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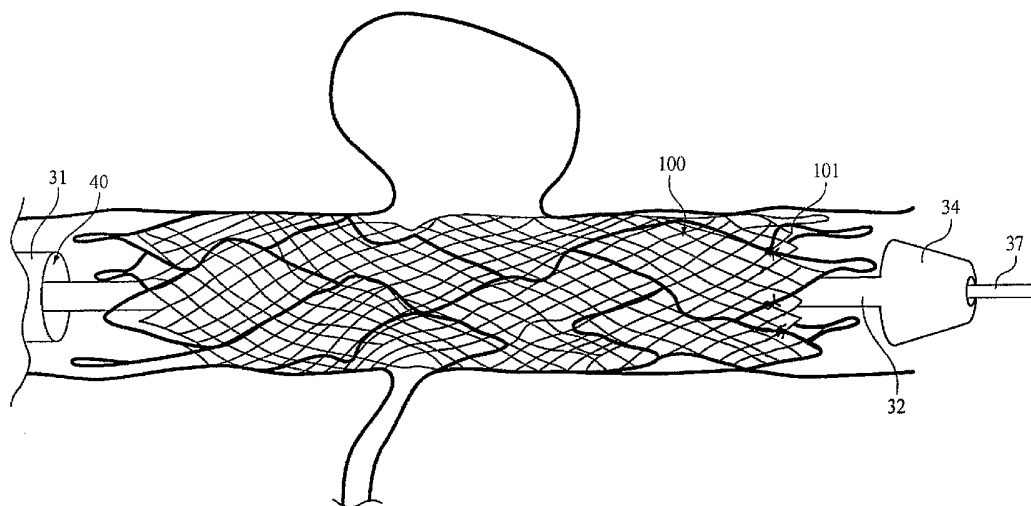
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(54) Title: MEDICAL DEVICES INCLUDING METALLIC FILMS AND METHODS FOR MAKING SAME



(57) Abstract: An endoprosthesis (150) for deployment within a body passage includes an external tubular framework (152) disposed about a tubular member (154), e.g., a metallic film having a thickness of about 50 μm or less. The tubular member may be sandwiched between the external tubular framework and an internal tubular framework located internally of the external tubular framework and the tubular member. Whether or not the internal tubular framework is included, the endoprosthesis can be self-expanding. During deployment of the endoprosthesis using a deployment device (30), the external tubular framework prevents substantial frictional contact between the deployment device and the tubular member.

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MEDICAL DEVICES INCLUDING METALLIC FILMS AND  
METHODS FOR MAKING SAME

FIELD OF THE INVENTION

5           The invention relates to medical devices, such as endoprostheses, and methods of making the devices.

BACKGROUND

10           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, or even replaced, with a medical endoprosthesis. An endoprosthesis is typically a tubular member that is placed in a lumen in the body. Endoprostheses can be delivered inside the  
15           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, for example, so that it can contact the walls of the lumen.

20           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.

25           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 radially 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.

SUMMARY OF THE INVENTION

The invention relates to medical devices, such as endoprostheses, and methods of making the devices. Exemplary endoprostheses include stents, covered stents, and stent-grafts.

5 In some embodiments, an endoprosthesis for deployment within a body passage includes a tubular framework and a metallic film having a thickness of about 50  $\mu\text{m}$  or less and disposed internally of the tubular framework. The endoprosthesis may be self-expanding.

10 The tubular framework may have an internal surface. The metallic film, which may be generally tubular in shape, may have an outer surface that contacts the internal surface of the tubular framework.

The film may be a deposited metallic film including, e.g., deposited nickel and titanium. The deposited film may have a thickness of about 50  $\mu\text{m}$  or less, 50  $\mu\text{m}$  or less, e.g., about 35  $\mu\text{m}$  or less. The deposited film may have a thickness of 4  $\mu\text{m}$  or  
15 greater. The film may exhibit super-elastic properties. In embodiments, the film is not shape set.

The endoprosthesis, when in a deployed state within a body passage, may exert an outward radial force against the body passage, with essentially all of the outward radial force resulting from the tubular framework.

20 The endoprosthesis may have an internal surface that is substantially defined by an internal surface of the metallic film.

In embodiments, the endoprosthesis includes only one framework.

In some embodiments, the endoprosthesis includes at least a second tubular framework. At least a portion or all of the metallic film is sandwiched between the  
25 tubular framework and the second tubular framework. The endoprosthesis may be self-expanding. In embodiments, neither the tubular framework nor the second tubular framework, by itself, exerts a radial force sufficient to secure the endoprosthesis within a body passage but together, the tubular framework and second tubular framework exert force sufficient to secure the endoprosthesis. In a deployed state, the tubular framework  
30 and the second tubular framework may each exert a radial force. The radial force of the

second tubular framework may greater than the radial force of the tubular framework.

A total radial thickness of the tubular framework and the second tubular framework may be about 75 microns or less. The tubular framework and the second tubular framework may have at least some relative freedom of movement along at least  
5 one of the radial, circumferential, and longitudinal dimensions..

Substantially all or all of the metallic film may be a single layer.

In some embodiments, a self-expanding endoprosthesis for deployment within a body passage includes a first tubular framework, a tubular member disposed around the first tubular framework, and a second tubular framework disposed around the tubular  
10 member.

In embodiments, neither of the first and second tubular frameworks alone exerts sufficient outward radial force to self-expand the endoprosthesis within a body passage but the first and second tubular frameworks together exert sufficient outward radial force to self-expand the endoprosthesis.

The film may be a deposited metallic film including, e.g., deposited nickel and titanium. The deposited film may have a thickness of about 50  $\mu\text{m}$  or less, 50  $\mu\text{m}$  or less, e.g., about 35  $\mu\text{m}$  or less. The deposited film may have a thickness of 4  $\mu\text{m}$  or greater. The film may exhibit super-elastic properties. In embodiments, the film is not  
15 shape set.

In embodiments, a delivery device for deploying an endoprosthesis within a body passage includes an elongate inner member, a self-expanding endoprosthesis disposed about a distal portion of the inner member, the endoprosthesis comprising a tubular framework disposed about a deposited metallic film and an outer sheath surrounding the elongate inner member and the self-expanding endoprosthesis, wherein the tubular  
20 framework prevents substantial frictional contact between the tubular member and the outer sheath.

In one aspect, the invention features an endoprosthesis including a metallic film, e.g., a vapor deposited film, including nickel, titanium, and chromium. A ratio of a weight of chromium of the metallic film to a combined weight of nickel, titanium, and chromium of the metallic film is at least 0.001 and can be less than 0.0075.  
25  
30

Other aspects, features, and advantages of the invention will be apparent from the description of the preferred embodiments thereof and from the claims.

#### BRIEF DESCRIPTION OF THE FIGURES

5 Fig. 1 is a side view of an endoprosthesis in the radially expanded state as deployed within a body passage adjacent an aneurysm.

Fig. 2a is a side view of a distal portion of a deployment device prior to radial expansion of the endoprosthesis.

10 Fig. 2b is a side view of the distal portion of the deployment device subsequent to radial expansion of the endoprosthesis adjacent the aneurysm.

Fig. 3 is a perspective view of an endoprosthesis.

Fig. 4 is a perspective view of an endoprosthesis.

Fig. 5 is an end-on cross-sectional view of an endoprosthesis.

#### 15 DETAILED DESCRIPTION

Referring to Fig. 1, an endoprosthesis 100 is deployed within a body passage, e.g., within a vessel weakened by an aneurysm, e.g., an aneurysm 25 of a vessel 26 of a human brain. Endoprosthesis 100 includes a framework, e.g., a stent body 52, covered by a tubular member or cover 54, made of thin metallic film. The stent body provides a  
20 relatively rigid framework that secures the endoprosthesis at the treatment site. The framework defines relatively large openings or fenestrations that contribute to the mechanical properties of the stent. The cover 54 is relatively thin and flexible and includes smaller fenestrations that contribute to the mechanical properties of the cover and can occlude the fenestrations of the stent.

25 In some embodiments, endoprosthesis 100 modifies an amount or velocity of blood passing between vessel 26 and aneurysm 25. For example, prosthesis 100 can be deployed to reduce or block blood flow between vessel 26 and aneurysm 25, e.g., to occlude the aneurysm 25. If so deployed, prosthesis 100 may sufficiently reduce blood flow to allow clotting or other healing processes to take place within aneurysm 25 and/or  
30 opening 29 thereof. Tubular member 54 can provide a greater attenuation of the blood

flow into the aneurysm 25 than stent body 52 alone. Endoprosthesis 100, however, can allow some flow to pass between vessel 26 and aneurysm 25 even while providing some reduction in the rate and/or volume of flow. Prosthesis 100 can also (or alternatively) allow blood to pass between vessel 26 containing the prosthesis and adjacent vessels, e.g., feeder vessel 27, while still providing reduced flow with respect to the aneurysm.

Referring to Fig. 2a, endoprosthesis 100 is deployed to aneurysm 25 using a deployment device 30, which includes a retractable outer sheath 31 and an inner catheter 32. Fig. 2a shows only a distal portion of the delivery device. An operator manipulates the device 30 using a proximal portion (not shown). Device 30 is introduced over a guide wire 37 extending along an interior 28 of vessel 26. During introduction, the endoprosthesis 100 is radially compacted between outer sheath 31 and inner catheter 32 adjacent a distal end 40 of the outer sheath. Endoprosthesis 100 is longitudinally restrained by a proximal stop 33 and a distal tip 34 of inner catheter 32. Device 30 includes distal and proximal markers 38,39, which can be radiographically monitored to determine when endoprosthesis 100 has reached aneurysm 25. Prosthesis 100 includes markers 75, to provide radiopacity, which can also or alternatively be used to visualize the position of endoprosthesis 100.

With reference to Fig. 2b, the outer sheath 31 is retracted upon reaching the desired deployment site, e.g., aneurysm 25. In some embodiments, endoprosthesis 100 self-expands by its own internal elastic restoring force when the radially restraining outer sheath is retracted. Alternatively, or in combination with self-expansion, deployment of prosthesis 100 may include use of a balloon or other device to radially expand prosthesis 100 within vessel 26. The inner catheter 32 and guide wire 37 are withdrawn from vessel 26. Suitable delivery systems include the Neuroform, Neuroform2, and Wingspan Stent System available from Boston Scientific Target Therapeutics, Fremont, CA. In embodiments, the outer sheath and/or inner catheter includes a reinforcing member to respectively resist elongation or compression as the outer sheath is withdrawn. Such reinforcing members include polymer shafts, braids, and coil structures. Endoprosthesis 100 can be deployed using a guidewireless deployment device.

Upon expansion, endoprosthesis 100 assumes a shape and radial extent generally

coextensive with an inner surface of the vessel 26, e.g., a tubular shape centered about a longitudinal axis  $a_1$  of the prosthesis (Fig. 1). Depending upon the application, prosthesis 100 can have a diameter  $d$  of between, for example, 1 mm to 46 mm. In certain embodiments, a prosthesis for deployment within a vessel at an aneurysm can have an expanded diameter  $d$  of from about 2 mm to about 6 mm, e.g., about 2.5 mm to about 4.5 mm. Depending upon the application, prosthesis 100 can have a length along axis  $a_1$  of at least 5 mm, at least 10 mm, e.g., at least about 30 mm. An exemplary embodiment has an expanded diameter of about 3.5 mm and a length of about 15 mm. In embodiments, the stent body has a closed cell framework, an open cell framework, a helical framework, a braided framework, or combination thereof.

In some embodiments the tubular member 54 of endprosthesis 100 includes a metallic film deposited by a vapor deposition process. Vapor deposited materials are formed by depositing film constituents from a vapor or a vacuum onto a surface. In embodiments, the constituents are vaporized by bombarding, heating or sputtering a bulk target. The vaporized constituents deposit on a substrate to form the film. Deposited films can exhibit highly uniform thickness and microstructure in very thin films, e.g. about 50 microns or less, e.g. 4-35 microns. Suitable vapor deposition processes are described in Busch et al. U.S. 5,061,914, Bose et al. U.S. 6,605,111, Johnston U.S. 6,533,905, and Gupta et al. U.S. 2004/0014253, the entire contents of all of which are hereby incorporated by reference.

In some embodiments, the deposited film can include an alloy of nickel and titanium present in amounts sufficient to provide the deposited film with desirable mechanical or shape memory properties. For example, the film may include an alloy, e.g., a superelastic or pseudo-elastic metal alloy, as described, for example, in Schetsky, L. McDonald, "Shape Memory Alloys," Encyclopedia of Chemical Technology (3rd ed.), John Wiley & Sons, 1982, vol. 20. pp. 726-736; and commonly assigned U.S.S.N. 10/346,487, filed January 17, 2003. The alloy may be nitinol. The alloy may include a third compound, e.g., chromium, which modifies a mechanical property, e.g., a hardness or elasticity, of the film. Tubular member 54 may include a deposited metal film including nickel, titanium, and, optionally, chromium. Exemplary films and deposition

of such films is described in U.S. application no. \*\*/\*\*\*\*,\*\*\*, filed concurrently herewith, titled MEDICAL DEVICES INCLUDING METALLIC FILMS AND METHODS FOR MAKING SAME, attorney docket no. 10527-570001, which application is incorporated herein by reference.

5 Referring to Fig. 3, an endoprosthesis 150 includes a framework, e.g., stent body 152, and a tubular member 154 disposed internally of stent body 152. Stent body 154 is defined by a plurality of circumferential bands 157 connected by longitudinal members 158 and defining fenestrations 160 therebetween. Tubular member 154 may be a deposited metallic film. Although not shown in Fig. 3, tubular member 154 may define a  
10 plurality of fenestrations, e.g., as discussed for tubular member 54. Because tubular member 154 is disposed internally of stent body 152, an interior 162 of endoprosthesis 150 is defined by a surface 163 of tubular member 154 and presents a generally smoother topography, e.g., with fewer projections, than if stent body 152 were internal of the tubular member.

15 During introduction via a delivery device along a body passageway, e.g., within a blood vessel, stent body 152 is positioned between the surrounding delivery device, e.g., the outer sheath 31 of device 30, and the tubular member 154. Upon deployment, as the outer sheath is retracted over the endoprosthesis, the substantially all or all of any friction between the sheath and endoprosthesis is experienced by the stent body 152 not the  
20 tubular member 154. For example, at least about 75% or at least 90% of the frictional contact between the sheath and the endoprosthesis during radial expansion may be between an inner surface of the outer sheath and the tubular framework. Such a configuration can protect the tubular member from damage, e.g., tears, when the endoprosthesis is loaded into the delivery device and during deployment.

25 As the endoprosthesis 150 radially expands against a body passageway, stent body 152 can limit or prevent contact between the internal surface of the body passageway and the tubular member. For example, locating the tubular member internal of the stent body prevents the stent body from forcing the tubular member against the body passageway during radial expansion. Hence, fenestrations of the tubular member, if  
30 present, will not slide with significant force against the body passageway internal surface



so as to minimize mechanical damage from the fenestrations to the body passageway.

In embodiments, the endoprosthesis is a re-sheathable endoprosthesis, such as a closed cell stent body with internal tubular member.

Once deployed, tubular member 154 shields blood flowing longitudinally through  
5 the endoprosthesis from stent body 152, e.g., from circumferential bands 157 and  
longitudinal members 158. Hence, a tendency for the blood flow to be disrupted or  
perturbed by stent body 152 is reduced or eliminated. A tendency for blood to clot within  
the interior 162 is also reduced or eliminated because the generally smoother topography  
presented by tubular member 154 offers fewer projections than if stent body 152 were  
10 internal of tubular member 152.

Because stent body 152 is disposed of connected circumferential bands rather  
than a more contiguous surface, stent body 152 presents less surface area to the wall of  
the passageway than would tubular member 154. Consequently, when radially expanded  
against the wall of a body passageway, e.g., vessel 26, endoprosthesis 150 produces less  
15 metal to tissue contact than if the stent body 152 were not positioned between the  
passageway wall and the tubular member 154. Additionally, interstices created by stent  
body 152 between the passageway wall and tubular member 154 can enhance endothelial  
growth and recovery.

Endoprosthesis 150 can be assembled by overexpanding stent body 152 to a  
20 greater diameter than it assumes in a body passageway and then sliding or drawing the  
tubular member into the interior of the stent body. Subsequently, stent body 152 is  
allowed to contract against the tubular member. In embodiments, when expanded within  
a body passageway, the tubular member is about as long as the stent body and may be  
shorter.

25 The tubular member and stent body can be secured, e.g., mechanically, with  
adhesive, or combination thereof. As shown, filaments 101 pass around portions of stent  
body 152 and through fenestrations 165 of tubular member 154. Filaments 101 can be  
formed of a polymer, a suture, a ductile metal wire, such as nitinol or gold wire, or other  
suitable material. In some embodiments, the tubular member differs from a fabric at least  
30 in that the tubular member is a metallic film that lacks fibers that can be pushed apart to

receive a filament as by sewing a fabric. Accordingly, the fenestrations can be formed prior to the process of passing the filament through the tubular member. Fenestrations that receive the filaments can be formed by, e.g., etching, laser cutting, or a photolithographic process. Other mechanical securing structures include fasteners, such as grommets and rivets. Securing techniques are described in USSN \_\_\_\_, {Attorney  
5 Docket No. 10527-566001}, filed contemporaneously herewith and incorporated herein by reference.

In embodiments, substantially all of the radial outward force exerted by endoprosthesis 150 is due to stent body 152. In some embodiments, tubular member 154  
10 is a deposited metallic film of a memory alloy that is shape set to a larger diameter than the radially expanded diameter of the stent body 152 within a body passageway. The resulting outward radial force exerted by the tubular member 154 against the stent body helps secure the tubular member and stent body. The tubular member outward force may supplement the outward force exerted by the stent body.

As shown in Fig. 3, the tubular member includes, along the radial dimension, only  
15 a single layer. In other embodiments, tubular member 154 itself, or endoprosthesis 150 as a whole, includes multiple tubular member layers, e.g., multiple deposited metallic film layers. For example, a second tubular member can be disposed external of stent body 152. In embodiments, the tubular member is a thin film of super-elastic alloy and is  
20 not shape set.

Referring to Fig. 4, an endoprosthesis 200 includes a tubular member 254 sandwiched between an internal stent body 252 and an external stent body 253. Each stent body 252, 253 alone may exert less outward radial force than required to maintain a position of the deployed endoprosthesis within a body passageway. Hence, each stent  
25 body 252, 253 alone may be more radially compliant than a single stent body that provides sufficient radial force to secure an endoprosthesis. When loading the endoprosthesis 200 into a deployment device, the compliant stent bodies tolerate radial compaction without damage. When deployed, however, stent bodies 252, 253 cooperate to exert sufficient outward radial force to maintain the endoprosthesis in position within a  
30 body lumen.

Either of stent bodies 252, 253 may exert a greater outward radial force than the other. In embodiments, internal stent body 252 exerts a greater radial outward force, which helps secure internal stent body 252 and tubular member 254 with respect to external stent body 253. In embodiments, a radial thickness of each stent body 252, 253  
5 is about 60  $\mu\text{m}$  or less, about 50  $\mu\text{m}$  or less, about 30  $\mu\text{m}$  or less, e.g., about 25  $\mu\text{m}$  or less. The total radial thickness of stent bodies 252, 253 may be about 120  $\mu\text{m}$  or less, about 100  $\mu\text{m}$  or less, about 60  $\mu\text{m}$  or less, e.g., about 50  $\mu\text{m}$  or less. One of the stent bodies 252, 253 may make up at least about 50%, at least about 75%, e.g., at least about 85% of the total radial thickness.

10 In some embodiments, stent bodies 252, 253 and tubular member 254 are secured with respect to one another by filaments 101, which pass through fenestrations 265 of the tubular member and pass around and/or are secured to either or both of stent bodies 252, 253. In embodiments, a given filament secures the tubular member with respect to one but not both stent bodies 252, 253.

15 Endoprosthesis 200 can be configured so that stent bodies 252, 253 have relative freedom of movement with respect to one another and/or with respect to tubular member 254. The freedom of movement may be provided along a given dimension, e.g., a radial, a circumferential, a longitudinal dimension, or combination thereof. For example, filaments 101 may have a length sufficient to provide some freedom of movement.  
20 Filaments that pass around longitudinal members 258 can allow longitudinal movement whereas filaments that pass around portions of circumferential bands 257 can allow circumferential movement. In some embodiments, stent bodies 252, 253 have essentially no freedom of movement along one or more dimensions, e.g., along one or all of the radial, circumferential, and longitudinal dimensions. Securing techniques alternative to  
25 or supplemental to filaments can be used.

Referring to Fig. 5, an endoprosthesis 300 includes a tubular member 354 sandwiched between an internal stent body and an external stent body. One or both of the stent bodies of endoprosthesis 300 can be secured to the other via radially extending projections. As seen in Fig. 5, the external stent body includes projections 353, each  
30 extending through a fenestration 365 of tubular member 354 and engaging a portion of

the internal stent body, e.g., an aperture 355. Apertures may or may not be closed and can be formed within a longitudinal member 359 or circumferential band of the stent body. The apertures are positioned to receive the projections when the two stent bodies mate.

5           An end 357 of each projection 353 can be flattened or otherwise broadened to prevent the projection from retracting through the aperture 355. Depending upon the relative shape and size of the apertures and projections, the apertures and projections can be configured to provide the stent bodies with radial, longitudinal and/or circumferential freedom of movement.

10           Other examples of endoprostheses including a thin film as well as related systems and methods are described in U.S. provisional patent application no. 60/549,287, filed March 2, 2004, which application is incorporated herein by reference.

          Methods and structures for securing a framework and one or more deposited thin film covers are described in U.S. patent application no. \*\*/\*\*, attorney docket no.  
15 10527-566001, titled MEDICAL DEVICES INCLUDING METALLIC FILMS AND METHODS FOR MAKING SAME, and filed concurrently herewith, which application is incorporated herein by reference.

          An endoprosthesis may include a cover disposed externally to a framework as shown and/or internally of a framework. Endoprostheses having a cover including, e.g., a  
20 deposited thin film, disposed internally of a framework are described in U.S. patent application no. \*\*/\*\*, attorney docket no. 10527-567001, titled MEDICAL DEVICES INCLUDING METALLIC FILMS AND METHODS FOR MAKING SAME, and filed concurrently herewith, which application is incorporated herein by reference.

          An endoprosthesis may include features to enhance a flexibility of the  
25 endoprosthesis as described in U.S. patent application no. \*\*/\*\*, attorney docket no. 10527-568001, titled MEDICAL DEVICES INCLUDING METALLIC FILMS AND METHODS FOR MAKING SAME, and filed concurrently herewith, which application is incorporated herein by reference.

          An endoprosthesis may include a deposited thin film and a polymer as described  
30 in U.S. patent application no. \*\*/\*\*, attorney docket no. 10527-596001, titled

MEDICAL DEVICES INCLUDING METALLIC FILMS AND METHODS FOR MAKING SAME, and filed concurrently herewith, which application is incorporated herein by reference.

5 An endoprosthesis may include one or more filaments, e.g., wires, adapted to enhance mechanical properties of a deposited thin film as described in U.S. patent application no. \*\*/\*\*, attorney docket no. 10527-621001, titled MEDICAL DEVICES INCLUDING METALLIC FILMS AND METHODS FOR MAKING SAME, and filed concurrently herewith, which application is incorporated herein by reference.

10 Methods for loading an endoprosthesis into a delivery device and systems for delivering an endoprosthesis to a treatment site are described in U.S. patent application no. \*\*/\*\*, attorney docket no. 10527-569001, titled MEDICAL DEVICES INCLUDING METALLIC FILMS AND METHODS FOR LOADING AND DEPLOYING SAME, which application is incorporated herein by reference.

15 All publications, references, applications, and patents referred to herein are incorporated by reference in their entirety.

Other embodiments are within the claims.

## CLAIMS

What is claimed is:

- 5 1. An endoprosthesis for deployment within a body passage, comprising:  
a tubular framework; and  
a metallic film having a thickness of about 50  $\mu\text{m}$  or less and disposed internally  
of the tubular framework.
2. The endoprosthesis of claim 1, wherein the endoprosthesis is self expandable.
- 10 3. The endoprosthesis of claim 1, wherein the tubular framework has an internal  
surface and wherein the metallic film is generally tubular in shape and has an outer  
surface that contacts the internal surface of the tubular framework.
4. The endoprosthesis of claim 1, wherein the metallic film comprises a super-elastic  
alloy of nickel and titanium.
- 15 5. The endoprosthesis of claim 1, wherein the endoprosthesis, when in a deployed  
state within a body passage, exerts an outward radial force against the body passage,  
essentially all of the outward radial force resulting from the tubular framework.
6. The endoprosthesis of claim 1, wherein the endoprosthesis has an internal  
surface, the internal surface substantially defined by an internal surface of the metallic  
20 film.
7. The endoprosthesis of claim 1, wherein the endoprosthesis comprises only one  
framework.
8. The endoprosthesis of claim 1, comprising a second tubular framework, the  
metallic film being sandwiched between the tubular framework and the second tubular  
25 framework.
9. The endoprosthesis of claim 8, wherein the endoprosthesis is self expanding.

10. The endoprosthesis of claim 8, wherein neither the tubular framework nor the second tubular framework, by itself, exerts a radial force sufficient to secure the endoprosthesis within a body passage.
11. The endoprosthesis of claim 10, wherein, when in a deployed state, the tubular  
5 framework and the second tubular framework each exerts a radial force, the radial force of the second tubular framework being greater than the radial force of the tubular framework.
12. The endoprosthesis of claim 8, wherein the metallic film comprises a super-elastic alloy comprising titanium and nickel, the super-elastic alloy not being shape set.
- 10 13. The endoprosthesis of claim 8, wherein a total radial thickness of the tubular framework and the second tubular framework is about 75 microns or less.
14. The endoprosthesis of claim 8, wherein the tubular framework and the second tubular framework have at least some relative freedom of movement along at least one of the radial, circumferential, and longitudinal dimensions..
- 15 15. The endoprosthesis of claim 1, wherein substantially all of the metallic film is a single layer.
16. The endoprosthesis of claim 15, wherein the entire metallic film is a single layer.
17. A self-expanding endoprosthesis for deployment within a body passage,  
comprising:
- 20 a first tubular framework;  
a tubular member disposed around the first tubular framework; and  
a second tubular framework disposed around the tubular member.
18. The self-expanding endoprosthesis of claim 17, wherein neither of the first and second tubular frameworks alone exerts sufficient outward radial force to self-expand the  
25 endoprosthesis within a body passage but the first and second tubular frameworks together exert sufficient outward radial force to self-expand the endoprosthesis.

19. The self-expanding endoprosthesis of claim 17, wherein the tubular member is a deposited metallic film comprising titanium and nickel and having a thickness of about 50  $\mu\text{m}$  or less.
20. A delivery device for deploying an endoprosthesis within a body passage,  
5 comprising:  
    an elongate inner member;  
    a self-expanding endoprosthesis disposed about a distal portion of the inner member, the endoprosthesis comprising a tubular framework disposed about a deposited metallic film; and  
10 an outer sheath surrounding the elongate inner member and the self-expanding endoprosthesis, wherein the tubular framework prevents substantial frictional contact between the tubular member and the outer sheath.



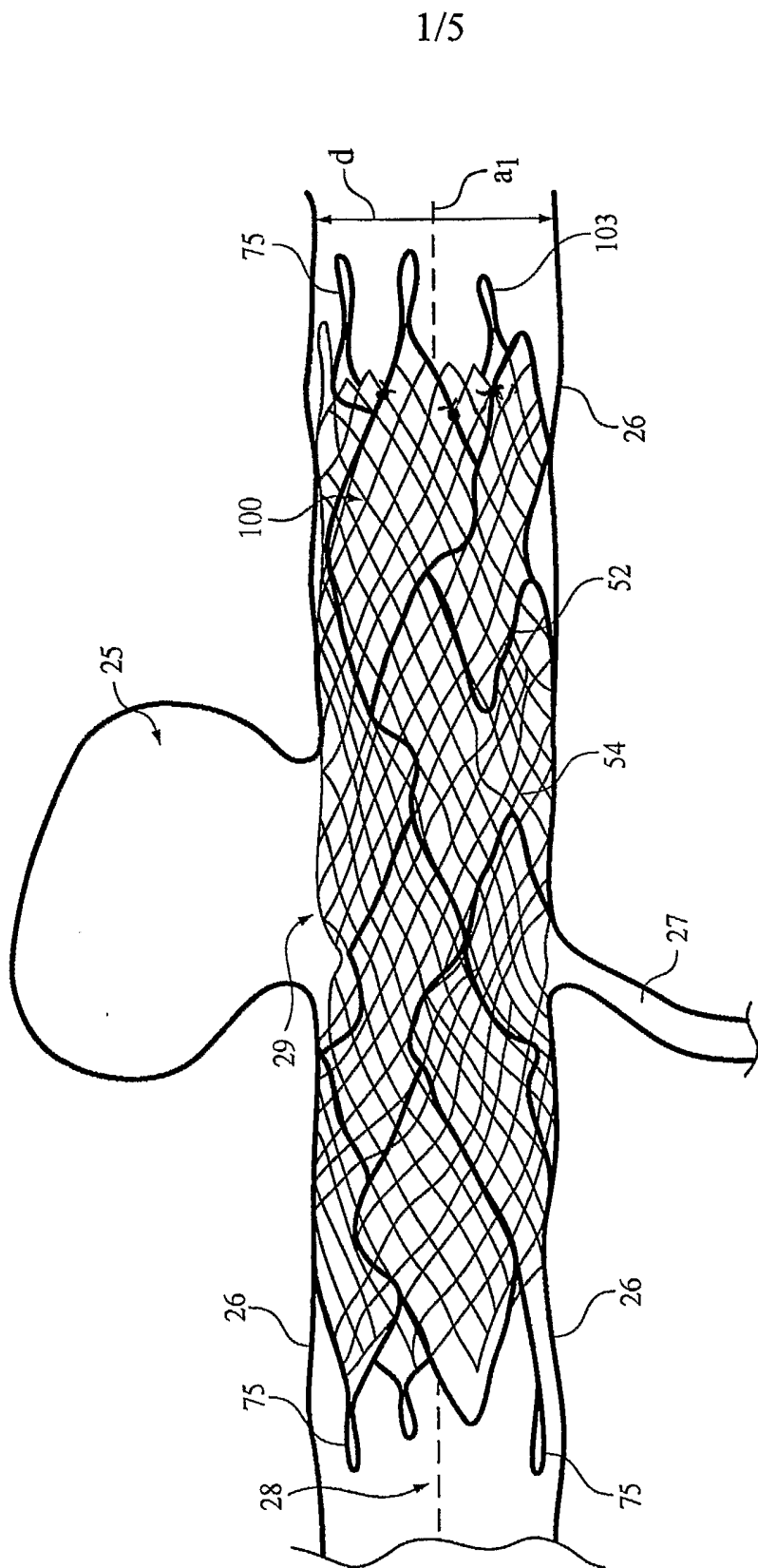


FIG. 1

SUBSTITUTE SHEET (RULE 26)

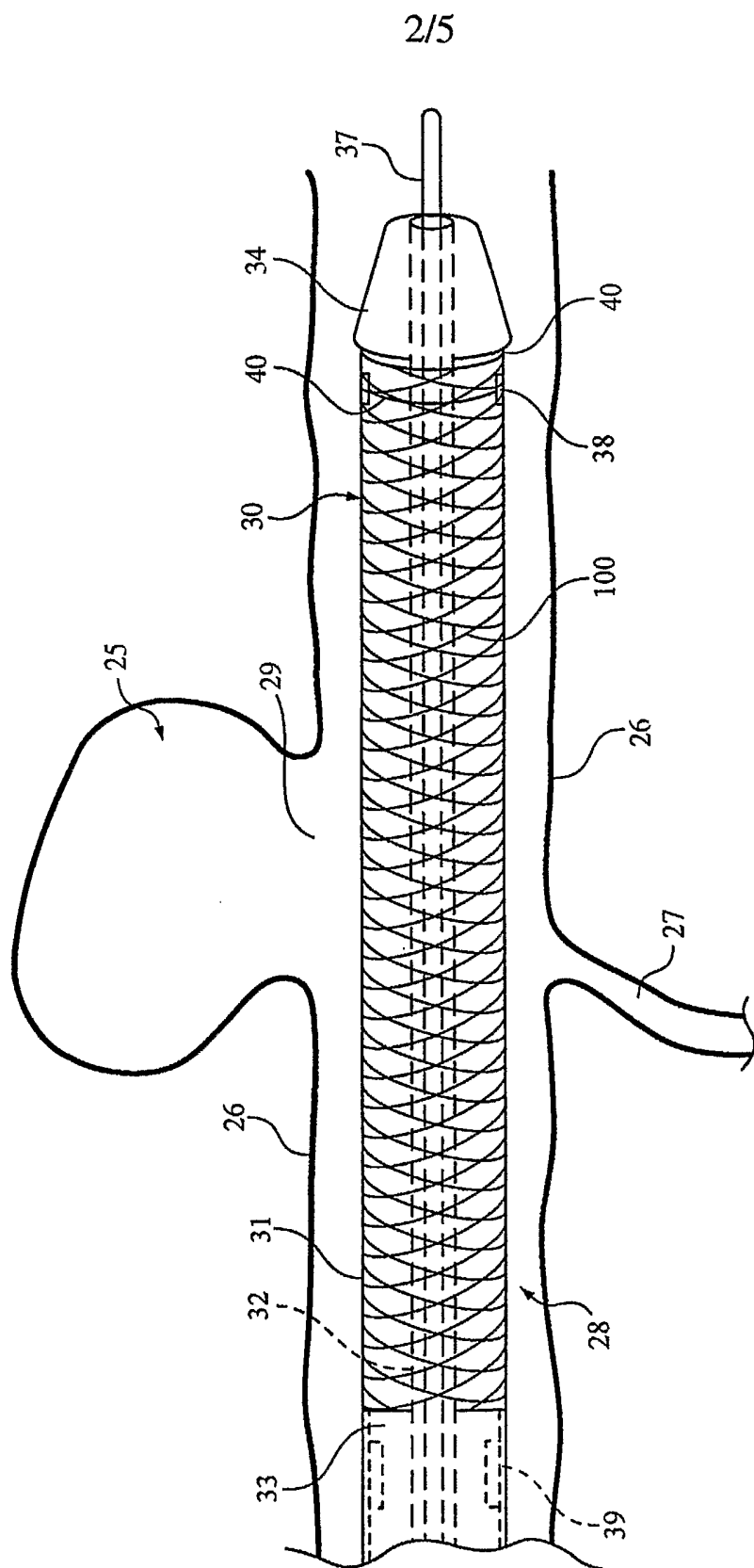


FIG. 2a

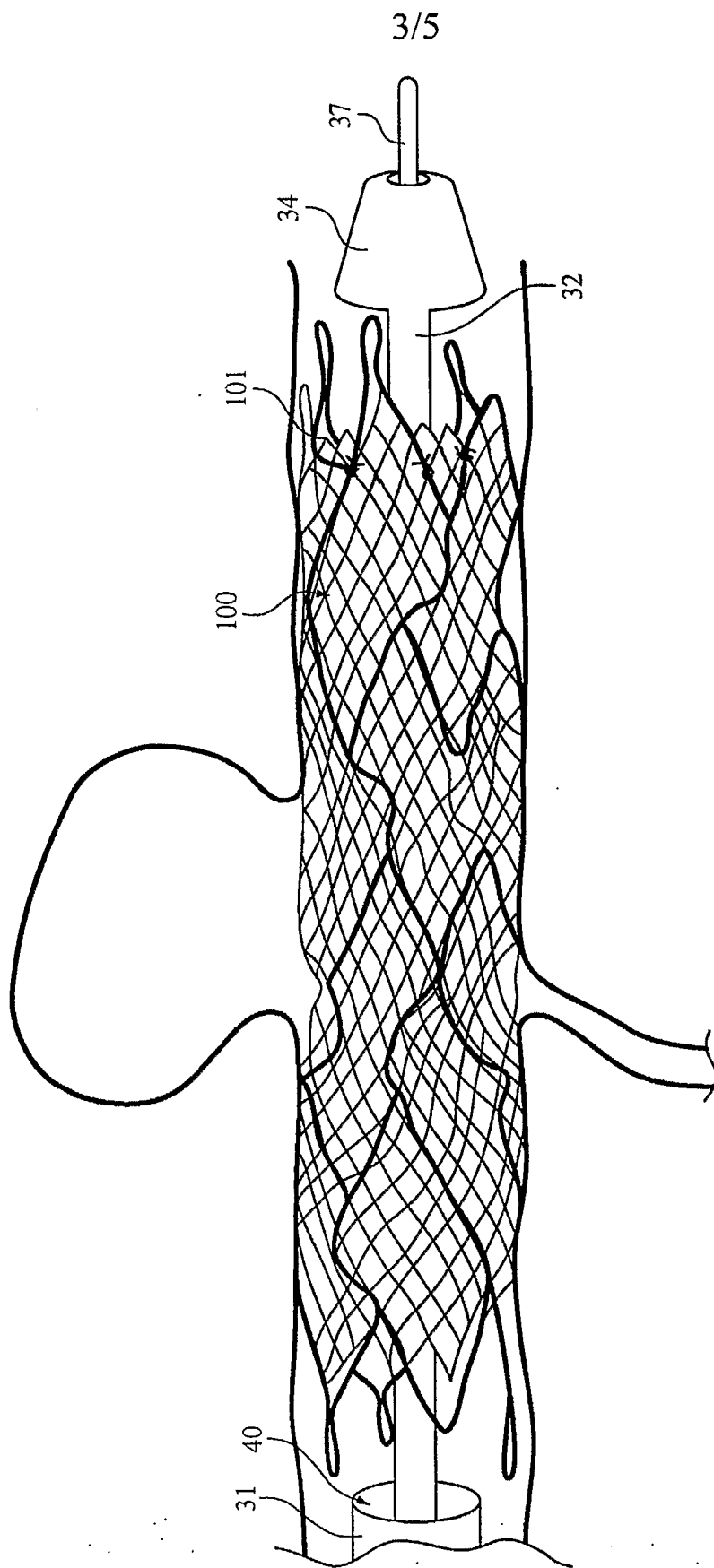


FIG. 2b

SUBSTITUTE SHEET (RULE 26)

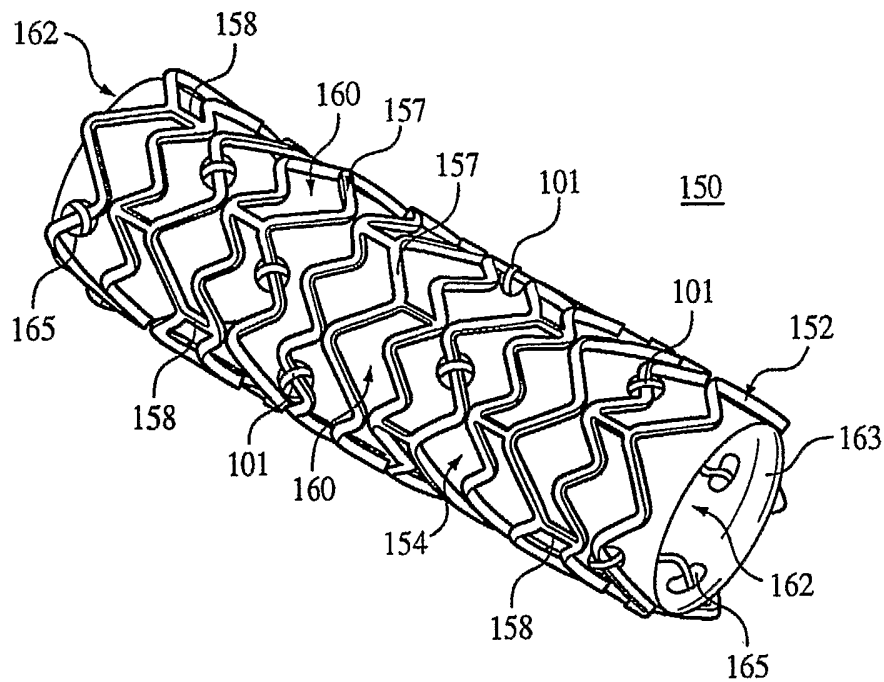


FIG. 3

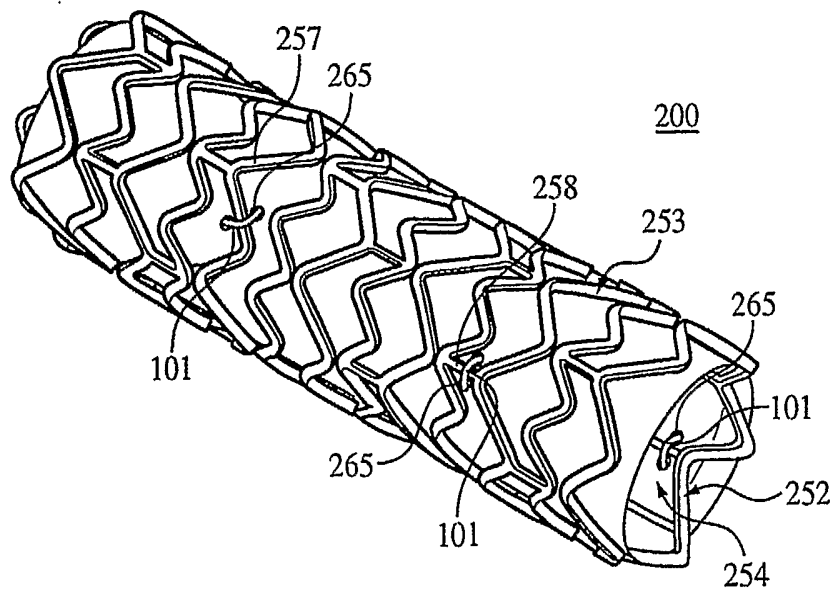


FIG. 4

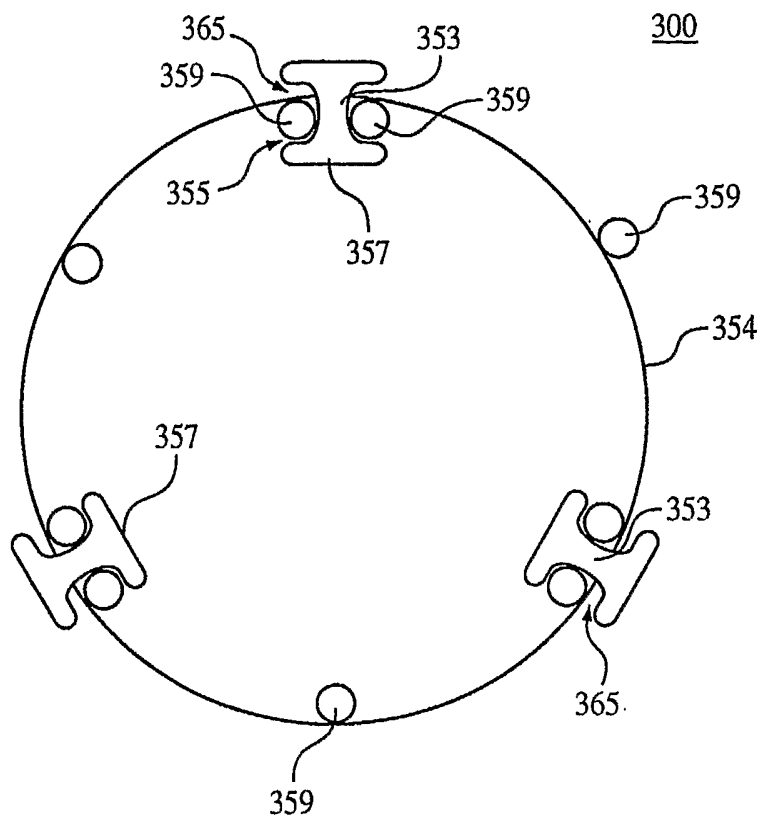


FIG. 5

# INTERNATIONAL SEARCH REPORT

In: Application No  
PCT/US2005/006993

|  |   |                                     |
|--|---|-------------------------------------|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>IPC 7 A61F2/06   |   |                                     |
| According to International Patent Classification (IPC) or to both national classification and IPC  |   |                                     |
| <b>B. FIELDS SEARCHED</b>  |   |                                     |
| Minimum documentation searched (classification system followed by classification symbols)<br>IPC 7 A61F C23C   |   |                                     |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  |   |                                     |
| Electronic data base consulted during the international search (name of data base and, where practical, search terms used)<br>EPO-Internal   |   |                                     |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>  |   |                                     |
| Category °   | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.               |
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| <input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.   |   |                                     |
| <input checked="" type="checkbox"/> Patent family members are listed in annex.   |   |                                     |
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| *E* earlier document but published on or after the international filing date   | *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  |                                     |
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| Date of the actual completion of the international search<br><br><p style="text-align: center;">4 July 2005</p>  | Date of mailing of the international search report<br><br><p style="text-align: center;">02/08/2005</p>   |                                     |
| Name and mailing address of the ISA<br>European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Authorized officer<br><br><p style="text-align: center;">Newman, B</p>  |                                     |

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| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT |  |   |
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Int Application No  
P... 005/006993

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