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(54) Title: MEDICAL DEVICE THAT INCLUDES A RHENIUM METAL ALLOY

(57) Abstract: A medical device that is at least partially formed of a rhenium metal alloy.

MEDICAL DEVICE THAT INCLUDES A RHENIUM METAL ALLOY

[0001] The present disclosure claims priority on United States Provisional Application Serial No. 63/226,270 filed July 28, 2021, which is incorporated herein by reference.

[0002] The disclosure relates generally to medical devices and medical device applications, and more particularly to a medical device that is at least partially formed of the biomedical material.

BACKGROUND OF DISCLOSURE

[0003] Stainless steel, cobalt-chromium alloys, and TiAlV alloys are some of the more common metal alloys used for medical devices. Although these alloys have been successful in forming a variety of medical devices, these alloys have several deficiencies.

[0004] Many cardiovascular devices such as stents, expandable heart valves, and the like are inserted into a patient via the vascular system of a patient and then expanded at the treatment site. These devices are typically crimped onto a catheter prior to insertion into a patient. The minimum diameter to which the cardiovascular device can be crimped onto the catheter will set a limit to the size of the cardiovascular passageway (e.g., blood vessel) to which the cardiovascular device can be inserted. Smaller crimp diameters can result in reduced damage to a blood vessel and/or organ (e.g., heart, etc.) when inserting into and/or placing the cardiovascular device at the treatment site. Smaller crimp diameters can also allow the cardiovascular device to be placed in smaller diameter blood vessels (e.g., blood vessels located in the brain, etc.).

[0005] The crimp diameter of the expandable cardiovascular device can be reduced by reducing the thickness and/or size of the frame, struts, etc., of the cardiovascular device. However, such reduction in size also affects the strength of the cardiovascular device after being expanded. After the cardiovascular device is expanded, it must retain its expanded shape at the treatment area, otherwise the cardiovascular device could become dislodged from the treatment area, could damage the treatment area, and/or fail to properly function at the treatment area. As such, cardiovascular devices formed of tradition materials such as stainless steel (e.g., 316L: 17-19 wt.% chromium, 13-15 wt.% nickel, 2-4 wt.% molybdenum, 2 wt.% max manganese, 0.75 wt.% max silicon, 0.03 wt.% max carbon, balance iron) and cobalt-chromium alloys (e.g., MP35N: 19-21 wt.% chromium, 34-36 wt.% nickel, 9-11 wt.% molybdenum, 1 wt.% max iron, 1 wt.% max

titanium, 0.15 wt.% max manganese, 0.15 wt.% max silver, 0.025 wt.% max carbon, balance cobalt) are required to maintain a frame and/or strut size/thickness that limits how small of crimping diameter can be obtained by the crimped cardiovascular device. Other types of cobalt-chromium alloys that have been used are Phynox and Elgiloy alloy (38-42 wt.% cobalt, 18-22 wt.% chromium, 14-18 wt.% iron, 13-17 wt.% 5 nickel, 6-8 wt.% molybdenum), and L605 alloy (18-22 wt.% chromium, 14-16 wt.% W, 9-11 wt.% nickel, balance cobalt).

[0006] Also, traditional materials such as stainless steel (316L) and cobalt-chromium alloys (e.g., MP35N, etc.) have a degree of recoil after being crimped and expanded that can interfere with obtaining a minimum crimping diameter and/or can adversely affect the placement of the expandable cardiovascular device at a treatment area. During a crimping process, a crimping device is typically used to crimp the cardiovascular device onto a catheter. After an initial crimping process, tradition materials such as stainless steel and cobalt-chromium alloys recoil to a larger diameter by 9+% of the minimum crimped diameter. As such, the cardiovascular device must be crimped multiple times onto a catheter to attempt to obtain a smaller crimped diameter on the catheter. However, subjecting the cardiovascular device to multiple crimpings can result in damage to the cardiovascular device (e.g., damage to the frame and/or struts of the cardiovascular device, damage to leaflets on an expandable heart valve, etc.). Likewise, when the cardiovascular device is expanded at a treatment area, the traditional materials of the cardiovascular device will recoil 9+% of the maximum expanded diameter. As such, the inflatable balloon on the catheter must be pressurized multiple times to repeatedly expand the cardiovascular device at the treatment area to ensure proper expansion of the cardiovascular device. However, subjecting the cardiovascular device to multiple balloon expansions can result in damage to the cardiovascular device (e.g., damage or breakage of a frame and/or strut, etc.) and/or damage to the treatment area (e.g., rupture of blood vessel, tear and/or puncture of tissue of an organ, etc.).

[0007] When a medical device is inserted into a patient, it is typically desirable for the medical device to resist ionization and/or corrosion while in the patient so as to not subject the patient to metal ions and/or oxides from the metals used to form the medical device while in the patient. Excessive ion release from the medical device can be potentially adverse to the patient. Although traditional materials such as stainless steel (316L) and cobalt-chromium alloys (e.g., MP35N, etc.) are very stable when inserted into patients, some degree of metal ion release occurs when the medical device is in the patient.

[0008] In view of the current state of the art of medical devices, there is a need for an improved medical device that a) produces less recoil compared to medical devices formed of stainless steel, cobalt-chromium alloys, or TiAlV alloys, b) can form smaller crimping diameters compared to medical devices formed of stainless steel, cobalt-chromium alloys, or TiAlV alloys, and/or c) has reduced metal ion release compared to medical devices formed of stainless steel, cobalt-chromium alloys, or TiAlV alloys.

SUMMARY OF THE DISCLOSURE

[0009] The present disclosure is direct to a medical device that is at least partially made of a rhenium metal alloy. The medical device can include an orthopedic device, PFO (patent foramen ovale) device, stent, valve (e.g., heart valve, TAVR valve, mitral valve replacement, tricuspid valve replacement, pulmonary valve replacement, etc.), spinal implant, frame and other structures for use with a spinal implant, vascular implant, graft, guide wire, sheath, catheter, needle, stent catheter, electrophysiology catheter, hypotube, staple, cutting device, any type of implant, pacemaker, dental implant, dental crown, dental braces, wire used in medical procedures, bone implant, artificial disk, artificial spinal disk, prosthetic implant or device to repair, replace and/or support a bone (e.g., acromion, atlas, axis, calcaneus, carpus, clavicle, coccyx, epicondyle, epitrochlea, femur, fibula, frontal bone, greater trochanter, humerus, ilium, ischium, mandible, maxilla, metacarpus, metatarsus, occipital bone, olecranon, parietal bone, patella, phalanx, radius, ribs, sacrum, scapula, sternum, talus, tarsus, temporal bone, tibia, ulna, zygomatic bone, etc.) and/or cartilage, bone plate nail, rod, screw, post, cage, plate, pedicle screw, cap, hinge, joint system, anchor, spacer, shaft, anchor, disk, ball, tension band, locking connector other structural assembly that is used in a body to support a structure, mount a structure, and/or repair a structure in a body such as, but not limited to, a human body, animal body, etc. In one non-limiting embodiment, the medical device includes an expandable frame (e.g., stent, prosthetic heart valve, etc.) that can plastically deform radially outwardly by an expansion arrangement (e.g., inflatable balloon, etc.). In another non-limiting embodiment, the rhenium metal alloy is not a self-expanding alloy.

[0010] In accordance with another and/or alternative non-limiting aspect of the present disclosure, there is provided a medical device partially or fully formed of a rhenium metal alloy. In one non-limiting embodiment, 50-100% (and all values and ranges therebetween) of the medical

device is formed of the rhenium metal alloy. In another non-limiting embodiment, at least 30 wt.% (e.g., 30-99 wt.% and all values and ranges therebetween) of the rhenium metal alloy includes rhenium. In another non-limiting embodiment, at least 35 wt.% of the rhenium metal alloy includes rhenium. In another non-limiting embodiment, at least 35 wt.% (e.g., 35-99.9 wt.% and all values and ranges therebetween) of the rhenium metal alloy includes rhenium, and 0.1-65 wt.% (and all values and ranges therebetween) of the rhenium metal alloy includes one or more of molybdenum, niobium, tantalum, tantalum, titanium, vanadium, chromium, manganese, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and/or iridium. In another non-limiting embodiment, 35-60 wt.% (and all values and ranges therebetween) of the rhenium metal alloy includes rhenium, and 40-65 wt.% (and all values and ranges therebetween) of the rhenium metal alloy includes one or more of molybdenum, niobium, tantalum, tungsten, titanium, vanadium, chromium, manganese, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and/or iridium. In another non-limiting embodiment, 35-60 wt.% (e.g., and all values and ranges therebetween) of the rhenium metal alloy includes rhenium, and 40-65 wt.% (and all values and ranges therebetween) of the rhenium metal alloy includes two or more of molybdenum, niobium, tantalum, tantalum, titanium, vanadium, chromium, manganese, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and/or iridium. In another non-limiting embodiment, 35-60 wt.% (e.g., and all values and ranges therebetween) of the rhenium metal alloy includes rhenium, and 40-65 wt.% (and all values and ranges therebetween) of the rhenium metal alloy includes three or more of molybdenum, niobium, tantalum, tantalum, titanium, vanadium, chromium, manganese, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and/or iridium.

[0011] In another non-limiting embodiment, the rhenium metal alloy includes 0-0.1 wt.% (and all values and ranges therebetween) of impurities (e.g., metals other than rhenium, molybdenum, niobium, tantalum, tantalum, titanium, vanadium, chromium, manganese, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium).

[0012] In another non-limiting aspect of the present disclosure, the metals used to form the rhenium metal alloy include at least 35 wt.% rhenium (e.g., 35-99.9 wt.% and all values and ranges therebetween) and one or more alloying agents such as, but are not limited to, molybdenum, niobium, tantalum, tantalum, titanium, vanadium, chromium, manganese, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and/or iridium, and/or alloys of one or more of

such components. In one non-limiting formulation, the rhenium metal alloy includes 40-99.9 wt.% rhenium and one or more molybdenum, niobium, tantalum, tantalum, titanium, vanadium, chromium, manganese, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and/or iridium. In one non-limiting formulation, the rhenium metal alloy includes 50-99.9 wt.% rhenium and one or more molybdenum, niobium, tantalum, tantalum, titanium, vanadium, chromium, manganese, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and/or iridium.

[0013] In another non-limiting aspect of the present disclosure, the metals used to form the rhenium metal alloy include rhenium, molybdenum, and one or more alloying metals selected from the group consisting of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium. In one non-limiting embodiment, a combined weight percentage of rhenium and alloy metals in the rhenium metal alloy is greater than or equal to the weight percent of molybdenum in the rhenium metal alloy. In another non-limiting embodiment, a combined weight percentage of rhenium and alloy metals in the rhenium metal alloy is greater than the weight percent of molybdenum in the rhenium metal alloy. In another non-limiting embodiment, a weight percent of molybdenum in the rhenium metal alloy is at least 10 wt.% and less than 60 wt.% (and all values and ranges therebetween). In another non-limiting embodiment, a weight percent of rhenium in the rhenium metal alloy is 35-60 wt.% (and all values and ranges therebetween). In another non-limiting embodiment, a combined weight percent of the alloying metals is 5-45 wt.% (and all values and ranges therebetween) of the rhenium metal alloy. In another non-limiting embodiment, a weight percent of the rhenium in the rhenium metal alloy is greater than a combined weight percent of the alloying metals. In another non-limiting embodiment, a combined weight percent of the rhenium, molybdenum, and the one or more alloying metals in the rhenium metal alloy is at least 99.9 wt.%. In another non-limiting embodiment, alloy metal includes chromium. In another non-limiting embodiment, the alloying metal includes chromium and one or more metals selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium. In another non-limiting embodiment, the alloying metal includes chromium and one or more metals selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium; and wherein an atomic ratio of chromium to an atomic ratio of each or all of the metals selected from the group consisting of bismuth, chromium, iridium, niobium,

tantalum, titanium, and yttrium is 0.4:1 to 2.5:1 (and all values and ranges therebetween). In another non-limiting embodiment, the alloying metal includes chromium and one or more metals selected from the group consisting of zirconium, niobium, and tantalum. In another non-limiting embodiment, the alloying metal includes a first metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium, and a second metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium; and wherein the first and second metals are different; and wherein an atomic ratio of the first metal to the second metal is 0.4:1 to 2.5:1 (and all values and ranges therebetween). In another non-limiting embodiment, the alloying metal a first metal selected from the group consisting of chromium, niobium, tantalum, and zirconium, and a second metal selected from the group consisting of chromium, niobium, tantalum, and zirconium; and wherein the first and second metals are different; and wherein an atomic ratio of the first metal to the second metal is 0.4:1 to 2.5:1 (and all values and ranges therebetween).

[0014] Several non-limiting examples of the rhenium metal alloy that can be made in accordance with the present disclosure are set forth below:

Wt. %	Ex. 1	Ex. 2	Ex. 3	Ex. 4
Re	35-60%	35-60%	35-60%	35-60%
Mo	10-55%	10-55%	10-55%	10-55%
Bi	1-42	0-32	0-32	0-32
Cr	0-32	1-42	0-32	0-32
Ir	0-32	0-32	1-42	0-32
Nb	0-32	0-32	0-32	1-42
Ta	0-32	0-32	0-32	0-32
Ti	0-32	0-32	0-32	0-32
Y	0-32	0-32	0-32	0-32
Zr	0-32	0-32	0-32	0-32
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

Wt. %	Ex. 5	Ex. 6	Ex. 7	Ex. 8
Re	35-60%	35-60%	35-60%	35-60%
Mo	15-55%	15-55%	15-55%	15-55%
Bi	0-32	0-32	0-32	0-32
Cr	0-32	0-32	0-32	0-32
Ir	0-32	0-32	0-32	0-32
Nb	0-32	0-32	0-32	0-32
Ta	1-42	0-32	0-32	0-32
Ti	0-32	1-42	0-32	0-32
Y	0-32	0-32	1-42	0-32
Zr	0-32	0-32	0-32	1-42
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

Wt. %	Ex. 9	Ex. 10	Ex. 11	Ex. 12
Re	41-59%	41-59%	41-59%	41-59%
Mo	18-45%	18-45%	18-45%	18-45%
Bi	1-42	0-32	0-32	0-32
Cr	0-32	1-42	0-32	0-32
Ir	0-32	0-32	1-42	0-32
Nb	0-32	0-32	0-32	1-42
Ta	0-32	0-32	0-32	0-32
Ti	0-32	0-32	0-32	0-32
Y	0-32	0-32	0-32	0-32
Zr	0-32	0-32	0-32	0-32
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

Wt. %	Ex. 13	Ex. 14	Ex. 15	Ex. 16
Re	41-59%	41-59%	41-59%	41-59%
Mo	18-45%	18-45%	18-45%	18-45%
Bi	0-32	0-32	0-32	0-32
Cr	0-32	0-32	0-32	0-32
Ir	0-32	0-32	0-32	0-32
Nb	0-32	0-32	0-32	0-32
Ta	1-42	0-32	0-32	0-32
Ti	0-32	1-42	0-32	0-32
Y	0-32	0-32	1-42	0-32
Zr	0-32	0-32	0-32	1-42
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

Wt. %	Ex. 17	Ex. 18	Ex. 19	Ex. 20
Re	41-59%	41-59%	41-59%	41-59%
Mo	18-45%	18-45%	18-45%	18-45%
Bi	0-15	0-15	1-36	0-15
Cr	1-20	1-20	1-20	1-20
Ir	0-15	0-15	0-15	0-15
Nb	1-36	0-15	0-15	0-15
Ta	0-15	1-36	0-15	0-15
Ti	0-15	0-15	0-15	0-15
Y	0-15	0-15	0-15	0-15
Zr	0-15	0-15	0-15	1-36
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

Wt. %	Ex. 21	Ex. 22	Ex. 23	Ex. 24
Re	41-59%	41-59%	41-59%	41-59%
Mo	18-45%	18-45%	18-45%	18-45%
Bi	1-36	0-15	0-15	0-15
Cr	1-20	1-20	1-20	1-20
Ir	0-15	1-36	0-15	0-15
Nb	0-15	0-15	0-15	0-15
Ta	0-15	0-15	0-15	0-15
Ti	0-15	0-15	1-36	0-15
Y	0-15	0-15	0-15	1-36
Zr	0-15	0-15	0-15	0-15
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

Wt. %	Ex. 25	Ex. 26	Ex. 27	Ex. 28
Re	41-59%	41-59%	41-59%	41-59%
Mo	18-45%	18-45%	18-45%	18-45%
Bi	1-34	0-15	0-15	0-15
Cr	0-15	0-15	0-15	0-15
Ir	0-15	0-15	0-15	1-34
Nb	3-27	3-27	3-27	3-27
Ta	0-42	1-34	0-15	0-15
Ti	0-15	0-15	0-15	0-15
Y	0-15	0-15	0-15	0-15
Zr	0-15	0-15	3-27	0-15
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

Wt. %	Ex. 29	Ex. 30	Ex. 31	Ex. 32
Re	41-59%	41-59%	41-59%	41-59%
Mo	18-45%	18-45%	18-45%	18-45%
Bi	0-15	0-15	0-15	0-15
Cr	0-15	0-15	0-15	0-15
Ir	0-15	1-34	0-15	0-15
Nb	0-15	0-15	0-15	0-15
Ta	1-34	0-15	3-27	0-15
Ti	0-15	0-15	0-15	0-15
Y	0-15	0-15	0-15	3-27
Zr	3-27	3-27	3-27	3-27
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

Wt. %	Ex. 33	Ex. 34	Ex. 35	Ex. 36
Re	41-59%	41-59%	41-59%	41-59%
Mo	18-45%	18-45%	18-45%	18-45%
Bi	0-15	0-15	0-15	0-15
Cr	0-15	0-15	0-15	1-10
Ir	1-34	0-25	3-27	0-15
Nb	0-15	3-27	0-15	0-15
Ta	0-15	0-15	1-34	0-15
Ti	0-15	0-15	0-15	0-15
Y	3-27	3-27	0-15	0-15
Zr	0-15	0-15	3-27	1-12
C	<0.06	<0.06	<0.06	<0.06
N	<0.06	<0.06	<0.06	<0.06
O	<0.06	<0.06	<0.06	<0.06

[0015] In Examples 1-36, it will be appreciated that all of the above ranges include any value between the range and any other range that is between the ranges set forth above. Any of the above

values that include the < symbol includes the range from 0 to the stated value and all values and ranges therebetween.

[0016] In another and/or alternative non-limiting aspect of the present disclosure, the weight percent of rhenium plus the weigh percent of the combined weight percentage of bismuth, niobium, tantalum, tungsten, titanium, vanadium, chromium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium is greater than the weight percent of molybdenum in the rhenium metal alloy. In one specific non-limiting formulation, the weight percent of rhenium plus the weigh percent of the combined weight percentage of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium, and zirconium is greater than the weight percent of molybdenum in the rhenium metal alloy. In another specific non-limiting formulation, the weight percent of rhenium plus the weigh percent of the combined weight percentage of chromium, niobium, tantalum, and zirconium is greater than the weight percent of molybdenum in the rhenium metal alloy. In another non-limiting specific non-limiting formulation, the weight percent of molybdenum in the rhenium metal alloy is at least 10 wt.% and less than 50 wt.% (and all values and ranges therebetween). In another non-limiting specific non-limiting formulation, the weight percent of rhenium in the rhenium metal alloy is 41-58.5 wt.% (and all values and ranges therebetween), the weight percent of molybdenum in the rhenium metal alloy is at least 15-45 wt.% (and all values and ranges therebetween), and the combined weight percent of bismuth, niobium, tantalum, tungsten, titanium, vanadium, chromium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium in the rhenium metal alloy is 11-41 wt.% (and all values and ranges therebetween). In another non-limiting specific non-limiting formulation, the weight percent of rhenium in the rhenium metal alloy is 41-58.5 wt.% (and all values and ranges therebetween), the weight percent of molybdenum in the rhenium metal alloy is at least 15-45 wt.% (and all values and ranges therebetween), and the combined weight percent of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium, and zirconium in the rhenium metal alloy is 11-41 wt.% (and all values and ranges therebetween). In another non-limiting specific non-limiting formulation, the weight percent of rhenium in the rhenium metal alloy is 41-58.5 wt.% (and all values and ranges therebetween), the weight percent of molybdenum in the rhenium metal alloy is at least 15-45 wt.% (and all values and ranges therebetween), and the combined weight percent of chromium, niobium, tantalum, and zirconium in the rhenium metal alloy is 11-41 wt.% (and all values and ranges therebetween). In another non-limiting embodiment

of the invention, the weight percent of rhenium in the rhenium metal alloy is greater than the combined weight percent of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium, and zirconium in the rhenium metal alloy. In another non-limiting specific non-limiting formulation, the weight percent of rhenium in the rhenium metal alloy is greater than the combined weight percent of chromium, niobium, tantalum, and zirconium in the rhenium metal alloy.

[0017] In another and/or alternative non-limiting aspect of the present disclosure, the atomic weight percent of rhenium to the atomic weight percent of the combination of bismuth, niobium, tantalum, tungsten, titanium, vanadium, chromium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium is 0.7:1 to 1.5:1 (and all values and ranges therebetween), typically 0.8:1 to 1.4:1, more typically 0.8:1 to 1.25:1, and still more typically about 0.9:1 to 1.1:1 (e.g., 1:1). In one specific non-limiting formulation, the atomic weight percent of rhenium to the atomic weight percent of the combination of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium, and zirconium is 0.7:1 to 5.1:1 (and all values and ranges therebetween), typically 0.8:1 to 1.5:1, more typically 0.8:1 to 1.25:1, and still more typically about 0.9:1 to 1.1:1 (e.g., 1:1). In one specific non-limiting formulation, the atomic weight percent of rhenium to the atomic weight percent of the combination of chromium, niobium, tantalum, and zirconium is 0.7:1 to 5.1:1 (and all values and ranges therebetween), typically 0.8:1 to 1.5:1, more typically 0.8:1 to 1.25:1, and still more typically about 0.9:1 to 1.1:1 (e.g., 1:1).

[0018] In another and/or alternative non-limiting aspect of the present disclosure, when the rhenium metal alloy includes two of bismuth, niobium, tantalum, tungsten, titanium, vanadium, chromium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium, the atomic ratio of the two metals is 0.4:1 to 2.5:1 (and all values and ranges therebetween), and typically 0.5:1 to 2:1. In one specific non-limiting formulation, when the rhenium metal alloy includes two of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium, and zirconium, the atomic ratio of the two metals is 0.4:1 to 2.5:1 (and all values and ranges therebetween), and typically 0.5:1 to 2:1. In another specific non-limiting formulation, when the rhenium metal alloy includes two of chromium, niobium, tantalum, and zirconium, the atomic ratio of the two metals is 0.4:1 to 2.5:1 (and all values and ranges therebetween), and typically 0.5:1 to 2:1.

[0019] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy optionally includes less than about 5 wt.% (e.g., 0-4.999999 wt.% and all values and

ranges therebetween) other metals and/or impurities, typically 0-1 wt.%, more typically 0-0.1 wt.%, even more typically 0-0.01 wt.%, and still even more typically 0-0.001 wt.%. A high purity level of the rhenium metal alloy results in the formation of a more homogeneous alloy, which in turn results in a more uniform density throughout the rhenium metal alloy, and also results in the desired yield and ultimate tensile strengths of the rhenium metal alloy. In one specific non-limiting formulation, the rhenium metal alloy is formed of rhenium plus at least two metals selected form the group of molybdenum, bismuth, niobium, tantalum, tungsten, titanium, vanadium, chromium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium, and the content of rhenium metal alloy that includes other elements and compounds is 0-0.1 wt.%, typically 0-0.01 wt.%, and more typically 0-0.001 wt.%. In another specific non-limiting formulation, the rhenium metal alloy is formed of rhenium plus at least two metals selected from the group of molybdenum, bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium, and zirconium, and the content of rhenium metal alloy that includes other elements and compounds is 0-0.1 wt.%, typically 0-0.01 wt.%, and more typically 0-0.001 wt.%. In another specific non-limiting formulation, the rhenium metal alloy is formed of rhenium plus at least three metals selected form the group of rhenium, molybdenum, chromium, niobium, tantalum, and zirconium, and the content of rhenium metal alloy that includes other elements and compounds is 0-0.1 wt.%, typically 0-0.01 wt.%, and more typically 0-0.001 wt.%.

[0020] In accordance with another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy, which can optionally be used to partially or fully form a medical device, includes 38-60 wt.% Re (and all values and ranges therebetween), 29 wt.% to less than 50 wt.% Mo (and all values and ranges therebetween), and 10-30 wt.% additive metal(and all values and ranges therebetween); wherein a combined content of Re and Mo constitutes 70-90 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein a combined content of Re, Mo and additive metal constitutes 99-100 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein said metal additive includes one or more metals selected from the group of bismuth, niobium, tantalum, tungsten, titanium, vanadium, chromium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium; and wherein an atomic ratio of Re to total content of additive material in the rhenium metal alloy is optionally 0.8:1 to 1.25:1 (and all values and ranges therebetween).

[0021] In accordance with another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy, which can optionally be used to partially or fully form a medical device, includes 40-55 wt.% Re (and all values and ranges therebetween), 30-46 wt.% Mo (and all values and ranges therebetween), and 12-20 wt.% additive metal(and all values and ranges therebetween); wherein a combined content of Re and Mo constitutes 80-88 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein a combined content of Re, Mo and additive metal constitutes 99-100 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein said metal additive includes one or more metals selected from the group of bismuth, niobium, tantalum, tungsten, titanium, vanadium, chromium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium; and wherein an atomic ratio of Re to total content of additive material in the rhenium metal alloy is optionally 0.8:1 to 1.25:1 (and all values and ranges therebetween).

[0022] In accordance with another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy, which can optionally be used to partially or fully form a medical device, includes 38-60 wt.% Re (and all values and ranges therebetween), 29 wt.% to less than 50 wt.% Mo (and all values and ranges therebetween), and 10-30 wt.% additive metal(and all values and ranges therebetween); wherein a combined content of Re and Mo constitutes 70-90 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein a combined content of Re, Mo and additive metal constitutes 99-100 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein said metal additive includes chromium and optionally one or more metals selected from the group of bismuth, niobium, tantalum, tungsten, titanium, vanadium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium; and wherein an atomic ratio of Re to total content of additive material in the rhenium metal alloy is optionally 0.8:1 to 1.25:1 (and all values and ranges therebetween).

[0023] In accordance with another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy, which can optionally be used to partially or fully form a medical device, includes 40-55 wt.% Re (and all values and ranges therebetween), 30-46 wt.% Mo (and all values and ranges therebetween), and 12-20 wt.% additive metal(and all values and ranges therebetween); wherein a combined content of Re and Mo constitutes 80-88 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein a combined content of Re, Mo and

additive metal constitutes 99-100 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein said metal additive includes chromium and one or more metals selected from the group of bismuth, niobium, tantalum, tungsten, titanium, vanadium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium; and wherein an atomic ratio of Re to total content of additive material in the rhenium metal alloy is optionally 0.8:1 to 1.25:1 (and all values and ranges therebetween).

[0024] In accordance with another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy, which can optionally be used to partially or fully form a medical device, includes 38-60 wt.% Re (and all values and ranges therebetween), 29 wt.% to less than 50 wt.% Mo (and all values and ranges therebetween), and 10-30 wt.% additive metal(and all values and ranges therebetween); wherein a combined content of Re and Mo constitutes 70-90 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein a combined content of Re, Mo and additive metal constitutes 99-100 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein said metal additive includes chromium and optionally one or more metals selected from the group of niobium, tantalum, and zirconium; and wherein an atomic ratio of Re to total content of additive material in the rhenium metal alloy is optionally 0.8:1 to 1.25:1.

[0025] In accordance with another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy, which can optionally be used to partially or fully form a medical device, includes 38-60 wt.% Re (and all values and ranges therebetween), 29 wt.% to less than 50 wt.% Mo (and all values and ranges therebetween), and 10-30 wt.% additive metal(and all values and ranges therebetween); wherein a combined content of Re and Mo constitutes 70-90 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein a combined content of Re, Mo and additive metal constitutes 99-100 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein said metal additive includes chromium and one or more metals selected from the group of bismuth, niobium, tantalum, tungsten, titanium, vanadium, manganese, yttrium, zirconium, technetium, ruthenium, rhodium, hafnium, osmium, copper, and iridium; and wherein an atomic ratio of Re to total content of additive material in the rhenium metal alloy is optionally 0.8:1 to 1.25:1 (and all values and ranges therebetween).

[0026] In accordance with another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy, which can optionally be used to partially or fully form a medical device,

includes 38-60 wt.% Re (and all values and ranges therebetween), 29 wt.% to less than 50 wt.% Mo (and all values and ranges therebetween), and 10-30 wt.% additive metal(and all values and ranges therebetween); wherein a combined content of Re and Mo constitutes 70-90 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein a combined content of Re, Mo and additive metal constitutes 99-100 wt.% (and all values and ranges therebetween) of the rhenium metal alloy; wherein said metal additive includes chromium and one or more metals selected from the group of niobium, tantalum, and zirconium; and wherein an atomic ratio of Re to total content of additive material in the rhenium metal alloy is optionally 0.8:1 to 1.25:1 (and all values and ranges therebetween).

[0027] In accordance with another and/or alternative non-limiting aspect of the present disclosure, there is provided a medical device (e.g., stent, prosthetic heart valve, etc.) that is configured to be radially collapsible to a collapsed or crimped state for introduction into the body on a delivery catheter and radially expandable to an expanded state for implanting the prosthetic heart valve at a desired location in the body (e.g., blood vessel, heart, ureter, bile duct, pancreatic duct, esophagus, lung, eyes, sinus, oral stent, etc.). The frame of the medical device can be formed of a plastically-expandable material that permits crimping of the frame to a smaller profile for delivery and expansion of the medical device using an expansion device such as the balloon of a balloon catheter.

[0028] In accordance with another and/or alternative non-limiting aspect of the present disclosure, there is provided a medical device including a frame that includes a plurality of angularly-spaced posts, vertically-extending posts, or struts. The posts can be interconnected via a lower row of circumferentially-extending struts and an upper row of circumferentially-extending struts. The struts can be arrangement in a variety of patterns (e.g., zig-zag pattern, saw-tooth pattern, triangular pattern, polygonal pattern, oval pattern, etc.). One or more of the posts and/or struts can have the same or different thicknesses and/or cross-sectional shape and/or cross-sectional area.

[0029] In accordance with another and/or alternative non-limiting aspect of the present disclosure, there is provided a medical device including a frame that can be optionally coated with a polymer material (e.g., silicone, PTFE, ePTFE, polyurethane, polyolefins, hydrogels, biological materials (e.g., pericardium or biological polymers such as collagen, gelatin, or hyaluronic acid derivatives), etc.). The coating can be used to partially or fully encapsulate the struts on the frame

and/or to fill in the openings between the struts.

[0030] In accordance with another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy used to form at least a portion of the medical device has one or more improved properties (e.g., strength, durability, hardness, biostability, bendability, coefficient of friction, radial strength, flexibility, tensile strength, tensile elongation, longitudinal lengthening, stress-strain properties, reduced recoil, radiopacity, heat sensitivity, biocompatibility, improved fatigue life, crack resistance, crack propagation resistance, reduced magnetic susceptibility, etc.), improved conformity when bent, less recoil, increased yield strength, improved fatigue ductility, improved durability, improved fatigue life, reduced adverse tissue reactions, reduced metal ion release, reduced corrosion, reduced allergic reaction, improved hydrophilicity, reduced toxicity, reduced thickness of metal component, improved bone fusion, and/or lower ion release into tissue. These one or more improved physical properties of the rhenium metal 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 at least partially formed from traditional stainless steel, titanium alloy, or cobalt and chromium alloy materials.

[0031] The rhenium metal alloy used to at least partially form 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 the medical device, 8) increase the hardness of the medical device, 9) improve the recoil properties of the medical device, 10) improve the biostability and/or biocompatibility properties of the medical device, 11) increase fatigue resistance of the medical device, 12) resist cracking in the medical device and resist propagation of crack, 13) enable smaller, thinner, and/or lighter weight medical device to be made, 14) reduce the outer diameter of a crimped medical device, 15) improve the conformity of the medical device to the shape of the treatment area when the medical device is used and/or expanded in the treatment area, 16) reduce the amount of recoil of the medical device to the shape of the treatment area when the medical device is expanded in the treatment area, 17) increase yield strength of the medical device,

18) improve fatigue ductility of the medical device, 18) improve durability of the medical device, 19) improve fatigue life of the medical device, 20) reduce adverse tissue reactions after implant of the medical device, 21) reduce metal ion release after implant of the medical device, 22) reduce corrosion of the medical device after implant of the medical device, 23) reduce allergic reaction after implant of the medical device, 24) improve hydrophilicity of the medical device, 25) reduce thickness of metal component of medical device, 26) improve bone fusion with medical device, 27) lower ion release from medical device into tissue, 28) reduce magnetic susceptibility of the medical device when implanted in a patient, and/or 29) reduce toxicity of the medical device after implant of the medical device.

[0032] The medical device is optionally subjected to one or more manufacturing processes. These manufacturing processes can include, but are not limited to, expansion, laser cutting, etching, crimping, annealing, drawing, pilgering, electroplating, electro-polishing, machining, plasma coating, 3D printed coatings, chemical vapor deposition, chemical polishing, cleaning, pickling, ion beam deposition or implantation, sputter coating, vacuum deposition, etc.

[0033] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy used to at least partially form the medical device optionally has a generally uniform density throughout the rhenium metal alloy, and also results in the desired yield and ultimate tensile strengths of the rhenium metal alloy. The density of the rhenium metal alloy is generally at least about 5 gm/cc (e.g., 5 gm/cc-21 gm/cc and all values and ranges therebetween; 10-20 gm/cc; etc.), and typically at least about 11-19 gm/cc. This substantially uniform high density of the rhenium metal alloy significantly improves the radiopacity of the rhenium metal alloy.

[0034] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy optionally includes a certain amount of carbon and oxygen; however, this is not required. These two elements have been found to affect the forming properties and brittleness of the rhenium metal alloy. The controlled atomic ratio of carbon and oxygen of the rhenium metal alloy also minimize the tendency of the rhenium metal alloy to form micro-cracks during the forming of the rhenium metal alloy at least partially into a medical device, and/or during the use and/or expansion of the medical device in a body. The control of the atomic ratio of carbon to oxygen in the rhenium metal alloy allows for the redistribution of oxygen in the rhenium metal alloy to minimize the tendency of micro-cracking in the rhenium metal alloy during the forming of the rhenium metal alloy at least partially into a medical device, and/or during the use and/or

expansion of the medical device in a body. The atomic ratio of carbon to oxygen in the rhenium metal alloy is believed to facilitate in minimizing the tendency of micro-cracking in the rhenium metal alloy and improve the degree of elongation of the rhenium metal alloy, both of which can affect one or more physical properties of the rhenium metal alloy that are useful or desired in forming and/or using the medical device. The carbon to oxygen atomic ratio can be as low as about 0.2:1 (e.g., 0.2:1 to 50:1 and all values and ranges therebetween). In one non-limiting formulation, the carbon to oxygen atomic ratio in the rhenium metal alloy is generally at least about 0.3:1. Typically the carbon content of the rhenium metal alloy is less than about 0.1 wt.% (e.g., 0-0.0999999 wt.% and all values and ranges therebetween), and more typically 0-0.01 wt.%. Carbon contents that are too large can adversely affect the physical properties of the rhenium metal alloy. Generally, the oxygen content is to be maintained at very low level. In one non-limiting formulation, the oxygen content is less than about 0.1 wt.% of the rhenium metal alloy (e.g., 0-0.0999999 wt.% and all values and ranges therebetween), and typically 0-0.01 wt.%. It is believed that the rhenium metal alloy will have a very low tendency to form micro-cracks during the formation of the medical device and after the medical device has been inserted into a patient by closely controlling the carbon to oxygen ration when the oxygen content exceeds a certain amount in the rhenium metal alloy. In one non-limiting arrangement, the carbon to oxygen atomic ratio in the rhenium metal alloy is at least about 2.5:1 when the oxygen content is greater than about 100 ppm in the rhenium metal alloy of the rhenium metal alloy.

[0035] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy optionally includes a controlled amount of nitrogen; however, this is not required. Large amounts of nitrogen in the rhenium metal alloy can adversely affect the ductility of the rhenium metal alloy. This can in turn adversely affect the elongation properties of the rhenium metal alloy. A too high nitrogen content in the rhenium metal alloy can begin to cause the ductility of the rhenium metal alloy to unacceptably decrease, thus adversely affect one or more physical properties of the rhenium metal alloy that are useful or desired in forming and/or using the medical device. In one non-limiting formulation, the rhenium metal alloy includes less than about 0.001 wt.% nitrogen (e.g., 0 wt.% to 0.0009999 wt.% and all values and ranges therebetween). It is believed that the nitrogen content should be less than the content of carbon or oxygen in the rhenium metal alloy. In one non-limiting formulation, the atomic ratio of carbon to nitrogen is at least about 1.5:1 (e.g., 1.5:1 to 400:1 and all values and ranges therebetween). In another non-

limiting formulation, the atomic ratio of oxygen to nitrogen is at least about 1.2:1 (e.g., 1.2:1 to 150:1 and all value and ranges therebetween).

[0036] In another and/or alternative non-limiting aspect of the present disclosure, the medical device is generally designed to include at least about 5 wt.% of the rhenium metal alloy (e.g., 5-100 wt.% and all values and ranges therebetween). In one non-limiting embodiment of the disclosure, the medical device includes at least about 50 wt.% of the rhenium metal alloy. In another non-limiting embodiment of the disclosure, the medical device includes at least about 95 wt.% of the rhenium metal alloy. In one specific configuration, when the medical device includes an expandable frame, the expandable frame is formed of 50-100 wt.% (and all values and ranges therebetween) of the rhenium metal alloy, and typically 75-100 wt.% of the rhenium metal alloy.

[0037] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy used to form all or part of the medical device 1) is optionally not clad, metal sprayed, plated, and/or formed (e.g., cold worked, hot worked, etc.) onto another metal, or 2) optionally does not have another metal or metal alloy metal sprayed, plated, clad, and/or formed onto the rhenium metal alloy.

[0038] In another and/or alternative non-limiting aspect of the present disclosure, the medical device can optionally be formed from a tube or rod of refractory metal, or be formed into a shape that is at least 80% of the final net shape of the medical device.

[0039] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy has several physical properties that positively affect the medical device when the medical device is at least partially formed of the rhenium metal alloy of the present disclosure. In one non-limiting embodiment of the disclosure, the average Vickers hardness of the rhenium metal alloy of the present disclosure used to at least partially form the medical device is optionally at least about 150 Vickers (e.g., 150-300 Vickers and all values and ranges therebetween), and typically 160-240 Vickers; however, this is not required. The rhenium metal alloy of the present disclosure generally has an average hardness that is greater than stainless steel. In another and/or alternative non-limiting embodiment of the disclosure, the average ultimate tensile strength of the rhenium metal alloy of the present disclosure is optionally at least about 125 ksi (e.g., 125-300 ksi and all values and ranges therebetween); however, this is not required. In still another and/or alternative non-limiting embodiment of the disclosure, the average yield strength of the rhenium metal alloy of the present disclosure is optionally at least about 100 ksi (e.g., 100-275 ksi and all

values and ranges therebetween); however, this is not required. In yet another and/or alternative non-limiting embodiment of the disclosure, the average grain size of the rhenium metal alloy of the present disclosure used to at least partially form the medical device is optionally no greater than about 4 ASTM (e.g., 4 ASTM to 20 ASTM using ASTM E112 and all values and ranges therebetween, e.g., 0.35 micron to 90 micron, and all values and ranges therebetween). The small grain size of the rhenium metal alloy of the present disclosure enables the medical device to have the desired elongation and ductility properties useful in enabling the medical device to be formed, crimped, and/or expanded.

[0040] In another and/or alternative non-limiting embodiment of the disclosure, the average tensile elongation of the rhenium metal alloy of the present disclosure used to at least partially form the medical device is optionally at least about 25% (e.g., 25-50% average tensile elongation and all values and ranges therebetween). An average tensile elongation of at least 25% for the rhenium metal alloy is useful to facilitate in the medical device being properly expanded when positioned in the treatment area of a body. A medical device that does not have an average tensile elongation of at least about 25% may be more prone to the formation of micro-cracks and/or break during the forming, crimping, and/or expansion of the medical device. The unique combination of the metals in the rhenium metal alloy of the present disclosure in combination with achieving the desired purity and composition of the alloy and the desired grain size of the rhenium 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 rhenium metal alloy having high radiopacity, 4) a reduction or prevention of micro-crack formation and/or breaking of the rhenium metal alloy of the present disclosure tube when the tube is sized and/or cut to form the medical device, 5) a reduction or prevention of micro-crack formation and/or breaking of the medical device when the device is crimped, 6) a reduction or prevention of micro-crack formation and/or breaking of the medical device when the medical device is bent and/or expanded in a body, 7) a medical device having the desired ultimate tensile strength and yield strength, 8) a medical device having very thin wall thicknesses and still having the desired radial forces needed to retain the medical device on an open state when expanded, 9) a medical device that exhibits less recoil when the medical device is crimped onto a delivery system and/or expanded in a body, 10) a medical device that exhibits improved conformity to the shape of the treatment area in the body when the medical device is expanded in a body, 11) a medical

device that exhibits improved fatigue ductility, and/or 12) a medical device that exhibits improved durability.

[0041] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy is optionally at least partially formed by a swaging process; however, this is not required. In one non-limiting embodiment, swaging is performed on the rhenium metal alloy to at least partially or fully achieve final dimensions of one or more portions of the medical device. The swaging dies can be shaped to fit the final dimension of the medical device; however, this is not required. Where there are undercuts of hollow structures in the medical device (which is not required), a separate piece of metal can be placed in the undercut to at least partially fill the gap. The separate piece of metal (when used) can be designed to be later removed from the undercut; however, this is not required. The swaging operation can be performed on the medical device in the areas to be hardened. For a round or curved portion of a medical device, the swaging can be rotary. For non-round portion of the medical device, the swaging of the non-round portion of the medical device can be performed by non-rotating swaging dies. The dies can optionally be made to oscillate in radial and/or longitudinal directions instead of or in addition to rotating. The medical device can optionally be swaged in multiple directions in a single operation or in multiple operations to achieve a hardness in desired location and/or direction of the medical device. Swaging temperatures for a particular rhenium metal alloy can vary. For a rhenium metal alloy, the swaging temperature can be from room temperature (RT) (e.g., 10-27°C and all values and ranges therebetween) to about 400°C (e.g., 10-400°C and all values and ranges therebetween) if the swaging is conducted in air or an oxidizing environment. The swaging temperature can be increased to up to about 1500°C (e.g., 10-1500°C and all values and ranges therebetween) if the swaging process is performed in a controlled neutral or non-reducing environment (e.g., inert environment). The swaging process can be conducted by repeatedly hammering the medical device at the location to be hardened at the desired swaging temperature. In one non-limiting embodiment, during the swaging process ions of boron and/or nitrogen are allowed to impinge upon rhenium atoms in the rhenium metal alloys that include rhenium so as to form ReB_2, ReN_2 and/or ReN_3; however, this is not required. It has been found that ReB_2, ReN_2 and/or ReN_3 are ultra-hard compounds. In one non-limiting process, the metal for the medical device can be machined and shape into the medical device when the metal is in a less hardened state. As such, the raw starting material can be first annealed to soften and then machined the metal into a desired

shape. After the rhenium metal alloy is shaped, the rhenium metal alloy can be re-hardened. The hardening of the rhenium metal alloy of the medical device improves the wear resistance and/or shape retention of the medical device. The rhenium metal alloy of the medical generally cannot be re-hardened by annealing, thus a special rehardening processes is required. Such rehardening can be achieved by the swaging process of the present disclosure.

[0042] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy can optionally be nitrided; however, this is not required. The nitrided layer on the rhenium metal alloy can function as a lubricating surface during the optional drawing of the rhenium metal alloy when partially or fully forming the medical device. After the rhenium metal alloy is nitrided, the rhenium metal alloy is typically cleaned; however, this is not required. During the nitriding process, the surface of the rhenium metal alloy is modified by the presence of nitrogen. The nitriding process can be by gas nitriding, salt bath nitriding, or plasma nitriding. In gas nitriding, the nitrogen diffuses onto the surface of the rhenium metal alloy, thereby creating a nitrided layer. The thickness and phase constitution of the resulting nitriding layers can be selected and the process optimized for the particular properties required. During gas nitriding, the rhenium metal alloy is generally nitrided in the presence of nitrogen gas or a nitrogen gas mixture (e.g., 90-99% vol.% N and 1-10 vol.% H, etc.) for at least 10 seconds at a temperature of at least about 400°C (e.g., 400-1000°C and all values and ranges therebetween). In one non-limiting nitriding process, the rhenium metal alloy is heated in the presence of nitrogen or a nitrogen-hydrogen mixture to a temperature of at least 400°C, and generally about 400-800°C (and all values and ranges therebetween) for at least 10 seconds (e.g., 10 seconds to 60 minutes and all values and ranges therebetween), and generally about 1-30 minutes. In salt bath nitriding, a nitrogen-containing salt such as cyanide salt is used. During the salt bath nitriding, the rhenium metal alloy is generally exposed to temperatures of about 520–590°C. In plasma nitriding, the gas used for plasma nitriding is usually pure nitrogen. Plasma nitriding is often coupled with physical vapor deposition (PVD) process; however, this is not required. Plasma nitriding of the rhenium metal alloy generally occurs at a temperature of 220-630°C (and all values and ranges therebetween). The rhenium metal alloy can optionally be exposed to argon and/or hydrogen gas prior to the nitriding process to clean and/or preheat the rhenium metal alloy. These gases can be optionally used to clean oxide layers and/or solvents from the surface of the rhenium metal alloy. During the nitriding process, the rhenium metal alloy can optionally be exposed to hydrogen gas to inhibit or

prevent the formation of oxides on the surface of the rhenium metal alloy. The thickness of the nitrided surface layer is less than about 1 mm. In one non-limiting embodiment, the thickness of the nitride surface layer is at least about 50 nanometer and less than about 1 mm (and all values and ranges therebetween). In another non-limiting embodiment, the thickness of the nitrided surface layer is at least about 50 nanometer and less than about 0.1 mm. Generally, the weight percent of nitrogen in the nitrided surface layer is 0.0001-5 wt.% nitrogen (and all values and ranges therebetween). In one non-limiting embodiment, the weight percent of nitrogen in the nitrided surface layer is generally less than one of the primary components of the rhenium metal alloy, and typically less than each of the two primary components of the rhenium metal alloy. For example, when a rhenium metal alloy is nitrided, the weight percent of the nitrogen in the nitrided surface layer is less than a weight percent of the rhenium in the nitrided surface layer. In one non-limiting composition of the nitrided surface layer on a rhenium metal alloy (e.g., 47-55 wt.% rhenium, 10-46 wt.% molybdenum, 0.1-30 wt.% additional metal alloying agent), the nitrided surface layer comprises at least 40 wt.% rhenium, at least 8 wt.% molybdenum, and 0.0001-5 wt.% nitrogen (and all values and ranges therebetween). In one non-limiting embodiment of the disclosure, the surface of the rhenium metal alloy is nitrided prior to at least one drawing step for the rhenium metal alloy. In another non-limiting aspect of this disclosure, after the rhenium metal alloy has been annealed, the rhenium metal alloy is nitrided prior to being drawn. In another and/or alternative non-limiting embodiment, the rhenium metal alloy is cleaned to remove nitride compounds on the surface of the rhenium metal alloy prior to annealing the rhenium metal alloy. The nitride compounds can be removed by a variety of steps such as, but not limited to, grit blasting, polishing, etc. After the rhenium metal alloy has been annealed, the rhenium metal alloy can be again nitrided prior to one or more drawing steps; however, this is not required. As can be appreciated, the complete outer surface of the rhenium metal alloy can be nitrided or a portion of the outer surface of the rhenium metal alloy can be nitrided. Nitriding only selected portions of the outer surface of the rhenium metal alloy can be used to obtain different surface characteristics of the rhenium metal alloy; however, this is not required. As can be appreciated, the final formed rhenium metal alloy can include a nitrided outer surface. The nitriding process for the rhenium metal alloy can be used to increase surface hardness and/or wear resistance of the medical device, and/or to inhibit or prevent discoloration of the rhenium metal alloy (e.g., discoloration by oxidation, etc.). For example, the nitriding process can be used to increase the wear resistance of

articulation surface or surfaces wear on the rhenium metal alloy used in the medical device to extend the life of the medical device, and/or increase the wear life of mating surfaces on the medical device (e.g., polyethylene liners of joint implants like knees, hips, shoulders, etc.), and/or to reduce particulate generation from use of the medical device, and/or to maintain the outer surface appearance of the rhenium metal alloy on the medical device.

[0043] In another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy, just prior to or after being partially or fully formed into the desired medical device, can optionally be cleaned, polished, sterilized, nitrided, etc., for final processing of the rhenium metal alloy. In one non-limiting embodiment of the disclosure, the rhenium metal alloy is electropolished. In one non-limiting aspect of this embodiment, the rhenium metal alloy is cleaned prior to being exposed to the polishing 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 rhenium metal alloy with a Kimwipe or other appropriate towel, and/or 2) by at least partially dipping or immersing the rhenium metal alloy in a solvent and then ultrasonically cleaning the rhenium metal alloy. As can be appreciated, the rhenium metal alloy can be 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. In yet another and/or alternative non-limiting aspect of this embodiment, the rhenium metal alloy is rinsed with water and/or a solvent and allowed to dry to remove polishing solution on the rhenium metal alloy.

[0044] In another and/or alternative non-limiting aspect of the present disclosure, the use of the rhenium metal alloy to partially or fully form the medical device can be used to increase the strength and/or hardness and/or durability of the medical device as compared with stainless steel or chromium-cobalt alloys or titanium alloys; thus, less quantity of rhenium 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 rhenium 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 rhenium metal alloy also can increase the radial strength of the medical device. For example, the thickness of the walls of the medical device and/or the wires used to at least partially 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, titanium alloys, or cobalt and chromium alloys. The rhenium 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 rhenium 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 rhenium metal alloy can enable the medical device to be more easily inserted into various regions of a body. The rhenium 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 rhenium 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 into various regions of a body. Also, the medical device better maintains its expanded profile after expansion 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 rhenium metal alloy, the rhenium 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 example, the rhenium metal alloy is believed to at least about 10-20% more radiopaque than stainless steel or cobalt-chromium alloy.

[0045] In yet another and/or alternative non-limiting aspect of the present disclosure, the medical device can optionally contain and/or be coated with one or more agents that facilitate in the success of the medical device and/or treated area. The term "agent" includes, but is not limited to, a substance, pharmaceutical, biologic, veterinary product, drug, and analogs or derivatives otherwise formulated and/or designed to prevent, inhibit, and/or treat one or more clinical and/or biological events, and/or to promote healing. Non-limiting examples of clinical events that can be addressed by one or more agents include, but are not limited to, viral, fungus and/or bacterial infection; vascular diseases and/or disorders, digestive diseases and/or disorders, reproductive diseases and/or disorders, lymphatic diseases and/or disorders, cancer, implant rejection, pain, nausea, swelling, arthritis, bone diseases and/or disorders, organ failure, immunity diseases and/or

disorders, cholesterol problems, blood diseases and/or disorders, lung diseases and/or disorders, heart diseases and/or disorders, brain diseases and/or disorders, neuralgia diseases and/or disorders, kidney diseases and/or disorders, ulcers, liver diseases and/or disorders, intestinal diseases and/or disorders, gallbladder diseases and/or disorders, pancreatic diseases and/or disorders, psychological disorders, respiratory diseases and/or disorders, gland diseases and/or disorders, skin diseases and/or disorders, hearing diseases and/or disorders, oral diseases and/or disorders, nasal diseases and/or disorders, eye diseases and/or disorders, fatigue, genetic diseases and/or disorders, burns, scarring and/or scars, trauma, weight diseases and/or disorders, addiction diseases and/or disorders, hair loss, cramp, muscle spasms, tissue repair, nerve repair, neural regeneration, and/or the like. The type and/or amount of agent included in the medical device and/or coated on medical device can vary. When two or more agents are included in and/or coated on the medical device, the amount of the two or more agents can be the same or different. The one or more agents can be coated on and/or impregnated in the medical device by a variety of mechanisms such as, but not limited to, spraying (e.g., atomizing spray techniques, etc.), flame spray coating, powder deposition, dip coating, flow coating, dip-spin coating, roll coating (direct and reverse), sonication, brushing, plasma deposition, depositing by vapor deposition, MEMS technology, and rotating mold deposition. In another and/or alternative non-limiting embodiment of the disclosure, the type and/or amount of agent included on, in, and/or in conjunction with the medical device is generally selected for the treatment of one or more medical treatments. The amount of two or more agents on, in, and/or used in conjunction with the medical device can be the same or different. The one or more agents, when used on and/or in the medical device, can optionally be released in a controlled manner so the area in question to be treated is provided with the desired dosage of agent over a sustained period of time. As can be appreciated, controlled release of one or more agents on the medical device is not always required and/or desirable. As such, one or more of the agents on and/or in the medical device can be uncontrollably released from the medical device during and/or after insertion of the medical device in the treatment area. It can also be appreciated that one or more agents on and/or in the medical device can be controllably released from the medical device and one or more agents on and/or in the medical device can be uncontrollably released from the medical device. It can also be appreciated that one or more agents on and/or in one region of the medical device can be controllably released from the medical device and one or more agents on and/or in the medical device can be uncontrollably

released from another region on the medical device. As such, the medical device can be designed such that 1) all the agent on and/or in the medical device is controllably released, 2) some of the agent on and/or in the medical device is controllably released and some of the agent on the medical device is non-controllably released, or 3) none of the agent on and/or in the medical device is controllably released. The medical device can also be designed such that the rate of release of the one or more agents from the medical device is the same or different. The medical device can also be designed such that the rate of release of the one or more agents from one or more regions on the medical device is the same or different. Non-limiting arrangements that can be used to control the release of one or more agents from the medical device include 1) at least partially coating one or more agents with one or more polymers, 2) at least partially incorporating and/or at least partially encapsulating one or more agents into and/or with one or more polymers, and/or 3) inserting one or more agents in pores, passageway, cavities, etc., in the medical device and at least partially coat or cover such pores, passageway, cavities, etc., with one or more polymers. As can be appreciated, other or additional arrangements can be used to control the release of one or more agents from the medical device. The one or more polymers, when used to at least partially control the release of one or more agents from the medical device, can be porous or non-porous. The one or more agents can be inserted into and/or applied to one or more surface structures and/or micro-structures on the medical device, and/or be used to at least partially form one or more surface structures and/or micro-structures on the medical device. As such, the one or more agents on the medical device can be 1) coated on one or more surface regions of the medical device, 2) inserted and/or impregnated in one or more surface structures and/or micro-structures, etc., of the medical device, and/or 3) form at least a portion or be included in at least a portion of the structure of the medical device. When the one or more agents are coated on the medical device, the one or more agents can 1) be directly coated on one or more surfaces of the medical device, 2) be mixed with one or more coating polymers or other coating materials and then at least partially coated on one or more surfaces of the medical device, 3) be at least partially coated on the surface of another coating material that has been at least partially coated on the medical device, and/or 4) be at least partially encapsulated between a) a surface or region of the medical device and one or more other coating materials and/or b) two or more other coating materials. As can be appreciated, many other coating arrangements can be additionally or alternatively used. When the one or more agents are optionally inserted and/or impregnated in one or more internal structures, surface structures

and/or micro-structures of the medical device, 1) one or more other coating materials can be applied at least partially over the one or more internal structures, surface structures, and/or micro-structures of the medical device, and/or 2) one or more polymers can be combined with one or more agents. As such, the one or more agents can be 1) embedded in the structure of the medical device, 2) positioned in one or more internal structures of the medical device, 3) encapsulated between two polymer coatings, 4) encapsulated between the base structure and a polymer coating, 5) mixed in the base structure of the medical device that includes at least one polymer coating, or 6) one or more combinations of 1, 2, 3, 4, and/or 5. In addition or alternatively, the one or more coating of the one or more polymers on the medical device can include 1) one or more coatings of non-porous polymers, 2) one or more coatings of a combination of one or more porous polymers and one or more non-porous polymers, 3) one or more coating of porous polymer, or 4) one or more combinations of options 1, 2, and 3.

[0046] As can be appreciated, different agents can optionally be located in and/or between different polymer coating layers and/or on the structure of the medical device. As can also be appreciated, many other and/or additional coating combinations and/or configurations can be used. The concentration of one or more agents, the type of polymer, the type and/or shape of internal structures in the medical device, and/or the coating thickness of one or more agents can be used to control the release time, the release rate, and/or the dosage amount of one or more agents; however, other or additional combinations can be used. As such, the agent and polymer system combination and location on the medical device can be numerous. As can also be appreciated, one or more agents can be deposited on the top surface of the medical device to provide an initial uncontrolled burst effect of the one or more agents prior to the 1) controlled release of the one or more agents through one or more layers of a polymer system that include one or more non-porous polymers, and/or 2) uncontrolled release of the one or more agents through one or more layers of a polymer system. The one or more agents and/or polymers can be coated on the medical device by a variety of mechanisms such as, but not limited to, spraying (e.g., atomizing spray techniques, etc.), dip coating, roll coating, sonication, brushing, plasma deposition, and/or depositing by vapor deposition.

[0047] In still a further and/or alternative aspect of the present disclosure, a variety of polymers can optionally be coated on the medical device and/or be used to form at least a portion of the medical device. The one or more polymers can be used on the medical device for a variety of

reasons such as, but not limited to, 1) forming a portion of the medical device, 2) improving a physical property of the medical device (e.g., improve strength, improve durability, improve biocompatibility, reduce friction, etc.), 3) forming a protective coating on one or more surface structures on the medical device, 4) at least partially forming one or more surface structures on the medical device, and/or 5) at least partially controlling a release rate of one or more agents from the medical device. As can be appreciated, the one or more polymers can have other or additional uses on the medical device. The one or more polymers can be porous, non-porous, biostable, biodegradable (i.e., dissolves, degrades, is absorbed, or any combination thereof in the body), and/or biocompatible. When the medical device is coated with one or more polymers, the polymer can include 1) one or more coatings of non-porous polymers, 2) one or more coatings of a combination of one or more porous polymers and one or more non-porous polymers, 3) one or more coatings of one or more porous polymers and one or more coatings of one or more non-porous polymers, 4) one or more coating of porous polymer, or 5) one or more combinations of options 1, 2, 3, and 4. The thickness of one or more of the polymer layers can be the same or different. When one or more layers of polymer are coated onto at least a portion of the medical device, the one or more coatings can be applied by a variety of techniques such as, but not limited to, vapor deposition and/or plasma deposition, spraying, dip-coating, roll coating, sonication, atomization, brushing, and/or the like; however, other or additional coating techniques can be used. The one or more polymers that can be coated on the medical device and/or used to at least partially form the medical device can be polymers that are considered to be biodegradable, bioresorbable, or bioerodable; polymers that are considered to be biostable; and/or polymers that can be made to be biodegradable and/or bioresorbable with modification. The thickness of each polymer layer is generally at least about 0.01 μm and is generally less than about 150 μm (e.g., 0.01 μm to 150 μm and all values and ranges therebetween); however, other thicknesses can be used. In one non-limiting embodiment, the thickness of a polymer layer and/or layer of agent is about 0.02-75μm, more particularly about 0.05-50 μm, and even more particularly about 1-30 μm. As can be appreciated, other thicknesses can be used.

[0048] In another and/or alternative non-limiting aspect of the present disclosure, the medical device, when including and/or is coated with one or more agents, can include and/or can be coated with one or more agents that are the same or different in different regions of the medical device and/or have differing amounts and/or concentrations in differing regions of the medical device.

For instance, the medical device can 1) be coated with and/or include one or more biologicals on at least one portion of the medical device and at least another portion of the medical device is not coated with and/or includes agent; 2) be coated with and/or include one or more biologicals on at least one portion of the medical device that is different from one or more biologicals on at least another portion of the medical device; and/or 3) be coated with and/or include one or more biologicals at a concentration on at least one portion of the medical device that is different from the concentration of one or more biologicals on at least another portion of the medical device.

[0049] In still yet another and/or alternative non-limiting aspect of the present disclosure, one or more portions of the medical device can optionally 1) include the same or different agents, 2) include the same or different amount of one or more agents, 3) include the same or different polymer coatings, 4) include the same or different coating thicknesses of one or more polymer coatings, 5) have one or more portions of the medical device controllably release and/or uncontrollably release one or more agents, and/or 6) have one or more portions of the medical device controllably release one or more agents and one or more portions of the medical device uncontrollably release one or more agents.

[0050] In still another and/or alternative non-limiting aspect of the present disclosure, one or more surfaces of the medical device can optionally be treated to achieve the desired coating properties of the one or more agents and one or more polymers coated on the medical device. Such surface treatment techniques include, but are not limited to, cleaning, buffing, smoothing, nitriding, annealing, swaging, cold working, etching (chemical etching, plasma etching, etc.), etc. As can be appreciated, other or additional surface treatment processes can be used prior to the coating of one or more agents and/or polymers on the surface of the medical device.

[0051] In yet another and/or alternative non-limiting aspect of the disclosure, the medical device can optionally include a marker material that facilitates enabling the medical device to be properly positioned in a body passageway. The marker material is typically designed to be visible to electromagnetic waves (e.g., x-rays, microwaves, visible light, infrared waves, ultraviolet waves, etc.); sound waves (e.g., ultrasound waves, etc.); magnetic waves (e.g., MRI, etc.); and/or other types of electromagnetic waves (e.g., microwaves, visible light, infrared waves, ultraviolet waves, etc.). The marker material can form all or a portion of the medical device and/or be coated on one or more portions (flaring portion and/or body portion, at ends of medical device, at or near transition of body portion and flaring section, etc.) of the medical device. The location of the

marker material can be on one or multiple locations on the medical device. The size of the one or more regions including the marker material can be the same or different. The marker material can be spaced at defined distances from one another to form ruler-like markings on the medical device to facilitate in the positioning of the medical device in a body passageway. The marker material can be a rigid or flexible material. The marker material can be a biostable or biodegradable material.

[0052] In a further and/or alternative non-limiting aspect of the present disclosure, the medical device or one or more regions of the medical device can optionally be constructed by use of one or more microelectromechanical manufacturing (MEMS) techniques (e.g., micro-machining, laser micro-machining, micro-molding, etc.); however, other or additional manufacturing techniques can be used.

[0053] The medical device can optionally include one or more surface structures (e.g., pore, channel, pit, rib, slot, notch, bump, teeth, needle, well, hole, groove, etc.). These structures can be at least partially formed by MEMS (e.g., micro-machining, etc.) technology and/or other types of technology.

[0054] The medical device can optionally include one or more micro-structures (e.g., micro-needle, micro-pore, micro-cylinder, micro-cone, micro-pyramid, micro-tube, micro-parallelopiped, micro-prism, micro-hemisphere, teeth, rib, ridge, ratchet, hinge, zipper, zip-tie like structure, etc.) on the surface of the medical device. As defined herein, a "micro-structure" is a structure having at least one dimension (e.g., average width, average diameter, average height, average length, average depth, etc.) that is no more than about 2mm, and typically no more than about 1 mm. As can be appreciated, when the medical device includes one or more surface structures, 1) all the surface structures can be micro-structures, 2) all the surface structures can be non-micro-structures, or 3) a portion of the surface structures can be micro-structures and a portion can be non-micro-structures. Typically, the micro-structures (when formed) extend from or into the outer surface no more than about 400 microns (0.01-400 microns and all values and ranges therebetween), and more typically less than about 300 microns, and more typically about 15-250 microns; however, other sizes can be used. The micro-structures can be clustered together or disbursed throughout the surface of the medical device. Similar shaped and/or sized micro-structures and/or surface structures can be used, or different shaped and/or sized micro-structures can be used. When one or more surface structures and/or micro-structures are designed to extend

from the surface of the medical device, the one or more surface structures and/or micro-structures can be formed in the extended position and/or be designed to extend from the medical device during and/or after deployment of the medical device in a treatment area. The micro-structures and/or surface structures can be designed to contain and/or be fluidly connected to a passageway, cavity, etc.; however, this is not required. The one or more surface structures and/or micro-structures can be used to engage and/or penetrate surrounding tissue or organs once the medical device has been positioned on and/or in a patient; however, this is not required. The one or more surface structures and/or micro-structures can be used to facilitate in forming and maintaining a shape of a medical device. In one non-limiting embodiment, the one or more surface structures and/or micro-structures can be at least partially formed of an agent and/or be formed of a polymer. One or more of the surface structures and/or micro-structures can include one or more internal passageways that can include one or more materials (e.g., agent, polymer, etc.); however, this is not required. The one or more coatings and/or one or more surface structures and/or micro-structures of the medical device can be used for a variety of purposes such as, but not limited to, 1) increasing the bonding and/or adhesion of one or more agents, adhesives, marker materials, and/or polymers to the medical device, 2) changing the appearance or surface characteristics of the medical device, and/or 3) controlling the release rate of one or more agents. The one or more micro-structures and/or surface structures can be biostable, biodegradable, etc. The medical device or one or more regions of the medical device can be at least partially covered and/or filled with a protective material to at least partially protect one or more regions of the medical device, and/or one or more micro-structures, and/or surface structures on the medical device from damage. The protective material can include one or more polymers previously identified above. The protective material can be 1) biostable and/or biodegradable and/or 2) porous and/or non-porous.

[0055] In still another and/or alternative aspect of the disclosure, the medical device can optionally be an expandable device that can be expanded by use of some other device (e.g., balloon, etc.). The expandable medical device can be fabricated from a material that has no or substantially no shape-memory characteristics.

[0056] In still yet another and/or alternative non-limiting aspect of the present disclosure, there is optionally provided a near net process for a frame or other metal component of the medical device. In one non-limiting embodiment of the disclosure, there is provided a method of powder pressing materials and increasing the strength post-sintering by imparting additional cold work. In

one non-limiting embodiment, the green part is pressed and then sintered. Thereafter, the sintered part is again pressed to increase its mechanical strength by imparting cold work into the pressed and sintered part. Generally, the temperature during the pressing process after the sintering process is 20-100°C (and all values and ranges therebetween), typically 20-80°C, and more typically 20-40°C. As defined herein, cold working occurs at a temperature of no more than 150°C (e.g., 10-150°C and all values and ranges therebetween). The change in the shape of the repressed post-sintered part needs to be determined so the final part (pressed, sintered and re-pressed) meets the dimensional requirements of the final formed part. For a rhenium metal alloy, a prepress pressure of 1-300 tsi (1 ton per square inch) (and all values and ranges therebetween) can be used followed by a sintering process of at least 1600°C (e.g., 1600-2600°C and all values and ranges therebetween) and a post sintering press at a pressure of 1-300 tsi (and all values and ranges therebetween) at a temperature of at least 20°C (e.g., 20-100°C and all values and ranges therebetween; 20-40°C, etc.). There is also provided a process of increasing the mechanical strength of a pressed metal part by repressing the post-sintered part to add additional cold work into the material, thereby increasing its mechanical strength. There is also provided a process of powder pressing to a near net or final part using metal powder. In one non-limiting embodiment, the metal powder used to form the near net or final part includes a minimum of 40 wt.% rhenium and at least 25 wt.% molybdenum, and the remainder can optionally include one or more elements of tungsten, tantalum, chromium, niobium, zirconium, iridium, titanium, bismuth, and yttrium. In another non-limiting embodiment, the metal powder used to form the near net or final part includes 40-60 wt.% rhenium (and all values and ranges therebetween), and two or more elements of tungsten, tantalum, molybdenum, chromium, niobium, zirconium, iridium, titanium, bismuth, and yttrium. In another non-limiting embodiment, the metal powder used to form the near net or final part includes 40-60 wt.% rhenium (and all values and ranges therebetween), and three or more elements of tungsten, tantalum, molybdenum, chromium, niobium, zirconium, iridium, titanium, bismuth, and yttrium. In another non-limiting embodiment, the metal powder used to form the near net or final part includes 41-58.5 wt.% rhenium (and all values and ranges therebetween), and 18-45 wt.% molybdenum (and all values and ranges therebetween), and one or more additional elements of tantalum, chromium, niobium, zirconium, iridium, titanium, bismuth, and yttrium. In another non-limiting embodiment, the metal powder used to form the near net or final part includes 41-58.5 wt.% rhenium (and all values and ranges therebetween), and 18-45 wt.% molybdenum

(and all values and ranges therebetween), and two or more additional elements of tantalum, chromium, niobium, zirconium, iridium, titanium, bismuth, and yttrium. In another non-limiting embodiment, the metal powder used to form the near net or final part includes 41-58.5 wt.% rhenium (and all values and ranges therebetween), and 18-45 wt.% molybdenum (and all values and ranges therebetween), and one or more elements of tantalum, chromium, niobium, and zirconium, wherein the combined weight percent of the one of more additional elements is 11-41 wt.%. In another non-limiting embodiment, the metal powder used to form the near net or final part includes 41-58.5 wt.% rhenium (and all values and ranges therebetween), and 18-45 wt.% molybdenum (and all values and ranges therebetween), and two or more elements of tantalum, chromium, niobium, and zirconium, wherein the combined weight percent of the two of more additional elements is 11-41 wt.%.

[0057] In still yet another and/or alternative non-limiting aspect of the present disclosure, there is optionally provided a press of near net or finished part composite. The process of pressing metals into near net of finished parts is well established; however, pressing a composite structure formed of metal powder and polymer for purposes of making complex part geometries and foam-like structures is new. Similarly, using a pressing process to impart particular biologic substances into the metal matrix is also new. In one non-limiting embodiment, there is provided a process of creating a metal part with pre-defined voids to create a trabecular or foam structure composed of mixing a metal and polymer powder, pressing the powder into a finished part or semi-finished green part, and then sintering the part under which conditions the polymer leaves the metal behind through a process of thermal degradation of the polymer. The resulting part has a porosity associated with the size of the polymer particles as well as the homogeneity of the mixture upon pressing prior to sintering. In another non-limiting embodiment, there is provided a process by which a residual of the polymer is left behind after thermal degradation, on the metal substrate, and the polymer residual has some desired biological affect (e.g., masking the metal from the body by encapsulation, promotion of cellular attachment and growth). The polymer and metal powders can be of varying sizes to create multiple voids--some large to create a pathway for cellular growth, and some small to create a ruff surface to promote cellular attachment.

[0058] As can be appreciated, the polymer can be uniformly or non-uniformly dispersed with the metal powder. For example, if the final formed part is to have a uniform density and pore structure, the polymer material is uniformly dispersed with the metal powder prior to consolidating

and pressing the polymer and metal powders together and then subsequently sintering together the metal powder to form the metal part or medical device. Alternatively, if the formed metal part or medical device is to have one or more channels, passageways, and/or voids on the outer surface and/or within the formed part or medical device, at least a portion of the polymer is not uniformly distributed with the metal powder, but instead is concentrated or forms all of the region that is to be the one or more channels, passageways, and/or voids on the outer surface and/or within the formed part or medical device such that when the polymer and metal powder is sintered, some or all of the polymer is degraded and removed from the part or medical device, thereby forming such one or more channels, passageways, and/or voids on the outer surface and/or within the formed part or medical device. As such, the use of the polymer in combination with metal powder and subsequent pressing and sintering can be used to form novel and customized shapes for the medical device or the near net form of the medical device. Generally, the polymer constitutes about 0.1-70 vol.% (and all values and ranges therebetween) of the consolidated and pressed material prior to the sintering step, typically the polymer constitutes about 1-60 vol.% of the consolidated and pressed material prior to the sintering step, more typically the polymer constitutes about 2-50 vol.% of the consolidated and pressed material prior to the sintering step, and even more typically the polymer constitutes about 2-45 vol.% of the consolidated and pressed material prior to the sintering step. As such, if the polymer constitutes about 5 vol.% of the consolidated and pressed material prior to the sintering step, if after the sintering step at least 99% of the polymer is degraded and removed from the part or medical device, then the part could include up to about 5 vol.% cavities and/or passageways in the part or medical device.

[0059] The type of polymer and the type of metal powder is non-limiting. The polymer and metal powders can be of varying sizes to create multiple voids/passageways/channels which can be used to create a pathway for cellular growth, create a ruff surface to promote cellular attachment, have a biological agent inserted into one or more of the voids/passageways/channels, have biological material inserted into one or more of the voids/passageways/channels, etc. In one non-limiting embodiment, the average particle size of the polymer is greater than the average particle size of the metal powder.

[0060] In another non-limiting aspect of the present disclosure, after the sintering process, at least 98 vol.% of the polymer is thermally degraded and/or removed from the sintered material, typically at least 99 vol.% of the polymer is thermally degraded and/or removed from the sintered

material, more typically at least 99.5 vol.% of the polymer is thermally degraded and/or removed from the sintered material, still even more typically at least 99.9 vol.% of the polymer is thermally degraded and/or removed from the sintered material, and even still more typically at least 99.95 vol.% of the polymer is thermally degraded and/or removed from the sintered material. The resulting part or medical device has a porosity associated with the size of the polymer particles as well as the homogeneity of the mixture upon pressing prior to sintering.

[0061] In another non-limiting aspect of the present disclosure, after the sintering process, some of the polymer remains in the sintered part of the medical device. The remaining polymer in the sintered part of the medical device can optionally have some desired biological affect (e.g., masking the metal from the body by encapsulation, promotion of cellular attachment and growth). The remaining polymer can optionally include one or more biological agents that remain active after the sintering process. In one non-limiting embodiment, after the sintering process, about 5-97.5 vol.% (and all values and ranges therebetween) of the polymer is thermally degraded and/or removed from the sintered material, typically about 10-95 vol.% of the polymer is thermally degraded and removed from the sintered material, and more typically about 10-80 vol.% of the polymer is thermally degraded and removed from the sintered material.

[0062] In a further and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy used to at least partially form the medical device is initially formed into a blank, a rod, a tube, etc., and then finished into final form by one or more finishing processes. The rhenium metal alloy blank, rod, tube, etc., can be formed by various techniques such as, but not limited to, 1) melting the rhenium metal alloy and/or metals that form the rhenium metal alloy (e.g., vacuum arc melting, etc.) and then extruding and/or casting the rhenium metal alloy into a blank, rod, tube, etc., 2) melting the rhenium metal alloy and/or metals that form the rhenium metal alloy, forming a metal strip, and then rolling and welding the strip into a blank, rod, tube, etc., or 3) consolidating the metal powder of the rhenium metal alloy and/or metal powder of metals that form the rhenium metal alloy into a blank, rod, tube, etc. When the rhenium metal alloy is formed into a blank, the shape and size of the blank is non-limiting. In one non-limiting process, the near net medical device, blank, rod, tube, etc., can be formed from one or more ingots of metal or rhenium metal alloy. In one non-limiting process, an arc melting process (e.g., vacuum arc melting process, etc.) can be used to form the near net medical device, blank, rod, tube, etc. In another non-limiting process, rhenium powder and tungsten powder and optionally molybdenum powder can be placed

in a crucible (e.g., silica crucible, etc.) and heated under a controlled atmosphere (e.g., vacuum environment, carbon monoxide environment, hydrogen and argon environment, helium, argon, etc.) by an induction melting furnace to form the near net medical device, blank, rod, tube, etc. It can be appreciated that other or additional processes can be used to form the rhenium metal alloy. In one non-limiting 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 2-63 microns, and more particularly about 5-40 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. Typically, the carbon content of the metal powder used to form the rhenium metal alloy is less than about 100 ppm, the oxygen content is less than about 50 ppm, and the nitrogen content is less than about 20 ppm. Typically, metal powder used to form the rhenium metal alloy has a purity grade of at least 99.9 and more typically at least about 99.95. The blend of metal powder is then pressed together to form a solid solution of the rhenium metal alloy into a near net medical device, blank, rod, tube, etc. Typically, the pressing process is by an isostatic process (i.e., uniform pressure applied from all sides on the metal powder); however other processes can be used. 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 performed 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 near net medical device, blank, rod, tube, etc., that is achieved by pressing together the metal powders is about 80-95% (and all values and ranges therebetween) of the final average density of the near net medical device, blank, rod, tube, etc., or about 70-96% (and all values and ranges therebetween) the minimum theoretical density of the rhenium metal alloy. Pressing pressures of at least about 300 MPa are generally used. Generally, the pressing pressure is about 400-700MPa; however, other pressures can be used. After the metal powders are pressed together, the pressed metal powders are sintered at a temperature of at least 1600°C (e.g., 1600-3500°C and all values and ranges therebetween) to partially or fully fuse the metal powders together to form the near net medical device, blank, rod, tube, etc. The sintering of the consolidated metal powder can be performed in an oxygen-reducing atmosphere (e.g., helium, argon, 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 near net medical device, blank, rod, tube, etc. The sintered metal powder generally has an as-sintered average density of about 90-99% the minimum theoretical density of the rhenium metal alloy. Typically, the sintered rhenium metal alloy has a final average density of at least about 5 gm/cc, and typically at least about 8.3 gm/cc, and can be up to or greater than about 16 gm/cc; however, this is not required. The density of the formed near net medical device, blank, rod, tube, etc., will generally depend on the type of rhenium metal alloy used.

[0063] In yet a further and/or alternative non-limiting aspect of the present disclosure, the near net medical device, blank, rod, tube, etc., can optionally be cleaned and/or polished after the near net medical device, blank, rod, tube, etc., has been form; however, this is not required. Typically, the near net medical device, blank, rod, tube, etc., is cleaned and/or polished prior to being further processed; however, this is not required. When the near net medical device, blank, rod, tube, etc., is resized and/or annealed, the resized and/or annealed, the near net medical device, blank, rod, tube, etc., 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 near net medical device, blank, rod, tube, etc., is used to remove impurities and/or contaminants from the surfaces of the near net medical device, blank, rod, tube, etc. Impurities and contaminants can become incorporated into the rhenium metal alloy during the processing of the near net medical device, blank, rod, tube, etc. The inadvertent incorporation of impurities and contaminants in the near net medical device, blank, rod, tube, etc., can result in an undesired amount of carbon, nitrogen and/or oxygen, and/or other impurities in the rhenium metal alloy. The inclusion of impurities and contaminants in the rhenium metal alloy can result in premature micro-cracking of the rhenium metal alloy and/or an adverse effect on one or more physical properties of the rhenium metal alloy (e.g., decrease in tensile elongation, increased ductility, increased brittleness, etc.). The cleaning of the rhenium 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 rhenium metal alloy with a Kimwipe or other appropriate towel, 2) by at least partially dipping or immersing the rhenium metal alloy in a solvent and then ultrasonically cleaning the rhenium metal alloy, and/or 3) by at least partially dipping or immersing the rhenium metal alloy in a pickling solution. As can be appreciated, the rhenium metal alloy can be cleaned in other or additional ways. If the

rhenium metal alloy is to be polished, the rhenium metal alloy is generally polished by use of a polishing solution that typically includes an acid solution; however, this is not required.

[0064] In still yet a further and/or alternative non-limiting aspect of the present disclosure, the near net medical device, blank, rod, tube, etc., can be resized to the desired dimension of the medical device. In one non-limiting embodiment, the cross-sectional area or diameter of the near net medical device, blank, rod, tube, etc., is reduced to a final near net medical device, blank, rod, tube, etc. dimension in a single step or by a series of steps. The reduction of the outer cross-sectional area or diameter of the near net medical device, blank, rod, tube, etc., may be obtained by centerless grinding, turning, electropolishing, drawing process, grinding, laser cutting, shaving, polishing, EDM cutting, etc. The outer cross-sectional area or diameter size of the near net medical device, blank, rod, tube, etc., can be reduced by the use of one or more drawing processes; however, this is not required. During the drawing process, care should be taken to not form micro-cracks in the near net medical device, blank, rod, tube, etc., during the reduction of the near net medical device, blank, rod, tube, etc., outer cross-sectional area or diameter.

[0065] In still a further and/or alternative non-limiting aspect of the present disclosure, the near net medical device, blank, rod, tube, etc., during the drawing process can optionally be nitrided; however, this is not required. The nitrided layer on the near net medical device, blank, rod, tube, etc., can function as a lubricating surface during the drawing process to facilitate in the drawing of the near net medical device, blank, rod, tube, etc. The near net medical device, blank, rod, tube, etc., is generally nitrided in the presence of nitrogen or a nitrogen mixture.

[0066] In still yet another and/or alternative non-limiting aspect of the present disclosure, the rhenium metal alloy near net medical device, blank, rod, tube, etc., after being formed to the desired medical device, can be cleaned, polished, sterilized, nitrided, etc., for final processing of the medical device. In one non-limiting embodiment of the disclosure, 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 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 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 cleaned in other or additional ways.

[0067] The use of the rhenium metal alloy to form all or a portion of the medical device can result in several advantages over medical devices formed from other materials. These advantages include, but are not limited to:

[0068] • The rhenium metal alloy has increased strength and/or hardness compared with stainless steel or chromium-cobalt alloys or titanium alloys, thus a lesser quantity of rhenium metal alloy can be used in the medical device to achieve similar strengths 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 rhenium metal alloy without sacrificing the strength and durability of the medical device. The medical device can also have a smaller profile, thus can be inserted into smaller areas, openings, and/or passageways. The thinner struts of rhenium metal alloy to form the frame or other portions of the medical device can be used to form a frame or other portion of the medical device having a strength that would require thicker struts or other structures of the medical device when formed by stainless steel, chromium-cobalt alloys, or titanium alloys.

[0069] • The increased strength of the rhenium metal alloy also results in the increased radial strength of the medical device. For instance, the thickness of the walls of 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, cobalt and chromium alloy, or titanium alloy.

[0070] • The rhenium metal alloy has improved stress-strain properties, bendability properties, elongation properties, and/or flexibility properties of the medical device compared with stainless steel or chromium-cobalt alloys, thus resulting in an increased life for the medical device. For instance, the medical device can be used in regions that subject the medical device to repeated bending. Due to the improved physical properties of the medical device from the rhenium metal alloy, the medical device has improved resistance to fracturing in such frequent bending environments. These improved physical properties at least in part result from the composition of the rhenium metal alloy, the grain size of the rhenium metal alloy, the carbon, oxygen, and nitrogen content of the rhenium metal alloy, and/or the carbon/oxygen ratio of the rhenium metal alloy.

[0071] • The rhenium metal alloy has a reduced degree of recoil during the crimping and/or expansion of the medical device compared with stainless steel or chromium-cobalt alloys or titanium alloys. The medical device formed of the rhenium metal alloy better maintains its crimped form and/or better maintains its expanded form after expansion due to the use of the rhenium 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 to facilitate in the success of the medical device in the treatment area.

[0072] • The use of rhenium metal alloy in the medical device medical device results in the medical device better conforming to an irregularly shaped body passageway when expanded in the body passageway as compared to a medical device formed by stainless steel, chromium-cobalt alloys, or titanium alloys.

[0073] • The rhenium metal alloy has improved radiopaque properties 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 rhenium metal alloy is at least about 10-20% more radiopaque than stainless steel or cobalt-chromium alloy.

[0074] • The rhenium metal alloy has improved fatigue ductility when subjected to cold-working as compared to the cold-working of stainless steel, chromium-cobalt alloys, or titanium alloys.

[0075] • The rhenium metal alloy has improved durability compared to stainless steel, chromium-cobalt alloys, or titanium alloys.

[0076] • The rhenium metal alloy has improved hydrophilicity compared to stainless steel, chromium-cobalt alloys, or titanium alloys.

[0077] • The rhenium metal alloy has reduced ion release in the body passageway as compared to stainless steel, chromium-cobalt alloys, or titanium alloys.

[0078] • The rhenium metal alloy is less of an irritant to the body than stainless steel, cobalt-chromium alloy, or titanium alloys, thus can result in reduced inflammation, faster healing, and increased success rates of the medical device. When the medical device 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 rhenium metal alloy compared to other metals such as stainless steel, cobalt-chromium alloy, or titanium alloy.

[0079] The medical devices which include expandable metal frames that are at least partially formed of rhenium metal alloy exhibit reduced amount of recoil, improved bending conformity, and greater radial strength compared to expandable frames formed of stainless steel, cobalt-chromium alloy, and TiAlV alloy, thereby resulting in the following non-limiting advantages

compared to expandable frames formed of stainless steel, cobalt-chromium alloy, or TiAlV alloy: 1) the formation of a frame for a medical device having thinner posts, struts, and/or strut joints which results in i) safer vascular access when inserting the medical device through a body passageway and to the treatment area, and/or ii) decreased risk of bleeding and/or damage to the body passageway and/or the treatment area when the medical device is delivered to the treatment area and/or expanded at the treatment area; 2) easier deliverability of the medical device to the treatment area which can result in i) decreased trauma to the body passageway (e.g., blood vessel, aortic arch trauma, etc.) during the insertion and/or expansion of the medical device at the treatment area, and/or ii) decreased risk of neuro complications-stroke; 3) less recoil which results in i) reduced crimping profile size, ii) increased conformability of the expanded medical device at the treatment area after expansion in the treatment area, iii) increased radial strength of the frame of the medical device after expansion at the treatment area, iv) only require a single crimping cycle to crimp the medical device on a balloon catheter or other type of delivery device, v) reduced incidence of damage to components of the medical device (e.g., struts, posts, strut joints, and/or other components of the expandable frame, leaflets, skirts, coatings, etc.) during the crimping, expansion, and operation of the medical device, vi) greater effective orifice area (EOA) of the medical device after expansion of the medical device, vi) decreased pulmonary valve regurgitation (PVR) after expansion of the medical device in the treatment area, and/or vii) require only a single expansion cycle of the balloon on the balloon catheter or other expansion mechanism to fully expand the medical device; and/or 4) creating a medical device having superior material biologic properties to i) improve tissue adhesion and/or growth on or about medical device, ii) reduce adverse tissue reactions with the medical device, iii) reduce toxicity of medical device, iv) potentially decrease in-valve thrombosis during the life of the medical device, and/or v) reduce the incidence of infection during the life of the medical device.

[0080] Medical devices, such as expandable medical devices (e.g., expandable heart valves, stents, etc.) that include the rhenium metal alloy in accordance with the present disclosure overcome several unmet needs that exist in expandable medical device that are formed of cobalt-chromium alloys, TiAlV alloys, and stainless steel. Such unmet needs addressed by the medical devices in accordance with the present disclosure include 1) not having to form a large hole in large arterial vessels or other blood vessels for initial insertion of the crimped medical device into the atrial vessel or other blood vessel, thereby reducing the incidence of lethal bleeding during a

treatment; 2) enabling the medical device to be delivered and implanted in abnormally shaped heart valves or through an abnormally shaped arterial vessel due to calcination in the heart valve and/or calcination and/or plaque in the arterial vessel by creating a medical device (e.g., stent, prosthetic heart valve, etc.) that has a reduced crimped profile smaller than medical devices formed of cobalt-chromium alloys, TiAlV alloys, and stainless steel; 3) reducing the incidence of a perivalvular leak and/or other types of leakage about the implanted medical device when the medical device is expanded in the treatment region by using a frame formed of the rhenium metal alloy that better conforms to the shape of the abnormally shaped heart valve orifice upon expansion of the prosthetic heart valve as comparted to prior art prosthetic heart valves formed of cobalt-chromium alloys, TiAlV alloys, and stainless steel, thereby reducing the incidence of stroke and/or by increasing the incidence of success of the implanted medical device; 4) improving the radial strength of the expanded struts, posts, and/or strut joints in the expandable frame and the strength of the expandable frame itself after expansion the medical device; 5) reducing the amount of recoil of the expandable frame during the crimping and/or expansion of the expandable frame of the medical device; 6) enabling the medical device to be used in a heart that has a permanent pacemaker; 7) reducing the incidence of minor stroke during the insertion and operation of the medical device at the treatment area; 8) reducing the incidence of coronary ostium compromise; 9) improving foreshortening; 10) reducing further aortic valve calcification and/or calcification in a blood vessel after implantation of the medical device; 11) reducing the need for multiple crimping cycles when inserting the medical device on a catheter or other type of delivery system; 12) reducing the incidence of frame/stent fracture during the crimping and/or expansion of the medical device; 13) reducing the incidence of biofilm-endocarditis after implantation of the medical device; 14) reducing allergic reactions to the medical device after implantation of the medical device; 15) improving the hydrophilicity of the medical device to improve tissue growth on and/or about the implanted medical device, 16) reducing the magnetic susceptibility of the medical device, 17) reducing the toxicity of the medical device, 18) reducing the amount of metal ion release from the medical device, and/or 19) increasing the longevity of leaflets and/or stent/frame and/or other components of the medical device after insertion of the medical device.

[0081] One non-limiting object of the present disclosure is the provision of rhenium metal alloy in accordance with the present disclosure that can be used to partially or fully form a medical device.

[0082] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that is partially or fully formed of the rhenium metal alloy of the present disclosure and which medical device has improved procedural success rates.

[0083] Another and/or alternative non-limiting object of the present disclosure is the provision of a method and process for forming the rhenium metal alloy in accordance with the present disclosure that inhibits or prevents the formation of micro-cracks during the processing of the rhenium metal alloy.

[0084] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that is partially or fully formed of the rhenium metal alloy in accordance with the present disclosure and wherein the medical device has improved physical properties.

[0085] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that is at least partially formed of the rhenium metal alloy in accordance with the present disclosure wherein the medical device has increased strength and/or hardness.

[0086] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that at least partially includes the rhenium metal alloy in accordance with the present disclosure and which rhenium metal alloy enables the medical device to be formed with less material without sacrificing the strength of the medical device as compared to prior medical devices.

[0087] Another and/or alternative non-limiting object of the present disclosure is the provision of a method and process for forming the rhenium metal alloy in accordance with the present disclosure to inhibit or prevent the formation of micro-cracks during the processing of the rhenium metal alloy into a medical device.

[0088] Another and/or alternative non-limiting object of the present disclosure is the provision of a method and process for forming the rhenium metal alloy in accordance with the present disclosure that inhibits or prevents crack propagation and/or fatigue failure of the rhenium metal alloy.

[0089] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy that has had a nitriding process to form a nitrided layer on the outer surface of the rhenium metal alloy.

[0090] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the refractor alloy has been

subjected to a swaging process.

[0091] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the refractor alloy has been subjected to a cold-working process.

[0092] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy that has increased strength and/or hardness compared with stainless steel, chromium-cobalt alloys, or titanium alloys.

[0093] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy, thereby requiring a lesser quantity of rhenium metal alloy to achieve similar strengths compared to medical devices formed of different metals.

[0094] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has a smaller crimped profile compared to medical devices formed of different metals.

[0095] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has thinner walls and still achieves a similar or improved radial strength compared with thicker walled medical devices formed of stainless steel, chromium-cobalt alloy, or titanium alloys.

[0096] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has improved stress-strain properties, bendability properties, elongation properties, and/or flexibility properties compared to medical devices formed of stainless steel, titanium steel, or chromium-cobalt alloys.

[0097] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has an increased life compared to medical devices formed of stainless steel, titanium steel, or chromium-cobalt alloys.

[0098] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has a reduced degree of recoil during the crimping and/or expansion of the medical device compared with stainless steel, chromium-cobalt alloys, or titanium alloys.

[0099] Another and/or alternative non-limiting object of the present disclosure is the provision

of a medical device that includes a rhenium metal alloy wherein the medical device better conforms to an irregularly shaped body passageway when expanded in the body passageway as compared to a medical device formed by stainless steel, chromium-cobalt alloys, or titanium alloys.

[00100] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has improved fatigue ductility when subjected to cold-working as compared to the cold-working of stainless steel, chromium-cobalt alloys, or titanium alloys.

[00101] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has improved durability compared to stainless steel, chromium-cobalt alloys, or titanium alloys.

[00102] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has improved hydrophilicity compared to stainless steel, chromium-cobalt alloys, or titanium alloys.

[00103] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device has reduced ion release in the body passageway compared to stainless steel, chromium-cobalt alloys, or titanium alloys.

[00104] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the medical device is less of an irritant to the body than stainless steel or cobalt-chromium alloy or titanium alloys, thus can result in reduced inflammation, faster healing, and increased success rates of the medical device.

[00105] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals selected from the group consisting of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium.

[00106] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals selected from the group consisting of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium; and

wherein a combined weight percentage of rhenium and alloy metals in said rhenium metal alloy is greater than or equal to the weight percent of molybdenum in the rhenium metal alloy.

[00107] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein a weight percent of molybdenum in the rhenium metal alloy is at least 10 wt.% and less than 60 wt.%; a weight percent of rhenium in the rhenium metal alloy is 35-60 wt.%; a combined weight percent of the alloying metals is 5-45 wt.% of the rhenium metal alloy; and wherein a combined weight percentage of rhenium and alloy metals in said rhenium metal alloy is greater than or equal to the weight percent of molybdenum in the rhenium metal alloy.

[00108] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein a weight percent of the rhenium in the rhenium metal alloy is greater than the combined weight percent of the alloying metals.

[00109] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein a combined weight percent of the rhenium, molybdenum, and the one or more alloying metals in the rhenium metal alloy is at least 99.9 wt.%.

[00110] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy includes chromium.

[00111] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy includes chromium and one or more metals selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium.

[00112] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the one or more alloying agents include chromium and one metal selected from the group consisting of bismuth, zirconium,

iridium, niobium, tantalum, titanium, and yttrium; and wherein an atomic ratio of the chromium to an atomic ratio of the one or more metals selected from the group consisting of zirconium, niobium, and tantalum is 0.4:1 to 2.5:1 (and all values and ranges therebetween).

[00113] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the one or more alloying agents include chromium and one or more metals selected from the group consisting of zirconium, niobium, and tantalum.

[00114] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and a first metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium, and a second metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium; and wherein the first and second metals are different.

[00115] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and a first metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium, and a second metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium; and wherein the first and second metals are different; and wherein an atomic ratio of the first metal to the second metal is 0.4:1 to 2.5:1 (and all values and ranges therebetween).

[00116] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and a first metal selected from the group consisting of chromium, niobium, tantalum, and zirconium, and a second metal selected from the group consisting of chromium, niobium, tantalum, and zirconium; and wherein an atomic ratio of the first metal to the second metal is 0.4:1 to 2.5:1 (and all values and ranges therebetween).

[00117] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the rhenium metal alloy includes less than 0.1 wt.% metals and impurities.

[00118] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the rhenium metal alloy has a controlled amount of nitrogen, oxygen, and carbon to reduce micro-cracking in said rhenium metal alloy, a nitrogen content in said rhenium metal alloy is less than a combined content of oxygen and carbon in said rhenium metal alloy, said rhenium metal alloy has an oxygen to nitrogen atomic ratio of at least about 1.2:1, said rhenium metal alloy has a carbon to nitrogen atomic ratio of at least about 2:1.

[00119] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein at least one region of the medical device includes at least one biological agent.

[00120] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein at least one region of the medical device includes at least one region of said medical device includes at least one polymer.

[00121] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein at least one region of the medical device includes at least one polymer, the at least one polymer at least partially coats, encapsulates, or combinations thereof at least one biological agent.

[00122] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein at least one region of the medical device includes at least one micro-structure on an outer surface of the medical device.

[00123] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein at least one region of the medical device includes at least one micro-structure on an outer surface of the medical device; and wherein the at least one microstructure is at least partially formed of, includes, or combinations thereof, a material consisting of a polymer, an agent, or combinations thereof.

[00124] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the medical device includes an expandable frame.

[00125] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the medical device includes an expandable frame; wherein the expandable frame includes a plurality of struts.

[00126] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the medical device includes an expandable frame; wherein the expandable frame is configured to be crimped to a crimped state such that a maximum outer diameter of the expandable frame when in the crimped state is less than a maximum outer diameter of the expandable frame when fully expanded to an expanded state.

[00127] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the medical device includes an expandable frame; wherein the expandable frame has a recoil of less than 5% after being subjected to a first crimping process.

[00128] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the medical device includes an expandable frame; wherein the expandable frame has a recoil of less than 5% after being expanded from the crimped state to the expanded state.

[00129] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the rhenium metal alloy has a hydrophilicity wherein a contact angle of a water droplet on a surface of the rhenium metal alloy of 25-45° (and all values and ranges therebetween).

[00130] Another and/or alternative non-limiting object of the present disclosure is the provision

of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the rhenium metal alloy has a maximum ion release of a primary component of the rhenium metal alloy when inserted or implanted on or in the body of the patient of no more than 0.5 $\mu g/cm^2$ per day; and wherein a primary component of the rhenium alloy is a metal in the rhenium alloy that constitutes at least 2 wt.% of the rhenium metal alloy.

[00131] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the rhenium metal alloy has an absolute increase in ion release per dose of the rhenium metal alloy in tissue about the medical device of no more than 50 days after inserted or implanted on or in the body of a patient.

[00132] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the medical device is an expandable stent or an expandable prosthetic heart valve.

[00133] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises rhenium, molybdenum, and one or more alloying metals; and wherein the one or more alloying metals selected from the group consists of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium; and wherein a combined weight percentage of rhenium and alloy metals in the rhenium metal alloy is greater than or equal to the weight percent of molybdenum in the rhenium metal alloy; and wherein a weight percent of molybdenum in the rhenium metal alloy is at least 10 wt.% and less than 60 wt.%; and wherein a weight percent of rhenium in the rhenium metal alloy is 35-60 wt.%; and wherein a combined weight percent of the alloying metals is 5-45 wt.% of the rhenium metal alloy; and wherein a weight percent of the rhenium in the rhenium metal alloy is greater than a combined weight percent of the alloying metals; and wherein a combined weight percent of the rhenium, molybdenum, and the one or more alloying metals in the rhenium metal alloy is at least 99.9 wt.%.

[00134] Another and/or alternative non-limiting object of the present disclosure is the provision of a medical device that includes a rhenium metal alloy wherein the rhenium metal alloy comprises

rhenium, molybdenum, and one or more alloying metals; and wherein the rhenium metal alloy has a maximum ion release of a primary component of the rhenium metal alloy when inserted or implanted on or in the body of the patient of no more than 0.5 $\mu g/cm^2$ per day; and wherein a primary component of the rhenium alloy is a metal in the rhenium alloy that constitutes at least 2 wt.% of the rhenium metal alloy.

[00135] These and other advantages will become apparent to those skilled in the art upon the reading and following of this description.

[00136] Although specific terms are used in the following description for the sake of clarity, these terms are intended to refer only to the particular structure of the embodiments selected for illustration in the drawings and are not intended to define or limit the scope of the disclosure. In the drawings and the following description below, it is to be understood that like numeric designations refer to components of like function.

[00137] The singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

[00138] As used in the specification and in the claims, the term "comprising" may include the embodiments "consisting of" and "consisting essentially of." The terms "comprise(s)," "include(s)," "having," "has," "can," "contain(s)," and variants thereof, as used herein, are intended to be open-ended transitional phrases, terms, or words that require the presence of the named ingredients/steps and permit the presence of other ingredients/steps. However, such description should be construed as also describing compositions or processes as "consisting of" and "consisting essentially of" the enumerated ingredients/steps, which allows the presence of only the named ingredients/steps, along with any unavoidable impurities that might result therefrom, and excludes other ingredients/steps.

[00139] Numerical values in the specification and claims of this application should be understood to include numerical values which are the same when reduced to the same number of significant figures and numerical values which differ from the stated value by less than the experimental error of conventional measurement technique of the type described in the present application to determine the value.

[00140] All ranges disclosed herein are inclusive of the recited endpoint and independently combinable (for example, the range of "from 2 grams to 10 grams" is inclusive of the endpoints, 2 grams and 10 grams, and all the intermediate values).

[00141] The terms "about" and "approximately" can be used to include any numerical value that can vary without changing the basic function of that value. When used with a range, "about" and "approximately" also disclose the range defined by the absolute values of the two endpoints, e.g. "about 2 to about 4" also discloses the range "from 2 to 4." Generally, the terms "about" and "approximately" may refer to plus or minus 10% of the indicated number.

[00142] Percentages of elements should be assumed to be percent by weight of the stated element, unless expressly stated otherwise.

[00143] In one non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals selected from the group consisting of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium.

[00144] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein a combined weight percentage of rhenium and alloy metals in the rhenium metal alloy is greater than or equal to the weight percent of molybdenum in the rhenium metal alloy.

[00145] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein a weight percent of molybdenum in the rhenium metal alloy is at least 10 wt.% and less than 60 wt.%; a weight percent of rhenium in the rhenium metal alloy is 35-60 wt.%; and a combined weight percent of the alloying metals is 5-45 wt.% of said rhenium metal alloy.

[00146] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein a weight percent of the rhenium in the rhenium metal alloy is greater than the combined weight percent of the alloying metals.

[00147] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein a combined weight percent of the rhenium, the molybdenum, and the one or more alloying metals in the rhenium metal alloy is at least 99.9 wt.%.

[00148] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the alloying metal includes chromium.

[00149] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the alloying metal includes chromium and one metal selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium.

[00150] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein an atomic ratio of chromium to an atomic ratio of the one or more metals selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium is 0.4:1 to 2.5:1.

[00151] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the alloying metal includes chromium and one or more metals selected from the group consisting of zirconium, niobium, and tantalum.

[00152] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein an atomic ratio of chromium to an atomic ratio of one or more metals selected from the group consisting of zirconium, niobium, and tantalum is 0.4:1 to 2.5:1.

[00153] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the alloying metal includes a first metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium, and a second metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium; and wherein the first and second metals are different; and wherein an atomic ratio of the first metal to the second metal is 0.4:1 to 2.5:1.

[00154] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the alloying metal includes a first metal selected from the group consisting of chromium, niobium, tantalum, and zirconium, and a second metal selected from the group consisting of chromium,

niobium, tantalum, and zirconium; and wherein the first and the second metals are different; and wherein an atomic ratio of the first metal to the second metal is 0.4:1 to 2.5:1.

[00155] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy includes less than 0.1 wt.% metals and impurities.

[00156] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein an atomic ratio of Re to total content of the alloying metal is 0.8:1 to 1.25:1.

[00157] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy has a controlled amount of nitrogen, oxygen, and carbon to reduce micro-cracking in said rhenium metal alloy, a nitrogen content in said rhenium metal alloy is less than a combined content of oxygen and carbon in said rhenium metal alloy, said rhenium metal alloy has an oxygen to nitrogen atomic ratio of at least about 1.2:1, said rhenium metal alloy has a carbon to nitrogen atomic ratio of at least about 2:1.

[00158] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy is used to at least partially form a medical device.

[00159] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy is used to at least partially form a medical device; and wherein at least one region of the medical device includes at least one biological agent.

[00160] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy is used to at least partially form a medical device; and wherein at least one region of the medical device includes at least one polymer.

[00161] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy is used to at least partially form a medical device; and wherein at least one region of the medical device includes at least one polymer, the at least one polymer at least partially coats, encapsulates, or combinations thereof at least one biological agent.

[00162] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy is used to at least partially form a medical device; and wherein at least one micro-structure is located on an outer surface of the medical device; and wherein the at least one microstructure optionally is at least partially formed of, includes, or combinations thereof, a material consisting of a polymer, an agent, or combinations thereof.

[00163] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy is used to at least partially form a medical device; and wherein the medical device includes an expandable frame formed of the rhenium metal alloy; the expandable frame including a plurality of struts; the expandable frame is optionally configured to be crimped to a crimped state such that a maximum outer diameter of the expandable frame when in the crimped state is less than a maximum outer diameter of the expandable frame when fully expanded to an expanded state; and wherein the expandable frame optionally has a recoil of less than 5% (e.g., 0.1-4.99 and all values and ranges therebetween) after being subjected to a first crimping process; and wherein the expandable frame optionally has a recoil of less than 5% (e.g., 0.1-4.99 and all values and ranges therebetween) after being expanded from the crimped state to the expanded state; and wherein the rhenium metal alloy optionally has a hydrophilicity wherein a contact angle of a water droplet on a surface of said rhenium metal alloy of 25-45° (e.g., 0.1-4.99 and all values and ranges therebetween); and wherein the rhenium metal alloy optionally has a maximum ion release of a primary component of said rhenium metal alloy when inserted or implanted on or in the body of the patient of no more than 0.5 $\mu g/cm^2$ per day (e.g., 0.001-0.5 $\mu g/cm^2$ per day and all values and ranges therebetween); and wherein the primary component constitutes at least 2 wt.% of the rhenium metal alloy; and wherein the rhenium metal alloy optionally has an absolute increase in ion release per dose of rhenium metal alloy in tissue about said medical device of no more than 50 days after inserted or implanted on or in the body of a patient.

[00164] In another non-limiting object of the present disclosure, there is provided a rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy is used to at least partially form a medical device; and wherein the medical device is an expandable stent or an expandable prosthetic heart valve.

[00165] In another non-limiting object of the present disclosure, there is provided a rhenium

metal alloy comprising rhenium, molybdenum, and one or more alloying metals, and wherein the rhenium metal alloy is optionally used to at least partially form a medical device; and wherein the one or more alloying metals are selected from the group consisting of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium; and wherein a combined weight percentage of rhenium and alloy metals in the rhenium metal alloy is optionally greater than or equal to a weight percent of molybdenum in the rhenium metal alloy; and wherein a weight percent of molybdenum in the rhenium metal alloy is at least 10 wt.% and less than 60 wt.% (and all values and ranges therebetween); and wherein a weight percent of rhenium in the rhenium metal alloy is 35-60 wt.% (and all values and ranges therebetween); and wherein a combined weight percent of the alloying metals is 5-45 wt.% of the rhenium metal alloy (and all values and ranges therebetween); and wherein a weight percent of the rhenium in the rhenium metal alloy is optionally greater than a combined weight percent of the alloying metals; and wherein a combined weight percent of the rhenium, molybdenum, and the one or more alloying metals in the rhenium metal alloy is at least 99.9 wt.%; and wherein the rhenium metal alloy optionally has a maximum ion release of a primary component of the rhenium metal alloy when inserted or implanted on or in a body of a patient of no more than 0.5 $\mu g/cm^2$ per day (e.g., 0.001-0.5 $\mu g/cm^2$ per day and all values and ranges therebetween); and wherein the primary component constitutes at least 2 wt.% of the rhenium metal alloy.

[00166] 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 disclosure, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense. The disclosure 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 disclosure provided herein. This disclosure is intended to include all such modifications and alterations insofar as they come within the scope of the present disclosure. It is also to be understood that the following claims are intended to cover all of the generic and specific features of the disclosure herein described and all statements of the scope of the disclosure, which, as a matter of language, might be said to fall therebetween.

What is claimed:

1. A rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals selected from the group consisting of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium; a combined weight percentage of rhenium and alloy metals in said rhenium metal alloy is greater than or equal to the weight percent of molybdenum in said rhenium metal alloy; a weight percent of molybdenum in said rhenium metal alloy is at least 10 wt.% and less than 60 wt.%; a weight percent of rhenium in said rhenium metal alloy is 35-60 wt.%; a combined weight percent of said alloying metals is 5-45 wt.% of said rhenium metal alloy; a weight percent of said rhenium in said rhenium metal alloy is greater than said combined weight percent of said alloying metals; a combined weight percent of said rhenium, said molybdenum, and said one or more alloying metals in said rhenium metal alloy is at least 99.9 wt.%.

2. The rhenium metal alloy as defined in claim 1, wherein said alloying metal includes chromium.

3. The rhenium metal alloy as defined in claim 1, wherein said alloying metal includes chromium and one or more metals selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium.

4. The rhenium metal alloy as defined in claim 2, wherein said alloying metal includes chromium and one or more metals selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium.

5. The rhenium metal alloy as defined in claim 3, wherein an atomic ratio of said chromium to an atomic ratio of said one or more metals selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium is 0.4:1 to 2.5:1.

6. The rhenium metal alloy as defined in claim 4, wherein an atomic ratio of said chromium to an atomic ratio of said one or more metals selected from the group consisting of bismuth, zirconium, iridium, niobium, tantalum, titanium, and yttrium is 0.4:1 to 2.5:1.

7. The rhenium metal alloy as defined in claim 1, wherein said alloying metal includes chromium and one or more metals selected from the group consisting of zirconium, niobium, and tantalum.

8. The rhenium metal alloy as defined in any one of claims 2-6, wherein said alloying metal includes chromium and one or more metals selected from the group consisting of zirconium, niobium, and tantalum.

9. The rhenium metal alloy as defined in claim 7, wherein an atomic ratio of said chromium to an atomic ratio of said one or more metals selected from the group consisting of zirconium, niobium, and tantalum is 0.4:1 to 2.5:1.

10. The rhenium metal alloy as defined in claim 8, wherein an atomic ratio of said chromium to an atomic ratio of said one or more metals selected from the group consisting of zirconium, niobium, and tantalum is 0.4:1 to 2.5:1.

11. The rhenium metal alloy as defined in claim 1, wherein said alloying metal includes a first metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium, and a second metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium; said first and second metals are different; an atomic ratio of said first metal to said second metal is 0.4:1 to 2.5:1.

12. The rhenium metal alloy as defined in any one of claims 2-10, wherein said alloying metal includes a first metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium, and a second metal selected from the group consisting of bismuth, chromium, iridium, niobium, tantalum, titanium, yttrium and zirconium;

said first and second metals are different; an atomic ratio of said first metal to said second metal is 0.4:1 to 2.5:1.

13. The rhenium metal alloy as defined in claim 1, wherein said alloying metal includes a first metal selected from the group consisting of chromium, niobium, tantalum, and zirconium, and a second metal selected from the group consisting of chromium, niobium, tantalum, and zirconium; said first and second metals are different; an atomic ratio of said first metal to said second metal is 0.4:1 to 2.5:1.

14. The rhenium metal alloy as defined in any one of claims 2-12, wherein said alloying metal includes a first metal selected from the group consisting of chromium, niobium, tantalum, and zirconium, and a second metal selected from the group consisting of chromium, niobium, tantalum, and zirconium; said first and second metals are different; an atomic ratio of said first metal to said second metal is 0.4:1 to 2.5:1.

15. The rhenium metal alloy as defined in claim 1, wherein said rhenium metal alloy includes less than 0.1 wt.% metals and impurities.

16. The rhenium metal alloy as defined in any one of claims 2-14, wherein said rhenium metal alloy includes less than 0.1 wt.% metals and impurities.

17. The rhenium metal alloy as defined in claim 1, wherein an atomic ratio of rhenium to total content of said alloying metal is 0.8:1 to 1.25:1.

18. The rhenium metal alloy as defined in any one of claims 2-16, wherein an atomic ratio of rhenium to total content of said alloying metal is 0.8:1 to 1.25:1.

19. The rhenium metal alloy as defined in claim 1, wherein said rhenium metal alloy has a controlled amount of nitrogen, oxygen, and carbon to reduce micro-cracking in said rhenium metal alloy, a nitrogen content in said rhenium metal alloy is less than a combined content of oxygen and carbon in said rhenium metal alloy, said rhenium metal alloy has an oxygen to nitrogen

atomic ratio of at least about 1.2:1, said rhenium metal alloy has a carbon to nitrogen atomic ratio of at least about 2:1.

20. The rhenium metal alloy as defined in any one of claims 2-18, wherein said rhenium metal alloy has a controlled amount of nitrogen, oxygen, and carbon to reduce micro-cracking in said rhenium metal alloy, a nitrogen content in said rhenium metal alloy is less than a combined content of oxygen and carbon in said rhenium metal alloy, said rhenium metal alloy has an oxygen to nitrogen atomic ratio of at least about 1.2:1, said rhenium metal alloy has a carbon to nitrogen atomic ratio of at least about 2:1.

21. A medical device that is at least partially formed of said rhenium metal alloy as defined in claim 1.

22. A medical device that is at least partially formed of said rhenium metal alloy as defined in any one of claims 2-20.

23. The medical device as defined in claim 21, wherein at least one region of said medical device includes at least one biological agent and/or at least one polymer.

24. The medical device as defined in claim 22, wherein at least one region of said medical device includes at least one biological agent and/or at least one polymer.

25. The medical device as defined in claim 23, wherein at least one region of said medical device includes at least one polymer, said at least one polymer at least partially coats, encapsulates, or combinations thereof said at least one biological agent.

26. The medical device as defined in claim 24, wherein at least one region of said medical device includes at least one polymer, said at least one polymer at least partially coats, encapsulates, or combinations thereof said at least one biological agent.

27. The medical device as defined in claim 21, further comprising at least one micro-structure on an outer surface of said medical device.

28. The medical device as defined in any one of claims 22-26, further comprising at least one micro-structure on an outer surface of said medical device.

29. The medical device as defined in claim 27, wherein said at least one microstructure is at least partially formed of, includes, or combinations thereof, a material consisting of a polymer, an agent, or combinations thereof.

30. The medical device as defined in claim 28, wherein said at least one microstructure is at least partially formed of, includes, or combinations thereof, a material consisting of a polymer, an agent, or combinations thereof.

31. The medical device as defined in claim 21, wherein said medical device includes an expandable frame formed of a rhenium metal alloy; said expandable frame including a plurality of struts; said expandable frame is configured to be crimped to a crimped state such that a maximum outer diameter of said expandable frame when in said crimped state is less than a maximum outer diameter of said expandable frame when fully expanded to an expanded state; said expandable frame has a recoil of less than 5% after being subjected to a first crimping process; said expandable frame has a recoil of less than 5% after being expanded from said crimped state to said expanded state; said rhenium metal alloy has a hydrophilicity wherein a contact angle of a water droplet on a surface of said rhenium metal alloy of 25-45°; said rhenium metal alloy has a maximum ion release of a primary component of said rhenium metal alloy when inserted or implanted on or in the body of the patient of no more than 0.5 $\mu g/cm^2$ per day, wherein said primary component constitutes at least 2 wt.% of said rhenium metal alloy; said rhenium metal alloy has an absolute increase in ion release per dose of rhenium metal alloy in tissue about said medical device of no more than 50 days after inserted or implanted on or in the body of a patient.

32. The medical device as defined in any one of claims 22-30, wherein said medical device includes an expandable frame formed of a rhenium metal alloy; said expandable frame

including a plurality of struts; said expandable frame is configured to be crimped to a crimped state such that a maximum outer diameter of said expandable frame when in said crimped state is less than a maximum outer diameter of said expandable frame when fully expanded to an expanded state; said expandable frame has a recoil of less than 5% after being subjected to a first crimping process; said expandable frame has a recoil of less than 5% after being expanded from said crimped state to said expanded state; said rhenium metal alloy has a hydrophilicity wherein a contact angle of a water droplet on a surface of said rhenium metal alloy of 25-45°; said rhenium metal alloy has a maximum ion release of a primary component of said rhenium metal alloy when inserted or implanted on or in the body of the patient of no more than 0.5 $\mu g/cm^2$ per day, wherein said primary component constitutes at least 2 wt.% of said rhenium metal alloy; said rhenium metal alloy has an absolute increase in ion release per dose of rhenium metal alloy in tissue about said medical device of no more than 50 days after inserted or implanted on or in the body of a patient.

33. The medical device as defined in claim 31, wherein said medical device is an expandable stent or an expandable prosthetic heart valve.

34. The medical device as defined in claim 33, wherein said medical device is an expandable stent or an expandable prosthetic heart valve.

35. A rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals selected from the group consisting of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium; a combined weight percentage of rhenium and alloy metals in said rhenium metal alloy is greater than or equal to the weight percent of molybdenum in said rhenium metal alloy; a weight percent of molybdenum in said rhenium metal alloy is at least 10 wt.% and less than 60 wt.%; a weight percent of rhenium in said rhenium metal alloy is 35-60 wt.%; a combined weight percent of said alloying metals is 5-45 wt.% of said rhenium metal alloy; a weight percent of said rhenium in said rhenium metal alloy is greater than said combined weight percent of said alloying metals; a combined weight percent of said rhenium, molybdenum, and said one or more alloying metals in said rhenium metal alloy is at least 99.9 wt.%; and wherein said rhenium metal alloy has a maximum ion release of a primary component of said rhenium

metal alloy when inserted or implanted on or in the body of the patient of no more than 0.5 $\mu g/cm^2$ per day, wherein said primary component constitutes at least 2 wt.% of said rhenium metal alloy.

36. A rhenium metal alloy comprising rhenium, molybdenum, and one or more alloying metals selected from the group consisting of bismuth, chromium, copper, hafnium, iridium, manganese, niobium, osmium, rhodium, ruthenium, tantalum, technetium, titanium, tungsten, vanadium, yttrium, and zirconium; a combined weight percentage of rhenium and alloy metals in said rhenium metal alloy is greater than or equal to the weight percent of molybdenum in said rhenium metal alloy; a weight percent of molybdenum in said rhenium metal alloy is at least 10 wt.% and less than 60 wt.%; a weight percent of rhenium in said rhenium metal alloy is 35-60 wt.%; a combined weight percent of said alloying metals is 5-45 wt.% of said rhenium metal alloy; a weight percent of said rhenium in said rhenium metal alloy is greater than said combined weight percent of said alloying metals; a combined weight percent of said rhenium, said molybdenum, and said one or more alloying metals in said rhenium metal alloy is at least 99.9 wt.%; said rhenium metal alloy has a hydrophilicity wherein a contact angle of a water droplet on a surface of said rhenium metal alloy of 25-45°; said rhenium metal alloy has a maximum ion release of a primary component of said rhenium metal alloy when inserted or implanted on or in the body of the patient of no more than 0.5 $\mu g/cm^2$ per day, wherein said primary component constitutes at least 2 wt.% of said rhenium metal alloy; said rhenium metal alloy has an absolute increase in ion release per dose of rhenium metal alloy in tissue about said medical device of no more than 50 days after inserted or implanted on or in the body of a patient; said rhenium metal alloy when formed into an expandable frame exhibits a recoil of less than 5% after the expandable frame has been subjected to a first crimping process; said rhenium metal alloy when formed into an expandable frame exhibits a recoil of less than 5% after the expandable frame has been expanded from a crimped state to an expanded state.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 22/14054

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61F 2/82; C22C 27/04; C22C 30/00 (2022.01)
CPC - A61L 31/022; C22C 27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	US 2017/0216494 A1 (ICON MEDICAL CORP.) 3 August 2017 (03.08.2017) - entire document especially claim 4 and para [0012], [0014], [0022], [0019], [0051], [0055], [0048], [0033], [0052], [0094], [0065], [0005], [0023], [0004], [0029], [0024]	1-11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33-35 --- 36
A	US 2009/0068249 A1 (FURST ET AL.) 12 March 2009 (12.03.2009) - entire document especially para [0012], [0014], [0056], [0048], [0018]	36
A	US 2013/0216421 A1 (BUCKMAN, JR. ET AL.) 22 August 2013 (22.08.2013) - entire document	1-11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33-36
A	US 2005/0079200 A1 (RATHENOW ET AL.) 14 April 2005 (14.04.2005) - entire document	1-11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33-36
A	US 2019/0046684 A1 (MIRUS LLC) 14 February 2019 (14.02.2019) - entire document	1-11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33-36
A	US 2018/0361017 A1 (MIRUS LLC) 20 December 2018 (20.12.2018) - entire document	1-11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33-36

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 March 2022 (30.03.2022)	APR 14 2022
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 22/14054

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.