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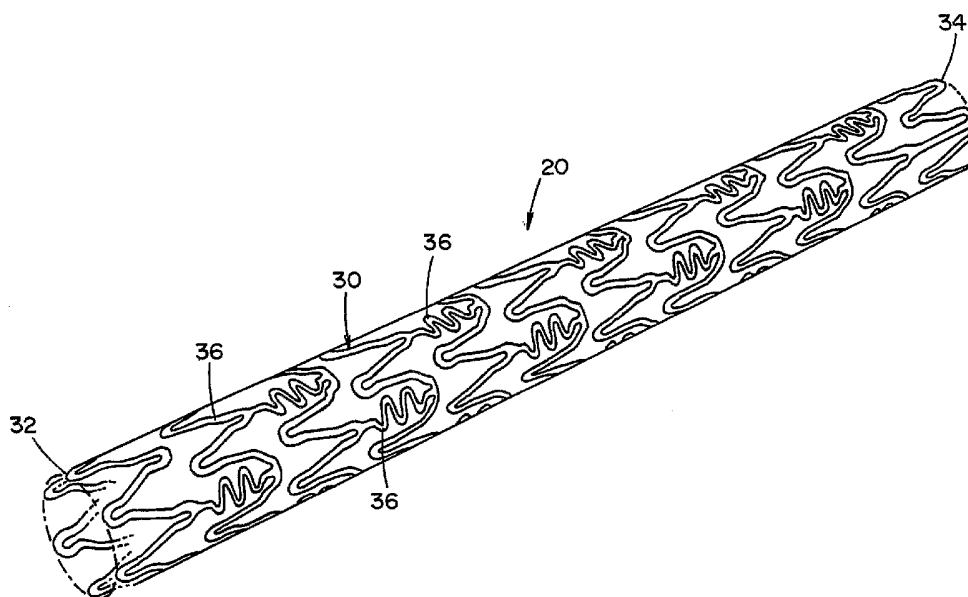
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(54) Title: PROCESS FOR FORMING AN IMPROVED METAL ALLOY STENT



(57) Abstract: A method and process for at least partially forming a medical device that is at least partially formed of a novel metal alloy which improves the physical properties of the medical device.

PROCESS FOR FORMING AN IMPROVED METAL ALLOY STENT

The present invention claims priority on United States Provisional Application Serial Nos. 60/658,226 filed March 3, 2005 entitled "Improved Metal Alloys for Medical Devices"; 60/694,881 filed June 29, 2005 entitled "Improved Metal Alloys for Medical Devices"; 60/694,891 filed June 29, 2005 entitled "Improved Metal Alloys for Medical Devices",
5 60/739,688 filed November 23, 2005 entitled "Process for Forming an Improved Metal Alloy Stent", all of which are incorporated herein by reference.

The invention relates generally to medical devices, and particularly to a method and process for forming a medical device that is at least partially formed of a novel metal alloy, and more particularly to a method and process for forming a stent that is at least partially formed of
10 a novel molybdenum and rhenium metal alloy.

BACKGROUND OF THE INVENTION

Medical treatment of various illnesses or diseases commonly includes the use of one or more medical devices. Two types of medical devices that are commonly used to repair various types of body passageways are an expandable graft or stent, or a surgical graft. These devices
15 have been implanted in various areas of the mammalian anatomy. One purpose of a stent is to open a blocked or partially blocked body passageway. When a stent is used in a blood vessel, the stent is used to open the occluded vessel to achieve improved blood flow which is necessary to provide for the anatomical function of an organ. The procedure of opening a blocked or partially blocked body passageway commonly includes the use of one or more stents in
20 combination with other medical devices such as, but not limited to, an introducer sheath, a guiding catheter, a guide wire, an angioplasty balloon, etc.

Various physical attributes of a stent can contribute directly to the success rate of the device. These physical attributes include radiopacity, hoop strength, radial force, thickness of the metal, dimensions of the metal and the like. Cobalt and chromium alloys and stainless steel
25 are commonly used to form stents. These materials are commonly used since such materials have a known history of safety, effectiveness and biocompatibility. These materials however have limited physical performance characteristics as to size, strength, weight, bendability, biostability and radiopacity. The present invention is generally directed to a method and process for manufacturing and producing a medical device, and more particularly directed to a method
30 and process for manufacturing and producing a stent that is at least partially formed of a novel

metal alloy.

SUMMARY OF THE INVENTION

The present invention is generally directed to a medical device that is at least partially made of a novel metal alloy having improved properties as compared to past medical devices.

5 The novel metal alloy used to at least partially form the medical device improves one or more properties (e.g., strength, durability, hardness, biostability, bendability, coefficient of friction, radial strength, flexibility, tensile strength, tensile elongation, longitudinal lengthening, stress-strain properties, improved recoil properties, radiopacity, heat sensitivity, biocompatibility, etc.) of such medical device. These one or more improved physical properties of the novel metal

10 alloy can be achieved in the medical device without having to increase the bulk, volume and/or weight of the medical device, and in some instances these improved physical properties can be obtained even when the volume, bulk and/or weight of the medical device is reduced as compared to medical devices that are at least partially formed from traditional stainless steel or cobalt and chromium alloy materials. The novel metal alloy that is used to at least partially form

15 the medical device can thus 1) increase the radiopacity of the medical device, 2) increase the radial strength of the medical device, 3) increase the yield strength and/or ultimate tensile strength of the medical device, 4) improve the stress-strain properties of the medical device, 5) improve the crimping and/or expansion properties of the medical device, 6) improve the bendability and/or flexibility of the medical device, 7) improve the strength and/or durability of

20 the medical device, 8) increase the hardness of the medical device, 9) improve the longitudinal lengthening properties of the medical device, 10) improve the recoil properties of the medical device, 11) improve the friction coefficient of the medical device, 12) improve the heat sensitivity properties of the medical device, 13) improve the biostability and/or biocompatibility properties of the medical device, and/or 14) enable smaller, thinner and/or lighter weight medical

25 devices to be made. The medical device generally includes one or more materials that impart the desired properties to the medical device so as to withstand the manufacturing processes that are needed to produce the medical device. These manufacturing processes can include, but are not limited to, laser cutting, etching, crimping, annealing, drawing, pilgering, electroplating, electro-polishing, chemical polishing, cleaning, pickling, ion beam deposition or implantation,

30 sputter coating, vacuum deposition, etc.

In one non-limiting aspect of the present invention, a medical device that can include the

novel metal alloy is a stent for use in a body passageway; however, it can be appreciated that other types of medical devices could be at least partially formed from the novel metal alloy. As used herein, the term "body passageway" is defined to be any passageway or cavity in a living organism (e.g., bile duct, bronchial tubes, nasal cavity, blood vessels, heart, esophagus, trachea, stomach, fallopian tube, uterus, ureter, urethra, the intestines, lymphatic vessels, nasal passageways, eustachian tube, acoustic meatus, etc.). The techniques employed to deliver the medical device to a treatment area include, but are not limited to, angioplasty, vascular anastomoses, interventional procedures, and any combinations thereof. For vascular applications, the term "body passageway" primarily refers to blood vessels and chambers in the heart. The stent can be an expandable stent that is expandable by a balloon and/or other means. The stent can have many shapes and forms. Such shapes can include, but are not limited to, stents disclosed in United States Patent Nos. 6,206,916 and 6,436,133; and all the prior art cited in these patents. These various designs and configurations of stents in such patents are incorporated herein by reference.

In another and/or alternative non-limiting aspect of the present invention, the medical device is generally designed to include at least about 25 weight percent of the novel metal alloy; however, this is not required. In one non-limiting embodiment of the invention, the medical device includes at least about 40 weight percent of the novel metal alloy. In another and/or alternative non-limiting embodiment of the invention, the medical device includes at least about 50 weight percent of the novel metal alloy. In still another and/or alternative non-limiting embodiment of the invention, the medical device includes at least about 60 weight percent of the novel metal alloy. In yet another and/or alternative non-limiting embodiment of the invention, the medical device includes at least about 70 weight percent of the novel metal alloy. In still yet another and/or alternative non-limiting embodiment of the invention, the medical device includes at least about 85 weight percent of the novel metal alloy. In a further and/or alternative non-limiting embodiment of the invention, the medical device includes at least about 90 weight percent of the novel metal alloy. In still a further and/or alternative non-limiting embodiment of the invention, the medical device includes at least about 95 weight percent of the novel metal alloy. In yet a further and/or alternative non-limiting embodiment of the invention, the medical device includes about 100 weight percent of the novel metal alloy.

In still another and/or alternative non-limiting aspect of the present invention, the novel

metal alloy that is used to form all or part of the medical device 1) is not clad, metal sprayed, plated and/or formed (e.g., cold worked, hot worked, etc.) onto another metal, or 2) does not have another metal or metal alloy metal sprayed, plated, clad and/or formed onto the novel metal alloy. It will be appreciated that in some applications, the novel metal alloy of the present invention may be clad, metal sprayed, plated and/or formed onto another metal, or another metal or metal alloy may be plated, metal sprayed, clad and/or formed onto the novel metal alloy when forming all or a portion of a medical device.

In yet another and/or alternative non-limiting aspect of the present invention, the novel metal alloy that is used to form all or a portion of the medical device includes rhenium and molybdenum. The novel alloy can include one or more other metals such as, but not limited to, calcium, chromium, cobalt, copper, gold, iron, lead, magnesium, nickel, niobium, platinum, rare earth metals, silver, tantalum, titanium, tungsten, yttrium, zinc, zirconium, and/or alloys thereof.

In still another and/or alternative non-limiting aspect of the present invention, the novel metal alloy that is used to form all or a portion of the medical device is a novel metal alloy that includes at least about 90 weight percent molybdenum and rhenium. In one non-limiting composition, the content of molybdenum and rhenium in the novel metal alloy is at least about 95 weight percent. In another and/or alternative non-limiting composition, the content of molybdenum and rhenium in the novel metal alloy is at least about 97 weight percent. In still another and/or alternative non-limiting composition, the content of molybdenum and rhenium in the novel metal alloy is at least about 98 weight percent. In yet another and/or alternative non-limiting composition, the content of molybdenum and rhenium in the novel metal alloy is at least about 99 weight percent. In still yet another and/or alternative non-limiting composition, the content of molybdenum and rhenium in the novel metal alloy is at least about 99.5 weight percent. In a further one non-limiting composition, the content of molybdenum and rhenium in the novel metal alloy is at least about 99.9 weight percent. In still a further and/or alternative non-limiting composition, the content of molybdenum and rhenium in the novel metal alloy is at least about 99.95 weight percent. In yet a further and/or alternative non-limiting composition, the content of molybdenum and rhenium in the novel metal alloy is at least about 99.99 weight percent. As can be appreciated, other weight percentages of the rhenium and molybdenum content of the novel metal alloy can be used. In one non-limiting composition, the purity level of the novel metal alloy is such so as to produce a solid solution of the novel metal alloy. A solid

solution or homogeneous solution is defined as a metal alloy that includes two or more primary metals and the combined weight percent of the primary metals is at least about 95 weight percent, typically at least about 99 weight percent, more typically at least about 99.5 weight percent, even more typically at least about 99.8 weight percent, and still even more typically at least about 99.9 weight percent. A primary metal is a metal component of the metal alloy that is not a metal impurity. A solid solution of a novel metal alloy that includes rhenium and molybdenum as the primary metals is an alloy that includes at least about 95-99 weight percent rhenium and molybdenum. It is believed that a purity level of less than 95 weight percent molybdenum and rhenium adversely affects one or more physical properties of the metal alloy that are useful or desired in forming and/or using a medical device. In one embodiment of the invention, the rhenium content of the novel metal alloy in accordance with the present invention is at least about 40 weight percent. In one non-limiting composition, the rhenium content of the novel metal alloy is at least about 45 weight percent. In still another and/or alternative non-limiting composition, the rhenium content of the novel metal alloy is about 45-50 weight percent. In yet another and/or alternative non-limiting composition, the rhenium content of the novel metal alloy is about 47-48 weight percent. In still yet another and/or alternative non-limiting composition, the rhenium content of the novel metal alloy is about 47.6-49.5 weight percent. As can be appreciated, other weight percentages of the rhenium content of the novel metal alloy can be used. In another and/or alternative embodiment of the invention, the molybdenum content of the novel metal alloy in accordance with the present invention is at least about 40 weight percent. In one non-limiting composition, the molybdenum content of the novel metal alloy is at least about 45 weight percent. In another and/or alternative non-limiting composition, the molybdenum content of the novel metal alloy is at least about 50 weight percent. In still another and/or alternative non-limiting composition, the molybdenum content of the novel metal alloy is about 50-60 percent. In yet another and/or alternative non-limiting composition, the molybdenum content of the novel metal alloy is about 50-56 weight percent. As can be appreciated, other weight percentages of the molybdenum content of the novel metal alloy can be used.

In still yet another and/or alternative non-limiting aspect of the present invention, the novel metal alloy that is used to form all or a portion of the medical device is a novel metal alloy that includes at least about 90 weight percent molybdenum and rhenium, and at least one

additional metal which includes titanium, yttrium, and/or zirconium. The addition of controlled amounts of titanium, yttrium, and/or zirconium to the molybdenum and rhenium alloy has been found to form a metal alloy that has improved physical properties over a metal alloy that principally includes molybdenum and rhenium. For instance, the addition of controlled amounts of titanium, yttrium, and/or zirconium to the molybdenum and rhenium alloy can result in 1) an increase in yield strength of the alloy as compared to a metal alloy that principally includes molybdenum and rhenium, 2) an increase in tensile elongation of the alloy as compared to a metal alloy that principally includes molybdenum and rhenium, 3) an increase in ductility of the alloy as compared to a metal alloy that principally includes molybdenum and rhenium, 4) a reduction in grain size of the alloy as compared to a metal alloy that principally includes molybdenum and rhenium, 5) a reduction in the amount of free carbon, oxygen and/or nitrogen in the alloy as compared to a metal alloy that principally includes molybdenum and rhenium, and/or 6) a reduction in the tendency of the alloy to form micro-cracks during the forming of the alloy into a medical device as compared to the forming of a medical device from a metal alloy that principally includes molybdenum and rhenium. In one non-limiting composition, the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy is at least about 90 weight percent. In another and/or alternative non-limiting composition, the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy is at least about 95 weight percent. In still another and/or alternative non-limiting composition, the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy is at least about 98 weight percent. In yet another and/or alternative non-limiting composition, the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy is at least about 99 weight percent. In still yet another and/or alternative non-limiting composition, the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy is at least about 99.5 weight percent. In a further one non-limiting composition, the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy is at least about 99.9 weight percent. In still a further and/or alternative non-limiting composition, the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy is at least about 99.95 weight percent. In yet a further and/or alternative non-limiting composition, the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy is at least about 99.99

weight percent. As can be appreciated, other weight percentages of the content of molybdenum and rhenium and the at least one additional metal in the novel metal alloy can be used. In one non-limiting composition, the purity level of the novel metal alloy is such so as to produce a solid solution of a rhenium and molybdenum and the at least one additional metal. A solid solution of a novel metal alloy that includes rhenium and molybdenum and the at least one additional metal of titanium, yttrium and/or zirconium as the primary metals is an alloy that includes at least about 95-99 weight percent rhenium and molybdenum and the at least one additional metal. It is believed that a purity level of less than 95 weight percent molybdenum and rhenium and the at least one additional metal adversely affects one or more physical properties of the metal alloy that are useful or desired in forming and/or using a medical device. In one embodiment of the invention, the rhenium content of the novel metal alloy in accordance with the present invention is at least about 40 weight percent. In one non-limiting composition, the rhenium content of the novel metal alloy is at least about 45 weight percent. In still another and/or alternative non-limiting composition, the rhenium content of the novel metal alloy is about 45-50 weight percent. In yet another and/or alternative non-limiting composition, the rhenium content of the novel metal alloy is about 47-48 weight percent. As can be appreciated, other weight percentages of the rhenium content of the novel metal alloy can be used. In another and/or alternative embodiment of the invention, the molybdenum content of the novel metal alloy is at least about 40 weight percent. In one non-limiting composition, the molybdenum content of the novel metal alloy is at least about 45 weight percent. In another and/or alternative non-limiting composition, the molybdenum content of the novel metal alloy is at least about 50 weight percent. In still another and/or alternative non-limiting composition, the molybdenum content of the novel metal alloy is about 50-60 percent. In yet another and/or alternative non-limiting composition, the molybdenum content of the novel metal alloy is about 50-56 weight percent. As can be appreciated, other weight percentages of the molybdenum content of the novel metal alloy can be used. The combined content of titanium, yttrium and zirconium in the novel metal alloy is less than about 5 weight percent, typically no more than about 1 weight percent, and more typically, no more than about 0.5 weight percent. A higher weight percent content of titanium, yttrium and/or zirconium in the novel metal alloy can begin to adversely affect the brittleness of the novel metal alloy. When titanium is included in the novel metal alloy, the titanium content is typically less than about 1 weight percent, more typically less than

about 0.6 weight percent, even more typically, about 0.05-0.5 weight percent, still even more typically, about 0.1-0.5 weight percent. As can be appreciated, other weight percentages of the titanium content of the novel metal alloy can be used. When zirconium is included in the novel metal alloy, the zirconium content is typically less than about 0.5 weight percent, more typically less than about 0.3 weight percent, even more typically about 0.01-0.25 weight percent, still even more typically about 0.05-0.25 weight percent. As can be appreciated, other weight percentages of the zirconium content of the novel metal alloy can be used. When titanium and zirconium are included in the novel metal alloy, the weight ratio of titanium to zirconium is about 1-10:1, typically about 1.5-5:1, and more typically about 1.75-2.5:1. When yttrium is included in the novel metal alloy, the yttrium content is typically less than about 0.3 weight percent, more typically less than about 0.2 weight percent, and even more typically about 0.01-0.1 weight percent. As can be appreciated, other weight percentages of the yttrium content of the novel metal alloy can be used. The inclusion of titanium, yttrium and/or zirconium in the novel metal alloy is believed to result in a reduction of oxygen trapped in the solid solution of the novel metal alloy. The reduction of trapped oxygen enables the formation of a smaller grain size in the novel metal alloy and/or an increase in the ductility of the novel metal alloy. The reduction of trapped oxygen in the novel metal alloy can also increase the yield strength of the novel metal alloy as compared to alloys of only molybdenum and rhenium (i.e., 2-10% increase). The inclusion of titanium, yttrium and/or zirconium in the novel metal alloy is also believed to cause a reduction in the trapped free carbon in the novel metal alloy. The inclusion of titanium, yttrium and/or zirconium in the novel metal alloy is believed to form carbides with the free carbon in the novel metal alloy. This carbide formation is also believed to improve the ductility of the novel metal alloy and to also reduce the incidence of cracking during the forming of the metal alloy into a medical device (e.g., stent, etc.). As such, the novel metal alloy exhibits increased tensile elongation as compared to alloys of only molybdenum and rhenium (i.e., 1-8% increase). The inclusion of titanium, yttrium and/or zirconium in the novel metal alloy is also believed to cause a reduction in the trapped free nitrogen in the novel metal alloy. The inclusion of titanium, yttrium and/or zirconium in the novel metal alloy is believed to form carbo-nitrides with the free carbon and free nitrogen in the novel metal alloy. This carbo-nitride formation is also believed to improve the ductility of the novel metal alloy and to also reduce the incidence of cracking during the forming of the metal alloy into a medical device (e.g., stent, etc.). As

such, the novel metal alloy exhibits increased tensile elongation as compared to alloys of only molybdenum and rhenium (i.e., 1-8% increase). The reduction in the amount of free carbon, oxygen and/or nitrogen in the novel metal alloy is also believed to increase the density of the novel metal alloy (i.e., 1-5% increase). The formation of carbides, carbo-nitrides, and/or oxides in the novel metal alloy results in the formation of dispersed second phase particles in the novel metal alloy, thereby facilitating in the formation of small grain sizes in the metal alloy.

In still another and/or alternative non-limiting aspect of the present invention, the novel metal alloy includes less than about 5 weight percent other metals and/or impurities. A high purity level of the novel metal alloy results in the formation of a more homogeneous alloy, which in turn results in a more uniform density throughout the novel metal alloy, and also results in the desired yield and ultimate tensile strengths of the novel metal alloy. The density of the novel metal alloy is generally at least about 12 gm/cc, and typically at least about 13-13.5 gm/cc. This substantially uniform high density of the novel metal alloy significantly improves the radiopacity of the novel metal alloy. In one non-limiting composition, the novel metal alloy includes less than about 1 weight percent other metals and/or impurities. In another and/or alternative non-limiting composition, the novel metal alloy includes less than about 0.5 weight percent other metals and/or impurities. In still another and/or alternative non-limiting composition, the novel metal alloy includes less than about 0.4 weight percent other metals and/or impurities. In yet another and/or alternative non-limiting composition, the novel metal alloy includes less than about 0.2 weight percent other metals and/or impurities. In still yet another and/or alternative non-limiting composition, the novel metal alloy includes less than about 0.1 weight percent other metals and/or impurities. In a further and/or alternative non-limiting composition, the novel metal alloy includes less than about 0.05 weight percent other metals and/or impurities. In still a further and/or alternative non-limiting composition, the novel metal alloy includes less than about 0.02 weight percent other metals and/or impurities. In yet a further and/or alternative non-limiting composition, the novel metal alloy includes less than about 0.01 weight percent other metals and/or impurities. As can be appreciated, other weight percentages of the amount of other metals and/or impurities in the novel metal alloy can exist.

In yet another and/or alternative non-limiting aspect of the present invention, the novel metal alloy includes a certain amount of carbon and oxygen. These two elements have been found to affect the forming properties and brittleness of the novel metal alloy. The controlled

atomic ratio of carbon and oxygen in the novel metal alloy also can be used to minimize the tendency of the novel metal alloy to form micro-cracks during the forming of the novel alloy into a medical device, and/or during the use and/or expansion of the medical device in a body passageway. In one non-limiting embodiment of the invention, the novel metal alloy includes up to about 200 ppm carbon and up to about 150 ppm oxygen. Higher carbon and oxygen contents in the novel metal alloy are believed to adversely affect one or more physical properties of the metal alloy that are useful or desired in forming and/or using a medical device. In one non-limiting formulation, the novel metal alloy includes up to about 150 ppm carbon. In still another and/or alternative non-limiting formulation, the novel metal alloy includes up to about 100 ppm carbon. In yet another and/or alternative non-limiting formulation, the novel metal alloy includes less than about 50 ppm carbon. In still yet another and/or alternative non-limiting formulation, the novel metal alloy includes up to about 100 ppm oxygen. In a further and/or alternative non-limiting formulation, the novel metal alloy includes up to about 75 ppm oxygen. In still a further and/or alternative non-limiting formulation, the novel metal alloy includes up to about 50 ppm oxygen. In yet a further and/or alternative non-limiting formulation, the novel metal alloy includes up to about 30 ppm oxygen. In still yet a further and/or alternative non-limiting formulation, the novel metal alloy includes less than about 20 ppm oxygen. In yet a further and/or alternative non-limiting formulation, the novel metal alloy includes less than about 10 ppm oxygen. As can be appreciated, other amounts of carbon and/or oxygen in the novel metal alloy can exist. In another and/or alternative non-limiting embodiment of the invention, the carbon to oxygen atomic ratio in the novel metal alloy is generally at least about 2:1 (i.e., weight ratio of about 1.5:1). The control of the atomic ratio of carbon to oxygen in the novel metal alloy allows for the redistribution of oxygen in the metal alloy so as to minimize the tendency of micro-cracking in the novel metal alloy during the forming of the novel alloy into a medical device, and/or during the use and/or expansion of the medical device in a body passageway. When the carbon to oxygen atomic ratio falls below 2-2.5:1 (i.e., weight ratio of about 1.5-1.88:1), the degree of elongation of the novel metal alloy decreases and the incidence of micro-cracking increases, thus adversely affecting one or more physical properties of the metal alloy that are useful or desired in forming and/or using the medical device. In one non-limiting formulation, the carbon to oxygen atomic ratio in the novel metal alloy is generally at least about 2.5:1 (i.e., weight ratio of about 1.88:1). In another and/or alternative non-limiting

formulation, the carbon to oxygen atomic ratio in the novel metal alloy is generally at least about 3:1 (i.e., weight ratio of about 2.25:1). In still another and/or alternative non-limiting formulation, the carbon to oxygen atomic ratio in the novel metal alloy is generally at least about 4:1 (i.e., weight ratio of about 3:1). In yet another and/or alternative non-limiting formulation, the carbon to oxygen atomic ratio in the novel metal alloy is generally at least about 5:1 (i.e., weight ratio of about 3.75:1). In still yet another and/or alternative non-limiting formulation, the carbon to oxygen atomic ratio in the novel metal alloy is generally about 2.5-50:1 (i.e., weight ratio of about 1.88-37.54:1). In a further and/or alternative non-limiting formulation, the carbon to oxygen atomic ratio in the novel metal alloy is generally about 2.5-20:1 (i.e., weight ratio of about 1.88-15:1). In still a further and/or alternative non-limiting formulation, the carbon to oxygen atomic ratio in the novel metal alloy is generally about 2.5-10:1 (i.e., weight ratio of about 1.88-7.5:1). In yet a further and/or alternative non-limiting formulation, the carbon to oxygen atomic ratio in the novel metal alloy is generally about 2.5-5:1 (i.e., weight ratio of about 1.88-3.75:1). As can be appreciated, other atomic ratios of the carbon to oxygen in the novel metal alloy can be used.

In still yet another and/or alternative non-limiting aspect of the present invention, the novel metal alloy includes a controlled amount of nitrogen. Large amounts of nitrogen in the novel metal alloy can adversely affect the ductility of the novel metal alloy. This can in turn adversely affect the elongation properties of the novel metal alloy. A nitrogen content in the novel metal alloy of over 20 ppm can begin to cause the ductility of the novel metal alloy to unacceptably decrease, thus adversely affect one or more physical properties of the metal alloy that are useful or desired in forming and/or using the medical device. In one non-limiting embodiment of the invention, the novel metal alloy includes less than about 30 ppm nitrogen. In one non-limiting formulation, the novel metal alloy includes less than about 25 ppm nitrogen. In still another and/or alternative non-limiting formulation, the novel metal alloy includes less than about 10 ppm nitrogen. In yet another and/or alternative non-limiting formulation, the novel metal alloy includes less than about 5 ppm nitrogen. As can be appreciated, other amounts of nitrogen in the novel metal alloy can exist.

In a further and/or alternative non-limiting aspect of the present invention, the novel metal alloy has several physical properties that positively affect the medical device when at least partially formed of the novel metal alloy. In one non-limiting embodiment of the invention, the

average hardness of the novel metal alloy tube used to form the medical device is generally at least about 60 (HRC) at 77°F. In one non-limiting aspect of this embodiment, the average hardness of the novel metal alloy tube used to form the medical device is generally at least about 70 (HRC) at 77°F, and typically about 80-100 (HRC) at 77°F. In another and/or alternative non-limiting embodiment of the invention, the average ultimate tensile strength of the novel metal alloy used to form the medical device is generally at least about 60 UTS (ksi). In non-limiting aspect of this embodiment, the average ultimate tensile strength of the novel metal alloy used to form the medical device is generally at least about 70 UTS (ksi), typically about 80-150 UTS (ksi), and more typically about 100-150 UTS (ksi). In still another and/or alternative non-limiting embodiment of the invention, the average yield strength of the novel metal alloy used to form the medical device is at least about 70 ksi. In one non-limiting aspect of this embodiment, the average yield strength of the novel metal alloy used to form the medical device is at least about 80 ksi, and typically about 100-140 (ksi). In yet another and/or alternative non-limiting embodiment of the invention, the average grain size of the novel metal alloy used to form the medical device is greater than 5 ASTM (e.g., ASTM E 112-96). The small grain size of the novel metal alloy enables the medical device to have the desired elongation and ductility properties that are useful in enabling the medical device to be formed, crimped and/or expanded. In one non-limiting aspect of this embodiment, the average grain size of the novel metal alloy used to form the medical device is about 5.2-10 ASTM, typically about 5.5-9 ASTM, more typically about 6-9 ASTM, still more typically about 6-8 ASTM, even more typically about 6-7 ASTM, and still even more typically about 6.5-7 ASTM. In still yet another and/or alternative non-limiting embodiment of the invention, the average tensile elongation of the novel metal alloy used to form the medical device is at least about 25%. An average tensile elongation of at least 25% for the novel metal alloy is important to enable the medical device to be properly expanded when positioned in the treatment area of a body passageway. A medical device that does not have an average tensile elongation of at least about 25% can form micro-cracks and/or break during the forming, crimping and/or expansion of the medical device. In one non-limiting aspect of this embodiment, the average tensile elongation of the novel metal alloy used to form the medical device is about 25-35%. The unique combination of the rhenium content in the novel metal alloy in combination with achieving the desired purity and composition of the alloy and the desired grain size of the novel metal alloy results in 1) a medical device having the

desired high ductility at about room temperature, 2) a medical device having the desired amount of tensile elongation, 3) a homogeneous or solid solution of a metal alloy having high radiopacity, 4) a reduction or prevention of microcrack formation and/or breaking of the metal alloy tube when the metal alloy tube is sized and/or cut to form the medical device, 5) a reduction or prevention of microcrack formation and/or breaking of the medical device when the medical device is crimped onto a balloon and/or other type of medical device for insertion into a body passageway, 6) a reduction or prevention of microcrack formation and/or breaking of the medical device when the medical device is bent and/or expanded in a body passageway, 7) a medical device having the desired ultimate tensile strength and yield strength, 8) a medical device that can have very thin wall thicknesses and still have the desired radial forces needed to retain the body passageway on an open state when the medical device has been expanded, and/or 9) a medical device that exhibits less recoil when the medical device is crimped onto a delivery system and/or expanded in a body passageway.

Several non-limiting examples of the novel metal alloy in accordance with the present invention are set forth below:

<u>Metal/Wt. %</u>	<u>Ex. 1</u>	<u>Ex. 2</u>	<u>Ex. 3</u>
C	<150 ppm	<50 ppm	<50 ppm
Mo	51-54%	52.5-55.5%	50.5-52.4%
O	<50 ppm	<10 ppm	<10 ppm
N	<20 ppm	<10 ppm	<10 ppm
Re	46-49%	44.5-47.5%	47.6-49.5%

<u>Metal/Wt. %</u>	<u>Ex. 4</u>	<u>Ex. 5</u>	<u>Ex. 6</u>	<u>Ex. 7</u>
C	≤50 ppm	≤50 ppm	≤50 ppm	≤50 ppm
Mo	51-54%	52.5-55.5%	52-56%	52.5-55%
O	≤20 ppm	≤20 ppm	≤10 ppm	≤10 ppm
N	≤20 ppm	≤20 ppm	≤10 ppm	≤10 ppm
Re	46-49%	44.5-47.5%	44-48%	45-47.5%
Ti	≤0.4%	≤0.4%	0.2-0.4%	0.3-0.4%
Y	≤0.1%	≤0.1%	0-0.08%	0.005-0.05%
Zr	≤0.2%	≤0.2%	0-0.2%	0.1-0.25%

<u>Metal/Wt. %</u>	<u>Ex. 8</u>	<u>Ex. 9</u>	<u>Ex. 10</u>	<u>Ex. 11</u>
C	≤40 ppm	≤40 ppm	≤40 ppm	≤40 ppm
Mo	50.5-53%	51.5-54%	52-55%	52.5-55%
O	≤15 ppm	≤15 ppm	≤15 ppm	≤10 ppm
N	≤10 ppm	≤10 ppm	≤10 ppm	≤10 ppm
Re	47-49.5%	46-48.5%	45-48%	45-47.5%

Ti	0.1-0.35%	0%	0%	0.1-0.3%
Y	0%	0.002-0.08%	0%	0%
Zr	0%	0%	0.1-0.2%	0.05-0.15%

5	<u>Metal/Wt. %</u>	<u>Ex. 12</u>	<u>Ex. 13</u>
	C	≤40 ppm	≤40 ppm
	Mo	52-55%	52.5-55.5%
	O	≤10 ppm	≤10 ppm
	N	≤10 ppm	≤10 ppm
10	Re	45-49%	44.5-47.5%
	Ti	0.05-0.4%	0%
	Y	0.005-0.07%	0.004-0.06%
	Zr	0%	0.1-0.2%

15 In examples 1-3 above, the novel metal alloy is principally formed of rhenium and molybdenum and the content of other metals and/or impurities is less than about 0.1 weight percent of the novel metal alloy, the atomic ratio of carbon to oxygen is about 2.5-10:1 (i.e., weight ratio of about 1.88-7.5:1), the average grain size of the novel metal alloy is about 6-9 ASTM, the tensile elongation of the metal alloy is about 25-35%, the average density of the metal alloy is at least about 13.4 gm/cc, the average yield strength of the metal alloy is about 98-122 (ksi), the average ultimate tensile strength of the metal alloy is about 100-150 UTS (ksi), and the average hardness of the metal alloy is about 80-100 (HRC) at 77°F. In examples 4-13 above, the novel metal alloy is principally formed of rhenium and molybdenum and at least one metal of titanium, yttrium and/or zirconium, and the content of other metals and/or impurities is less than about 0.1 weight percent of the novel metal alloy, the ratio of carbon to oxygen is about 2.5-10:1, the average grain size of the novel metal alloy is about 6-9 ASTM, the tensile elongation of the metal alloy is about 25-35%, the average density of the metal alloy is at least about 13.6 gm/cc, the average yield strength of the metal alloy is at least about 110 (ksi), the average ultimate tensile strength of the metal alloy is about 100-150 UTS (ksi), and the average hardness of the metal alloy is about 80-100 (HRC) at 77°F.

35 In another and/or alternative non-limiting aspect of the present invention, the use of the novel metal alloy in the medical device can increase the strength of the medical device as compared with stainless steel or chromium-cobalt alloys, thus less quantity of novel metal alloy can be used in the medical device to achieve similar strengths as compared to medical devices formed of different metals. As such, the resulting medical device can be made smaller and less

bulky by use of the novel metal alloy without sacrificing the strength and durability of the medical device. Such a medical device can have a smaller profile, thus can be inserted in smaller areas, openings and/or passageways. The novel metal alloy also can increase the radial strength of the medical device. For instance, the thickness of the walls of the medical device and/or the wires used to form the medical device can be made thinner and achieve a similar or improved radial strength as compared with thicker walled medical devices formed of stainless steel or cobalt and chromium alloy. The novel metal alloy also can improve stress-strain properties, bendability and flexibility of the medical device, thus increase the life of the medical device. For instance, the medical device can be used in regions that subject the medical device to bending. Due to the improved physical properties of the medical device from the novel metal alloy, the medical device has improved resistance to fracturing in such frequent bending environments. In addition or alternatively, the improved bendability and flexibility of the medical device due to the use of the novel metal alloy can enable the medical device to be more easily inserted into a body passageway. The novel metal alloy can also reduce the degree of recoil during the crimping and/or expansion of the medical device. For example, the medical device better maintains its crimped form and/or better maintains its expanded form after expansion due to the use of the novel metal alloy. As such, when the medical device is to be mounted onto a delivery device when the medical device is crimped, the medical device better maintains its smaller profile during the insertion of the medical device in a body passageway. Also, the medical device better maintains its expanded profile after expansion so as to facilitate in the success of the medical device in the treatment area. In addition to the improved physical properties of the medical device by use of the novel metal alloy, the novel metal alloy has improved radiopaque properties as compared to standard materials such as stainless steel or cobalt-chromium alloy, thus reducing or eliminating the need for using marker materials on the medical device. For instance, the novel metal alloy is at least about 10-20% more radiopaque than stainless steel or cobalt-chromium alloy. Specifically, the novel metal alloy can be at least about 33% more radiopaque than cobalt-chromium alloy and at least about 41.5% more radiopaque than stainless steel.

In still yet another and/or alternative non-limiting aspect of the present invention, the medical device that is at least partially formed from the novel metal alloy can be formed by a variety of manufacturing techniques. In one non-limiting embodiment of the invention, the

medical device can be formed from a rod or tube of the novel metal alloy. If a solid rod of the novel metal alloy is formed, the rod can be drilled (e.g., gun drilled, EDM, etc.) to form a cavity or passageway partially or fully through the rod. The rod or tube can be cleaned, polished, annealed, drawn, etc. to obtain the desired diameter and/or wall thickness of the metal tube.

5 After the metal tube has been formed to the desired diameter and wall thickness, the metal tube can be formed into a medical device by a process such as, but not limited to, laser cutting, etching, etc. After the medical device has been formed, the medical device can be cleaned, polished, sterilized, etc. for final processing of the medical device. As can be appreciated, other or additional process steps can be used to at least partially form the medical device from the
10 novel metal alloy.

In a further and/or alternative non-limiting aspect of the present invention, the novel alloy used to at least partially form the medical device is initially formed into a rod or a tube of novel metal alloy. The novel metal alloy rod or tube can be formed by various techniques such as, but not limited to, 1) melting the novel metal alloy and/or metals that form the novel metal alloy
15 (e.g., vacuum arc melting, etc.) and then extruding and/or casting the novel metal alloy into a rod or tube, 2) melting the novel metal alloy and/or metals that form the novel metal alloy, forming a metal strip and then rolling and welding the strip into a tube, or 3) consolidating metal powder of the novel metal alloy and/or metal powder of metals that form the novel metal alloy. In one non-limiting process, the rod or tube of the novel metal alloy is formed by consolidating metal
20 power. In this process, fine particles of molybdenum and rhenium along with any additives are mixed to form a homogenous blend of particles. Typically, the average particle size of the metal powders is less than about 200 mesh (e.g., less than 74 microns). A larger average particle size can interfere with the proper mixing of the metal powders and/or adversely affect one or more physical properties of the rod or tube formed from the metal powders. In one non-limiting
25 embodiment, the average particle size of the metal powders is less than about 230 mesh (e.g., less than 63 microns). In another and/or alternative non-limiting embodiment, the average particle size of the metal powders is about 230-635 mesh (i.e., about 20-63 microns). As can be appreciated, smaller average particle sizes can be used. The purity of the metal powders should be selected so that the metal powders contain very low levels of carbon, oxygen and nitrogen.
30 Typically the carbon content of the molybdenum metal powder is less than about 100 ppm, the oxygen content of the molybdenum metal powder is less than about 50 ppm, and the nitrogen

content of the molybdenum metal powder is less than about 20 ppm. Typically, the carbon content of the rhenium metal powder is less than about 100 ppm, the oxygen content of the rhenium metal powder is less than about 50 ppm, and the nitrogen content of the rhenium metal powder is less than about 20 ppm. Typically, metal powder having a purity grade of at least 99.9 and more typically at least about 99.95 should be used to obtain the desired purity of the powders of molybdenum and rhenium. When titanium, yttrium and/or zirconium powder is added to the metal powder mixture, the amount of carbon, oxygen and nitrogen in the powder should also be minimized. Typically, metal powder having a purity grade of at least 99.8 and more typically at least about 99.9 should be used to obtain the desired purity of the powders of titanium, yttrium and/or zirconium. The blend of metal powder is then pressed together to form a solid solution of the novel metal alloy into a rod or tube. Typically, the pressing process is by an isostatic process (i.e., uniform pressure applied from all sides on the metal powder). When the metal powders are pressed together isostatically, cold isostatic pressing (CIP) is typically used to consolidate the metal powders; however, this is not required. The pressing process can be preformed in an inert atmosphere, an oxygen reducing atmosphere (e.g., hydrogen, argon and hydrogen mixture, etc.) and/or under a vacuum; however, this is not required. The average density of the rod or tube that is achieved by pressing together the metal powders is about 80-90% of the final average density of the rod or tube or about 70-95% the minimum theoretical density of the novel metal alloy. After the metal powders are pressed together, the pressed metal powders are sintered at high temperature (e.g., 2000-2500°C) to fuse the metal powders together to form the solid metal rod or tube. The sintering of the consolidated metal powder can be preformed in an oxygen reducing atmosphere (e.g., hydrogen, argon and hydrogen mixture, etc.) and/or under a vacuum; however, this is not required. At the high sintering temperatures, a high hydrogen atmosphere will reduce both the amount of carbon and oxygen in the formed rod or tube. The sintered metal powder generally has an as-sintered average density of about 90-99% the minimum theoretical density of the novel metal alloy. Typically, the sintered rod or tube has a final average density of at least about 12 gm/cc, typically, at least about 12.5 gm/cc, and more typically, about 13-14 gm/cc. Typically, the rod or tube is formed to have a length of about 48 inches or less; however, longer lengths can be formed. A rod or tube formed by this process typically has an average concentricity deviation that is less than a rod or tube formed by an arc melting and molding process and a sheet and welding process. Generally, the average

concentricity deviation of the rod or tube that is formed from compressed and sintered metal powders is less than about 20%, typically about 1-18%, and more typically about 1-5%. The average outer diameter of the rod or tube is typically less than about 2 inches, more typically less than about 1 inch, and even more typically, no more than about 0.5 inch; however, larger tube sizes can be formed. In one non-limiting tube configuration, the tube has an inner diameter of about 0.31 inch plus or minus about 0.002 inch and an outer diameter of about 0.5 inch plus or minus about 0.002 inch. The wall thickness of the tube is about 0.095 inch plus or minus about 0.002 inch. As can be appreciated, this is just one example of many different sized tubes that can be formed.

In still a further and/or alternative non-limiting aspect of the present invention, when a solid rod of the novel metal alloy is formed, the rod is then formed into a tube prior to reducing the diameter of the rod. The rod can be formed into a tube by a variety of processes such as, but not limited to, drilling (e.g., gun drilling, etc.) or by cutting (e.g., EDM, etc.). The cavity or passageway formed in the rod typically is formed fully through the rod; however, this is not required.

In yet a further and/or alternative non-limiting aspect of the present invention, the rod or tube can be cleaned and/or polished after the rod or tube has been formed; however, this is not required. Typically, the rod or tube is cleaned and/or polished prior to being further processed; however, this is not required. When a rod of the novel metal alloy is formed into a tube, the formed tube is typically cleaned and/or polished prior to being further processed; however, this is not required. When the rod or tube is resized and/or annealed as discussed in detail below, the resized and/or annealed rod or tube is typically cleaned and/or polished prior to and/or after each or after a series of resizing and/or annealing processes; however, this is not required. The cleaning and/or polishing of the rod or tube is used to remove impurities and/or contaminants from the surfaces of the rod or tube. Impurities and contaminants can become incorporated into the novel metal alloy during the processing of the rod or tube. The inadvertent incorporation of impurities and contaminants in the rod or tube can result in an undesired amount of carbon, nitrogen and/or oxygen, and/or other impurities in the novel metal alloy. The inclusion of impurities and contaminants in the novel metal alloy can result in premature micro-cracking of the novel metal alloy and/or an adverse affect on one or more physical properties of the novel metal alloy (e.g., decrease in tensile elongation, increased ductility, etc.). The cleaning of the

novel metal alloy can be accomplished by a variety of techniques such as, but not limited to, 1) using a solvent (e.g., acetone, methyl alcohol, etc.) and wiping the novel metal alloy with a Kimwipe or other appropriate towel, 2) by at least partially dipping or immersing the novel metal alloy in a solvent and then ultrasonically cleaning the novel metal alloy, and/or 3) by at least partially dipping or immersing the novel metal alloy in a pickling solution. As can be appreciated, the novel metal alloy can be cleaned in other or additional ways. If the novel metal alloy is to be polished, the novel metal alloy is generally polished by use of a polishing solution that typically includes an acid solution; however, this is not required. In one non-limiting example, the polishing solution includes sulfuric acid; however, other or additional acids can be used. In one non-limiting polishing solution, the polishing solution can include by volume 60-95% sulfuric acid and 5-40% de-ionized water (DI water). Typically, the polishing solution that includes an acid will increase in temperature during the making of the solution and/or during the polishing procedure. As such, the polishing solution is typically stirred and/or cooled during making of the solution and/or during the polishing procedure. The temperature of the polishing solution is typically about 20-100°C, and typically greater than about 25°C. One non-limiting polishing technique that can be used is an electro-polishing technique. When an electro-polishing technique is used, a voltage of about 2-30V, and typically about 5-12V is applied to the rod or tube during the polishing process; however, it will be appreciated that other voltages can be used. The time used to polish the novel metal alloy is dependent on both the size of the rod or tube and the amount of material that needs to be removed from the rod or tube. The rod or tube can be processed by use of a two-step polishing process wherein the novel metal alloy piece is at least partially immersed in the polishing solution for a given period (e.g., 0.1-15 minutes, etc.), rinsed (e.g., DI water, etc.) for a short period of time (e.g., 0.02-1 minute, etc.), and then flipped over and at least partially immersed in the solution again for the same or similar duration as the first time; however, this is not required. The novel metal alloy can be rinsed (e.g., DI water, etc.) for a period of time (e.g., 0.01-5 minutes, etc.) before rinsing with a solvent (e.g., acetone, methyl alcohol, etc.); however, this is not required. The novel metal alloy can be dried (e.g., exposure to the atmosphere, maintained in an inert gas environment, etc.) on a clean surface. These polishing procedures can be repeated until the desired amount of polishing of the rod or tube is achieved.

In still yet a further and/or alternative non-limiting aspect of the present invention, the

rod or tube is resized to the desired dimension of the medical device. In one non-limiting embodiment, the diameter of the rod or tube is reduced to a final rod or tube dimension in a single step or by a series of steps. During the reduction a rod or tube, the outer rod or tube diameter, the inner rod or tube diameter and/or wall thickness of the rod or tube are typically reduced; however, this is not required. The outer diameter size of the rod or tube is typically reduced by the use of one or more drawing processes. During the drawing process, care should be taken to not form micro-cracks in the rod or tube during the reduction of the rod or tube outer diameter. Generally, the rod or tube should not be reduced in outer diameter by more about 25% each time the rod or tube is drawn through a reducing mechanism (e.g., a die, etc.). In one non-limiting process step, the rod or tube is reduced in outer diameter by about 0.1-20% each time the rod or tube is drawn through a reducing mechanism. In another and/or alternative non-limiting process step, the rod or tube is reduced in outer diameter by about 1-15% each time the rod or tube is drawn through a reducing mechanism. In still another and/or alternative non-limiting process step, the rod or tube is reduced in outer diameter by about 2-15% each time the rod or tube is drawn through reducing mechanism. In yet another one non-limiting process step, the rod or tube is reduced in outer diameter by about 5-10% each time the rod or tube is drawn through reducing mechanism. In another and/or alternative non-limiting embodiment of the invention, the rod or tube of novel metal alloy is drawn through a die to reduce the outer diameter of the rod or tube. The drawing process is typically a cold drawing process or a plug drawing process through a die. When a cold drawing or mandrel drawing process is used, a lubricant (e.g., grease, etc.) is typically coated on the outer surface of the rod or tube and the rod or tube is then drawn through the die. Typically, little or no heat is used during the cold drawing process. After the rod or tube has been drawn through the die, the outer surface of the rod or tube is typically cleaned with a solvent to remove the lubricant so as to limit the amount of impurities that are incorporated in the novel metal alloy. This cold drawing process can be repeated several times until the desired outer diameter, inner diameter and/or wall thickness of the rod or tube is achieved. A plug drawing process can also or alternatively be used to size the rod or tube. The plug drawing process typically does not use a lubricant during the drawing process. The plug drawing process typically includes a heating step to heat the rod or tube prior and/or during the drawing of the rod or tube through the die. The elimination of the use of a lubricant can reduce the incidence of impurities being introduced into the metal alloy during the

drawing process. During the plug drawing process, the rod or tube can be protected from oxygen and nitrogen by use of a vacuum environment, an oxygen reducing environment (e.g., hydrogen, argon and hydrogen mixture, etc.) or an inert environment. One non-limiting protective environment includes argon, hydrogen or argon and hydrogen; however, other or additional inert gasses can be used. As indicated above, the rod or tube is typically cleaned after each drawing process to remove impurities and/or other undesired materials from the surface of the rod or tube; however, this is not required.

In still yet a further and/or alternative non-limiting aspect of the present invention, the rod or tube is annealed after one or more drawing processes. The metal alloy rod or tube can be annealed after each drawing process or after a plurality of drawing processes. The metal alloy rod or tube is typically annealed prior to about a 60% outer diameter size reduction of the metal alloy rod or tube. In other words, the rod or tube should not be reduced in outer diameter by more than 60% before being annealed. A too large of a reduction in the outer diameter of the metal alloy rod or tube during the drawing process prior to the rod or tube being annealed can result in micro-cracking of the rod or tube. In one non-limiting processing step, the metal alloy rod or tube is annealed prior to about a 50% outer diameter size reduction of the metal alloy rod or tube. In another and/or alternative non-limiting processing step, the metal alloy rod or tube is annealed prior to about a 45% outer diameter size reduction of the metal alloy rod or tube. In still another and/or alternative non-limiting processing step, the metal alloy rod or tube is annealed prior to about a 1-45% outer diameter size reduction of the metal alloy rod or tube. In yet another and/or alternative non-limiting processing step, the metal alloy rod or tube is annealed prior to about a 5-30% outer diameter size reduction of the metal alloy rod or tube. In still yet another and/or alternative non-limiting processing step, the metal alloy rod or tube is annealed prior to about a 5-15% outer diameter size reduction of the metal alloy rod or tube. When the rod or tube is annealed, the rod or tube is typically heated to a temperature of about 1300-1700°C for a period of about 2-200 minutes; however, other temperatures and/or times can be used. In one non-limiting processing step, the metal alloy rod or tube is annealed at a temperature of about 1400-1600°C for about 2-30 minutes. The annealing process typically occurs in an inert environment or an oxygen reducing environment so as to limit the amount of impurities that may embed themselves in the novel metal alloy during the annealing process. One non-limiting oxygen reducing environment that can be used during the annealing process

is a hydrogen environment; however, it can be appreciated that a vacuum environment can be used or one or more other or additional gasses can be used to create the oxygen reducing environment. At the annealing temperatures, a hydrogen containing atmosphere can further reduce the amount of oxygen in the rod or tube. The chamber in which the rod or tube is annealed should be substantially free of impurities (e.g., carbon, oxygen, and/or nitrogen) so as to limit the amount of impurities that can embed themselves in the rod or tube during the annealing process. The annealing chamber typically is formed of a material that will not impart impurities to the rod or tube as the rod or tube is being annealed. A non-limiting material that can be used to form the annealing chamber includes, but is not limited to, molybdenum, rhenium, tungsten, molybdenum TZM alloy, ceramic, etc. When the rod or tube is restrained in the annealing chamber, the restraining apparatuses that are used to contact the novel metal alloy rod or tube are typically formed of materials that will not introduce impurities to the novel metal alloy during the processing of the rod or tube. Non-limiting examples of materials that can be used to at least partially form the restraining apparatuses include, but are not limited to, molybdenum, titanium, yttrium, zirconium, rhenium and/or tungsten.

In another and/or alternative non-limiting aspect of the present invention, the rod or tube can be cleaned prior to and/or after being annealed. The cleaning process is designed to remove impurities and/or other materials from the surfaces of the rod or tube. Impurities that are on one or more surfaces of the rod or tube can become permanently embedded into the rod or tube during the annealing processes. These imbedded impurities can adversely affect the physical properties of the novel metal alloy as the rod or tube is formed into a medical device, and/or can adversely affect the operation and/or life of the medical device. In one non-limiting embodiment of the invention, the cleaning process includes a delubrication or degreasing process which is typically followed by pickling process; however, this is not required. The delubrication or degreasing process followed by pickling process are typically used when a lubricant has been used on the rod or tube during a drawing process. Lubricants commonly include carbon compounds and other types of compounds that can adversely affect the novel metal alloy if such compounds and/or elements in such compounds become associated and/or embedded with the novel metal alloy during an annealing process. The delubrication or degreasing process can be accomplished by a variety of techniques such as, but not limited to, 1) using a solvent (e.g., acetone, methyl alcohol, etc.) and wiping the novel metal alloy with a Kimwipe or other

appropriate towel, and/or 2) by at least partially dipping or immersing the novel metal alloy in a solvent and then ultrasonically cleaning the novel metal alloy. As can be appreciated, the novel metal alloy can be delubricated or degreased in other or additional ways. After the novel metal alloy rod or tube has been delubricated or degreased, the rod or tube can be further cleaned by use of a pickling process. The pickling process, when used, includes the use of one or more acids to remove impurities from the surface of the rod or tube. Non-limiting examples of acids that can be used as the pickling solution include, but are not limited to, nitric acid, acetic acid, sulfuric acid, hydrochloric acid, and/or hydrofluoric acid. These acids are typically analytical reagent (ACS) grade acids. The acid solution and acid concentration are selected to remove oxides and other impurities on the rod or tube surface without damaging or over etching the surface of the rod or tube. A rod or tube surface that includes a large amount of oxides typically requires a stronger pickling solution and/or long pickling process times. Non-limiting examples of pickling solutions include 1) 25-60% DI water, 30-60% nitric acid, and 2-20% sulfuric acid; 2) 40-75% acetic acid, 10-35% nitric acid, and 1-12% hydrofluoric acid; and 3) 50-100% hydrochloric acid. As can be appreciated, one or more different pickling solutions can be used during the pickling process. During the pickling process, the rod or tube is fully or partially immersed in the pickling solution for a sufficient amount of time to remove the impurities from the surface of the rod or tube. Typically, the time period for pickling is about 2-120 seconds; however, other time periods can be used. After the rod or tube has been pickled, the rod or tube is typically rinsed with a water (e.g., DI water, etc.) and/or a solvent (e.g., acetone, methyl alcohol, etc.) to remove any pickling solution from the rod or tube and then the rod or tube is allowed to dry. The rod or tube may be kept in a protective environment during the rinse and/or drying process to inhibit or prevent oxides from reforming on the surface of the rod or tube prior to the rod or tube being annealed; however, this is not required.

In yet another and/or alternative non-limiting aspect of the present invention, the restraining apparatuses that are used to contact the novel metal alloy rod or tube during an annealing process and/or drawing process are typically formed of materials that will not introduce impurities to the novel metal alloy during the processing of the rod or tube. In one non-limiting embodiment, when the metal alloy rod or tube is exposed to temperatures above 150°C, the materials that contact the novel metal alloy rod or tube during the processing of the rod or tube are typically made from molybdenum, rhenium and/or tungsten. When the novel

metal alloy rod or tube is processed at lower temperatures (i.e., 150°C or less), materials made from Teflon parts can also or alternatively be used.

In still another and/or alternative non-limiting aspect of the present invention, the novel metal alloy rod or tube, after being formed to the desired outer diameter, inner diameter and/or wall thickness, can be cut and/or etched to at least partially form the desired configuration of the medical device (e.g., stent, etc.). In one non limiting embodiment of the invention, the novel metal alloy rod or tube is at least partially cut by a laser. The laser is typically desired to have a beam strength which can heat the novel metal alloy rod or tube to a temperature of at least about 2200-2300°C. In one non-limiting aspect of this embodiment, a pulsed YAGI-ND or CO₂ laser is used to at least partially cut a pattern of medical device out of the novel metal alloy rod or tube. In another and/or alternative non-limiting aspect of this embodiment, the cutting of the novel metal alloy rod or tube by the laser can occurs in a vacuum environment, an oxygen reducing environment, or an inert environment; however, this is not required. It has been found that laser cutting of the rod or tube in a non-protected environment can result in impurities being introduced into the cut rod or tube, which introduced impurities can induce micro-cracking of the rod or tube during the cutting of the rod or tube. One non-limiting oxygen reducing environment includes a combination of argon and hydrogen; however, a vacuum environment, an inert environment, or other or additional gasses can be used to form the oxygen reducing environment. In still another and/or alternative non-limiting aspect of this embodiment, the novel metal alloy rod or tube is stabilized so as to limit or prevent vibration of the rod or tube during the cutting process. The apparatus used to stabilize the rod or tube can be formed of molybdenum, rhenium, tungsten, molybdenum TZM alloy, ceramic, etc. so as to not introduce contaminants to the rod or tube during the cutting process; however, this is not required. Vibrations in the rod or tube during the cutting of the rod or tube can result in the formation of micro-cracks in the rod or tube as the rod or tube is cut. The average amplitude of vibration during the cutting of the rod or tube should be no more than about 150% the wall thickness of the rod or tube. In one non-limiting aspect of this embodiment, the average amplitude of vibration should be no more than about 100% the wall thickness of the rod or tube. In another non-limiting aspect of this embodiment, the average amplitude of vibration should be no more than about 75% the wall thickness of the rod or tube. In still another non-limiting aspect of this embodiment, the average amplitude of vibration should be no more than about 50% the wall

thickness of the rod or tube. In yet another non-limiting aspect of this embodiment, the average amplitude of vibration should be no more than about 25% the wall thickness of the rod or tube. In still yet another non-limiting aspect of this embodiment, the average amplitude of vibration should be no more than about 15% the wall thickness of the rod or tube.

5 In still yet another and/or alternative non-limiting aspect of the present invention, the novel metal alloy rod or tube, after being formed to the desired medical device, can be cleaned, polished, sterilized, etc. for final processing of the medical device. In one non-limiting embodiment of the invention, the medical device is electropolished. In one non-limiting aspect of this embodiment, the medical device is cleaned prior to being exposed to the polishing
10 solution; however, this is not required. The cleaning process, when used, can be accomplished by a variety of techniques such as, but not limited to, 1) using a solvent (e.g., acetone, methyl alcohol, etc.) and wiping the medical device with a Kimwipe or other appropriate towel, and/or 2) by at least partially dipping or immersing the medical device in a solvent and then ultrasonically cleaning the medical device. As can be appreciated, the medical device can be
15 cleaned in other or additional ways. In another and/or alternative non-limiting aspect of this embodiment, the polishing solution can include one or more acids. One non-limiting formulation of the polishing solution includes about 10-80 percent by volume sulfuric acid. As can be appreciated, other polishing solution compositions can be used. In still another and/or alternative non-limiting aspect of this embodiment, about 5-12 volts are directed to the medical
20 device during the electropolishing process; however, other voltage levels can be used. In yet another and/or alternative non-limiting aspect of this embodiment, the medical device is rinsed with water and/or a solvent and allowed to dry to remove polishing solution on the medical device.

25 In a further and/or alternative non-limiting aspect of the present invention, one or more biological agents can be used with the medical device to facilitate in the success of the medical device and/or treated area. The term "biological agent" includes, but is not limited to, a substance, drug or otherwise formulated and/or designed to prevent, inhibit and/or treat one or more biological problems, and/or to promote the healing in a treated area. The one or more layers of biological agent can be applied to the medical device by a variety of techniques (e.g.,
30 dipping, rolling, brushing, spraying, particle atomization, etc.). One non-limiting coating technique is by an ultrasonic mist coating process wherein ultrasonic waves are used to break

up the droplet of biological agent and form a mist of very fine droplets. These fine droplets have an average droplet diameter of about 0.1-3 microns. The fine droplet mist facilitates in the formation of a uniform coating thickness and can increase the coverage area on the medical device.

5 In yet another and/or alternative non-limiting aspect of the invention, the medical device can include a marker material that facilitates enabling the medical device to be properly positioned in a body passageway.

10 In one non-limiting process for manufacturing a medical device in accordance with the present invention, the process includes the following process steps: 1) forming a novel metal alloy rod or tube; 2) resizing the rod or tube, 3) cleaning and/or pickling the surface of the rod or tube prior to annealing the rod or tube; 4) annealing the rod or tube; and 5) repeating steps 2-4 until the rod or tube has been sized to the desired size. In another and/or alternative non-limiting process for manufacturing a medical device in accordance with the present invention, the process includes the following process steps: 1) forming a novel metal alloy rod or tube; 2) resizing the rod or tube by use of a mandrel and/or plug drawing process, 3) cleaning and/or pickling the surface of the rod or tube prior to annealing the rod or tube; 4) annealing the rod or tube prior to a 60% outer diameter size reduction of the rod or tube; 5) repeating steps 2-4 until the rod or tube has been sized to the desired size; 6) cutting and/or etching the rod or tube to at least partially form the medical device; and 7) cleaning and/or electropolishing the medical device.

20 In still another and/or alternative non-limiting process for manufacturing a medical device in accordance with the present invention, the process includes the following process steps: 1) consolidating metal power of the novel metal alloy and/or metal powder of metals that form the novel metal alloy into a tube; 2) resizing the tube one or more times by use of a plug drawing process, 3) cleaning and/or pickling the surface of the tube after each plug drawing process; 4) annealing the tube prior to a 45% outer diameter size reduction of the tube; 5) repeating steps 2-4 until the tube has been sized to the desired size; 6) laser cutting the tube to at least partially form the medical device; and 7) cleaning and/or electropolishing the medical device. As can be appreciated, other or additional process steps can be used to form the medical device from a novel metal alloy. In each of the non-limiting processes set forth above, the medical device can be further processed to include 1) a marker material, 2) one or more biological agents and/or 3) one or more polymer coatings.

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The use of the novel metal alloy to form all or a portion of a stent results in several advantages over stent formed from other materials. These advantages include, but are not limited to,

- The novel metal alloy has increased strength as compared with stainless steel or chromium-cobalt alloys, thus less quantity of novel metal alloy can be used in the stent to achieve similar strengths as compared to stents formed of different metals. As such, the resulting stent can be made smaller and less bulky by use of the novel metal alloy without sacrificing the strength and durability of the stent. The stent can also have a smaller profile, thus can be inserted into smaller areas, openings and/or passageways. The increased strength of the novel metal alloy also results in the increased radial strength of the stent. For instance, the thickness of the walls of the stent and/or the wires used to form the stent can be made thinner and achieve a similar or improved radial strength as compared with thicker walled stents formed of stainless steel or cobalt and chromium alloy.

- The novel metal alloy has improved stress-strain properties, bendability properties, elongation properties and/or flexibility properties of the stent as compared with stainless steel or chromium-cobalt alloys, thus resulting in an increase life for the stent. For instance, the stent can be used in regions that subject the stent to repeated bending. Due to the improved physical properties of the stent from the novel metal alloy, the stent has improved resistance to fracturing in such frequent bending environments. These improved physical properties at least in part result from the composition of the novel metal alloy; the grain size of the novel metal alloy; the carbon, oxygen and nitrogen content of the novel metal alloy; and/or the carbon/oxygen ratio of the novel metal alloy.

- The novel metal alloy has a reduce the degree of recoil during the crimping and/or expansion of the stent as compared with stainless steel or chromium-cobalt alloys. The stent formed of the novel metal alloy better maintains its crimped form and/or better maintains its expanded form after expansion due to the use of the novel metal alloy. As such, when the stent is to be mounted onto a delivery device when the stent is crimped, the stent better maintains its smaller profile during the insertion of the stent in a body passageway. Also, the stent better maintains its expanded profile after expansion so as to facilitate in the success of the stent in the treatment area.

- The novel metal alloy has improved radiopaque properties as compared to

standard materials such as stainless steel or cobalt-chromium alloy, thus reducing or eliminating the need for using marker materials on the stent. For instance, the novel metal alloy is at least about 10-20% more radiopaque than stainless steel or cobalt-chromium alloy.

• The novel metal alloy is less of an irritant to the body than stainless steel or cobalt-chromium alloy, thus can result in reduced inflammation, faster healing, increased success rates of the stent. When the stent is expanded in a body passageway, some minor damage to the interior of the passageway can occur. When the body begins to heal such minor damage, the body has less adverse reaction to the presence of the novel metal alloy than compared to other metals such as stainless steel or cobalt-chromium alloy.

One non-limiting object of the present invention is the provision of a method and process for forming a novel metal alloy into a medical device.

Another and/or alternative non-limiting object of the present invention is the provision of a method and process for forming a novel metal alloy that inhibits or prevent the formation of micro-cracks during the processing of the alloy into a medical device.

Still another and/or alternative non-limiting object of the present invention is the provision of a method and process for forming a novel metal alloy that inhibits or prevents in the introduction of impurities into the alloy during the processing of the alloy into a medical device.

These and other advantages will become apparent to those skilled in the art upon the reading and following of this description taken together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference may now be made to the drawings, which illustrate various embodiments that the invention may take in physical form and in certain parts and arrangements of parts wherein:

FIGURE 1 is a perspective view of a section of a medical device in the form of an unexpanded stent which permits delivery of the stent into a body passageway; and,

FIGURE 2 is one non-limiting process in accordance with the invention for manufacturing a stent from a molybdenum and rhenium alloy.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings wherein the showing is for the purpose of illustrating preferred embodiments of the invention only and not for the purpose of limiting the same, FIGURE 1 discloses a medical device in the form of a stent for use in a body passageway. The stent is particularly useful in the cardiovascular field; however, the stent can be used in other

medical fields such as, but not limited to, orthopedic field, cardiology field, pulmonology field, urology field, nephrology field, gastroenterology field, gynecology field, otolaryngology field or other surgical fields. Additionally or alternatively, the medical device is not limited to a stent, thus can be in the form of many other medical devices (e.g., a staple, an orthopedic implant, a valve, a vascular implant, a pacemaker, a spinal implant, a guide wire, etc.).

The stent, when used for vascular applications, can be used to addresses various medical problems such as, but not limited to, restenosis, atherosclerosis, atherogenesis, angina, ischemic disease, congestive heart failure or pulmonary edema associated with acute myocardial infarction, atherosclerosis, thrombosis, controlling blood pressure in hypertension, platelet adhesion, platelet aggregation, smooth muscle cell proliferation, vascular complications, wounds, myocardial infarction, pulmonary thromboembolism, cerebral thromboembolism, thrombophlebitis, thrombocytopenia or bleeding disorders.

As illustrated in FIGURE 1, stent 20 is in the form of an expandable stent that includes at least one tubular shaped body member 30 having a first end 32, a second end 34, and member structures 36 disposed between the first and second ends. As can be appreciated, the stent can be formed of a plurality of body members connected together. Body member 30 has a first diameter which permits delivery of the body member into a body passageway. The first diameter of the body member is illustrated as substantially constant along the longitudinal length of the body member. As can be appreciated, the body member can have a varying first diameter along at least a portion of the longitudinal length of the body member. The body member also has a second expanded diameter, not shown. The second diameter typically varies in size; however, the second diameter can be non-variable in size. The stent can be expanded in a variety of ways such as by a balloon. A balloon expandable stent is typically pre-mounted or crimped onto an angioplasty balloon catheter. A balloon catheter is then positioned into the patient via a guide wire. Once the stent is properly positioned, the balloon catheter is inflated to the appropriate pressure for stent expansion. After the stent has been expanded, the balloon catheter is deflated and withdrawn, leaving the stent deployed at the treatment area.

One or more surfaces of the stent can be treated so as to have generally smooth surfaces; however, this is not required. Generally, one or more ends of the stent are treated by filing, buffing, polishing, grinding, coating, and/or the like to remove or reduce the number of rough and/or sharp surfaces; however, this is not required. The smooth surfaces of the ends reduce

potential damage to surrounding tissue as the stent is positioned in and/or expanded in a body passageway.

The stent can be at least partially coated with one or more biological agents, not shown. One or more polymers, not shown, can be used in conjunction with the one or more biological agents to 1) facilitate in the bonding of the one or more biological agents to the stent, and/or 2) at least partially control the release of one or more biological agents from the stent.

Referring now to FIGURE 2, there is illustrated one non-limiting process for forming the stent as illustrated in FIGURE 1. The first step to form a stent is to form a tube of a solid solution of molybdenum and rhenium alloy. The tube can be form in a variety of ways. Process step 100 illustrates that metal powders of molybdenum and rhenium are selected to form the tube. The powders of molybdenum and rhenium constitute a majority weight percent of the materials used to form the metal tube. Small amounts of an additional metal such as titanium, yttrium and/or zirconium can also be used; however, this is not required. The purity of the metal powders is selected to minimize the carbon, oxygen and nitrogen content in the metal powder. Typically the carbon content of the metal powders is less than about 150 ppm, the oxygen content of the metal powders is less than about 100 ppm and the nitrogen content of the metal powders is less than about 40 ppm.

After the metal powders have been selected, the metal powders are substantially homogeneously mixed together as illustrated in process step 110. After the metal powders are mixed together, the metal powers are isostatically consolidated to form a tube. One non-limiting isostatic consolidation process is a cold isostatic pressing (CIP) process. The isostatic consolidation process typically occurs in a vacuum environment, an oxygen reducing environment, or in an inert atmosphere. The average density of the metal tube obtained by the isostatic consolidation process is about 80-90% of the final average density of the tube. One non-limiting composition of the tube is a solid solution of about 44-48 weight percent rhenium, about 52-56 weight percent molybdenum, up to about 0.5 weight percent Ti, Y and/or Zr, and no more than about 0.1 weight impurities. After the metal powder has been pressed together, the metal power is sintered to fuse the metal powders together and to form the tube of novel metal alloy. The sinter of the metal powders occurs at a temperature of about 2000-2500°C for about 5-120 minutes; however, other temperatures and/or sintering time can be used. The sintering of the metal powder typically takes place in an oxygen reducing environment to inhibit

or prevent impurities from becoming embedded in the novel metal alloy and/or to further reduce the amount of carbon and/or oxygen in the formed tube. After the sintering process, the tube is formed of a solid solution of the novel metal alloy and has an as-sintered average density of about 90-99% the minimum theoretical density of the novel metal alloy. Typically, the sintered tube has a final average density of about 13-14 gm/cc. The length of the formed tube is typically about 48 inches or less; however, longer lengths can be formed. The average concentricity deviation of the tube is typically about 1-18%. In one non-limiting tube configuration, the tube has an inner diameter of about 0.31 inch plus or minus about 0.002 inch and an outer diameter of about 0.5 inch plus or minus about 0.002 inch. The wall thickness of the tube is about 0.095 inch plus or minus about 0.002 inch. As can be appreciated, this is just one example of many different sized tubes that can be formed.

The tube can be cleaned after the tube has been form sintered; however, this is not required. The cleaning of the tube is used to remove impurities and/or contaminants from the surfaces of the tube. Impurities and contaminants (e.g., carbon, oxygen, etc.) can become incorporated into the novel metal alloy during the processing of the tube. The inclusion of impurities and contaminants in the novel metal alloy can result in premature micro-cracking of the novel metal alloy and/or the adverse affect on one or more physical properties of the novel metal alloy. The cleaning of the tube can be accomplished by a variety of techniques such as, but not limited to, 1) using a solvent (e.g. acetone, methyl alcohol, etc.) and wiping the novel metal alloy with a Kimwipe or other appropriate towel, and/or 2) by at least partially dipping or immersing the novel metal alloy in a solvent and then ultrasonically cleaning the novel metal alloy. As can be appreciated, the tube can be cleaned in other or additional ways.

After the tube has been sintered, and optionally cleaned, the tube is then drawn through a die one or more times to reduce the inner and outer diameter of the tube and the wall thickness of the tube to the desired size. As illustrated in process step 130, the tube is reduced in size by the use of a plug drawing process. During the plug drawing process, the tube is heated (i.e., up to about 300°C) and protected in a vacuum environment, an oxygen reducing environment, or inert environment. One non-limiting oxygen reducing environment includes argon and about 1-10 volume percent hydrogen. The amount of outer diameter draw down of the tube each time the tube is plug drawn is typically no more than about 10%. Controlling the degree of draw down facilitates in preventing the formation of micro-cracks during the drawing process. After

each drawing process, the tube can be cleaned; however, this is not required.

Prior to the tube being drawn down more than about 35-45% from its original outer diameter after the sintering process, the tube is annealed as illustrated in process step 150. If the tube is to be further drawn down after being initially annealed, a subsequent annealing process should be completed prior to the outer diameter of the tube being drawn down more than about 35-45% since a previous annealing process. As such, the tube should also be annealed at least once prior to the tube outer diameter being drawn down more than about 35-45% since being originally sintered or being previously annealed. This controlled annealing facilitates in preventing the formation of micro-cracks during the drawing process. The annealing process of the tube typically takes place in a vacuum environment, an inert atmosphere, or an oxygen reducing environment (e.g., argon, argon and 1-10% hydrogen, etc.) at a temperature of about 1400-1500°C for a period of about 5-30 minutes; however, other temperatures and/or times can be used. The use of an oxygen reducing environment during the annealing process can be used to reduce the amount of oxygen in the tube. The chamber in which the tube is annealed should be substantially free of impurities such as, but not limited to, carbon, oxygen, and/or nitrogen. The annealing chamber typically is formed of a material that will not impart impurities to the tube as the tube is being annealed. One non-limiting material that can be used to form the annealing chamber is a molybdenum TZM alloy.

Prior to each annealing process, the tube is cleaned and/or pickled to remove oxides and/or other impurities from the surface of the tube as illustrated in process step 140. Typically the tube is cleaned by first using a solvent (e.g. acetone, methyl alcohol, etc.) and wiping the novel metal alloy with a Kimwipe or other appropriate towel, and/or by at least partially dipping or immersing the tube in a solvent and then ultrasonically cleaning the novel metal alloy. As can be appreciated, the tube can be cleaned other and/or additional ways. After the tube has been cleaned by use of a solvent, the tube is typically further cleaned by use of a pickling process. The pickling process includes the use of one or more acids to remove impurities from the surface of the tube. Non-limiting examples of acids that can be used as the pickling solution include, but are not limited to, nitric acid, acetic acid, sulfuric acid, hydrochloric acid, and/or hydrofluoric acid. The acid solution and acid concentration and time of pickling are selected to remove oxides and other impurities on the tube surface without damaging or over etching the surface of the tube. During the pickling process, the tube is fully or partially immersed in the pickling

solution for a sufficient amount of time to remove the impurities from the surface of the tube. After the tube has been pickled, the tube is typically rinsed with a solvent (e.g., acetone, methyl alcohol, etc.) to remove any pickling solution from the tube and then the tube is allowed to dry. The cleaning of the tube prior to the tube being annealed removes impurities and/or other materials from the surfaces of the tube that could become permanently embedded into the tubing during the annealing processes. These imbedded impurities could adversely affect the physical properties of the novel metal alloy as the tube is formed into a medical device, and/or can adversely affect the operation and/or life of the medical device. As can be appreciated, the tube can be again clean and/or pickled after being annealed and prior to be drawn down in the plug drawing process; however, this is not required.

Process steps 130-150 can be repeated as necessary until the tube is drawn down to the desired size. In one non-limiting process, a tube that is originally formed after being sintered has an inner diameter of about 0.31 inch plus or minus about 0.002 inch, an outer diameter of about 0.5 inch plus or minus about 0.002 inch, and a wall thickness of about 0.095 inch plus or minus about 0.002 inch. After the tube has been fully drawn down, the tube has an outer diameter of about 0.070 inch, a wall thickness of about 0.0021-0.00362 inch, and the average concentricity deviation of less than about 10%. Such small sizes for stents which can be successfully used in a vascular system have heretofore not been possible when formed by other types of metal alloys. Typically the wall thickness of stent had to be at least about 0.0027-0.003 inch, or the stent would not have sufficient radial force to maintain the stent in an expanded state after being expanded. The novel metal alloy of the present invention is believed to be able to have a wall thickness of as small as about 0.0015 inch and still have sufficient radial force to maintain a stent in an expanded state after being expanded. As such, when a tube is formed into a stent, the wall thickness of the tube can be drawn down to less than about 0.0027 inch to form a stent. As can be appreciated, this is just one example of many different sized tubes that can be formed by the process of the present invention.

Once the tube has been drawn down to its final size, the tube is typically cleaned (Process Step 140), annealed (Process Step 150) and then again cleaned (Process Step 160). The cleaning step of process step 160 can include merely solvent cleaning, or can also include pickling.

After the tube has been cleaned in process step 160, the tube is then cut into the form of a stent as illustrated in FIGURE 1. As can be appreciated, other stent designs can be formed

during the cutting process as set forth in process step 170. The cutting of the tube is typically conducted by a laser. The laser that is used to cut the tube is selected so that has a beam strength used to heat the tube can obtain a cutting temperature of at least about 2350°C. Non-limiting examples of lasers that can be used include a pulsed YAG-ND or CO₂ laser. The cutting of the tube by the laser occurs in an oxygen reducing environment such as an argon and 1-10 percent by volume hydrogen environment; however, a vacuum environment, an inert environment, or another type of oxygen reducing environment can be used. During the cutting of the tube, the tube is typically stabilized so as to inhibit or prevent vibration of the tube during the cutting process, which vibrations can result in the formation of micro-cracks in the tube as the tube is cut. The tube is typically stabilized by an apparatus formed of molybdenum, rhenium, tungsten, molybdenum TZM alloy, ceramic, etc. so as to not introduce contaminants to the tube during the cutting process; however, this is not required. The average amplitude of vibration during the cutting of the tube is typically no more than about 50% the wall thickness of the tube. As such, for a tube having a wall thickness of about 0.0024 inch, the average amplitude of vibration of the tube during the cutting process is no more than about 0.0012 inch.

The formed stent typically has a tensile elongation of about 25-35%, an average density of about 13.4-14 gm/cc., an average yield strength of at least about 100 (ksi), an average ultimate tensile strength of about 100-150 UTS (ksi), and an average hardness of about 80-100 (HRC) at 77°F. The solid or homogeneous solution of the metal alloy that is used to form the stent has the unique characteristics of purity, ductility, grain size, tensile elongation, yield strength and ultimate tensile strength that permits 1) the metal alloy to be fabricated into the stent from the tube without creating microcracks which are detrimental to the stent properties, and 2) the manufacture of a stent that has improved physical properties over stents formed from different materials.

After the stent has been cut, the stent can be further processed; however, this is not required. The one or more processes can include, but are not limited to, 1) electropolishing the stent, 2) treating one or more surfaces of the stent to create generally smooth surfaces (e.g., filing, buffing, polishing, grinding, coating, etc.), 3) at least partially coating the stent with one or more biological agents, 4) at least partially coating the stent with one or more polymers, 5) forming one or more surface structures and/or micro-structures on one or more portions of the stent, and/or 6) inserting one or more markers on one or more portions of the stent.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained, and since certain changes may be made in the constructions set forth without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall
5 be interpreted as illustrative and not in a limiting sense. The invention has been described with reference to preferred and alternate embodiments. Modifications and alterations will become apparent to those skilled in the art upon reading and understanding the detailed discussion of the invention provided herein. This invention is intended to include all such modifications and alterations insofar as they come within the scope of the present invention. It is also to be
10 understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope of the invention, which, as a matter of language, might be said to fall therebetween.

We claim:

1. A method for forming a medical device comprising the steps of:
 - a) forming a rod or tube having a surface and an outer diameter, said rod or tube including a metal alloy that is formed of at least about 99.9 weight percent of a solid solution and includes carbon and oxygen, said metal alloy having a carbon to oxygen atomic ratio of at least about 2:1;
 - b) drawing down said outer diameter of said rod or tube by a reducing mechanism that reduces said outer diameter by less than about 25% each time said rod or tube is processed by said reducing mechanism;
 - c) cleaning said surface of said rod or tube; and,
 - d) annealing said rod or tube prior to said rod or tube having said outer diameter draw down by more than about 50%.
2. The method as defined in claim 1, wherein said step of forming said rod or tube includes a process of isostatically pressing metal powder together and subsequently sintering said metal powder to form said rod or tube.
3. The method as defined in claim 2, wherein said step of isostatically pressing metal powder together creates a rod or tube having an average density of about 0.7-0.95 a minimum theoretical density of said metal alloy.
4. The method as defined in claim 2 or 3, wherein said step of sintering said isostatically pressed metal powder creates a rod or tube average density of about 0.9-0.99 a minimum theoretical density of said metal alloy.
5. The method as defined in claims 2-4, wherein said step of sintering said isostatically pressed metal powder creates a rod or tube have an average density of about 12-14 gm/cc.
6. The method as defined in claims 2-5, wherein said step of sintering said

isostatically pressed metal powder occurs in an inert atmosphere, an oxygen reducing atmosphere, or a vacuum.

7. The method as defined in claims 1-6, wherein said metal alloy includes about 46-49 weight percent rhenium, about 51-54 weight percent molybdenum, and up to about 0.5 weight percent additional metal, said additional metal including a metal selected from the group consisting of titanium, yttrium, zirconium, or mixtures thereof.

8. The method as defined in claims 1-7, wherein said step of drawing down said outer diameter of said rod or tube by a reducing mechanism that reduces said outer diameter by less than about 10% each time said rod or tube is processed by said reducing mechanism.

9. The method as defined in claims 1-8, wherein said reducing mechanism includes a plug drawing process.

10. The method as defined in claims 1-9, wherein said step of drawing down said outer diameter of said rod or tube at least partially occurs in an inert atmosphere, an oxygen reducing atmosphere, or a vacuum.

11. The method as defined in claims 1-10, wherein said step of annealing said rod or tube occurs prior to said rod or tube having said outer diameter drawn down by more than about 45%.

12. The method as defined in claims 1-11, wherein said step of annealing said rod or tube occurs at a temperature of at least about 1300°C for at least about 2 minutes.

13. The method as defined in claims 1-12, wherein said step of annealing said rod or tube occurs at least partially occurs in an inert atmosphere, an oxygen reducing atmosphere, or a vacuum.

14. The method as defined in claims 1-13, wherein said step of cleaning said surface

occurs prior to each said step of annealing.

15. The method as defined in claims 1-14, wherein said step of cleaning said surface occurs after said step of drawing down said outer diameter of said rod or tube.

16. The method as defined in claims 1-15, including the step of cutting said annealed rod or tube at least partially into said medical device.

17. The method as defined in claim 16, wherein said step of cutting is at least partially by a laser.

18. The method as defined in claim 16 or 17, wherein step of cutting includes the step of restraining said rod or tube to inhibit vibration of said rod or tube as said rod or tube is at least partially cut.

19. The method as defined in claims 16-18, wherein said step of cutting at least partially occurs in an inert atmosphere, an oxygen reducing atmosphere, or a vacuum.

20. The method as defined in claims 16-19, including the step of electro-polishing said medical device after said step of cutting.

21. The method as defined in claims 1-20, wherein said medical device is a stent, graft, valve, screw, nail, rod, PFO device, prosthetic device, sheath, guide wire, balloon catheter, hypotube, catheter, electrophysiology catheter, staple or cutting device.

22. The method as defined in claims 1-21, including the step of applying at least one biological agent on at least one region of said medical device.

23. The method as defined in claim 22, including the step of applying at least one polymer to at least one region of said medical device to at least partially coat, encapsulate or combinations thereof said at least one biological agent.

24. The method as defined in claims 1-23, wherein the medical device is a stent and has a wall thickness of less than about 0.0027 inch.

25. A method for forming a medical device comprising the steps of:

- a) selecting at least two different metal powders, said metal powders having an average particle size of less than about 200 mesh;
- b) substantially homogeneously mixing together said metal powders;
- c) forming a tube from said metal powders by pressing said metal powders together and sintering said metal powders, said tube having a surface and an outer diameter, said tube including a metal alloy that is formed of at least about 99.9 weight percent of a solid solution and includes carbon and oxygen, said metal alloy having a carbon to oxygen atomic ratio of at least about 2.5:1;
- d) drawing down said outer diameter of said tube by a plug drawing process to reduce said outer diameter of said tube by less than about 15% each time said tube is processed by said plug drawing process;
- e) cleaning said surface of said tube after said plug drawing process;
- f) annealing said tube prior to said tube having said outer diameter draw down by more than about 45% since said tube had been last sintered or annealed; and,
- g) laser cutting said annealed tube to at least partially form said medical device, said tube at least partially stabilized during said laser cutter such that an average amplitude of vibration of said tube during said laser cutter is no more than about 50% of a wall thickness of said tube.

26. The method as defined in claim 25, wherein said step of pressing said metal powders includes a process of isostatically pressing metal powders to create a tube having an average density of about 0.7-0.95 a minimum theoretical density of said metal alloy.

27. The method as defined in claim 25 or 26, wherein said step of sintering creates a tube having an average density of about 13-14 gm/cc.

28. The method as defined in claims 25-27, wherein said step of sintering occurs in

an inert atmosphere, an oxygen reducing atmosphere, or a vacuum.

29 The method as defined in claims 25-28, wherein said substantially homogeneous mixture of metal powders includes about 46-49 weight percent rhenium, about 51-54 weight percent molybdenum, and up to about 0.5 weight percent additional metal, said additional metal including a metal selected from the group consisting of titanium, yttrium, zirconium, or mixtures thereof.

30. The method as defined in claims 25-29, wherein said step of drawing down said outer diameter of said tube reduces said outer diameter by less than about 10% each time said tube is processed by said plug drawing process, said step of drawing down said outer diameter of said tube at least partially occurring in an inert atmosphere, an oxygen reducing atmosphere, or a vacuum.

31. The method as defined in claims 25-30, wherein said step of annealing said tube occurs at a temperature of at least about 1300°C for at least about 2 minutes, and in an inert atmosphere, an oxygen reducing atmosphere, or a vacuum.

32. The method as defined in claims 25-31, wherein said tube is drawn down a plurality of times prior to at least one anneal step.

33. The method as defined in claims 25-32, wherein said step of cleaning said surface occurs prior to each said step of annealing.

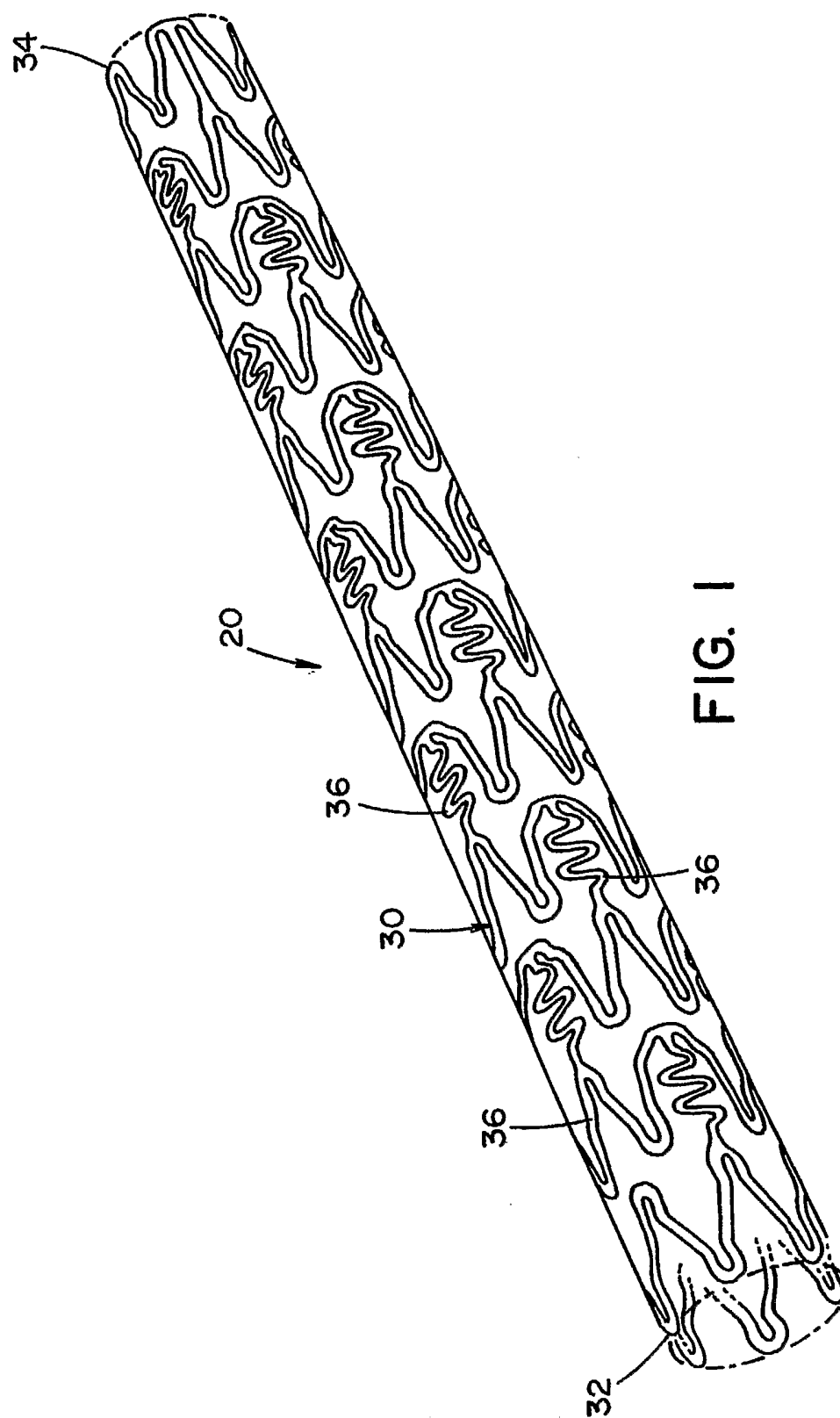
34. The method as defined in claims 25-33, wherein said step of cutting said annealed tube occurs in an inert atmosphere, an oxygen reducing atmosphere, or a vacuum.

35. The method as defined in claims 25-34, including the step of electro-polishing said medical device after said step of laser cutting.

36. The method as defined in claims 25-35, wherein said medical device is a stent.

37. The method as defined in claims 25-36, including the step of applying at least one biological agent on at least one region of said medical device.

38. The method as defined in claim 37, including the step of applying at least one polymer to at least one region of said medical device to at least partially coat, encapsulate or combinations thereof said at least one biological agent.



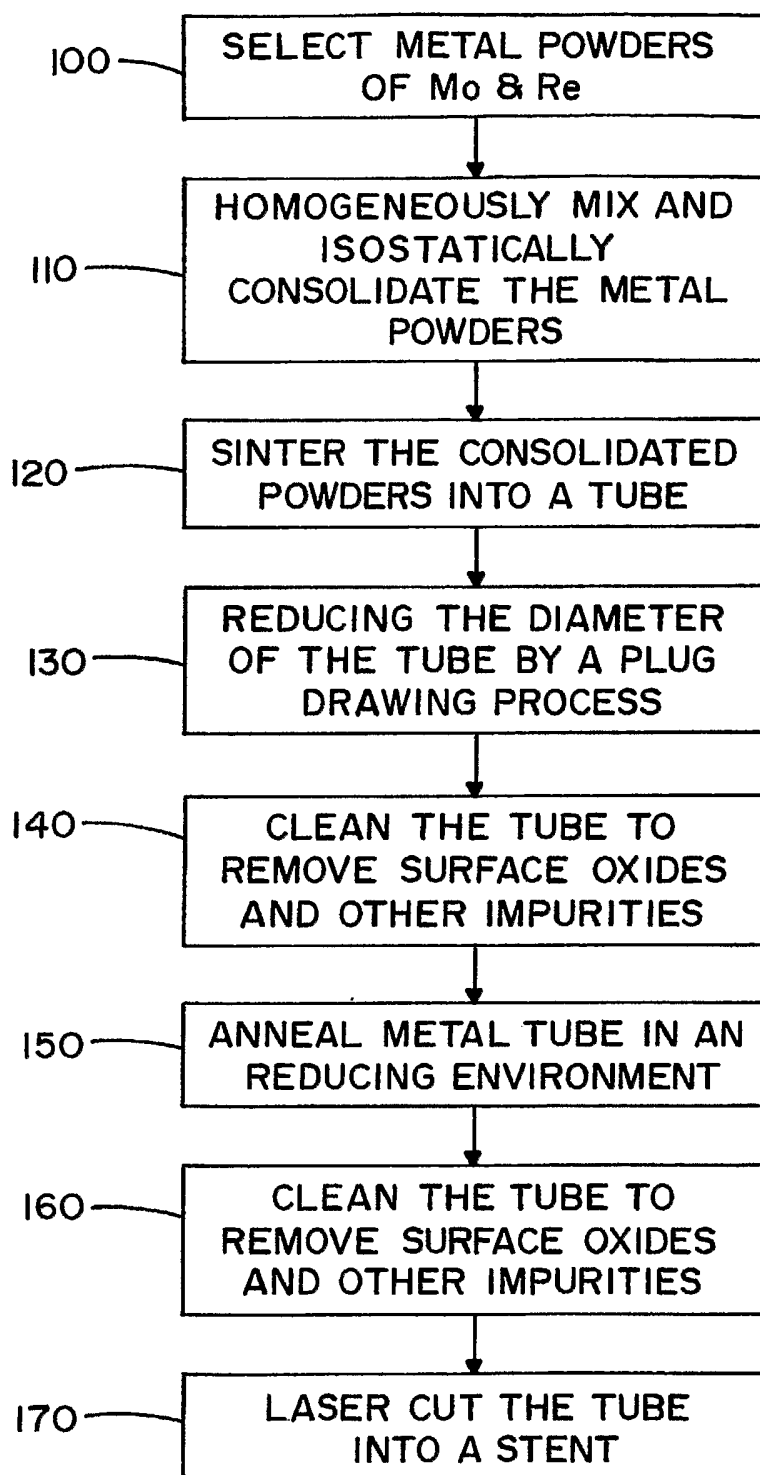


FIG. 2