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(54) **OXIDATION RESISTANT TREATMENT FOR METALLIC MEDICAL DEVICES**

Related U.S. Application Data

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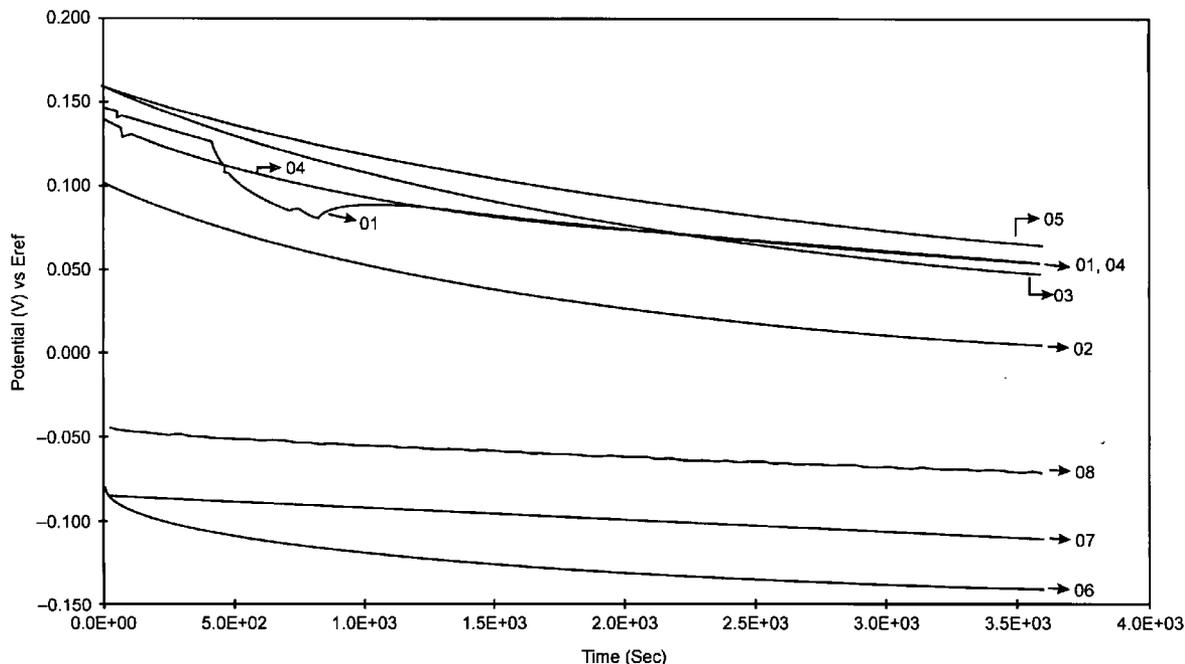
(57) **ABSTRACT**

A method of treating a metallic medical device is disclosed and includes providing a metallic medical device, ionizing the media surrounding at least one electrode to produce an energized plasma proximate to the electrode, and exposing the metallic device to the plasma prior to use of the metallic device. In one embodiment a vascular stent is the medical device.

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Corrosion Potential
Control samples: #1 through #5
Corona treated samples: #6 through #8



Sample	Atomic Concentration (%)														
	C	N	O	F	Na	Mg	Si	P	S	K ^c	Ca	Cr	Fe	Ni	Mo
<u>#1</u>	32.6	- ^d	44.7	-	1.7	1.8	-	1.9	1.0	-	0.6	8.3	5.7	1.2	0.6
<u>#2</u>	23.3	1.4	52.7	-	0.6	1.7	0.9	1.5	0.8	-	0.9	6.2	6.9	2.6	0.6
<u>#3</u>	26.4	0.9	52.5	-	0.9	-	0.9	1.5	-	-	-	6.9	6.4	2.9	0.7
<u>#4</u>	18.6	1.3	57.4	-	0.4	1.8	1.5	1.1	-	0.2	0.6	5.7	7.6	3.3	0.7
<u>#5</u>	23.0	1.1	55.9	0.9	0.2	-	-	1.2	-	0.2	0.6	5.4	7.5	3.5	0.5
<u>#6</u>	21.3	1.3	55.0	-	0.2	2.2	1.1	0.9	-	0.3	-	5.9	8.1	2.9	0.7
<u>#7</u>	23.3	0.8	54.0	-	0.1	2.0	1.2	1.2	-	0.3	-	6.0	6.9	3.6	0.6

FIG. 1

Investigations Test Database Log ID Number	Sample Number	Corrosion Potential, E _{corr} (mV)	Breakdown Potential, E _b (mV)	Repassivation Potential, E _p (mV)	E _b - E _{corr} (mV)	E _b - E _p (mV)	E _p - E _{corr} (mV)
ID # 12137 Control Samples	6	-142	610	189	752	421	331
	7	-111	272	110	383	162	221
	8	-72	503	268	575	235	340
Average		-108	462	189	570	273	297
StDev		35	173	79	185	134	66
Min		-142	272	110	383	162	221
Max		-72	610	268	752	421	340

FIG. 2

Investigations Test Database Log ID Number	Sample Number	Corrosion Potential, Ecorr (mV)	Breakdown Potential, Eb (mV)	Repassivation Potential, Ep (mV)	Eb - Ecorr (mV)	Eb - Ep (mV)	Ep - Ecorr (mV)
3199	1B	-145	none	N/A	N/A	N/A	N/A
	2B*	NV	NV	NV	N/A	N/A	N/A
	3B	-170	882	196	1052	686	366
	4B	-149	575	208	724	367	357
	5B*	NV	NV	NV	N/A	N/A	N/A
	6B	-153	593	216	746	377	369
	1A	-180	847	276	1027	571	456
	2A*	NV	NV	NV	N/A	N/A	N/A
	3A	-181	500	248	681	252	429
	4A	-144	908	168	1052	740	312
3720	5A	-167	none	N/A	N/A	N/A	N/A
	6A	-210	701	167	911	534	377
	1	-128	612	189	740	423	317
	2	-129	428	153	557	275	282
	3	-155	479	134	634	345	289
Test Results From LaQue Corrosion (May 1999)	4	-124	641	136	765	505	260
	5	-135	613	134	748	479	269
	1	-103	550	207	653	343	310
	2	-84	670	265	754	405	349
	3	-91	600	181	691	419	272
	4	-89	672	194	761	478	283
	5	-106	1083	155	1189	928	261
	6	-46	579	188	625	391	234
	7	-93	589	-142	682	N/A	N/A
	8	-62	611	263	673	348	325
	9	-61	640	377	701	263	438
	10	-59	579	-114	638	N/A	N/A
	11	-51	544	none	595	N/A	N/A
	12	-53	653	-142	706	N/A	N/A
	13	-66	637	-133	703	N/A	N/A
14	-108	346	-150	454	N/A	N/A	
4031	15	-81	528	-84	609	N/A	N/A
	3	128	560	215	432	345	87
	5	70	431	160	361	271	90
	34	128	780	217	652	563	89
	40	138	595	153	457	442	15
	41	132	none	N/A	N/A	N/A	N/A
4405	43	156	none	N/A	N/A	N/A	N/A
	46	143	399	none	256	N/A	N/A
	1	339	1020	N/A	681	N/A	N/A
	2	-76	none	N/A	N/A	N/A	N/A
2666	3	-57	822	151	879	671	208
	1A	-161	509	261	670	248	422
	1BB	-106	none	N/A	N/A	N/A	N/A
	1B	-128	none	N/A	N/A	N/A	N/A
	1C	-155	none	N/A	N/A	N/A	N/A
	2A*	-137	none	N/A	N/A	N/A	N/A
	2B*	-191	807	241	998	566	432
2C	-211	none	N/A	N/A	N/A	N/A	

FIG. 3

Investigation Test Database Log ID Number	Sample Number	Corrosion Potential, Ecorr (mV)	Breakdown Potential, Eb (mV)	Repassivation Potential, Ep (mV)	Eb - Ecorr (mV)	Eb - Ep (mV)	Eb - Ecorr (mV)
ID # 12137 Control treated samples	1	53	1158	144	1105	1014	91
	2	2	1039	None	1037	N/A	N/A
	3	47	992	None	945	N/A	N/A
	4	53	781	189	728	592	136
	5	65	754	320	689	434	255
Average		44	945	218	901	680	S161
StDev		24	173	91	185	300	85
Min		2	754	144	689	434	91
Max		65	1158	320	1105	1014	255

FIG. 4

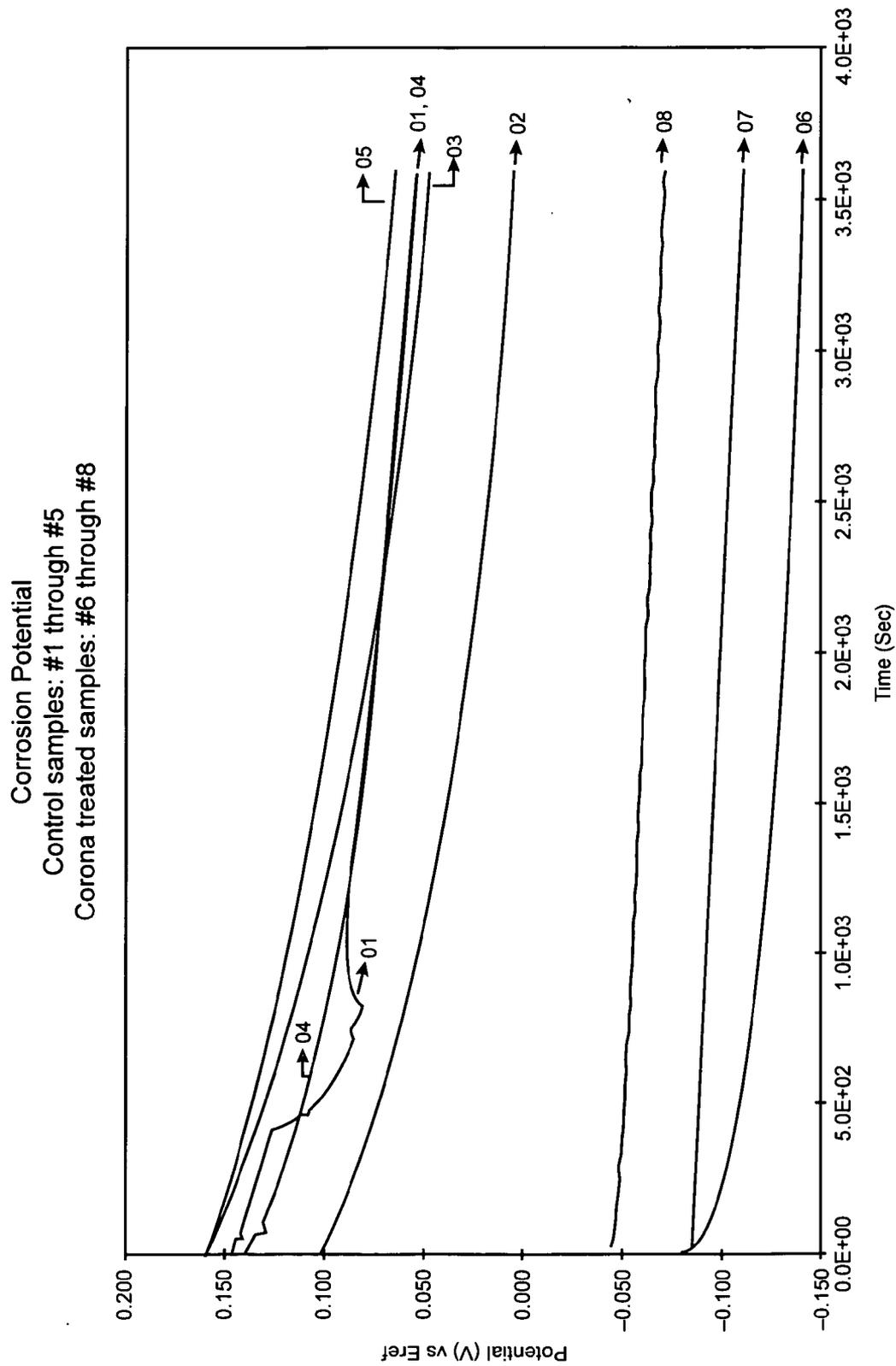


FIG. 5

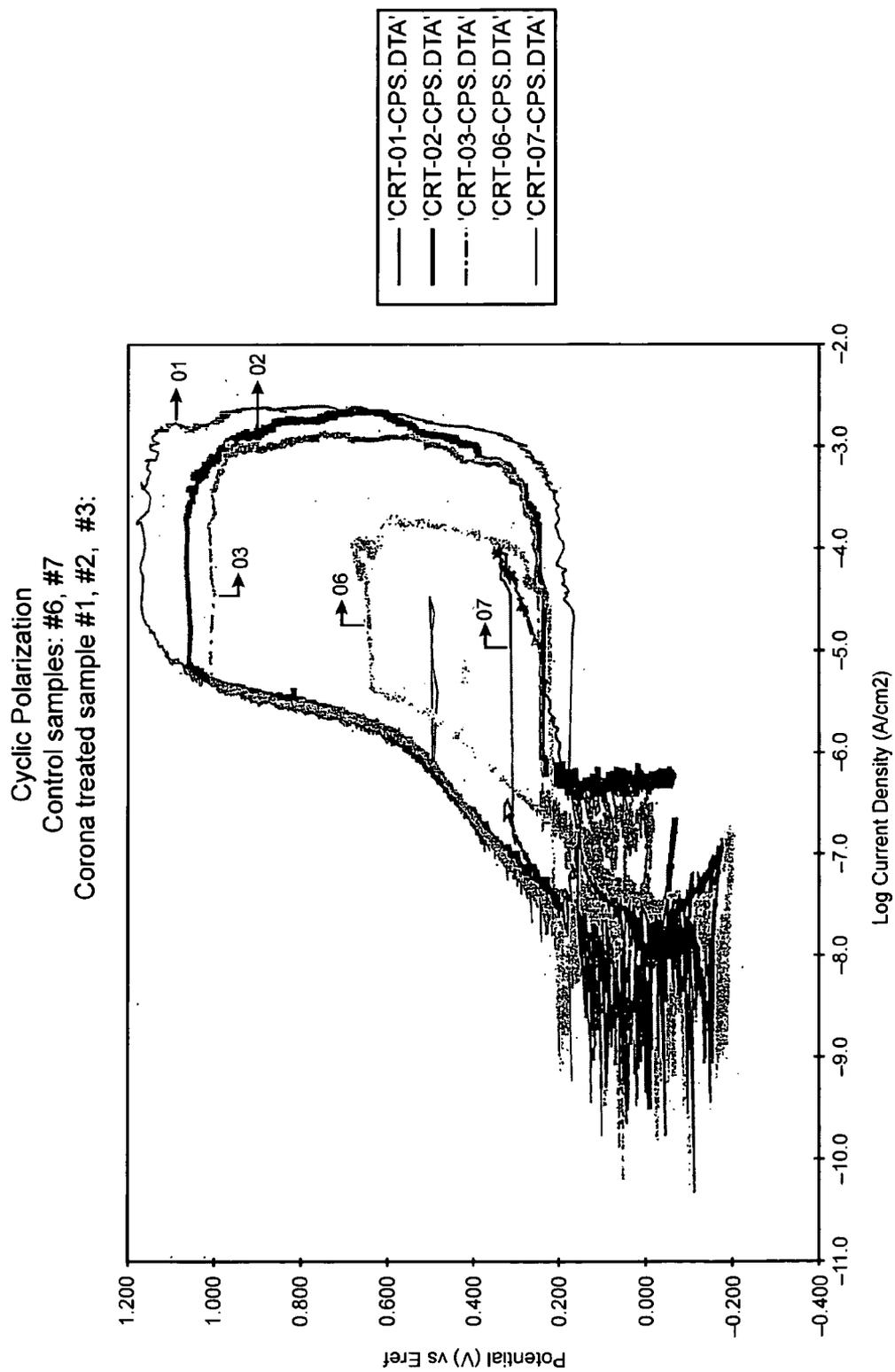


FIG. 6

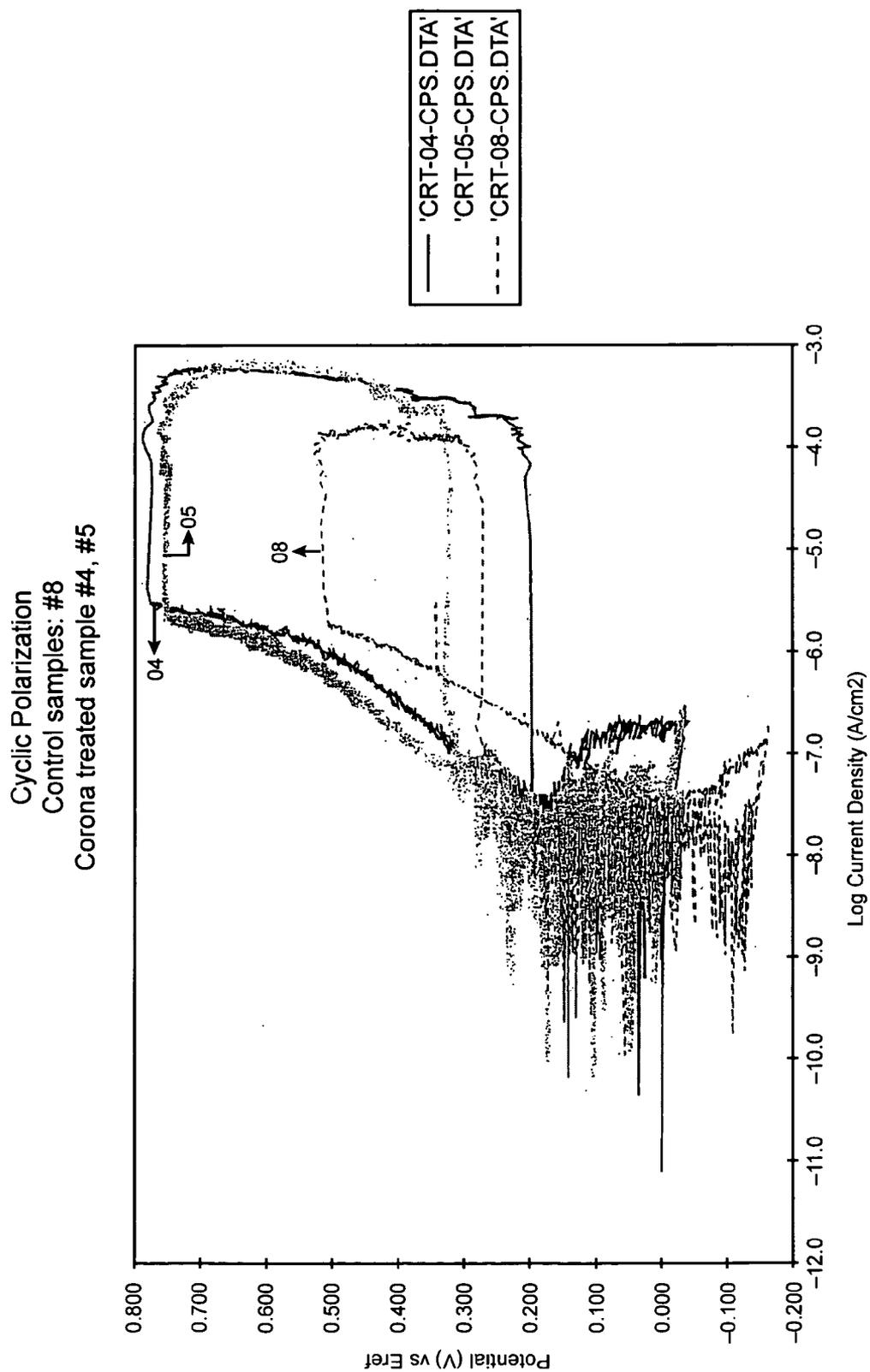


FIG. 7

OXIDATION RESISTANT TREATMENT FOR METALLIC MEDICAL DEVICES

RELATED APPLICATIONS

[0001] The present application claims priority to U.S. provisional patent application Ser. No. 60/460,365 filed Apr. 3, 2003 the entire contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to a process for passivating a metallic surface. Specifically, an oxidation treatment is described herein is capable of efficiently passivating a metallic medical device thereby improving the corrosion resistance of the treated device. In one embodiment of the present invention the medical device is a vascular stent.

BACKGROUND OF THE INVENTION

[0003] Devices manufactured from at least one metallic material are commonly implanted within the body of patient to treat a variety of conditions. For example, stents, shunts, or other mechanical scaffoldings may be inserted into an occluded region of a lumen or luminal structure to provide and maintain patency therethrough. In an alternate embodiment, metallic screws, braces, or plates may be positioned within or attached to skeletal structures throughout the patient's body to provide support thereto. Recently, total joint replacement devices such as replacement hip prosthetics and replacement knee prosthetics have been used to replace incompetent natural joint systems.

[0004] Presently, implantable metallic devices are manufactured from a variety of materials, including, stainless steel, tantalum, titanium, Nickel-Titanium alloys, shape memory alloys, super elastic alloys, low-modulus Ti—Nb—Zr alloys, and cobalt-nickel alloy steel (MP-35N). While implantable metallic devices manufactured these materials have proven useful in treating a variety of physiological conditions, a number of shortcomings associated with implantable metallic devices have been identified. For example, the extended exposure of the implanted metallic devices to bodily fluids and biological materials may result in device corrosion. As a result, the performance of the implanted device may be compromised.

[0005] In response, the materials used in the manufacture of implantable metallic devices generally undergo a chemical passivation process during the manufacture of the implantable device. Typically, the device is coated with, submerged in, or otherwise exposed to an oxidizing agent or compound. For example, nitric acid is frequently used as an oxidizing agent when passivating stainless steel. As a result, free metals on the surface of the implantable device may be removed and a non-reactive protective oxide layer capable of reducing or preventing material corrosion may be formed thereon. While the chemical passivating process has been effective in passivating implantable metallic devices, a number of shortcomings have been identified. For example, the chemical passivating processes tend to be time intensive procedures typically requiring the implantable device be exposed to an oxidizing agent for 15 minutes or more. In addition, oxidizing agents are hazardous materials and pose

a health risk to exposed workers and may result in the unwanted deposition of chemical residues on the treated device.

[0006] Thus, in light of the foregoing, there is a need oxidation treatment for metallic medical devices capable of quickly passivating a metallic device without leaving chemical residues thereon.

BRIEF SUMMARY OF THE INVENTION

[0007] The oxidation treatment described herein is capable of efficiently passivating a metallic medical device thereby improving the corrosion resistance of the treated device. In addition, the oxidation treatment disclosed herein reduces or eliminates the possibility of residual chemical impurities remaining on the treated device as a result of the passivating procedure.

[0008] In one embodiment, a method of treating a metallic medical device is disclosed and includes providing a metallic medical device, ionizing the media surrounding at least one electrode to produce an energized plasma proximate to the electrode, and exposing the metallic device to the plasma prior to use of the metallic device.

[0009] In an alternate embodiment, a method of passivating a medical device is described herein and includes providing a metallic medical device, positioning at least one electrode within an atmosphere containing at least oxygen, applying energy to the electrode, forming a plasma by ionizing the atmosphere proximate to the electrode, and exposing the metallic medical device to the plasma to produce an corrosion resistant oxidation layer thereon.

[0010] In another embodiment, an oxidation treatment for a metallic stent is disclosed and includes providing a metallic stent, forming a plasma within an atmosphere containing at least oxygen, and positioning the stent within the plasma.

[0011] In addition, a corrosion resistant medical device is described and comprises a metallic body and at least a corrosion resistant oxidation layer formed on the metallic body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 shows a table detailing the surface composition of stents subjected to the oxidation treatment of the present invention as compared with the surface composition of untreated control stents;

[0013] FIG. 2 shows a table summarizing the test results of a cyclic potentiodynamic polarization tests performed on untreated control stents;

[0014] FIG. 3 shows a table summarizing the historical test results relating to cyclic potentiodynamic polarization tests performed on the untreated stents;

[0015] FIG. 4 shows a table summarizing the test results of a cyclic potentiodynamic polarization tests performed on stents treated with the oxidation treatment of the present invention;

[0016] FIG. 5 shows a graph illustrating the corrosion potential of the stents treated using an oxidation treatment disclosed herein as compared to the corrosion potential of untreated control stents;

[0017] FIG. 6 shows a graph illustrating the cyclic polarization of the treated stent sample numbers 1, 2, and 3 as compared to the cyclic polarization of untreated control stent sample numbers 6 and 7; and

[0018] FIG. 7 shows a graph illustrating the cyclic polarization of the treated stent sample numbers 4 and 5 as compared to the cyclic polarization of untreated stent sample number 8.

DETAILED DESCRIPTION OF THE INVENTION

[0019] The oxidation treatment disclosed herein may be used to passivate metallic medical devices to be used within the body of a patient, thereby improving the ability of the device to resist corrosion once implanted. Generally, passivation may be described as the removal of exogenous contaminants or compounds from the surface of a metallic device. When passivating a stainless steel item, for example, exogenous iron or iron compounds may be removed from the surface of the item, thereby altering the surface chemistry thereof. In addition, the oxidation treatment disclosed herein results in formation of an oxidation layer on the surface of the item. In addition to passivating metallic devices, the oxidation treatment of the present invention provides a metallic device substantially free of organic residues, unlike conventional passivating procedures utilizing wet chemical techniques which may result in the deposition of an organic contaminants on the implantable device.

[0020] The oxidation treatment of the present invention may be used to passivate a variety of metallic devices used throughout the body of a patient. For example, a metallic vascular stent may be subjected to the oxidation treatment disclosed herein prior to implantation with the vasculature of a patient. In another embodiment, the metallic medical device may include components of a replacement joint such as a replacement ball and socket joint, a metallic heart valve, implantable screws, pins, bolts, plates, skeletal fusion devices, spinal fusion devices, bone anchors, shunts, staples, fasteners, dental implants or devices including orthodontic braces and retainers, or other metallic devices capable of being implanted into the body of a patient. In an alternate embodiment, the oxidation treatment described herein may be used to passivate or otherwise treat a variety of medical devices used prior to, during, or following a surgical or therapeutic procedure. For example, the disclosed oxidation treatment may be used to improve the corrosion resistance of retractors, retainers, couplings, scalpels, needles, forceps, dental tools or devices, bone cutters, saws, and/or other surgical or dental tools or devices. In addition, the present oxidation treatment may be used to passivate various metals, including, without limitation, stainless steel, tantalum, titanium, Nickel-Titanium alloys, shape memory alloys, super elastic alloys, low-modulus Ti-Nb-Zr alloys, and cobalt-nickel alloy steel (MP-35N).

[0021] The oxidation treatment of the present invention utilizes a commercially available corona discharge or corona treatment system to produce the electrochemical reaction resulting in the passivation of the metallic device. A voltage sufficient to ionize the surrounding environment is applied to at least one electrode. In one embodiment, approximately 18 kV of direct current (DC) may be applied to the electrode thereby generating a corona discharge proximate thereto,

although any voltage or current capable of creating a corona discharge may be used. Similarly, any number of electrodes may be used in the present invention. For example, a first charged electrode may be positioned proximate to a second electrode. The first charged electrode may be separated from the second electrode by a separation gap. The electrodes may be positioned within an air environment, although those skilled in the art will appreciate that the electrodes may be located within environments containing other materials or gases. For example, the electrodes may be positioned within a field containing argon, helium, neon, or xenon. The application of sufficient voltage to the first charged electrode ionizes the media surrounding the electrode, for example, oxygen, thereby forming ozone (O_3) and producing a plasma between or proximate to the first and second electrodes. Further, the Applicants theorize the Ozone forming the plasma is capable of chemically reacting with various metals of the metallic device and resulting in the oxidation thereof.

[0022] The metallic device may be subjected to or positioned within the ionized environment formed proximate to the electrode. For example, a stainless steel device (for example stainless steel 316L) may be subjected to the high energy plasma generated between or proximate to at least one electrode. As a result, the atoms of ozone forming the plasma react with atoms of iron, nickel, and chromium within the stainless steel substrate material thereby forming or depositing a corrosive resistant oxidation layer thereon. Those skilled in the art will appreciate that the metallic device undergoing the oxidation treatment disclosed herein is maintained at an ambient or near ambient temperature during the treatment procedure. Unlike wet oxidation procedures which may result in the deposition of residual materials on the metallic device and may require additional cleaning processes, the metallic device treated with the method disclosed herein may be sterilized and packaged for shipment. In addition, those skilled in the art will appreciate that the oxidation treatment disclosed herein results in the deposition of a corrosion resistant layer to the metallic device in substantially less time than presently required using a wet oxidation process. In one embodiment, the metallic device may be passivated by subjecting the metallic device to the corona discharge for about 3 seconds to several minutes, although those skilled in the art will appreciate that the metallic device may be subject to the corona discharge for a considerably less or more time as desired by the manufacturer. In contrast, the present wet passivating procedures using nitric acid typically require the metallic device be exposed to the oxidizing agent for a period of 15 minutes or more.

[0023] A further, non-limiting illustration of the oxidation treatment disclosed herein is illustrated in the following examples.

EXAMPLE 1

[0024] Seven stainless steel S670 stents manufactured by Medtronic AVE were washed for three minutes within an ultrasound bath containing 99% isopropyl alcohol (IPA). Thereafter, the seven stents were removed from the IPA bath and dried within a gaseous flow of nitrogen.

[0025] Once dried, the stents were number 1 through 7. Sample number 1 was left untreated. Sample numbers 2 through 7 underwent passivation using the oxidation treat-

ment disclosed herein. A corona discharge device included an electrode was positioned within an oxygen environment. Approximately 18 kV of direct current electrical energy was applied to the electrode, thereby ionizing the oxygen proximate to the electrode and resulting in the creation of an ionizing plasma. As Table 1 shows, sample numbers 2-7 were exposed to a plasma created from a corona discharge device for varying lengths of times.

TABLE 1

SAMPLE NO.	CORONA EXPOSURE TIME
1	0 sec (control)
2	5 sec.
3	10 sec.
4	20 sec.
5	20 sec. (Dwell)
6	60 mm. (Dwell)
7	95 mm. (Dwell)

[0026] Following the oxidation treatment, sample number 1 (the untreated control sample) and treated sample numbers 2-7 underwent Electron Spectroscopy for Chemical Analysis (hereinafter ESCA) to determine the effects of the oxidation treatment on the surface composition of the stents. During the ESCA process, a small diameter x-ray beam is focused across an area of each stent, thereby causing electrons to be emitted from the of each stent. The emitted electrons are collected and examined to determine the surface composition of the device under test. FIG. 1 shows the results of the ESCA testing on samples 1-7.

[0027] As shown in FIG. 1, the surface composition of sample number 1 (the untreated control sample) included significantly higher concentrations of carbon when compared with the surface composition of the treated samples (sample numbers 2-7). In addition, the treated sample numbers 2-7 exhibited higher surface concentrations of nitrogen and nickel than the untreated sample 1. Furthermore, the chromium to iron ratio in the treated samples sample number 2-7) was greatly reduced as a result of the oxidation treatment when compared with the untreated sample (sample number 1), thereby producing a more corrosion-resistant device than presently available.

EXAMPLE 2

[0028] Eight stainless steel S670 stents manufactured by Medtronic AVE were washed for three minutes within an ultrasound bath containing 99% isopropyl alcohol (IPA). Thereafter, the eight stents were removed from the IPA bath and dried within a gaseous flow of Nitrogen.

[0029] Once dried, the stents were number 1 through 8. Sample numbers 6-8 were left untreated. Sample numbers 1 through 5 underwent passivation using the oxidation treatment disclosed within. A corona discharge device included an electrode was positioned within an oxygen environment. Approximately 18 kV of direct current electrical energy was applied to the electrode, thereby ionizing the oxygen proximate to the electrode and resulting in the creation of an ionizing plasma. As Table 1 shows, sample numbers 1-5 were exposed to the plasma created from a corona discharge device for varying lengths of times between 5 seconds and 10 seconds.

TABLE 3

SAMPLE NO.	CORONA EXPOSURE TIME
1	5-10 sec.
2	5-10 sec.
3	5-10 sec.
4	5-10 sec.
5	5-10 sec.
6	0 (control)
7	0 (control)
8	0 (control)

[0030] Thereafter, the stents were subjected to cyclic potentiodynamic corrosion testing to determine the corrosion resistance of each sample. FIG. 2 shows a table summarizing the cyclic potentiodynamic polarization test results for the untreated samples (sample numbers 6-8). FIG. 3 shows historical data of potentiodynamic polarization testing of similar S670 stents manufactured by Medtronic AVE. As illustrated, the corrosion potential for the untreated samples (sample numbers 6-8) was comparable with the historical data obtained by previous potentiodynamic polarization tests performed on untreated S670 stent samples. The corrosion potential of the untreated samples (sample numbers 6-8) averaged -108 mV, while the breakdown potential averaged 462 mV.

[0031] FIG. 4 shows a table summarizing the cyclic potentiodynamic polarization test results for the treated samples (sample numbers 1-5). As shown, the breakdown potential of the treated samples (sample numbers 1-5) was consistently higher than the untreated samples (sample number 6-8). In addition, the potential difference (i.e. the average difference between the corrosion potential and the breakdown potential ($E_b - E_{corr}$)) was greater in the treated samples (sample numbers 1-5) than the untreated samples (sample numbers 6-8), thereby suggesting that the oxidation treatment had improved the corrosion resistance of the treated samples (sample numbers 1-5).

[0032] FIGS. 5-7 graphically illustrate the effects of the oxidation treatment on the treated samples (sample numbers 1-5) as compared with the untreated samples (sample numbers 6-8). FIG. 5 shows the corrosion potential ($(V_{pot}/E_{ref})/t$) of the treated samples (sample number 1-5) and the untreated samples (sample numbers 6-8). As shown, the corrosion potential of the treated samples (sample numbers 1-5) is considerably higher than the untreated samples (sample numbers 6-8). Further, FIGS. 6 and 7 show the cyclic polarization ($(V_{pot}/E_{ref})/(A/cm^2)$) of the treated samples (sample numbers 1-5) and the untreated samples (sample numbers 6-8). More specifically, FIG. 6 shows the cyclic polarization of treated sample numbers 1, 2, and 3 and untreated sample numbers 6 and 7. FIG. 8 shows the cyclic polarization of treated sample numbers 4 and 5, and untreated sample number 8. As shown in FIGS. 2 and 3, the treated samples (sample numbers 1-5) exhibited a higher cyclic polarization than the untreated samples (sample numbers 6-8).

[0033] In light of the foregoing, cyclic potentiodynamic polarization test revealed a higher breakdown potential and an increased difference between the rest potential and the breakdown potential for the treated stents (sample numbers 1-5) than found in the untreated stents (sample number 6-8).

As a result, the oxidation treatment disclosed herein reduced the treated stent's susceptibility to localized corrosion thereby improving the treated stent's resistance to corrosion.

[0034] In closing it is understood that the embodiments of the invention disclosed herein are illustrative of the principles of the invention. In addition, those skilled in the art will appreciate that the oxidation treatment described herein may be used to provide the user with a variety of corrosion resistant metallic medical device, including, for example, vascular stents, replacement joints, metallic heart valves, screws, pins, bolts, staples, fasteners, plates, skeletal fusion devices, spinal fusion devices, bone anchors, shunts, staples, fasteners, dental implants, orthodontic braces, dental retainers, retractors, retainers, couplings, scalpels, needles, forceps, dental tools, surgical tools, bone cutters, and saws. Accordingly, the present invention is not limited to that precisely as shown and described in the present invention.

What is claimed is:

- 1. A method of treating a metallic medical device, comprising:
 - providing a metallic medical device;
 - ionizing the media surrounding at least one electrode to produce an energized plasma proximate to the electrode; and
 - exposing the metallic device to the plasma prior to use of the metallic device.
- 2. The method of claim 1 further comprising positioning the electrode in an atmosphere containing at least one material selected from the group consisting of Oxygen, Argon, Helium, Neon, and Xenon.
- 3. The method of claim 1 further comprising forming an oxidation layer a surface of the metallic device.
- 4. The method of claim 1 wherein the metallic device is selected from the group consisting of vascular stents, replacement joints, metallic heart valves, screws, pins, bolts, staples, fasteners, plates, skeletal fusion devices, spinal fusion devices, bone anchors, shunts, staples, fasteners, dental implants, orthodontic braces, dental retainers, retractors, retainers, couplings, scalpels, needles, forceps, dental tools, surgical tools, bone cutters, and saws.

- 5. The method of passivating a medical device, comprising:
 - providing a metallic medical device;
 - positioning at least one electrode within an atmosphere containing at least Oxygen;
 - applying energy to the electrode;
 - forming a plasma by ionizing the atmosphere proximate to the electrode and
 - exposing the metallic medical device to the plasma to produce an corrosion resistant oxidation layer thereon.
- 6. The method of claim 5 wherein the metallic device is selected from the group consisting of vascular stents, replacement joints, metallic heart valves, screws, pins, bolts, staples, fasteners, plates, skeletal fusion devices, spinal fusion devices bone anchors, shunts, staples, fasteners, dental implants, orthodontic braces, dental retainers, retractors, retainers, couplings, scalpels, needles, forceps, dental tools, surgical tools, bone cutters, and saws.
- 7. An oxidation treatment for a metallic stent, comprising:
 - providing a metallic stent;
 - forming a plasma within an atmosphere containing at least Oxygen; and
 - positioning the stent within the plasma.
- 8. A corrosion resistant medical device, comprising:
 - a metallic body; and
 - at least a corrosion resistant oxidation layer formed on the metallic body.
- 9. The device of claim 8 wherein the metallic body is manufactured from stainless steel;
- 10. The device of claim 8 wherein the medical device is selected from the group consisting of vascular stents, replacement joints, metallic heart valves, screws, pins, bolts, staples, fasteners, plates, skeletal fusion devices, spinal fusion devices, bone anchors, shunts, staples, fasteners, dental implants, orthodontic braces, dental retainers, retractors, retainers, couplings, scalpels, needles, forceps, dental tools, surgical tools, bone cutters, and saws.

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