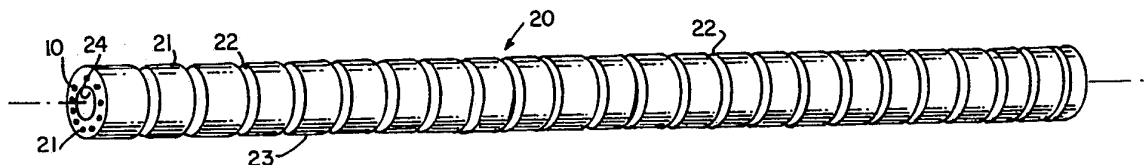




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(54) Title: IMPREGNATED STENT**(57) Abstract**

A stent assembly (20), delivery system (Fig. 5) and method of manufacture (Fig. 4) therefor. A stent assembly (20) includes a compact stent (10). A dissolvable material (35) impregnates the stent (10) in liquid form. In its cured, solid form, the material (35) contains the stent (10) in its compact form. When the stent (10) is positioned in a vessel (85), the temperature and liquids in the vessel (85) dissolve the material (35) thereby to release the stent (10) for positioning in a final configuration. The expansion of the stent (10) then allows removal of the delivery system.

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AMENDED CLAIMS

[received by the International Bureau on 3 May 1993 (03.05.93);

original claims 46 and 52 cancelled;

original claims 2, 12, 14, 28, 32, 33, 40, 41, 44, 45, 47-49, 53, 54, 57-59 and 62 amended;

remaining claims unchanged (10 pages)]

1. A stent assembly for insertion in a vessel bounded by a vessel wall comprising:
 - A. compact mesh stent means in a cylindrical form for expanding into engagement with a vessel wall, and
 - B. cured, dissolvable means impregnating said mesh for containing said mesh in its compact form, said cured, dissolvable means transforming from a solid to a liquid state when said stent assembly is in position in the vessel thereby to free said stent and enable its expansion into a vessel wall.
2. A stent assembly as recited in claim 1 wherein said stent means consists of a filament formed of a biocompatible material that resists deformation in an expanded form.
3. A stent assembly as recited in claim 1 wherein said stent assembly is disposed along a longitudinal axis and additionally comprises central support means at the interior of said stent assembly that is concentric with the axis.
4. A stent assembly as recited in claim 3 wherein said central support means includes means for expanding said mesh stent into its final expanded form.
5. A stent assembly as recited in claim 1 wherein said cured, dissolvable means in said stent assembly comprises discrete axial segments for improving the flexibility of said stent assembly.
6. A stent assembly as recited in claim 5 wherein a cylindrical surface of said cured, dissolvable means has a helical groove formed therein for producing said axial segments.
7. A stent assembly as recited in claim 1 wherein said dissolvable means additionally entrains a disparate constituent for release into the vessel as said dissolvable means dissolves.
8. A stent assembly as recited in claim 1 wherein said dissolvable means comprises gelatin.

9. A stent assembly as recited in claim 8 wherein said mesh stent means is formed of a material taken from the group of materials consisting of super elastic alloys and plastic deformable alloys.
- 5 10. A stent assembly as recited in claim 8 wherein said mesh stent means is formed of Nitinol.
11. A stent assembly as recited in claim 10 wherein said cured, dissolvable means forms a cylinder and said stent assembly additionally comprises a central
- 10 coaxial support for said cylindrical cured, dissolvable means.
12. A stent assembly as recited in claim 10 wherein said stent means is formed of a material taken from a group consisting of stainless steel and tantalum.
- 15 13. A stent assembly as recited in claim 12 wherein said cured, dissolvable means forms a cylinder and said stent assembly additionally comprises a central coaxial support for said cylindrical cured, dissolvable means, said central coaxial support means
- 20 includes means for expanding said mesh stent into its final expanded form.
14. A stent delivery system for positioning a stent in a vessel having a defining vessel wall and comprising:
- 25 A. . an elongated stent including mesh means including a cylindrical mesh stent for expanding from a compact form to an expanded form to engage the vessel wall and a cured, dissolvable means that impregnates said mesh means for containing said mesh means in its compact state,
- 30 B. delivery means for positioning said stent at a predetermined position in the vessel, and
- C. stent support means coaxial and coextensive with said stent means for affixing said stent means to said delivery means, said cured, dissolvable means being soluble in the vessel thereby to
- 35 dissolve and free said mesh means for expansion into the vessel wall.

15. A stent delivery system as recited in claim 14 wherein said compact mesh means is formed by a filament taken from the group of materials consisting of shape memory materials including Nitinol and of super elastic alloys including stainless steel and tantalum.
16. A stent delivery system as recited in claim 15 wherein said stent has a cylindrical shape extending along an axis and said stent support means comprises a coaxial tube means for contacting the inner cylindrical surface of said stent and distal tip means and proximal bushing means mounted to said coaxial tube means at the distal and proximal ends of said stent means respectively for preventing axial motion of said stent relative to said coaxial tube means.
17. A stent delivery system as recited in claim 16 wherein said delivery means includes:
- i. cylindrical sheath means for overlying said stent and said stent support means, and
 - ii. steering means connected to said proximal bushing means for moving said sheath means and contained stent means to a predetermined position in the body canal,
- said delivery means including means for moving said sheath means relative to said steering means to withdraw said sheath from said stent thereby to enable said cured, dissolvable means to dissolve and said mesh means to expand into contact with the body canal.
18. A stent delivery system as recited in claim 17 wherein said distal tip means includes means for sealing against said sheath means thereby to prevent fluid from contacting said cured, dissolvable means during the positioning of said stent.
19. A stent delivery system as recited in claim 15 wherein said stent comprise a mesh formed of Nitinol.

20. A stent delivery system as recited in claim 14 wherein said mesh means is formed of a plastic deformable material and said stent support means includes expansion means for expanding said mesh means into the body canal after said cured, dissolvable means dissolves.
21. A stent delivery system as recited in claim 20 wherein said expansion means comprises balloon catheter means.
22. A stent delivery system as recited in claim 21 wherein said stent delivery system additionally comprises means for inflating said balloon catheter to position said mesh means against the vessel wall and for deflating said balloon catheter thereby to separate said mesh means and said catheter and to enable the removal of said delivery system from the vessel.
23. A stent delivery system as recited in claim 14 for use with a guidewire wherein each of said delivery means and stent support means have a common axial passage therethrough for allowing said delivery means to be positioned along the guidewire.
24. A stent delivery system as recited in claim 14 wherein said cured, dissolvable means in said stent assembly comprises discrete axial segments for improving the flexibility of said stent assembly.
25. A stent delivery system as recited in claim 24 wherein a cylindrical surface of said cured, dissolvable means has a helical groove formed therein for producing said axial segments.
26. A stent delivery system as recited in claim 14 wherein said cured, dissolvable means additionally includes an entrained disparate material that dissolves in the body as it is released as said dissolvable means dissolves.
27. A stent delivery system as recited in claim 14 wherein said stent support means includes marker

means for enabling a determination of the location of the stent support means within a vessel.

28. A method for making a stent assembly comprising the steps of:
- 5 A. producing a cylindrical stent in a compact form,
 - B. impregnating the stent with a dissolvable substance in liquid form while the stent is in its compact form, and
 - C. curing the dissolvable substance thereby to form
 - 10 a solid retaining structure for maintaining the stent in the compact form, the substance decomposing in the environment of a body.
29. A method for making a stent assembly as recited in claim 28 wherein said producing step includes
- 15 wrapping a filament about the compact stent, said filament being formed of a material that does not bond with the dissolvable substance as it cures.
30. A method for making a stent assembly as recited in claim 29 wherein said impregnation of the stent is
- 20 produced by dipping the compact stent into the dissolvable substance in a liquid state and thereafter removing excess dissolvable substance.
31. A method for making a stent assembly as recited in claim 29 wherein said impregnation of the stent is
- 25 produced by rotating the compact stent and by pouring the dissolvable substance in a liquid state onto the stent and thereafter by removing excess dissolvable substance.
32. A method for making a stent assembly as recited in
- 30 claim 29 wherein said producing step includes positioning the stent form on a mandrel and wrapping spaced turns of a filament about the compact stent and affixing the ends of the filament to the mandrel at the axial ends of the compact stent, said method
- 35 including the additional step of removing the filament from the stent after said curing step thereby to form a continuous groove in the surface of the cured, impregnated stent.

33. A method for making a stent assembly as recited in claim 29 wherein said producing step includes positioning the stent form on a mandrel and said wrapping step includes wrapping spaced turns of a filament comprised of an elastic material containing polymeric silicones about the compact stent and affixing the ends of the filament to the mandrel at the opposite ends of the compact stent, said method including the additional steps of stretching and removing the filament from the stent after said curing step is completed thereby to form a continuous groove in the surface of the cured, impregnated stent.
34. A method for making a stent assembly as recited in claim 29 wherein said method additionally includes mounting at least one marker to the compact stent thereby to enable the position of the stent to be determined in use.
35. A method for making a stent assembly as recited in claim 28 wherein said impregnation of the stent is produced by dipping the compact stent into the dissolvable substance in liquid form and thereafter removing excess amounts of the dissolvable substance.
36. A method for making a stent assembly as recited in claim 28 wherein said impregnation of the stent is produced by rotating the compact stent and by pouring the dissolvable substance in a liquid state onto the stent and thereafter by removing any excess amounts of the dissolvable substance.
37. A method for making a stent assembly as recited in claim 28 wherein said method additionally includes mounting at least one marker to the compact stent thereby to enable the position of the stent to be determined in use.
38. A method for making a stent assembly as recited in claim 28 wherein during the stent formation said stent is produced from a super elastic material

whereby the stent is self-expanding when the cured dissolvable substance dissolves in use.

39. A method for making a stent assembly as recited in claim 38 wherein said method additionally comprises the step of mounting termination elements at each end of a mandrel after said curing step has completed.
40. A method for making a stent assembly as recited in claim 38 wherein said method additionally comprises the steps of mounting on a mandrel the cured, impregnated stent and termination elements in an open-ended sheath and affixing to one of the termination elements steering means for enabling the stent assembly and sheath to be positioned in use.
41. A method for making a stent assembly as recited in claim 28 wherein producing the stent includes the steps of forming a filament into the stent form whereby the stent form is expandable and positioning the stent form on a mandrel.
42. A method for making a stent assembly as recited in claim 41 wherein said filament formation step includes the manipulation of a filament composed of a plastic deformable material.
43. A method for making a stent assembly as recited in claim 41 wherein the mandrel is formed of an elastic material containing polymeric silicones and said method comprises the additional step of stretching and removing the mandrel from the cured, impregnated stent after said curing step is completed.
44. A method for making a stent assembly as recited in claim 41 wherein said stent positioning step includes the positioning of the stent on an expandable mandrel whereby the mandrel carries the stent in use and expands the stent after the dissolvable substance dissolves.
45. A tubular endoprosthesis device for location in a vessel having a wall structure comprised of an open fabric of loosely interlocked loops of filament material, the device having a first relatively small

diameter form for a low profile introduction into a body passageway, said interlocked loops being made from a self-expanding metallic alloy to permit radial self-expansion thereof in a vessel and dissolvable impregnating means impregnating said loops for restraining the wall structure in its small diameter form.

47. A tubular endoprosthesis device as recited in claim 45 wherein said impregnating means comprises a cured dissolvable material which shifts from a solid phase to a liquid phase in a vessel thereby to release said wall structure for expansion.

48. A tubular endoprosthesis for placement in a lumen defined by a wall body, said endoprosthesis comprising a wall structure of loosely interlocked knitted loops of metal filament, said wall structure being radially compactible to a small radial size without deformation to produce an internal self-restoring force for introduction lengthwise into the lumen, said wall structure, when free, being radially self-expanding to tubular form to engage the wall of the lumen and a dissolvable polymer for impregnating said wall structure to contain said endoprosthesis in its compacted configuration.

49. An endoprosthesis as recited in claim 48 wherein said metal filament is formed of a shape memory metal.

50. An endoprosthesis as recited in claim 48 wherein said metal filament comprises substantially nitinol.

51. An endoprosthesis as recited in claim 48 wherein the ratio of the radii of said tubular wall structure in its expanded and compacted forms is in the order 10:1.

53. A placement system for an endoprosthesis in a lumen defined by a wall of a body comprising:

A. an endoprosthesis having tubular wall means of loosely interlocked knitted loops of metal filament, said wall being radially compactible

- to a small radial size without plastic deformation of the filament to produce an internal self-restoring force, and to facilitate the lengthwise introduction of said endoprosthesis into the lumen, said wall means, when free, being radially self-expandable to tubular form to engage the wall of said lumen,
- 5
- B. means for placing said endoprosthesis in the lumen, and
- 10
- C. dissolvable restraint means impregnating said knitted loops for maintaining said endoprosthesis in its compacted form and for freeing said endoprosthesis for self-expansion into engagement with the wall of the lumen at the site of
- 15
- placement within the body.
54. A placement system as recited in claim 53 wherein said filament is formed from a shape memory metal.
55. A placement system as recited in claim 53 wherein said filament comprises substantially nitinol.
- 20
56. A placement system as recited in claim 53 wherein the ratio of the radii of said tubular wall structure in its expanded and compacted forms is in the order 10:1.
57. A placement system as recited in claim 53 wherein
- 25
- said dissolvable restraint means comprises a dissolvable polymer.
58. A placement system as recited in claim 53 wherein said delivery system additionally includes a cylindrical sheath overlying said endoprosthesis, said
- 30
- sheath being retractable to expose said endoprosthesis and said dissolvable restraint means to the body lumen.
59. A placement system as recited in claim 58 wherein said filament is formed from a shape memory metal.
- 35
60. A placement system as recited in claim 58 wherein said filament comprises substantially nitinol.

61. A placement system as recited in claim 58 wherein the ratio of the radii of said tubular wall structure in its expanded and compacted forms is in the order 10:1.
- 5 62. A placement system as recited in claim 58 wherein said dissolvable restraint means includes a dissolvable polymer for maintaining said endoprosthesis in its compacted configuration, the removal of said cylindrical sheath enabling said
- 10 polymer to dissolve and thereby release said endoprosthesis for self-expansion.