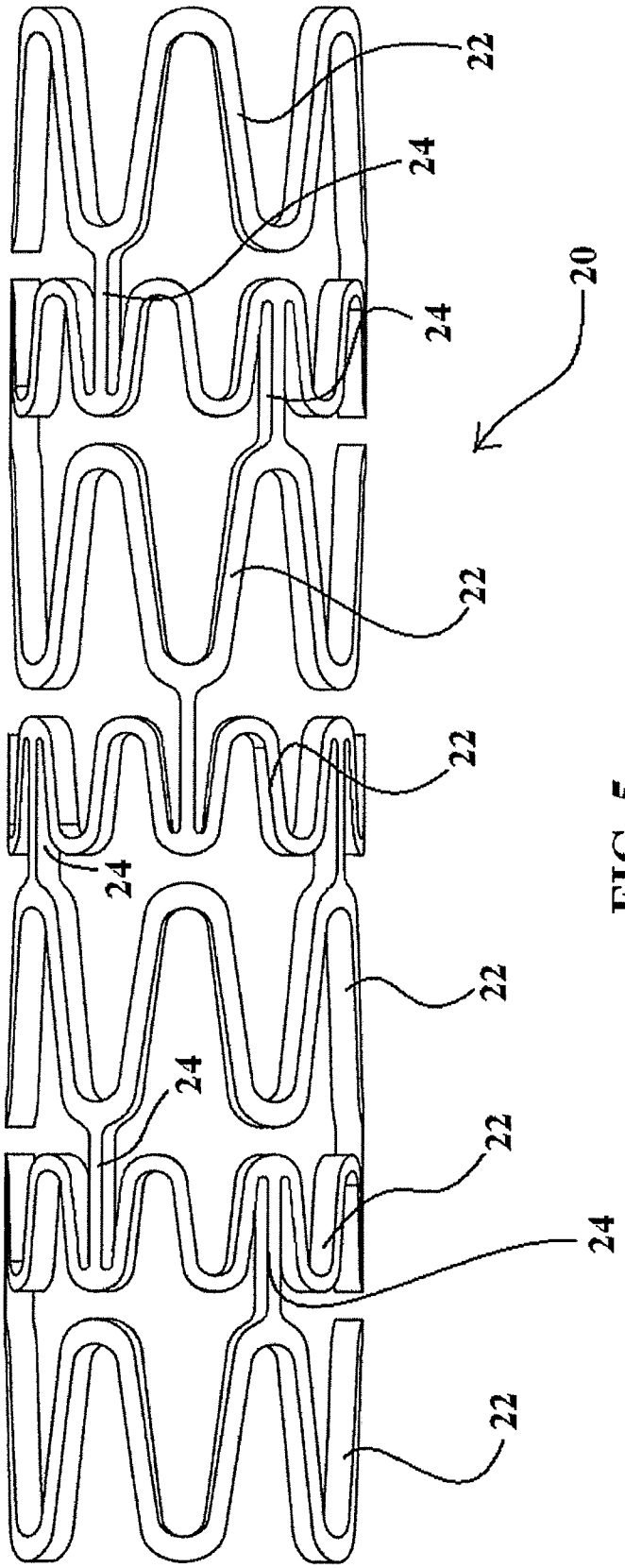


FIG. 5

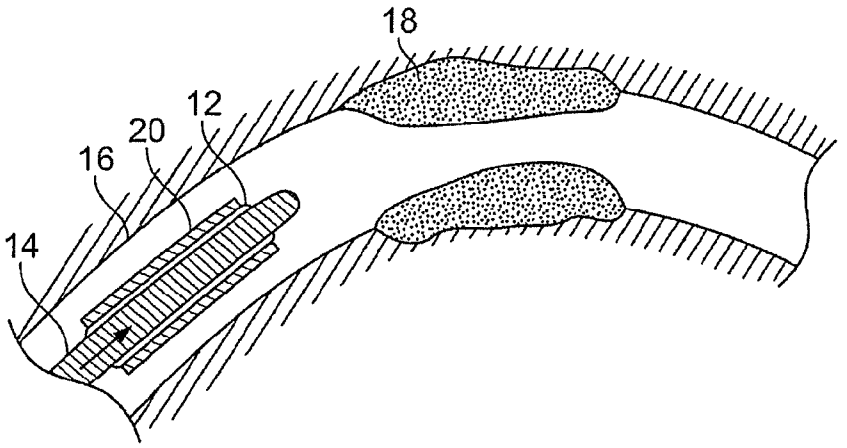


FIG. 6A

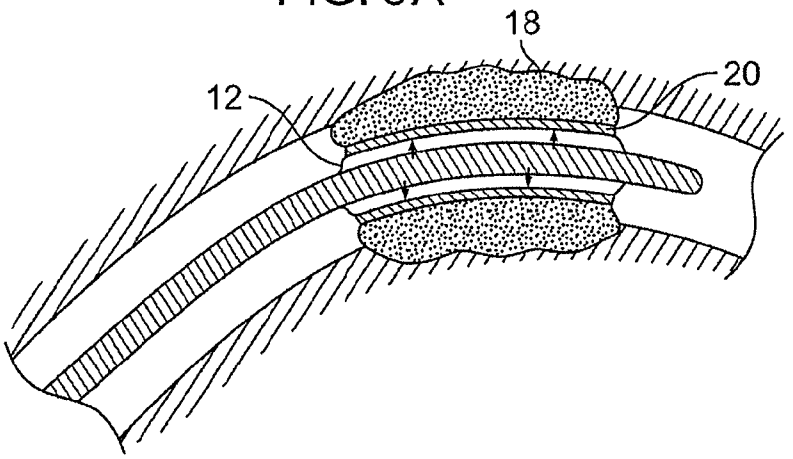


FIG. 6B

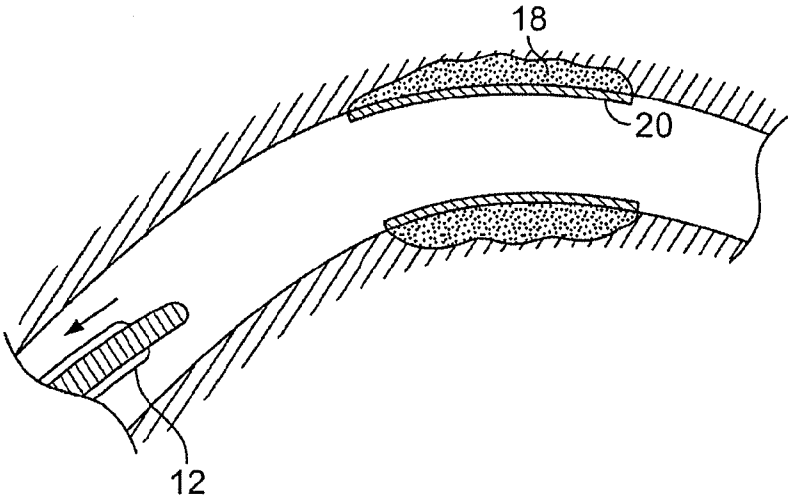


FIG. 6C

BIOERODIBLE ENDOPROSTHESIS

CROSS REFERENCE TO RELATED CASES

[0001] This application is a continuation of and claims priority under 35 U.S.C. §120 to U.S. patent application Ser. No. 12/182,768, filed on Jul. 30, 2008, the entire contents of which are incorporated herein by reference.

TECHNICAL FIELD

[0002] This invention relates to bioerodible endoprostheses.

BACKGROUND

[0003] The body includes various passageways such as arteries, other blood vessels, and other body lumens. These passageways sometimes become occluded or weakened. For example, the passageways can be occluded by a tumor, restricted by plaque, or weakened by an aneurysm. When this occurs, the passageway can be reopened or reinforced with a medical endoprosthesis. An endoprosthesis is typically a tubular member that is placed in a lumen in the body. Examples of endoprostheses include stents, covered stents, and stent-grafts.

[0004] Endoprostheses can be delivered inside the body by a catheter that supports the endoprosthesis in a compacted or reduced-size form as the endoprosthesis is transported to a desired site. Upon reaching the site, the endoprosthesis is expanded, e.g., so that it can contact the walls of the lumen.

[0005] The expansion mechanism may include forcing the endoprosthesis to expand radially. For example, the expansion mechanism can include the catheter carrying a balloon, which carries a balloon-expandable endoprosthesis. The balloon can be inflated to deform and to fix the expanded endoprosthesis at a predetermined position in contact with the lumen wall. The balloon can then be deflated, and the catheter withdrawn from the lumen.

[0006] In another delivery technique, the endoprosthesis is formed of an elastic material that can be reversibly compacted and expanded, e.g., elastically or through a material phase transition. During introduction into the body, the endoprosthesis is restrained in a compacted condition. Upon reaching the desired implantation site, the restraint is removed, for example, by retracting a restraining device such as an outer sheath, enabling the endoprosthesis to self-expand by its own internal elastic restoring force.

[0007] It is sometimes desirable for an implanted endoprosthesis to erode over time within the passageway. For example, a fully erodible endoprosthesis does not remain as a permanent object in the body, which may help the passageway recover to its natural condition. Erodible endoprostheses can be formed from, e.g., a polymeric material, such as polylactic acid, or from a metallic material, such as magnesium, iron or an alloy thereof.

SUMMARY

[0008] There is described an endoprosthesis that includes a plurality of struts defining a flow passage. At least one strut includes (a) a body comprising a bioerodible material and having a thickness and (b) a coating overlying the body. The coating includes a plurality of regions that allow physiological fluids to contact a plurality of corresponding areas of the underlying body when the endoprosthesis is implanted in a physiological environment. The plurality of regions are sized and arranged so that the contacted areas of the body erode substantially through the body in the thickness direction while the coating remains on the body when the endoprosthesis is implanted in the physiological environment.

[0009] The body can include bioerodible material that erodes isotropically and/or anisotropically. The rate of erosion of the body in the thickness direction multiplied by the thickness of the body can be less than a rate of erosion of the body along an interface between the body and the coating multiplied by the distance between adjacent regions. In some embodiments, the rate of erosion of the body in the thickness direction multiplied by the thickness of the body can be less than a rate of erosion of the body along an interface between the body and the coating multiplied by ½ of the distance between adjacent regions. For example, the plurality of regions can be arranged such that the distance between adjacent regions is equal to at least the thickness of the body (e.g., at least twice the thickness of the body).

[0010] The bioerodible material of the body can have a first electric potential and the coating has a second electric potential different from the first electric potential so that the body and the coating form a galvanic couple when the endoprosthesis is implanted in a physiological environment. In some embodiments, the first electric potential can be less than the second electrode potential so that the body acts as an anode and the coating acts as a cathode when the endoprosthesis is implanted in a physiological environment. For example, the body can include a bioerodible metal selected from the group consisting of magnesium, iron, zinc, and alloys thereof and the coating can include a metal selected from the group consisting of platinum, iridium, and alloys thereof. In other embodiments, the first electric potential can be greater than the second electrode potential so that the body acts as a cathode and the coating acts as an anode when the endoprosthesis is implanted within a physiological environment.

[0011] The bioerodible material of the body can be a bioerodible metal and/or a bioerodible polymer. For example, the body can include a bioerodible metal selected from magnesium, iron, zinc, and alloys thereof and/or a bioerodible polymer selected from polyglutamic acid, poly(ethylene oxide), polycaprolactam, poly(lactic-co-glycolic acid), polysaccharides, and combinations thereof.

[0012] The coating can surround or partially surround the circumference of the body. The coating can include a bioerodible material having a slower erosion rate than the bioerodible material of the body.

[0013] The regions of the coating can include voids, pores, and/or can have a higher erosion rate than the remainder of the coating in a physiological environment.

[0014] The endoprosthesis, in some embodiments, can be a stent.

[0015] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

[0016] FIGS. **1**A-**1**D depict a first embodiment of an endoprosthesis strut.

[0017] FIGS. **2**A-**2**D depict a second embodiment of an endoprosthesis strut.

[0018] FIGS. **3**A-**3**D depict a third embodiment of an endoprosthesis strut.

[0019] FIGS. **4**A-**4**D depict a third embodiment of an endoprosthesis strut.

[0020] FIG. **5** is a perspective view of an embodiment of an expanded stent.

[0021] FIGS. **6**A-**6**C are longitudinal cross-sectional views illustrating delivery of a stent in a collapsed state, expansion of the stent, and deployment of the stent.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0022] FIGS. **1**A-**1**D, **2**A-**2**D, **3**A-**3**D, and **4**A-**4**D depict different of an endoprosthesis strut having a body **30** that includes a bioerodible material and a coating **32** overlying at least a portion of the body **30**. The coating **32** includes a plurality of regions **34** that expose a plurality of corresponding areas of the underlying body **30** to a physiological environment when the endoprosthesis is implanted within a physiological environment. As shown, the regions are simply voids in the coating. In other embodiments, the regions **34** can be porous regions and/or regions designed to erode prior to the remainder of the coating **32**. The regions **34** are sized and arranged so that the exposed areas of the body erode substantially through the body in the thickness direction before the coating **32** separates from the body **30**. The spacing of the regions can account for an undercutting of the coating during the erosion of the body of the endoprosthesis, namely the erosion of the bioerodible body along the interface between the body and the coating. For example, the coating can separate from the body **30** due to this erosion of the body **30** along the interface between the body **30** and the coating **32**. If the regions are spaced too closely, this undercutting can result in a premature separation of the coating from the body.

[0023] The arrangement of regions, particularly the spacing between adjacent regions, is determined, in part, based on the thickness of the body and the erosion characteristics of the body **30** (e.g., whether the body **30** erodes isotropically or anisotropically). For a body **30** that erodes isotropically (i.e., homogeneously in all directions), the spacing S between adjacent regions can be at least equal to the thickness T of the body. For example, as shown in FIGS. **1**C, **1**D, **2**C, **2**D, **3**C, and **3**D, a body **30** that erodes isotropically can produce undercuts **36** beneath the edges of the regions **34** of the coating **32**. For embodiments where the coating **32** is only on one side of the body **30**, such as shown in FIGS. **1**A-**1**D, a thickness T can be less than or equal to the spacing S between adjacent regions **34** to ensure that the body erodes substantially through the thickness T before the coating **32** separates from the body **30**. In some embodiments, the body can be formed of a single bioerodible material having consistent erosion properties. In other embodiments, the body can be a composite of a plurality of bioerodible materials and can have varying erosion properties. The size and arrangement of the regions in the coating can depend on the overall erosion properties of the body.

[0024] As shown in FIGS. **1**C and **1**D, an uncoated opposite side **38** of the body **30** can erode in a substantially uniform manner across its surface, and at substantially the same rate as the body erodes inward in the thickness direction from the exposed areas of the regions **34**. Having a thickness T that is less than the spacing S can ensure that the body **30** erodes substantially through the thickness, from both sides of the body, before adjacent undercuts from adjacent regions **34** erode into each other. In some embodiments, however, the placement of the endoprosthesis within a physiological environment can alter the rate of erosion of particular portions and/or sides of the endoprosthesis. For example, a side of an isotropic body **30** placed against a vessel wall may erode at a slower or faster rate than a portion of the body **30** positioned adjacent to flowing blood, depending on the characteristics of the material(s) of the body **30**. The pH of the physiological environment can alter the erosion rate of some bioerodible materials and the erosion of various bioerodible materials can alter the pH of the surrounding fluids and/or tissues. The endoprosthesis can be designed so that the contacted areas of the body erode substantially through the body in the thickness direction while the coating remains on the body even with these variations to the erosion rate of the body.

[0025] The body **30** can also include coatings on selected portions of the surface of the body (e.g., on more than one side). In some embodiments, the coating **32** can surround the entire circumference of the body **30**. In other embodiments, the coating can extend along the length of the body **30** in selected portions around the circumference of the body **30**. For example, as shown in FIGS. **3**A-**3**C, the body can have coatings on opposite sides of the body **30**, but have adjacent sides of the body remain exposed. The coatings on portions (or sides) of the body can have uniform or non-uniform patterns of regions. For example, as shown in FIGS. **2**A-**2**B, a coating **32** can have identical patterns on opposite sides of the body and have adjacent sides without the presence of any regions. As shown, the regions of the opposite sides are aligned. In other embodiments, the regions can be offset. In some embodiments, opposite sides can have completely different arrangements of regions, different sizes of regions, and/or different spacing of regions. Although the body **30** is shown as having a rectangular cross-sectional shape, the body can have other cross-sectional shapes (e.g., circular or polygonal) and can have a non-constant cross-sectional shapes, thicknesses, and/or widths.

[0026] An isotropically eroding body **30** having identical and aligned patterns of regions on opposite sides of the body **30**, as shown in FIGS. **2**A-**2**D, can have a thickness T of less than or equal to the spacing S between adjacent regions **34**. As shown in FIG. **2**D, the regions **34** of opposite sides of the body **30** allow for erosions paths through the thickness of the body **30** that meet at the approximate center of the body **30**, which provides an erosion path through the thickness of the body **30** prior to the separation of the coating **32** from the body **30** along the interface between the body **30** and the coating **32**. A body **30** having different patterns of regions **34** on opposite sides of body **30** can allow for different maximum thicknesses depending on an amount of time required for erosion paths on opposite sides to intersect (if at all). If erosion paths do not intersect, for example, if body **30** has a region-free coating **40** on the opposite side **38** of the body **30** as shown in FIGS. **3**A-**3**D, the thickness T of the body can be less than or equal to half of the spacing S between adjacent regions. As shown in FIG. **3**D, the body **30** can erode through its thickness T prior to the separation of the coating **32** from the body **30**. For example, iron and magnesium erode isotropically.

[0027] A body **30** that erodes anisotropically can allow for different arrangements of regions in the coating **32**. The arrangement, however, must account for the different rates of erosion of the body in each direction. For example, as shown in FIGS. **4**A-**4**D, an endoprosthesis having a body **30** that erodes anisotropically can allow for a closer spacing of adja-

cent regions **34** if the body **30** erodes at a faster rate in the thickness direction than in directions parallel with the coating. FIGS. **4**C and **4**D depict a preferred erosion direction E that results in a faster erosion rate in the thickness direction. In other embodiments, the preferred erosion direction E can be parallel to the thickness direction. In embodiments having a non-coated opposite underside **38** of the body as shown in FIGS. **4**A-**4**D, the thickness T of the body can be less than or equal to the minimum spacing between the plurality of regions multiplied by the average rate of erosion of the body along an interface of the body and the coating multiplied by divided by the rate of erosion of the body in the thickness direction. The same can apply to an anisotropic body having coatings with regions **34** on opposite sides of the body where the regions on opposite sides are aligned along an axis parallel to the direction of preferred erosion E. In other embodiments, such as those having an region-free coating **40** on the opposite side (e.g., the underside **38**) of the body **30**, the thickness can be up to 50% of the minimum spacing between the plurality of regions multiplied by the average rate of erosion of the body along an interface of the body and the coating divided by the rate of erosion of the body in the thickness direction. For example, some bioerodible polymers erode anisotropically.

[0028] The size, spacing, and arrangement of the regions can also control the size of the particles dispensed into the surrounding body fluid. As shown in FIGS. **1**D, **2**D, **3**D, and **4**D, different arrangements of the regions combined with different body characteristics can impact the size and shape of the pieces of the eroding endoprosthesis that separate from the reminder of the endoprosthesis once a path erodes through the thickness direction of the body and the coating **32** separates from the body. In some embodiments, the arrangement of regions can vary to ensure that particular parts of a body of an endoprosthesis separate from the remainder of the endoprosthesis in a particular order.

[0029] The body **30** includes a bioerodible material (e.g., a bioerodible metal, a bioerodible polymer, a bioerodible ceramic, and/or a bioerodible metal salt). Examples of bioerodible metals suitable for use in the body **30** include magnesium, iron, zinc, and alloys thereof. An example of a suitable bioerodible iron alloy includes Fe-35Mn. Examples of bioerodible polymers suitable for use as the body **30** include polyglutamic acid, polylactic acid (PLA), poly(ethylene oxide) (PEO), poly-serine, polycaprolactam, poly(lactic-co-glycolic acid) (PLGA), cyclodextrins, polysaccharides (e.g., chitosan and hyaluronan), copolymers thereof, and combinations thereof. Other examples of bioerodible polymers include polyglycolic acid (PGA), polycaprolactone (PCL), polyorthoesters, polydioxanone, poly(trimethylene carbonate) (PTMC), polyphosphazenes, polyketals, proteins (e.g., glycoproteins, fibrin, collagen, gelatin, pectin), polyanhydrides (e.g., poly(ester anhydride)s, fatty acid-based polyanhydrides, amino acid-based polyanhydrides), polyesters, polyester-polyanhydride blends, polycarbonate-polyanhydride blends, and/or combinations thereof. The bioerodible polymers can be blended and/or copolymerized to alter the degradation characteristics.

[0030] The coating **32** can include a biocompatible material that can protect the underlying material from erosion. The portion of the coating **32** that separates the plurality of regions **34** can protect the underlying body from contact with physiological fluids at least until the contacted areas of the body erode substantially through the body in the thickness direction. For example, the portion of the coating **32** that separates the plurality of regions **34** can be non-porous. The coating **32** can include bioerodible materials and/or more stable materials. A coating of a bioerodible material can have a slower erosion rate than the body **30**. The thickness of the coating **32** can be such that at least a portion of the coating remains non-eroded and on the body **30** at least until the contacted areas of the body erode substantially through the body in the thickness direction. The coating **32** can be between 10 nanometera and 10 microns thick. Examples of suitable bioerodible materials for use in the coating include bioerodible polymers, bioerodible metals, biological materials, and combinations thereof. Suitable bioerodible metals include iron, zinc, and alloys thereof. Suitable bioerodible polymers can include polyglutamic acid, polylactic acid, poly(ethylene oxide), poly-serine, polycaprolactam, poly(lactic-co-glycolic acid), cyclodextrins, polysaccharides, copolymers thereof, and combinations thereof. The bioerodible polymers can be blended to alter the degradation characteristics. Suitable biological materials can include collagen, hyaluronic acid, glycoproteins, polysaccharides, pectin, and combinations thereof. In some embodiments, the coating **32** and the body **30** can form a galvanic couple that can allow for the preferential erosion of the body **30** (e.g., the body can act as an anode while the coating acts as a cathode). For example, a magnesium body can have an iron coating so that the magnesium body erodes preferentially.

[0031] A coating **32** can also include more stable materials, which can be selected from polymers, metals, ceramics, salts, and biological materials. Examples of relatively stable metals suitable for use in the coating **32** include: tantalum, titanium, cobalt, chromium, stainless steel, cobalt-chromium alloys, platinum enhanced stainless steel alloys, Nitinol alloys, and noble metals, such as platinum, palladium, iridium, and ruthenium. Suitable ceramics can include, for example, CrOx, AlOx, ZrOx, SiOx, TiNOx, and oxides of noble metals such as IrOx. Suitable polymers can included SIBS and PVDF. Suitable biologic materials can include collagen, fibrin, alginates, and polysaccharides. A relatively stable coating **32** can provide a firm substrate to an otherwise eroding structure, thus facilitating endothelial cell growth and/or attachment while retaining sufficient flexibility to facilitate delivery and deployment of the endoprosthesis. Moreover, the visibility of the endoprosthesis to imaging methods, e.g., X-ray and/or Magnetic Resonance Imaging (MRI), can be enhanced, even after the endoprosthesis is partly eroded, by e.g., incorporating a radiopaque material into the coating **32**.

[0032] The regions **34** allow for a plurality of corresponding areas of the underlying body to be exposed to a physiological environment when the endoprosthesis is implanted in a physiological environment. As shown in FIGS. **1**A-**1**D, **2**A-**2**D, **3**A-**3**D, and **4**A-**4**D, the regions **34** are merely square shaped voids in the coating. The regions **34**, however, can have other shapes (e.g., circular, elliptical, polygonal, etc). The size and/or shape of different regions **34** of a single coating **32** can be different or the same. In other embodiments, not shown, the regions **34** can include pores that allow the underlying areas of the body **30** to be contacted by physiological fluids when the endoprosthesis is implanted into a physiological environment. These regions of pores can be surrounded by other portions of the coating **32** that do not allow the underlying surface of the body to be contacted by physiological fluids. For example, a coating **32** having porous regions can be produced by implanting ions in selected regions of the coating, followed by leaching or burning the

ions out to create porosity in those selected regions (regions **34**). The regions **34**, can also include areas of the coating designed to erode to expose underlying areas of the body **30** prior to the erosion of the remainder of the coating **32**. The spacing between these regions **34** of faster erosion allow the underlying areas of the body to erode substantially through the body in the thickness direction while at least a portion of the coating remains on the body. For example, the regions **34** can have a substantially thinner thickness than the remainder of the coating, can include a material that erodes at a faster rate than the remainder of the coating, and/or can include a nano/micron scale roughening of the coating that accelerates the erosion rate of the regions **34** versus other portions of the coating **32**.

[0033] The coating **32** can be deposited on the body **30** of the endoprosthesis by conventional coating techniques or can be created on the surface of a body **30** by modifying the surface of the body **30**. Conventional masking, lithographic, and templating techniques can be used to control the placement of the regions **34** in the coating **32**. For example, a coating **32** can be produced with a mask made of a set of fine wires or a mesh of a desired pattern. The mask can be set against the inner and/or outer diameters of an endoprosthesis (e.g., a stent), a dense coating of the desired materials can be deposited, and the mask removed.

[0034] Lithographic techniques can include soft lithography or nano-sphere (or micro-sphere) lithography. Soft lithography is well suited for nonplanar surfaces and can include techniques such as microcontact printing, replica molding, microtransfer molding, micromolding in capillaries ("MIMIC"), and solvent assisted micromolding ("SAMIM"). Microcontact printing can use a PDMS stamp to print a single molecule thick pattern of ink molecules on a surface of an endoprosthesis. A desired coating material can then be deposited on the surface and a lift process can then be used to remove the coating applied to the inked areas of the endoprosthesis. This can generate a surface including regions of a desired size, spacing, and arrangement corresponding to the printed pattern. The PDMS stamp can be made by conventional photolithography.

[0035] Nano-sphere lithography is an effective way to grow periodic and large-area nano-structures. Nano-sphere lithography uses self-assembled nano-spheres (e.g., polystyrene) as a template followed by a deposition process to deposit coating materials in the void spaces between portions of the template. The nanosphere template can be deposited on an endoprosthesis surface by drop coating, spray coating, spin coating, self assembly, sedimentation in a force field, or via crystallization. The nano-spheres can be held to the surface by Van der Waals forces, electro static forces, a thin adhesive layer, and/or plating a thin layer of nickel, titanium, platinum chromium to secure the particles to the stent surface. The deposited template nano-spheres generally assemble in a close packed fashion. The spheres can be isolated by reactive ion etching of the spheres, after deposition, to reduce the sphere diameter and hence isolate the nano-spheres. Once the template has been dried, the void spaces between the templated spheres can be filled with a variety of metals and oxide materials through electrochemical deposition, e.g., by physical vapor deposition ("PVD") or chemical vapor deposition ("CVD"). The void spaces can also be filled with liquid precursor(s) of one or more polymers, sol-gel precursors of a ceramic material, a solution containing an inorganic salt, and/or a dispersion of nano metal or oxide particles to form the coating **32**. The coating is formed such that the spheres are partially exposed. Once the coating material is deposited, the spheres can be removed by calcination in air or by dissolution in a chemical solution. Additionally, the spheres can be mixed with biocompatible materials, such as silica or titania, prior to deposition, and the spheres removed prior to the deposition of the coating to produce porous regions surrounded by areas of the coating that protect the underlying body **30** surface area from erosion.

[0036] Bioerodible materials can also be used to template the surface of a body of an endoprosthesis. For example, a bioerodible polymer can be deposited onto select regions of the surface of an iron endoprosthesis that correspond to the regions **34** to be formed once the coating material is deposited. The coating material can then be deposited onto the remaining exposed iron surfaces of the endoprosthesis. In other embodiments, the remaining exposed surfaces of the iron endoprosthesis can be modified to create the coating **32**. The bioerodible polymer can then be removed. In some embodiments, the bioerodible polymer can remain present as part of the regions **34** and allowed to erode once the endoprosthesis is implanted in a physiological environment. The bioerodible polymer left in the regions **34** to erode in a physiological environment, can include one or more therapeutic agents.

[0037] Physical vapor deposition ("PVD") can be used to deposit the coating material. For example, a coating **32** of biocompatible materials, such as iridium oxide, tantalum, titanium, and/or titanium-oxy-nitride, can be deposited onto a bioerodible body, such as magnesium and/or iron, by PVD techniques. The use of PVD techniques can allow the precise placement of regions **34**. PVD techniques can also create a coating where the regions **34** are select regions of the coating **32** having a porosity that allows a corresponding area of the body to be exposed to a physiological environment when the endoprosthesis is implanted while the surrounding areas of the coating **32** protect the underlying body surface area from erosion. In some embodiments, a modified Holistic Process Performance Measurement System ("mHPPMS") PVD process can be used to deposit coating **32** onto the body **30** to create a strong bond between the body **30** and the coating **32**. A discussion of HPPMS can be found in the following articles, which are hereby incorporated by reference: U. Krausea, M. Lista & H. Fuchsb, *Requirements of Power Supply Parameters for High-Power Pulsed Magnetron Sputtering,* 392 Thin Solid Films 196-200 (2001) & S. Konstantinidis, J. P. Dauchot & M. Hecq, *Titanium Oxide Thin Films Deposited by High-Power Impulse Magnetron Sputtering,* 515 Thin Solid Films 1182-1186 (2006).

[0038] Co-deposition processes can also be used to deposit a coating **32** having regions **34**, including a material having a faster erosion rate than the remainder of the coating **32**. For example, a relatively stable material, such as tantalum, cobalt, and/or chromium, can be deposited with a bioerodible material, such as magnesium, to create regions **34** including a higher percentage of magnesium than the remainder of the coating **32**. Once the magnesium of the composite coating **32** erodes, the regions **34** can allow for the erosion of the underlying material of the body, while the remainder of the coating **32** continues to protect the underlying surface area of the body from erosion. For example, the erosion of the magnesium can leave fine pores through the coating **32** in the areas of the regions **34**.

[0039] The surface of a bioerodible endoprosthesis can also be modified to create a coating **32**. For example, alloying materials can be implanted to produce a relatively stable and/or more slowly eroding material on the surface of an iron, magnesium, or zinc containing endoprosthesis. For example, alloying materials can be implanted on the surface of an iron stent to create a thin coating of stainless steel.

[0040] The body **30** and the coating **32** can, in some embodiments, include materials that form a galvanic couple between the body and the coating when the endoprosthesis is implanted in a physiological environment. The body and the coating can be electrically conductive to ensure that the materials of the galvanic couple remain in electrical contact with each other. The galvanic couple, in the presence of ion-containing fluids, such as plasma and/or blood, forms an electrochemical cell in which the body **30** and the coating **32** act as electrodes and the fluid acts as an ion-conducting electrolyte. The galvanic couple can be formed between metals, electrically conductive polymers (e.g., polyvinylidene fluoride, polyaniline, and the like), and electrically conductive polymer composites (e.g., polymer matrices containing electrically conductive particles, wires, meshes, or the like).

[0041] The galvanic couple can impact the rate of erosion of overall endoprosthesis, or a portion thereof. For example, a body **30** having a material acting as the galvanic anode and a coating **32** acting as a galvanic cathode can allow for a preferential erosion of the body (e.g., a body **30** including magnesium, zinc, and/or iron with a coating **32** including platinum and/or iridium). The greater the difference in electric potential between the materials of the body and the coating, the greater the preferential erosion of the body. Alternatively, a body having a bioerodible material acting as a cathode and a relatively stable coating acting as an anode can result in a reduced erosion rate for the body.

[0042] The endoprosthesis includes a plurality of struts. The struts define a flow passage. One or more of the struts can include a body **30** having a coating **32**, as described above. In some embodiments, the endoprosthesis can include a plurality of different struts bodies **30** of different bioerodible materials and/or coatings having regions of different sizes, spacing, arrangements, and/or of different coating materials. For example, the endoprosthesis can be a stent. Referring to FIG. **5**, the endoprosthesis can be in the form of a balloon-expandable stent **20**. The stent body is in the form of a tubular member defined by a plurality of struts (e.g., the bands **22** and connectors **24**). The connectors **24** extend between and connect adjacent bands **22**. During use, bands **22** can be expanded from an initial, smaller diameter to a larger diameter to contact the stent **20** against a wall of a vessel, thereby maintaining the patency of the vessel. Connectors **24** can provide the stent **20** with the flexibility and conformability that allow the stent to adapt to the contours of the vessel. The stent **20** defines a flow passage therethrough and is capable of maintaining patency in a blood vessel. In other embodiments, the endoprosthesis can be in the form of a self-expanding stent.

[0043] The stent **20** can, in some embodiments, include a plurality of different struts having bodies **30** of different bioerodible materials and/or coatings having regions of different sizes, spacing, arrangements, and/or of different coating materials. For example, an iron stent can have different struts having different coatings **32** over bodies of iron. One coating can have a pattern of regions designed to decrease the overall erosion rate of the strut relative to the remainder of the stent **20**. Additionally, one or more struts could include a coating of a material to increase the overall erosion rate of the one or more struts relative to uncoated iron struts. For example, the erosion rate increasing coating can act as a galvanic cathode to increase the erosion rate of the strut. Each coating can include a coating material and a pattern of regions designed to effect a particular erosion rate for each strut. For example, connectors **24** can be designed to erode prior to the erosion of the bands **22**. In other embodiments, selected regions of the stent **20**, each including a plurality of bands and connectors, can have different coatings **32**, and perhaps select regions without any coating, to produce a stent **20** that erodes to produce a shorter stent **20** prior to complete erosion.

[0044] Stent **20** can be of any desired shape and size (e.g., superficial femoral artery stents, coronary stents, aortic stents, peripheral vascular stents, gastrointestinal stents, urology stents, and neurology stents). Depending on the application, the stent can have a diameter of between, for example, 1 mm to 46 mm. In certain embodiments, a coronary stent can have an expanded diameter of from 2 mm to 6 mm. In some embodiments, a peripheral stent can have an expanded diameter of from 5 mm to 24 mm. In certain embodiments, a gastrointestinal and/or urology stent can have an expanded diameter of from 6 mm to about 30 mm. In some embodiments, a neurology stent can have an expanded diameter of from about 1 mm to about 12 mm. An Abdominal Aortic Aneurysm (AAA) stent and a Thoracic Aortic Aneurysm (TAA) stent can have a diameter from about 20 mm to about 46 mm.

[0045] Stents can be used, e.g., delivered and expanded, using a catheter delivery system. Catheter systems are described in, for example, Wang U.S. Pat. No. 5,195,969, Hamlin U.S. Pat. No. 5,270,086, and Raeder-Devens, U.S. Pat. No. 6,726,712. Stents and stent delivery are also exemplified by the Sentinol® system, available from Boston Scientific Scimed, Maple Grove, Minn. Referring to FIGS. **6**A-**6**C, a balloon-expandable stent **20** can be placed over a balloon **12** carried near a distal end of a catheter **14**, and directed through the lumen **16** (FIG. **6**A) until the portion carrying the balloon and stent reaches the region of an occlusion **18**. The stent **20** is then radially expanded by inflating the balloon **12** and compressed against the vessel wall with the result that occlusion **18** is compressed, and the vessel wall surrounding it undergoes a radial expansion (FIG. **6**B). The pressure is then released from the balloon and the catheter is withdrawn from the vessel (FIG. **6**C).

[0046] In some embodiments, stents can also be a part of a covered stent or a stent-graft. In other embodiments, a stent can include and/or be attached to a biocompatible, non-porous or semi-porous polymer matrix made of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, urethane, or polypropylene.

[0047] In some embodiments, stents can be formed by fabricating a wire having a bioerodible body and a coating including a plurality of the above described regions, and knitting and/or weaving the wire into a tubular member.

[0048] In some embodiments, stents can include therapeutic agents incorporated into one or more portions of the body **30** and/or the coating **32** (including the regions **34**). Stents can also include additional drug eluding layers and/or deposits of therapeutic agents.

[0049] A number of embodiments have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of

this disclosure. Accordingly, other embodiments are within the scope of the following claims.

What is claimed is:

1. An endoprosthesis comprising a plurality of struts defining a flow passage, at least one strut comprising:

(a) a body comprising a bioerodible material having a thickness, and

(b) a coating overlying the body, the coating comprising a plurality of regions that allow physiological fluids to contact a plurality of corresponding areas of the underlying body when the endoprosthesis is implanted in a physiological environment, the plurality of regions being sized and arranged so that the contacted areas of the body erode substantially through the body in the thickness direction while the coating remains on the body when the endoprosthesis is implanted in the physiological environment.

2. The endoprosthesis of claim **1**, wherein the bioerodible material erodes isotropically.

3. The endoprosthesis of claim **2**, wherein the plurality of regions are arranged such that the distance between adjacent regions is equal to at least the thickness of the body.

4. The endoprosthesis of claim **2**, wherein the plurality of regions are arranged such that the distance between adjacent regions is equal to at least twice the thickness of the body.

5. The endoprosthesis of claim **1**, wherein the bioerodible material erodes anisotropically.

6. The endoprosthesis of claim **1**, wherein a rate of erosion of the body in the thickness direction multiplied by the thickness of the body is less than a rate of erosion of the body along an interface between the body and the coating multiplied by ½ of the distance between adjacent regions.

7. The endoprosthesis of claim **1**, wherein the bioerodible material has a first electric potential and the coating has a second electric potential different from the first electric potential so that the body and the coating form a galvanic couple when the endoprosthesis is implanted in a physiological environment.

8. The endoprosthesis of claim **7**, wherein the first electric potential is less than the second electrode potential so that the body acts as an anode and the coating acts as a cathode when the endoprosthesis is implanted in a physiological environment.

9. The endoprosthesis of claim **7**, wherein the bioerodible material of the body is a bioerodible metal selected from the group consisting of magnesium, iron, zinc, and alloys thereof and the coating comprises a metal selected from the group consisting of platinum, iridium, and alloys thereof.

10. The endoprosthesis of claim **7**, wherein the first electric potential is greater than the second electrode potential so that the body acts as a cathode and the coating acts as an anode when the endoprosthesis is implanted in a physiological environment.

11. The endoprosthesis of claim **1**, wherein the bioerodible material of the body is a bioerodible metal selected from the group consisting of magnesium, iron, zinc, and alloys thereof.

12. The endoprosthesis of claim **1**, wherein the body comprises a bioerodible polymer selected from the group consisting of polyglutamic acid, poly(ethylene oxide), polycaprolactam, poly(lactic-co-glycolic acid), polysaccharides, and combinations thereof.

13. The endoprosthesis of claim **1**, wherein the coating surrounds the circumference of the body.

14. The endoprosthesis of claim **1**, wherein the coating partially surrounds the circumference of the body.

15. The endoprosthesis of claim **1**, wherein the regions comprise voids in the coating.

16. The endoprosthesis of claim **1**, wherein the regions comprise pores in the coating.

17. The endoprosthesis of claim **1**, wherein the regions have a higher erosion rate than the remainder of the coating in a physiological environment.

18. The endoprosthesis of claim **1**, wherein the coating comprises a bioerodible material having a slower erosion rate than the bioerodible material of the body.

19. The endoprosthesis of claim **1**, wherein the endoprosthesis is a stent.

20. An endoprosthesis comprising a plurality of struts defining a flow passage, at least one strut comprising:

(a) a body comprising a bioerodible material having a thickness, and

(b) a coating overlying the body, the coating defining a plurality of voids that allow physiological fluids to contact a plurality of corresponding areas of the underlying body when the endoprosthesis is implanted in a physiological environment, the plurality of voids being sized and arranged so that the contacted areas of the body erode substantially through the body in the thickness direction while the coating remains on the body when the endoprosthesis is implanted in the physiological environment.

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