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(54) **ELECTROPLATED PART AND MANUFACTURING METHOD THEREFOR, FIXTURE FOR MANUFACTURING, AND APPARATUS**

(57) An electroplated part, which contains hardly any organic residues and has a uniform electroplated layer. An electroplating method for preparing the electroplated part is also provided. By controlling the ratio of the length of a motion trajectory of the electroplated part relative to an anode during the electroplating process to the width of the anode, and adding auxiliary cathodes to the electroplated part, the electroplating method improves the uniformity of the thickness of the electroplated layer at various positions of the electroplated part. A fixture for implementing the electroplating method and an electroplating apparatus are provided. The electroplated layer of the electroplated part prepared by the electroplating method has relatively uniform thickness and a high coverage rate, problems such as burn and fracture have hardly occurred during the electroplating process of the electroplated part, the yield of electroplated parts is high, and the scrap rate is low. In addition, the precision of the weight of plated layers of electroplated parts can reach 99% or above.

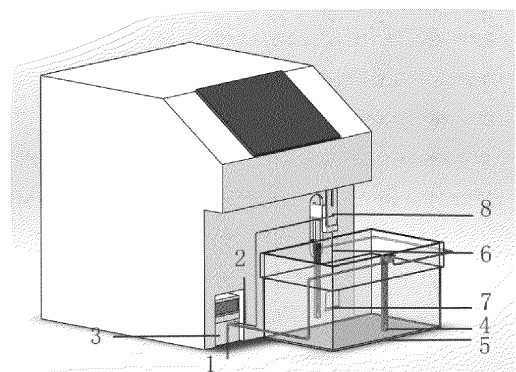


FIG. 1

Description

Technical Field

[0001] The present invention belongs to the technical field of electroplating, and particularly relates to an electroplated part and a preparation method thereof, a fixture for preparation, and an apparatus, and more particularly relates to an electroplated part for a medical device and a preparation method thereof, a fixture for preparation, and an apparatus.

Background Art

[0002] Since medical devices are eventually implanted in the human body and interact with human tissues for a long period of time, they need to have high safety, good biocompatibility, and effectiveness. Therefore, there are high requirements for the composition and content of various components of the device. Not only must the components pass the corresponding safety verification, but also the degradation products released by the components in vivo during the degradation process should not accumulate around the device to a level that would have a negative or adverse effect on the human body. According to relevant studies, even trace organic residues in the electroplated layer of the device may cause obvious safety reactions, such as inflammation, pustules, and other adverse reactions. Therefore, it is very necessary to control the types of components in the electroplated layer on the surface of the device, the content of harmful components, etc., so as to ensure that the electroplated part has good biocompatibility in the human body, thereby improving the safety and effectiveness of the device in vivo.

[0003] Currently, electroplating is widely used in industry. Generally, in industrial electroplating, electroplating mainly includes two methods: rack plating and barrel plating. Rack plating involves fixing a workpiece through a customized fixture and placing a plating part in an electroplating solution for electroplating. This method is more suitable for a large-sized workpiece. However, barrel plating involves placing a large number of small workpieces into a roller and applying a certain current from the electroplating power supply for electroplating for a corresponding time to obtain a desired thickness of the plated layer. Currently, it is mainly used for electroplating small-sized workpieces, is relatively simple to operate, and is also easier to achieve scale production.

[0004] However, various organic additives are added to the electroplating solution currently used in industrial electroplating. Due to the existence of various organic additives, the uniformity of industrial electroplated parts and the precision of electroplating are high. However, for medical devices, these organic additives are deposited on the surface of the device substrate more or less together with the electroplated layer so that there is a certain residue on the electroplated layer. However, even

a very small amount of organic residues will cause very serious adverse reactions at the implantation site of the device, thus causing safety problems. Therefore, there is an urgent need to develop an electroplating method suitable for medical devices.

Summary of the Invention

[0005] In order to overcome the above-mentioned drawbacks existing in the related art, the present invention provides an electroplated part for a medical device suitable for application to the human body, which avoids cell or tissue toxicity after implantation into the human body by strictly controlling the types and contents of components in the electroplated layer, thereby preventing causing severe inflammatory reactions and other adverse reactions. That is, the present invention provides an electroplated part having high biological safety.

[0006] The technical solution of the present invention provides an electroplated part, including a substrate and an electroplated layer. The electroplated layer covers the substrate, and the content of organic residues in the electroplated layer is less than 0.2%. During the preparation process of the electroplated part, various substances are added to an electroplating solution, especially some organic functional substances, which may significantly improve the efficiency of electroplating and the quality of the electroplated part, including uniformity and brightness, etc.. However, these organic functional substances may contain certain functional groups that may carry or adsorb a certain amount of charges in the solution. As a result, they can easily deposit on the electroplated layer during the electroplating process along with the formation of the electroplated layer. The trace organic residues deposited on the electroplated layer, after an electroplated part or finished medical device is implanted into the human body, may gradually be released into the human blood as the electroplated layer degrades, which may easily cause biological toxicity and thus lead to a series of adverse reactions. Therefore, it is necessary to strictly control the components in the electroplated layer of the electroplated part for a medical device to avoid serious safety problems of the device due to trace components.

[0007] Further, the content of organic residues in the electroplated layer provided by the present invention is less than 0.1%. Further, the content of organic residues in the electroplated layer is less than 0.05%. Further, the content of organic residues in the electroplated layer is less than 0.019%. Further, the content of organic residues in the electroplated layer is less than 0.01%. Further, the electroplated layer of the present invention contains hardly any organic residues.

[0008] The uniformity of the thicknesses of the electroplated layer at various positions of the medical device not only has a great effect on the corrosion rate of the substrate, corrosion period of the substrate, device fracture time, and effective supporting time of the substrate, but

also may cause fibrin deposition and proliferation of some tissues near the device due to the non-uniformity of the thicknesses of the electroplated layer. If cell proliferation occurs at the site of lumen stenosis, it will further cause lumen restenosis. Therefore, it is very necessary to control the uniformity of the thicknesses of the electroplated layer on the surface of the device at various positions of the substrate, so as to ensure that the device can avoid cell proliferation and lumen restenosis, etc. while meeting the corrosion rate, corrosion period, and effective supporting time of the device, thus improving the safety and effectiveness of the device in vivo.

[0009] In the above-mentioned technical solution provided by the present invention, a ratio of a thickness of the electroplated layer at the thickest place to a thickness at the thinnest place on the substrate is controlled to be (1-30): 1. Further, the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is (1-20): 1. Further, the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is (1-15): 1. Further, the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is (1-12): 1. Further, the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is (1-8): 1. Further, the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is (1-5): 1. Further, the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is [2-5]: 1.

[0010] According to the electroplated part provided in the above-mentioned technical solution, the thickness of the electroplated layer at the thickest place on the substrate is (1, 7.5] times an average thickness. Further, the thickness of the electroplated layer at the thickest place on the substrate is (1, 5] times the average thickness. After the average thickness of the electroplated layer is determined, the closer a ratio of the thickness of the electroplated layer at the thickest place on the substrate to the average thickness is to 1, the more uniform the electroplated layer is.

[0011] According to the electroplated part provided in the above-mentioned technical solution, the thickness of the electroplated layer at the thinnest place on the substrate is [0.25, 1) times the average thickness. After the average thickness of the electroplated layer is determined, the closer a ratio of the thickness of the electroplated layer at the thinnest place on the substrate to the average thickness is to 1, the more uniform the electroplated layer is.

[0012] In the present invention, the uniformity of the electroplated layer is controlled by controlling the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate, the ratio of the thickness of the electroplated layer at the thickest place to the average thickness of the

electroplated layer, and the ratio of the thickness of the electroplated layer at the thinnest place to the average thickness of the electroplated layer. The situation that some areas of the electroplated layer is too thick and others are too thin needs to be avoided as much as possible. If some areas of the electroplated layer are too thin, it is easy to cause premature degradation of the electroplated layer in these areas, thus resulting in that the electroplated layer cannot perform corresponding functions well, such as regulating substrate corrosion or promoting endothelialization. Conversely, if some areas of the electroplated layer are too thick, after the nearby thin electroplated layer is degraded, the subsequent degradation rate of the thick areas of the electroplated layer is easily accelerated due to electric potential and other reasons so that a large amount of degradation products of plated layer components are released in a short period of time, and then the degradation products of the plated layer are easily accumulated too much in a short period of time to cause a certain cell or tissue toxicity reaction. For example, when electroplating a zinc-containing layer on an iron-based device to control the early corrosion rate and mechanical performance of the iron base, insufficient zinc plating in some areas may easily cause premature degradation of the zinc layer in these areas and expose the iron base, thus leading to premature corrosion and premature fracture of the iron base in these areas. In addition, in some application scenarios, insufficient zinc plating in some areas is also unfavorable for the endothelialization of the device. However, if the zinc plating is too thick in some areas, after the nearby zinc layer is corroded and degraded, only a large amount of zinc remains in these areas. Under the influence of the electric potential, the release rate of this zinc layer is greatly increased, which causes a large amount of zinc ions to accumulate in these areas in a short period of time, thereby causing cytotoxicity, fibrin deposition, and cell proliferation. Therefore, in the present invention, the uniformity of the plated layer is controlled by controlling the above-mentioned ratios of the electroplated layer to ensure that the plated layer can satisfy its function without causing other adverse reactions.

[0013] According to the electroplated part provided in the above-mentioned technical solution, the average thickness of the electroplated layer is 0.5-5 μm . Further, the average thickness of the electroplated layer is 0.5-4 μm . The electroplated layer generally plays a very important role in the device, such as preventing substrate corrosion, ensuring that the substrate meets the early mechanical performance, or promoting endothelialization. However, if the thickness of the plated layer is too small, the plated layer may not meet the corresponding requirements. If the thickness of the plated layer is too large, it may cause other negative effects, such as making the device oversized and difficult to deliver in vivo, as well as deteriorating the overall mechanical performance of the device. The plated layer is a foreign substance to the human body after all, and too high content will cause

more burden on the human body, inevitably causing a series of adverse reactions. If the content of zinc plating on the iron-based stent is too small and the average thickness of zinc plating is too small, it is easy to lead to premature corrosion of the iron base, and it is unable to ensure that the iron base is not corroded or less corroded within 6 months after implantation, thus leading to premature fracture of the device. However, if the zinc plating on the iron-based stent is too thick, the profile of the stent after crimping is too large. Thus, the stent is not well delivered after implantation in the human body. Meanwhile, the accumulation of a large amount of zinc ions near the device easily causes cytotoxicity, leading to cell proliferation and vascular restenosis.

[0014] It should be noted that the "average thickness D of the electroplated layer" described in the present invention is calculated based on the total mass M_{total} of the electroplated layer, the density ρ , and the sum S_{total} of areas of all plateable surfaces of the electroplated part according to the following formula:

$$D = \frac{M_{total}}{S_{total} \rho}$$

[0015] Further, in the present invention, the thicknesses at the thickest place and the thinnest place of the electroplated layer are strictly controlled, respectively, thereby further ensuring the uniformity of the electroplated layer and ensuring that the electroplated layer can meet the corresponding functional requirements well with as little negative reaction to the human body as possible.

[0016] In the above-mentioned technical solution provided by the present invention, the thickness of the electroplated layer at the thinnest place on the substrate is 0.25-4.25 μm . Further, the thickness of the electroplated layer at the thinnest place on the substrate is 0.375-3.2 μm . Further, the thickness of the electroplated layer at the thinnest place on the substrate is 0.6-3.2 μm . Further, the thickness of the electroplated layer at the thinnest place on the substrate is 0.6-2.5 μm .

[0017] In the above-mentioned technical solution provided by the present invention, the thickness of the electroplated layer at the thickest place on the substrate is 1.1-15 μm . Further, the thickness of the electroplated layer at the thickest place on the substrate is 1.1-9.75 μm . Further, the thickness of the electroplated layer at the thickest place on the substrate is 1.1-7.5 μm . Further, the thickness of the electroplated layer at the thickest place on the substrate is 1.2-5 μm .

[0018] According to the electroplated part provided in the above-mentioned technical solution, the electroplated layer covers more than 99% of a surface of the substrate. Further, the electroplated layer covers more than 99.5% of the surface of the substrate. Further, the electroplated layer covers more than 99.9% of the surface of the substrate.

[0019] According to the electroplated part provided in

the above-mentioned technical solution, the electroplated layer is a pure metal layer or an alloy layer. According to needs, the electroplated layer may be degradable or non-degradable. Further, the electroplated layer is degradable. In some examples of the present invention, the electroplated layer is a pure zinc layer. In some examples of the present invention, the electroplated layer is a zinc-iron alloy layer. In other examples of the present invention, the electroplated layer is a pure iron plated layer. In still other examples of the present invention, the electroplated layer is a pure magnesium layer. In still other examples of the present invention, the electroplated layer is a magnesium alloy layer.

[0020] According to the electroplated part provided in the above-mentioned technical solution, the electroplated layer is a pure zinc layer or a zinc alloy layer. Further, the content of zinc in the electroplated layer is more than 50%. Further, the content of zinc in the electroplated layer is more than 99%.

[0021] According to the technical solution provided in the above-mentioned technical solution, a medical device includes a vascular stent, a non-vascular endoluminal stent, an occluder, an orthopedic implant, a heart valve, a spacer, an artificial vessel, a dental implant device, a vascular clamp, a dental implant, a respiratory implant, a gynecological implant, an andrological implant, a suture, and a bolt.

[0022] According to the technical solution provided in the above-mentioned technical solution, the device is a degradable medical device which may be gradually degraded in vivo and absorbed by the human body. Further, in the present invention, the substrate is made of a degradable metal or a degradable non-metal material. Further, in the present invention, the substrate is made of a degradable pure metal or a metal alloy. Further, in the present invention, the substrate includes at least one of pure iron, an iron alloy, pure zinc, a zinc alloy, pure magnesium, and a magnesium alloy.

[0023] Further, in the above-mentioned technical solution of the present invention, the electroplated part is a tubular hollowed-out medical device. Further, in the above-mentioned technical solution of the present invention, the electroplated part is a stent or other derivatives with a stent structure, such as a heart valve. In the present invention, the stent includes a vascular stent and a non-vascular stent.

[0024] According to the above-mentioned technical solution provided by the present invention, a mass-to-volume ratio of the electroplated part is 0.001-10 g/cm^3 . Further, the mass-to-volume ratio of the electroplated part is 0.001-5 g/cm^3 . Further, the mass-to-volume ratio of the electroplated part is 0.001-0.4 g/cm^3 . Further, the mass-to-volume ratio of the electroplated part is 0.005-0.3 g/cm^3 . Further, the mass-to-volume ratio of the electroplated part is 0.01-0.2 g/cm^3 . In the present invention, the smaller the mass-to-volume ratio of the electroplated part, the more complicated the structure of the electroplated part and the more difficult the electro-

plating.

[0025] The "mass-to-volume ratio of the electroplated part" described in the present invention refers to the mass M of the electroplated part divided by the total volume covered by its external contour lines. For example, when the electroplated part is a hollowed-out tubular stent, the volume of the electroplated part is $V = 2\pi R \times d$, where R is an outer diameter of the stent, and d is the length of the stent. Therefore, the mass-to-volume ratio of the electro-

plated part is $\frac{M}{V} = \frac{M}{2\pi R d}$.

[0026] According to the technical solution provided in the above-mentioned technical solution, the substrate is made of a degradable metal or a degradable non-metal material. Further, the substrate includes at least one of pure iron, an iron alloy, pure zinc, a zinc alloy, pure magnesium, and a magnesium alloy. Further, the iron alloy includes at least one of a low alloy steel or an iron-based alloy having a carbon content of no more than 2.5 wt.%.

[0027] In order to ensure the safety of the electroplated part described in the present invention, the components of the electroplating solution are strictly controlled in the preparation process of the electroplated part of the present invention to ensure that all the components deposited on the plated layer have good biocompatibility and do not cause serious adverse reactions. The limitation of the added components in the electroplating solution will inevitably affect the uniformity of the electroplated layer and other indicators. However, the electroplated parts for medical devices are mainly applied in the human body, mostly accompanied by certain functionality, have complex shapes and precise structures, and have high requirements for the uniformity of electroplated layer, the coverage rate of the plated layer, and the precision of the plated layer quality. However, the direct use of the conventional electroplating method for electroplating is prone to problems such as a low coverage rate of the electroplated layer of the electroplated part, burns or even fracture of some parts of the device, and low yield, which in turn leads to the quality of the electroplated part not reaching the standard, a low qualification rate, and failure to satisfy the corresponding quality and safety requirements.

[0028] Based on this, the present invention provides a method that does not introduce a large amount of organic residues in the electroplated layer of the electroplated part while ensuring good uniformity of the electroplated layer.

[0029] According to the present invention, there is provided an electroplating method suitable for an electroplated part requiring relatively high uniformity and safety of an electroplated layer. The method may not only significantly improve the in vivo safety of the electroplated part without causing significant inflammatory reactions and pustules in the contacted tissues, but also ensure the uniformity of the thicknesses of the plated layer at various positions so that uniformity indicators of

the electroplated part may be optimized, thereby greatly improving the uniformity of the electroplated part.

[0030] The technical solution of the present invention provides an electroplating method for an electroplated part. The electroplated part is placed in an electroplating solution and moves relative to an anode at a certain amplitude and frequency with a fixture. A length of a motion trajectory of the electroplated part relative to the anode during an electroplating process is 2-980 times a width of the anode; and/or auxiliary cathodes are connected to the electroplated part.

[0031] In the present invention, on the one hand, the uniformity of electroplating at various positions of the electroplated part is improved by increasing the ratio of the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process to the width of the anode, and on the other hand, the uniformity of electroplating at various positions of the electroplated part is improved by connecting auxiliary cathodes to the electroplated part. When the ratio of the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process to the width of the anode is larger, the thicknesses of the electroplated layer at various positions of the electroplated part will be more uniform. However, as the ratio of the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process to the width of the anode increases, higher requirements are put forward for the size of the electroplating bath, the usage of the electroplating solution, and the electric quantity. When the ratio of the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process to the width of the anode is larger, the size of the electroplating bath needs to be increased, which will also lead to a corresponding increase in the usage of electroplating solution and the consumption of electric quantity. This results in a waste of resources and even increased emissions. When the ratio of the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process to the width of the anode is small, such as less than 2, the uniformity of thicknesses at various positions of the electroplated part is significantly reduced, resulting in a thickness of less than 0.2 μm at the thinnest place of the device, thereby making the device produced less effective after implantation in the body. According to another aspect of the present invention, the uniformity of electroplating at various positions of the electroplated part is improved by connecting auxiliary cathodes to the electroplated part. In the process of device electroplating, the thickness of the electroplated layer tends to be thicker at two ends and also thicker on the outer layers. However, the thickness of the electroplated layer becomes thinner towards the middle and also thinner on the inner layers. In addition, electroplating exhibits a tip effect, where the closer to the tip, the thicker the electroplated layer, and the farther from the tip, the thinner the electroplated layer becomes. Therefore, during the electroplating process,

the thickness at two ends of the electroplated part is thick, and the thickness in the middle is relatively uniform. Therefore, in the present application, the uniformity of the electroplated layer at various positions of the electroplated part is improved by adding a section of auxiliary cathode at each end of the electroplated part during the electroplating process.

[0032] The electroplated part in the present invention is connected to an electroplating apparatus through a fixture, may move relative to the anode under the drive of the fixture, or may be fixed by the fixture. The anode moves under the drive of a driver. That is, "the electroplated part moves relative to the anode during the electroplating process" described in the present invention may refer to that the anode is stationary and the electroplated part moves relative to the anode, or that the electroplated part is stationary and the anode moves relative to the electroplated part.

[0033] In the present invention, the motion trajectory of the electroplated part relative to the anode during the electroplating process may be a straight line, a curved line, a circle, a cone, and a regular or irregular polygon. In some examples of the present invention, the electroplated part, driven by the fixture, performs a curvilinear motion relative to the anode. In some examples of the present invention, the electroplated part, driven by the fixture, performs a rectilinear motion relative to the anode. In other examples of the present invention, the electroplated part, driven by the fixture, performs a regular polygonal motion relative to the anode. In still other examples of the present invention, the electroplated part, driven by the fixture, performs an irregular polygonal motion relative to the anode. In still other examples of the present invention, the electroplated part, driven by the fixture, performs a circular motion relative to the anode.

[0034] Further, the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 2-540 times the width of the anode. Further, the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 2-400 times the width of the anode. Further, the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 2-240 times the width of the anode. Further, the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 2-150 times the width of the anode. In the present invention, a ratio of the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process to the width of the anode is reduced, and the waste of resources, cost control, and the waste liquid emission may be avoided as much as possible while ensuring that the uniformity of the plated layer on the surface of the electroplated part meets the requirements.

[0035] In some examples of the present invention, the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is

3, 5, 10, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 150, 180, 190, 200, and 220 times the width of the anode. In some examples of the present invention, the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 65, 75, 85, 25, 35, 45, 55, 95, 105, 125, 160, 170, and 195 times the width of the anode.

[0036] It should be specifically noted that "the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process" described in the present invention refers to the length of the trajectory of the electroplated part moving relative to the anode for one cycle during the electroplating process. The width of the anode refers to the width of one anode.

[0037] In the present invention, the uniformity of the electroplated layer at various positions of the electroplated part may be greatly improved by controlling the relative magnitude relationship between the length of the motion trajectory of the electroplated part relative to the anode and the width of the anode. When the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is controlled within the range of 2-240 times the width of the anode, the uniformity of the electroplated layer is greatly improved, thereby ensuring that the device can avoid cell proliferation and lumen restenosis while satisfying the corrosion rate, corrosion period, and effective supporting time of the device.

[0038] Further, in the present invention, the ratio of the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process to the width of the anode is increased by decreasing the width of the anode, increasing the length of the cathode, increasing the amplitude of swing of the fixture, and controlling the effective swing length of the fixture. Various parameters may be regulated at the same time or individually to achieve the corresponding purpose, i.e., improving the uniformity the plated layer of the electroplated part.

[0039] Further, the width of the anode is ≥ 0.1 cm. In some examples of the present invention, the width of the anode may be 0.1 cm. In other examples of the present invention, the width of the anode may be 5 cm. In other examples of the present invention, the width of the anode may be 10 cm. In still other examples, the width of the anode may even be 20 cm or more. Although there is no further limitation on the width of the anode in the present invention, when the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is constant, the smaller the width of the anode, the higher the uniformity of the thicknesses of the electroplated part at various positions.

[0040] According to the above-mentioned technical solution provided by the present invention, in the present invention, the uniformity of the electroplated layer is further controlled by regulating the amplitude of swing of the electroplated part relative to the anode. The amplitude of swing of the electroplated part relative to the

anode is controlled in the range of 0°-180°. Further, in the present invention, the uniformity of the electroplated layer is further controlled by regulating the amplitude of swing of the electroplated part relative to the anode. The amplitude of swing of the electroplated part relative to the anode is controlled in the range of 0°-160°. When the electroplated part performs a curvilinear, rectilinear, or conical motion relative to the anode, the amplitude of swing of the electroplated part relative to the anode is (0°, 160°]. When the electroplated part performs a circular, regular, or irregular polygonal motion relative to the anode, the amplitude of swing of the electroplated part relative to the anode is 0°. When the electroplated part performs a curvilinear, rectilinear, or conical motion relative to the anode, the amplitude of swing of the electroplated part relative to the anode is further (0°, 150°] or (0°, 145°]. In some examples of the present invention, the amplitude of swing of the electroplated part relative to the anode is 0.5°, 0.8°, 1°, 2°, 5°, 8°, 10°, 15°, 20°, 25°, 30°, 35°, 40°, 45°, 50°, 55°, or 60°. In other examples of the present invention, the amplitude of swing of the electroplated part relative to the anode is 70°, 80°, 90°, 100°, 110°, 120°, 130°, or 135°. In other examples of the present invention, the amplitude of swing of the electroplated part relative to the anode is 138°, 140°, 145°, 148°, 150°, 155°, or 158°.

[0041] The "amplitude of swing of the electroplated part relative to the anode" described in the present invention refers to the magnitude of an included angle formed between two lines that connect two highest points of the relative positions of the motion trajectory of the electroplated part relative to the anode to a fixed point/rotation point of the fixture that drives the motion of the electroplated part or their intersection. For example, when the motion trajectory of the electroplated part relative to the anode is a curved or straight line, an included angle formed between two lines that connect the highest points at two ends of the curved or straight trajectory to the fixed point/rotation point of the fixture that drives the motion of the electroplated part is taken, and when there are two fixed points or rotation points, an included angle formed between two lines that connect the highest points at two ends of the curved or straight trajectory to the intersection of the two fixed points/rotation points of the fixture that drives the motion of the electroplated part is taken.

[0042] Further, in the present invention, the auxiliary cathodes are connected to two ends of the electroplated part in a long axis direction or in a direction parallel to an anode surface. The uniformity of the thicknesses of the device at various positions may be significantly improved by connecting the auxiliary cathodes to two ends of the electroplated part in the long axis direction or in the direction parallel to the anode surface and then removing the auxiliary cathodes after the electroplating of the device is completed.

[0043] Further, an area of the auxiliary cathode is 30%-70% of an area of a cathode. Further, the auxiliary

cathode has a length of 0.5 mm-20 mm. Preferably, the auxiliary cathode has a length of 0.5 mm-10 mm. Preferably; the auxiliary cathode has a length of 1 mm-10 mm. A high reproducibility or precision may be maintained while ensuring an improved uniformity of the thickness of the electroplated layer of the device by properly regulating the area fraction of the auxiliary cathode relative to the entire cathode and/or the length of the auxiliary cathode, thereby ensuring a high qualification rate of the device electroplating process.

[0044] According to "the area of the auxiliary cathode is 30%-70% of the area of the cathode" described in the present invention, "the area of the cathode" includes a surface area of the stent, an exposed area of the fixture, and the area of the auxiliary cathode.

[0045] Further, the auxiliary cathode is of any shape. Further, the auxiliary cathode includes at least one of a linear type, an annular type, a ring type, a prismatic type, a pyramidal type, a spiral type, a wheel type, a cylindrical type, and a corrugated type. In some examples, the auxiliary cathode is of one of the above-mentioned shapes. In other examples, the auxiliary cathode is of a shape that combines/connects at least two of the above-mentioned shapes. In other examples, the auxiliary cathode includes any one of the above-mentioned shapes. In other examples, the auxiliary cathode includes a plurality of shapes described above. In some examples, the various shapes described above may be combined/connected together in a short axis direction of the device to form an auxiliary cathode. In other examples, the various shapes of auxiliary cathodes described above may be combined/connected together in the long axis direction of the device.

[0046] It should be noted that the "prismatic type, pyramidal type, spiral type, wheel type, and cylindrical type" in the present invention may be solid, hollowed-out, or hollow.

[0047] Further, a cross-sectional area of the auxiliary cathode in a direction perpendicular to an anode surface or a long axis direction of the electroplated part is larger than a cross-sectional area of a short axis of the electroplated part. That is, the auxiliary cathode completely covers the interface of the device at a distal end, i.e., a projection of the auxiliary cathode on an interface perpendicular to the long axis direction of the device is greater than a projection of the device on the interface.

[0048] Further, the auxiliary cathode is connected to the electroplated part through a linkage or a point. In some examples of the present invention, a plurality of auxiliary cathodes of wire-like structures are connected to each other at a point at the distal end of the device through a point to form an outwardly radiating rib-like structure. In other examples of the present invention, a plurality of auxiliary cathodes of annular structures are connected together in layers along the long axis direction of the device through the linkage.

[0049] Further, the linkage is fixedly or detachably connected to the electroplated part, the fixture, and the

auxiliary cathode. In some examples of the present invention, the auxiliary cathode of the above-mentioned shape and the electroplated part as well as the fixture and the auxiliary cathode may be wholly detachably connected or partially detachably connected. When they are partially detachably connected, the rest may be fixedly connected.

[0050] Further, the linkage is one of a straight line or a non-straight line. The linkage is at least one of a linear type, an S type, a ω type, or a Ω type. For example, in some examples of the present invention, the auxiliary cathode is hollowed-out cylindrical.

[0051] Further, the linkage is detachably or fixedly connected to at least one of the electroplated part, the fixture, and the auxiliary cathode. In some examples, the linkage is ω -shaped or Ω -shaped, and the auxiliary cathode is hollowed-out cylindrical. The auxiliary cathode is fixedly connected to the device through the linkage.

[0052] According to the above-mentioned technical solution provided by the present invention, in the present invention, the quality of the plated layer, such as uniformity, is further controlled by adjusting the frequency of motion of the electroplated part relative to the anode, and the frequency of motion of the electroplated part relative to the anode is controlled to be 0.1-20 s/cycle. Further, the frequency of motion of the electroplated part relative to the anode is controlled to be 0.2-18 s/cycle. Further, the frequency of motion of the electroplated part relative to the anode is controlled to be 0.2-15 s/cycle. In some examples of the present invention, the frequency of motion of the electroplated part relative to the anode is 0.3 s/cycle, 0.8 s/cycle, 1 s/cycle, 2 s/cycle, 3 s/cycle, 4 s/cycle, 5 s/cycle, 7 s/cycle, 8 s/cycle, 9 s/cycle, 10 s/cycle, or 11 s/cycle. In other examples of the present invention, the frequency of motion of the electroplated part relative to the anode is 12 s/cycle, 13 s/cycle, 14 s/cycle, 15 s/cycle, 16 s/cycle, 17 s/cycle, 18 s/cycle, or 19 s/cycle. In the present invention, regulating the frequency of motion of the electroplated part relative to the anode may not only avoid the poor quality of the plated layer due to a too-low frequency but also prevent problems of sparking, deformation of the stent, etc., due to a too-high frequency.

[0053] For the electroplated part with a relatively light mass and a hollowed-out shape, such as a stent, described in the present invention, the interaction force formed between the stent and the fixture in the electroplating solution is relatively small due to the buoyancy of the electroplating solution and its own small mass. In addition, since the electroplated part has a relatively high requirement for the coverage rate for the plated layer, i.e., a contact area between the fixture and the electroplated part needs to be very small, it is possible to ensure that all the surfaces of the stent are substantially exposed to the electroplating solution. In this case, when the current density is relatively high, a "sparking" phenomenon easily occurs, and the stent rod is broken down so that a part of the stent rod is burnt or even fractured. Therefore, in

the present invention, the interaction force and contact area between the fixture and the stent are controlled by improving the shape of the fixture and the interaction relationship between the fixture and the stent. Controlling the magnitude of the interaction force can not only avoid the phenomenon of "sparking" and burn and fracture of the stent due to too small interaction force between the fixture and the stent, but also avoid the deformation of the stent rod due to too large interaction force between the fixture and the stent, thereby further improving the yield of the stent in the electroplating process and reducing the scrap rate. Therefore, in the technical solution of the present invention, the situation of burn and fracture of the stent rod is overcome by controlling the force applied to the electroplated part by the fixture during the electroplating process through the fixture, where the magnitude of the force is 1×10^{-3} -0.5 N. Further, the magnitude of the force applied to the electroplated part by the fixture during the electroplating process is 1×10^{-3} -0.35 N. Further, the magnitude of the force applied to the electroplated part by the fixture during the electroplating process is 1×10^{-3} -0.28 N.

[0054] In the examples of the present invention, the force by the fixture is simply referred to as a clamping force.

[0055] It should be specifically noted that in the present invention, the magnitude of the force applied to the electroplated part by the fixture during the electroplating process has a great relationship with the electroplated part itself. When the quality, shape, etc., of the electroplated part changes, the range of the force applied to the electroplated part by the fixture also changes. For example, for a 30018 stent, when the force applied to the stent by the fixture is within the range of 0.005-0.05 N, the stent will neither be deformed nor burnt. For a larger stent than the 30018 stent model, the optimal range of the force shall exceed 0.05 N, and even reach 0.5 N. For orthopedics and other devices with a weight significantly greater than the stent, the appropriate maximum force will be greater. For a smaller stent or medical device than the 30018 stent model, the minimum force and maximum force of a fixture which are suitable will be smaller than that of the 30018 stent.

[0056] According to the above-mentioned technical solution provided by the present invention, in the present invention, the force applied to the electroplated part by the fixture during the electroplating process is an extrusion force.

[0057] According to the above-mentioned technical solution provided by the present invention, a contact area between the electroplated part and the fixture is not more than 0.1 mm^2 . In the present invention, the shape of the fixture is controlled so that the contact mode between the fixture and the electroplated part is point-to-point contact or point-to-surface contact, rather than surface-to-surface contact. Therefore, the contact area between the fixture and the electroplated part is very small and less than 0.1 mm^2 , and the total contact area accounts for less

than 0.1% of the total surface area of the stent. In the present invention, the exposed area of the electroplated part in the electroplating solution is sufficiently improved by controlling the contact area between the electroplated part and the fixture so that 99% or even more than 99.9% of the surface of the stent may be directly contacted with the electroplating solution. That is, 99% or even more than 99.9% of the surface of the stent may be covered with the electroplated layer, and the coverage rate of the electroplated layer is very high, thereby effectively preventing problems such as unsatisfactory corrosion and safety of the surface of the stent due to insufficient coverage of the plated layer.

[0058] In the present invention, the contact area between the electroplated part and the fixture is not more than 0.1 mm², and the total contact area accounts for less than 0.1% of the total surface area of the stent. Therefore, the exposed area of the electroplated part in the electroplating solution, equivalent to the area of the electroplated part, refers to the areas of all electroplated parts that may be in direct contact with the electroplating solution. When the electroplated part is a stent, the area of the electroplated part includes areas of all surfaces of the stent rod, i.e., the sum of the areas of all surfaces of the stent that may be in direct contact with the solution.

[0059] According to the above-mentioned technical solution provided by the present invention, a temperature of the electroplating solution during the electroplating process of the electroplated part is 10-50°C. The current density of the electroplating is 1-20 A·dm². In the present invention, the current density of electroplating should be matched with the speed of electroplating and combined with the above-mentioned contact area and force between the electroplated part and the fixture to comprehensively regulate.

[0060] According to the above-mentioned technical solution provided by the present invention, the electroplating time during the electroplating process of the electroplated part is 10-300 s. Further, the electroplating time during the electroplating process of the electroplated part is 10-95 s. In the present invention, the average thickness of the electroplated layer is controlled by a combination of current, current density, and electroplating time.

[0061] The electroplating method provided by the present invention is suitable for zinc plating, nickel plating, copper plating, silver plating, gold plating, and various-alloy plating, such as a zinc-copper alloy. In the present invention, the electroplated part is a degradable material, suitable for electroplating on pure iron, an iron alloy, zinc, a zinc alloy, and other metals, and also suitable for electroplating of a stent and other nonstent devices.

[0062] In the present invention, according to the components of the plated layer, the anode material may be regulated. When the plated layer contains zinc, the anode is zinc, and when the plated layer is silver, the anode is silver, and so on. The anode in the present invention may be at least one of zinc, nickel, copper, a nickel-copper alloy, a nickelzinc alloy, gold, and a copper-gold

alloy.

[0063] In the electroplating method provided by the present invention, the components of the electroplating solution are also involved. When the electroplated part of the present invention is a medical device, the composition of the electroplating solution is highly required, a composition unfavorable to the human body cannot be introduced into the electroplating solution. Therefore, the present invention provides a safe electroplating solution formulation without any organic functional agent. Thus, any organic residue having poor biocompatibility is not introduced into the electroplated layer of the finally prepared electroplated part, and serious adverse reactions to human tissues at the implantation site will not occur, thereby greatly improving the safety of the medical device and the effectiveness of implantation.

[0064] Further, the components of the electroplating solution provided in the present invention are all inorganic components, i.e., there is no organic additive in the electroplating solution.

[0065] Further, when zinc is contained in a plated layer, the electroplating solution includes 3.4-4.5 wt.% of a zinc-containing component and 2.1-3.1 wt.% of a pH adjusting agent; or the electroplating solution includes 1.5-3.0 wt.% of the zinc-containing component and 6.5-8.8 wt.% of the pH adjusting agent;

the zinc-containing component is at least one of zinc chloride, zinc sulfate, and zinc oxide;

the pH adjusting agent is at least one of boric acid, sodium borate, potassium borate, calcium borate, sodium hydroxide, and potassium hydroxide.

[0066] According to the above-mentioned technical solution provided by the present invention, the electroplating solution further includes 15.5-19.5 wt.% of a chloride salt, and the chloride salt is at least one of sodium chloride, potassium chloride, and ammonium chloride.

[0067] Further, when zinc is contained in a plated layer, the electroplating solution includes 3.4-4.5 wt.% of a zinc-containing component and 2.1-3.1 wt.% of a pH adjusting agent; or the electroplating solution includes 1.5-3.0 wt.% of the zinc-containing component and 6.5-8.8 wt.% of the pH adjusting agent;

the zinc-containing component is at least one of zinc chloride, zinc sulfate, and zinc oxide;

the pH adjusting agent is at least one of boric acid, sodium borate, potassium borate, calcium borate, sodium hydroxide, and potassium hydroxide.

[0068] The electroplating solution further includes 15.5-19.5 wt.% of a chloride salt, and the chloride salt is at least one of sodium chloride, potassium chloride, and ammonium chloride.

[0069] The technical solution of the present invention

further provides a fixture for the above-mentioned electroplating method, which is configured to fix the electroplated part in an electroplating bath and drive the electroplated part to move relative to the anode.

[0070] Further, the fixture includes a connecting portion and clamping portions perpendicularly connected to the connecting portion. The clamping portion is parallel to a long axis direction of the electroplated part. An end of the connecting portion near the electroplated part has at least two connecting rods. In the present invention, two or more clamping portions and connecting rods work together to "clamp" the electroplated part so that the electroplated part can be maintained in a relatively stable state during the electroplating process without the occurrence of burn and fracture. In some examples of the present invention, there are two connecting rods and two clamping portions. In other examples, there are three connecting rods and three clamping portions. In still other examples, there are four, five, six, eight, or more connecting rods and clamping portions.

[0071] According to the fixture provided in the above-mentioned technical solution, a distance between two connecting rods is less than a distance between corresponding contact points of the electroplated part and the connecting rod. Further, the distance between two connecting rods is [0.6, 0.98] times the distance between corresponding contact points of the electroplated part and the connecting rod. Further, the distance between two connecting rods is [0.6, 0.95] times the distance between corresponding contact points of the electroplated part and the connecting rod. Further, the distance between two connecting rods is [0.7, 0.95] times the distance between corresponding contact points of the electroplated part and the connecting rod. Further, the distance between two connecting rods is [0.8, 0.95] times the distance between corresponding contact points of the electroplated part and the connecting rod. When there are two connecting rods and two clamping portions, the two connecting rods and two clamping portions of the fixture together clamp two ends of the electroplated part in the length direction. At this time, the distance between two connecting rods is the width of the clamp, and the distance between corresponding contact points of the electroplated part and the connecting rod is the long length of the electroplated part. However, it should be noted that the connecting rod and the clamping portion of the fixture of the present invention do not merely clamp the electroplated part from the length direction of the electroplated part, but also clamp the electroplated part from the thickness and width directions of the electroplated part, especially when the electroplated part has other special structures, and may also clamp the electroplated part from the middle or any other position of the electroplated part. For example, when the electroplated part is a stent, the connecting rod and the clamping portion of the fixture may clamp the stent from any two stent rods of the stent. In the present invention, the force applied to the electroplated part by the fixture is controlled

by controlling a ratio of the distance between two connecting rods to the distance between corresponding contact points of the electroplated part and the connecting rod.

[0072] According to the fixture provided in the above-mentioned technical solution, the fixture is in contact with the electroplated part in a point-to-point or point-to-surface manner, and the clamping portion may be cylindrical, cubic, regular, or irregular.

[0073] According to the fixture provided in the above-mentioned technical solution, a ratio of a distance between any two points connected by a straight line on a cross section of the clamping portion perpendicular to a length direction of the electroplated part to an inner diameter of the electroplated part is 1: 1-1: 20. The distance between any two points connected by a straight line on the cross section of the clamping portion perpendicular to the length direction of the electroplated part is smaller relative to the inner diameter of the electroplated part, the smaller the contact area with the device, and the more conducive to the all-around electroplating of the surface of the device. In the present invention, the contact area between the electroplated part and the fixture is not more than 0.1 mm².

[0074] According to the fixture provided in the above-mentioned technical solution, the clamping portion has a length of 0.16-7 mm. The length of the clamping portion will not only affect the weight of the final plated layer on the electroplated part, but also affect the interaction force between the fixture and the electroplated part. When the length of the clamping portion is too long, more plated layers will be coated on the clamping portion during the electroplating process so that the actual quality of the plated layer on the electroplated part is significantly lower. When the length of the clamping portion is too short to clamp the electroplated part well, the electroplated part tends to slip off during the electroplating process.

[0075] According to the fixture provided in the above-mentioned technical solution, $\geq 95\%$ of a surface area of the fixture is covered with an insulating layer; or more than 25% of the surface of the fixture is covered with the insulating layer. In some technical solutions of the present invention, as far as possible, the surfaces of the portions of the fixture exposed to the electroplating solution are covered with an insulating layer, and plating of the electroplating solution on the fixture is reduced, thereby allowing the weight of the plated layer covered on the electroplated part to be controlled with high precision. In some examples of the present invention, the insulating layer covers the entire surface of the connecting portion. In some examples of the present invention, the insulating layer covers a substantial portion of the surface of the connecting portion. In other examples of the present invention, the insulating layer covers the surfaces of the connecting portion and the fixing part. In still other examples of the present invention, the insulating layer covers the surfaces of the connecting portion, the fixing part, and a part of the clamping portion. In other solutions

of the present invention, the auxiliary cathode is fixedly connected to the fixture, and at this time, more than 25% of the surface of the fixture is covered with an insulating layer.

[0076] According to the fixture provided in the above-mentioned technical solution, the insulating layer is made of a high molecular material, which may be one of PVC, PET, polyolefin, and polyresin. The material of the main body of the fixture is a conductive metal such as stainless steel, iron, copper, and titanium.

[0077] According to the fixture provided in the above-mentioned technical solution, a fixing part is further connected to an end of the connecting portion away from the electroplated part. The fixture is connected/fixed to the electroplating apparatus through the fixing part.

[0078] The technical solution of the present invention further provides an electroplating apparatus including the above-mentioned fixture. The electroplating apparatus further includes a power supply, an electrolytic bath, and anodes, and the fixture is connected to the electroplating apparatus through a supporting rod.

[0079] According to the electroplating apparatus provided in the above-mentioned technical solution, the number of the anodes is greater than or equal to 2. In some examples of the present invention, the number of the anodes is 2. In other examples of the present invention, the number of anodes is 3, 4, 6, or 8. In other examples of the present invention, the number of the anodes is 10 or more.

[0080] According to the electroplating apparatus provided in the above-mentioned technical solution, a center position of a plurality of anodes coincides with a center position of a motion trajectory of the electroplated part. In the present invention, the anode is provided to ensure, as much as possible, that various positions of the electroplated part are subject to the same magnitude of current density in the electroplating solution, thereby ensuring better uniformity of the thicknesses of the plated layer at various positions of the electroplated part.

[0081] According to the electroplating apparatus provided in the above-mentioned technical solution, the width of the anode is ≥ 0.1 cm.

[0082] According to the electroplating apparatus provided in the above-mentioned technical solution, the electroplating apparatus further includes a component configured to control and drive relative motion of the fixture and the anode. In some examples of the present invention, the component controls and drives the motion of the fixture. In other examples, the component controls and drives the motion of the anode. In still other examples, the controller simultaneously controls relative motion of the electroplated part and the anode. In the present invention, the component may control the length of a motion trajectory of the fixture relative to the anode to be 2-980 or even 2-240 times the width of the anode.

[0083] According to the electroplating apparatus provided in the above-mentioned technical solution, the electroplating apparatus further includes a display

screen.

[0084] According to the electroplating apparatus provided in the above-mentioned technical solution, the power supply is a direct current power supply or a direct current pulse power supply.

[0085] According to the electroplating apparatus provided in the above-mentioned technical solution, the shape of the anode is a regular or irregular shape. The shape or projected shape of the anode may be a regular shape such as a square, a rectangle, a triangle, an ellipse, a circle, a heart, or an irregular shape.

[0086] According to the electroplating apparatus provided in the above-mentioned technical solution, the shape of the electrolytic bath is not limited and may be a circle, a square, or a rectangle. The size of the electrolytic bath is also not limited and may be matched to the width of the anode by controlling the motion trajectory of the electroplated part relative to the anode.

[0087] According to the method provided in the present invention, the uniformity of the thickness of the zinc plating may be greatly improved so that the ratio between the thicknesses of the electroplated part at the thickest place and the thinnest place may be reduced by several times to several tens of times and approach to 1 as much as possible. In addition, the defect rate of electroplated parts during the electroplating process may be reduced as much as possible, and the qualification rate and safety performance of products may be improved. Meanwhile, a high degree of precision is provided among the electroplated parts, a plurality of electroplated parts to be electroplated consecutively have a high degree of uniformity and stability in terms of the thickness of the plated layer, the quality of the plated layer, etc., and the RSD among the plurality of electroplated parts to be electroplated consecutively may be controlled within 1%.

[0088] The fixture provided in the present invention has good elasticity and durability and may be reused without loss. The contact area between the fixture and the electroplated part may be very small, and the fixture may apply a just suitable force to the electroplated part so that the electroplated part is not burnt during the electroplating process, and the stent will not be deformed.

[0089] It should be specifically noted that the present invention is only described by taking zinc plating as an example, which does not represent that the technical solution disclosed in the present invention is only suitable for the zinc plating. The electroplating method, the fixture for electroplating, and the electroplating apparatus in the present invention are suitable for plating any coating on all metal substrates. The metal substrates may be pure iron, iron alloys, pure zinc, zinc alloys, pure magnesium, magnesium alloys, some other pure metals or metal alloys. The coating may be a pure zinc layer, a zinc alloy layer, a pure nickel layer, a nickel alloy layer, a pure copper layer, a copper alloy layer, a pure silver layer, a silver alloy layer, a pure gold layer, a gold alloy layer, a pure platinum layer, a platinum alloy layer, or any other metal coatings. The method and fixture of the present

invention are suitable for the electroplating of small and light electroplated parts. The electroplated part may be a stent or any other small and light electroplated part with relative high requirements for the electroplated layer, and may belong to a non-device class, and especially a device class. The present invention is only described by taking a stent as an example, which does not represent that the method and apparatus in the present invention are only suitable for the electroplating of the stent. The present invention is only described by taking zinc plating as an example, which does not represent that the method and apparatus in the present invention are only suitable for the zinc plating.

[0090] It should be specifically noted that the drawing of the electroplating apparatus according to the present invention is merely one way of presentation, and that the relative positional relationship between the components may be changed randomly in the case where the same function may be realized and the same component or structure is provided.

[0091] The value of the interval range involved in the present invention is not limited to the provided interval range, but should be the value of a new interval composed of any two values in the interval or any specific value in the interval. For example, according to "the current density of the electroplating is $1-20 \text{ A} \cdot \text{dm}^2$ " in the present invention, the value of the content of the current density agent is not limited to only the range of $1-20 \text{ A} \cdot \text{dm}^2$, and may be a new interval composed of any two values in an infinite number of values within $1-20 \text{ A} \cdot \text{dm}^2$, such as $1.5-18 \text{ A} \cdot \text{dm}^2$, $2-15 \text{ A} \cdot \text{dm}^2$, $1-10 \text{ A} \cdot \text{dm}^2$, and $1-8 \text{ A} \cdot \text{dm}^2$. In addition, when there are a plurality of numerical combinations, each parameter may have any value within its value range, and the values of the plurality of parameters may be arbitrarily matched.

[0092] It should be understood that the terms used herein are for the purpose of describing particular exemplary embodiments only and are not intended to form a limitation. As used herein, the singular forms "a", "an", and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. The terms "comprising", "including", "containing", and "having" are inclusive, and therefore specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or combinations thereof. The method steps, processes, and operations described herein are not to be construed as necessarily requiring that they be performed in the particular order described or illustrated, unless the order of performance is explicitly stated. It should also be understood that additional or alternative steps may be used.

Brief Description of the Drawings

[0093] Various other advantages and benefits will become apparent to a person skilled in the art upon reading

the following detailed description of the preferred embodiments. The drawings are only for the purpose of illustrating the preferred embodiments and are not to be construed as limiting the present invention. Moreover, throughout the accompanying drawings, the same components are indicated by the same reference numerals.

FIG. 1 is an exemplary view of an electroplating apparatus adopted in examples and comparative examples of the present invention, where: 1-positive electrode, 2-negative electrode, 3-direct current power supply, 4-anode, 5-electroplating bath, 6-fixtured (cathode), 7-electroplated part, and 8-transmission mechanism; and

FIGS. 2-8 are exemplary views of fixtures adopted in examples and comparative examples of the present invention, where: 1-fixing part, 2-connecting portion, 3-clamping portion, D-distance between connecting rods, i.e., width of the connecting portion, and 9-auxiliary cathode.

Detailed Description of the Invention

[0094] The following descriptions are only preferred embodiments of the present invention, and the protection of the present invention is not limited to the following preferred embodiments. For example, in the examples, the description is given by taking a stent or a stent of a certain model as an example, but it does not represent that the technical solution of the present invention is only suitable for the stent or the stent of a certain model. It should be noted that several variations and improvements made by a person skilled in the art based on the present inventive concept fall within the scope of the present invention. The reagents or instruments used are conventional products that are commercially available through regular channels without specifying the manufacturer.

Test methods

1. Determination of thickness of electroplated layer

[0095] In the present invention, the thickness of the electroplated layer is determined using an X-ray fluorescence plating thickness gauge method. Firstly, the apparatus is calibrated using a standard block of a corresponding element. After the calibration is completed, a stent sample for testing the thickness of the electroplated layer is fixed on a sample stage and put into the X-ray fluorescence plating thickness gauge. The types of coating and substrate metal are set, the measurement time is set as 10-15 s, and the thickness is in μm . OK is clicked to test the thicknesses of the plated layer at various positions on the electroplated part, and the thicknesses at the thickest place and the thinnest place are determined.

2. Determination of organic residues in plated layer

[0096] According to the method recorded in the national standard "GB/T 2013-2006/ISO 15350:2000 Steel and iron - Determination of total carbon and sulfur content - Infrared absorption method after combustion in an induction furnace", the carbon contents C_1 and C_2 in the electroplated part substrate and the electroplated part are detected, respectively, and the carbon content $C = C_1 - C_2$ in the electroplated layer is determined.

[0097] According to the statistics on the percentage contents of carbon atoms in various types of organic substances, formic acid has the lowest carbon content of 26.1%. Benzene and acetylene have the highest carbon content of 92.3%. Therefore, it can be considered that the carbon content in organic substances is generally between 26.1%-92.3%, and therefore the content of organic residues is 1.083-3.831 times the carbon content. Therefore, in the present application, the percentage of organic residues in the present application is obtained by multiplying the carbon content measured according to the above-mentioned national standard by 3.831.

[0098] It should be noted that, in the present invention, the carbon content in the electroplated part is determined using the method recorded in the national standard "GB/T 2013-2006/ISO 15350:2000 Steel and iron - Determination of total carbon and sulfur content - Infrared absorption method after combustion in an induction furnace", and in the second paragraph of "1 Scope" of this standard, it is clearly stated that "the method is applicable to the determination of carbon content with a mass fraction of 0.005%-4.3%". Therefore, the organic residues in the electroplated layer have a low mass fraction ranging from 0.019% to 16.47. Therefore, in the present invention, when the carbon content in a test object cannot be measured using the method, it can be considered that the carbon content in the test object is less than 0.005%, and further it can be considered that the mass percentage content of the organic residues in the test object is less than 0.019%, and even less than 0.0125% (based on the calculation from the carbon content in glucose).

Example 1

[0099] As shown in FIG. 1, an anode width was 20 mm, a trajectory of one cycle of stent motion was 50 mm, a motion period was 1 s, and a swing angle was 60°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, a 30018 stent was used for electroplating. The solution temperature was 10°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. As shown in FIG. 2, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.005 N. With a current of 0.09 A, a current density of 10 A/dm²,

and an electroplating time of 19 s, a zinc layer with an average thickness of 1 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 3.5 μm, the minimum thickness at a middle part of an inner wall was 0.75 μm, and a ratio of the maximum thickness to the minimum thickness was 4.67. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.35%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 74 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with no cell proliferation and no stent rod fracture.

Example 2

[0100] As shown in FIG. 1, an anode width was 20 mm, a trajectory of one cycle of stent motion was 80 mm, a motion period was 2 s, and a swing angle was 90°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, a 30018 stent was used for electroplating. The solution temperature was 20°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. As shown in FIG. 2, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.005 N. With a current of 0.09 A, a current density of 10 A/dm², and an electroplating time of 19 s, a zinc layer with an average thickness of 1 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 3.0 μm, the minimum thickness at a middle part of an inner wall was 0.76 μm, and a ratio of the maximum thickness to the minimum thickness was 3.94. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.34%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 76 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with no cell proliferation and no stent rod fracture.

Example 3

[0101] As shown in FIG. 1, an anode width was 20 mm, a trajectory of one cycle of stent motion was 120 mm, a motion period was 3 s, and an angle was 120°. In a zinc plating solution containing 15 g/L zinc oxide and 120 g/L sodium hydroxide, a 30018 stent was used for electroplating. The solution temperature was 30°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. As shown in FIG. 5, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.005 N. With a current of 0.09 A, a current density of 10 A/dm², and an electroplating time of 19 s, a zinc layer with an average thickness of 1 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 2.8 μm, the minimum thickness at a middle part of an inner wall was 0.77 μm, and a ratio of the maximum thickness to the minimum thickness was 3.63. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.33%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 78 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with no cell proliferation and no stent rod fracture.

Example 4

[0102] As shown in FIG. 1, an anode width was 20 mm, a trajectory of one cycle of stent motion was 160 mm, a motion period was 4 s, and an angle was 135°. In a zinc plating solution containing 15 g/L zinc oxide and 120 g/L sodium hydroxide, a 30018 stent was used for electroplating. The solution temperature was 40°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. As shown in FIG. 4, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.005 N. With a current of 0.09 A, a current density of 10 A/dm², and an electroplating time of 19 s, a zinc layer with an average thickness of 1 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 2.6 μm, the minimum thickness at a middle part of an inner wall was 0.78 μm, and a ratio of the maximum thickness to the minimum thickness was 3.33. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was

0.32%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 81 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with no cell proliferation and no stent rod fracture.

Example 5

[0103] As shown in FIG. 1, an anode width was 20 mm, a trajectory of one cycle of stent motion was 800 mm, a motion period was 5 s, and a swing angle was 150°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, an 80023 stent was used for electroplating. The solution temperature was 50°C, a stent area was 0.025 dm², a mass-lumen volume ratio was 0.033 g/cm³, and a stent length was 23 mm. As shown in FIG. 2, a fixture width d was 18.5 mm, a ratio of the fixture width to an electroplated part length was 0.8, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.05 N. With a current of 0.25 A, a current density of 10 A/dm², and an electroplating time of 19 s, a zinc layer with an average thickness of 1 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 2.2 μm, the minimum thickness at a middle part of an inner wall was 0.79 μm, and a ratio of the maximum thickness to the minimum thickness was 3.09. Five stents were electroplated consecutively, and the RSD of the weight of the electroplated layer was 0.31%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 83 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with no cell proliferation and no stent rod fracture.

Example 6

[0104] As shown in FIG. 1, an anode width was 200 mm, a trajectory of one cycle of stent motion was 200 mm, a motion period was 1 s, and a swing angle was 60°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, a 30018 stent was used for electroplating. The solution tempera-

ture was 25°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. As shown in FIG. 3, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.005 N. With a current of 0.06 A, a current density of 5 A/dm², and an electroplating time of 19 s, a zinc layer with an average thickness of 0.5 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 2.5 μm, the minimum thickness at a middle part of an inner wall was 0.375 μm, and a ratio of the maximum thickness to the minimum thickness was 4.67. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.25%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 50 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with no cell proliferation and partial stent rod fracture.

Example 7

[0105] As shown in FIG. 1, an anode width was 200 mm, a trajectory of one cycle of stent motion was 400 mm, a motion period was 1 s, and a swing angle was 60°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, a 30018 stent was used for electroplating. The solution temperature was 25°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. As shown in FIG. 7, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.005 N. With a current of 0.15 A, a current density of 10 A/dm², and an electroplating time of 57 s, a zinc layer with an average thickness of 3 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 9.75 μm, the minimum thickness at a middle part of an inner wall was 2.34 μm, and a ratio of the maximum thickness to the minimum thickness was 4.17. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.30%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than

a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 90 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with slight cell proliferation, a vascular stenosis rate reaching 27%, and no stent rod fracture.

Example 8

[0106] As shown in FIG. 1, an anode width was 200 mm, a trajectory of one cycle of stent motion was 400 mm, a motion period was 1 s, and a swing angle was 60°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, a 30018 stent was used for electroplating. The solution temperature was 25°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. As shown in FIG. 8, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.005 N. With a current of 0.27 A, a current density of 15 A/dm², and an electroplating time of 50.7 s, a zinc layer with an average thickness of 4 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 12.8 μm, the minimum thickness at a middle part of an inner wall was 3.2 μm, and a ratio of the maximum thickness to the minimum thickness was 4. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.35%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 94 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with slight cell proliferation in some sites, a vascular stenosis rate reaching 30%, and no stent rod fracture.

Example 9

[0107] As shown in FIG. 1, an anode width was 20 mm, a trajectory of one cycle of stent motion was 400 mm, a motion period was 1 s, and a swing angle was 60°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, a 30018 stent was used for electroplating. The solution temperature was 25°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length

was 18 mm. As shown in FIG. 6, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm^2 , and the clamping force was 0.010 N. With a current of 0.36 A, a current density of 20 A/dm^2 , and an electroplating time of 47.5 s, a zinc layer with an average thickness of $5 \text{ }\mu\text{m}$ was obtained. The maximum thickness at a head end of an outer wall of the stent was $15 \text{ }\mu\text{m}$, the minimum thickness at a middle part of an inner wall was $4.25 \text{ }\mu\text{m}$, and a ratio of the maximum thickness to the minimum thickness was 3.53. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.35%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 98 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with certain cell proliferation in some sites, a vascular stenosis rate reaching 35%, and no stent rod fracture.

Example 10

[0108] As shown in FIG. 1, an anode width was 200 mm, a trajectory of one cycle of stent motion was 400 mm, a motion period was 1 s, and a swing angle was 60° . In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, two sections of electroplating were added at two ends of a 30018 stent. The solution temperature was 25°C , a stent area was 0.012 dm^2 , a mass-lumen volume ratio was 0.012 g/cm^3 , and a stent length was 22 mm. As shown in FIG. 2, a fixture width d was 20 mm, a ratio of the fixture width to an electroplated part length was 0.91, a contact area between the fixture and the stent was 0.1 mm^2 , and the clamping force was 0.005 N. With a current of 0.06 A, a current density of 5 A/dm^2 , and an electroplating time of 38 s, a zinc layer with an average thickness of $1 \text{ }\mu\text{m}$ was obtained. Each of two sections at the ends of the stent was removed by 2 mm. The maximum thickness at a head end of an outer wall of the stent was $2.48 \text{ }\mu\text{m}$, the minimum thickness at a middle part of an inner wall was $0.6 \text{ }\mu\text{m}$, and a ratio of the maximum thickness to the minimum thickness was 4.13. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.35%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of

rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 76 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with no cell proliferation and no stent rod fracture.

Example 11

[0109] As shown in FIG. 1, an anode width was 200 mm, a trajectory of one cycle of magnesium bone nail motion was 400 mm, a motion period was 1 s, and a swing angle was 60° . In an electroplating solution containing 90 g/L zinc chloride, 10 g/L ferrous sulfate, and 200 g/L potassium chloride, the magnesium bone nail was electroplated. The solution temperature was 25°C , a bone nail surface area was 0.009 dm^2 , and a bone nail length was 18 mm. As shown in FIG. 3, a fixture width d was 16 mm, a ratio of the fixture width to the bone nail length was 0.89, a contact area between the fixture and the bone nail was 0.1 mm^2 , and the clamping force was 0.28 N. With a current of 0.018 A, a current density of 2 A/dm^2 , and an electroplating time of 95 s, a zinc-iron alloy layer with an average thickness of $1 \text{ }\mu\text{m}$ was obtained, which contained 99.5% zinc and 0.5% iron. The maximum thickness at a head end of the bone nail was $2.4 \text{ }\mu\text{m}$, the minimum thickness at a middle part was $0.8 \text{ }\mu\text{m}$, and a ratio of the maximum thickness to the minimum thickness was 3.0. Five bone nails were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.25%. There was no burn or fracture of the bone nails. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two bone nails were implanted into the ankle joint of rabbits. A first bone nail was removed after 3 months, and the bone nail structure was complete. A second stent was removed after 6 months with no cell proliferation, and the bone nail substrate was basically free from corrosion.

Example 12

[0110] As shown in FIG. 1, an anode width was 200 mm, a trajectory of one cycle of ironmanganese occluder motion was 100 mm, a motion period was 1 s, and a swing angle was 60° . Electroplating was performed in a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride. The solution temperature was 25°C , the occluder had a surface area of 0.09 dm^2 and a diameter of 18 mm. As shown in FIG. 2, a fixture width d was 16 mm, a ratio of the fixture width to the occluder diameter was 0.89, a contact area between the fixture and the occluder was 0.1 mm^2 , and the clamping force was 0.35 N. With a current of 0.72 A, a current density of 8 A/dm^2 , and an electroplating time of 23.8 s, a zinc layer with an average thickness of $1 \text{ }\mu\text{m}$ was ob-

tained. The maximum thickness of a circumference of the occluder was 7.5 μm , the minimum thickness of a central interior was 0.25 μm , and a ratio of the maximum thickness to the minimum thickness was 30. Five bone nail were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.25%. There was no burn or fracture of the occluders. Two occluders were implanted into the interatrial septum of rabbits. A first occluder was removed after 1 month with no endothelialization in the middle position and removed after 2 months with no endothelialization in the middle position and complete endothelialization at the end portion of an outer wall. A second occluder was removed after 6 months, and cell proliferation at the end portion was severe.

Example 13

[0111] As shown in FIG. 1, an anode width was 120 mm, a trajectory of one cycle of stent motion was 120 mm, a motion period was 3 s, and an angle was 120°. In a zinc plating solution containing 15 g/L zinc oxide and 120 g/L sodium hydroxide, a 30018 stent was used for electroplating. The solution temperature was 30°C, a stent area was 0.009 dm^2 , a mass-lumen volume ratio was 0.012 g/cm^3 , and a stent length was 18 mm. As shown in FIG. 2, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm^2 , and the clamping force was 0.005 N. With a current of 0.09 A, a current density of 10 A/dm^2 , and an electroplating time of 19 s, a zinc layer with an average thickness of 1 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 5.0 μm , the minimum thickness at a middle part of an inner wall was 0.6 μm , and a ratio of the maximum thickness to the minimum thickness was 8.33. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.3%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months. The stent structure was complete, and the measured radial support strength was 65 kPa, which met the mechanical performance requirements for the early 3 months of implantation. A second stent was removed after 6 months with no cell proliferation and no stent rod fracture.

Comparative example 1

[0112] As shown in FIG. 1, an anode width was 20 mm, a trajectory of one cycle of stent motion was 50 mm, a motion period was 1 s, and an angle was 60°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L

boric acid, and 200 g/L potassium chloride, a 30018 stent was used for electroplating. The solution temperature was 10°C, a stent area was 0.009 dm^2 , a mass-lumen volume ratio was 0.012 g/cm^3 , and a stent length was 18 mm. As shown in FIG. 2, a fixture width d was 17.5 mm, a ratio of the fixture width to an electroplated part length was 0.97, a contact area between the fixture and the stent was 0.1 mm^2 , and the clamping force was 0.0005 N. With a current of 0.09 A, a current density of 10 A/dm^2 , and an electroplating time of 19 s, a zinc layer with an average thickness of 1 μm was obtained. The maximum thickness at a head end of an outer wall of the stent was 3.6 μm , the minimum thickness at a middle part of an inner wall was 0.76 μm , and a ratio of the maximum thickness to the minimum thickness was 4.73. Two ends of the stent were ablated and fused with the fixture, resulting in disqualification. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%.

Comparative example 2

[0113] As shown in FIG. 1, an anode width was 20 mm, a trajectory of one cycle of stent motion was 80 mm, a motion period was 2 s, and a swing angle was 90°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, and 200 g/L potassium chloride, a 30018 stent was used for electroplating. The solution temperature was 20°C, a stent area was 0.009 dm^2 , a mass-lumen volume ratio was 0.012 g/cm^3 , and a stent length was 18 mm. As shown in FIG. 2, a fixture width d was 12 mm, a ratio of the fixture width to an electroplated part length was 0.67, a contact area between the fixture and the stent was 0.1 mm^2 , and the clamping force was 0.8 N. With a current of 0.09 A, a current density of 10 A/dm^2 , and an electroplating time of 19 s, a zinc layer with an average thickness of 1 μm was obtained. The stent was disqualified due to overall distortion and deformation. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.4%. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%.

Comparative example 3

[0114] As shown in FIG. 1, an anode width was 200 mm, a trajectory of one cycle of stent motion was 200 mm, a motion period was 1 s, and a swing angle was 60°. In a zinc plating solution containing 50 g/L zinc chloride, 25 g/L boric acid, 200 g/L potassium chloride, 0.1 g/L benzylideneacetone, 0.6 g/L fatty alcohol polyoxyethylene ether O-20, and 0.2 g/L sodium benzenesulfonate, a 30018 stent was used for electroplating. The solution

temperature was 25°C, a stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. As shown in FIG. 2, a fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.89, a contact area between the fixture and the stent was 0.1 mm², and the clamping force was 0.005 N. With a current of 0.09 A, a current density of 10 A/dm², and an electroplating time of 19 s, a zinc layer with an average thickness of 1 µm was obtained. The maximum thickness at a head end of an outer wall of the stent was 2.4 µm, the minimum thickness at a middle part of an inner wall was 0.8 µm, and a ratio of the maximum thickness to the minimum thickness was 3. Five stents were electroplated consecutively, the RSD of the mass of the electroplated layer was 0.25%, and there was no burn or fracture of the stents. The mass percentage content of the organic residues in the electroplated layer was 0.8%. Two weeks after stent implantation in the abdominal aorta of rabbits, the stent was removed, and the vessels showed massive inflammation and pustules.

Comparative example 4

[0115] As shown in FIG. 1, an anode width was 600 mm, a trajectory of one cycle of stent motion was 50 mm, a motion period was 4 s, and an angle was 35°. In a zinc plating solution containing 15 g/L zinc oxide and 120 g/L sodium hydroxide, a 30018 stent was used for electroplating. The solution temperature was 40°C, a total stent area was 0.009 dm², a mass-lumen volume ratio was 0.012 g/cm³, and a stent length was 18 mm. A single fixture width d was 16 mm, a ratio of the fixture width to an electroplated part length was 0.87, a contact area between the fixture and the stent was 1 mm², and the single clamping force was 0.005 N. With a current of 0.09 A, a current density of 10 A/dm², and an electroplating time of 95 s, a zinc layer with an average thickness of 5 µm was obtained. The maximum thickness at a head end of an outer wall of the stent was 18 µm, the minimum thickness at a middle part of an inner wall was 0.34 µm, and a ratio of the maximum thickness to the minimum thickness was 52.9. Five stents were electroplated consecutively, and the RSD of the mass of the electroplated layer was 0.5%. There was no burn or fracture of the stents. The carbon content was not detected, and the content of organic residues in the electroplated layer was lower than a detection limit. Therefore, the mass percentage content of the organic residues in the electroplated layer was less than 0.019%. Two stents were implanted into the abdominal aorta of rabbits. A first stent was removed after 3 months, and the stent structure was complete. A second stent was removed after 6 months with obvious cell proliferation in most sites, a vascular restenosis rate reaching 70%, and partial stent rod fracture.

[0116] Numerous other examples of the present invention are possible. Without departing from the spirit of the present invention and the essence thereof, a person skilled in the art may make various corresponding

changes and deformations in accordance with the present invention, and these corresponding changes and deformations shall fall within the scope of the claims appended to the present invention.

Claims

1. An electroplated part, comprising a substrate and an electroplated layer, the electroplated layer covering the substrate, wherein the content of organic residues in the electroplated layer is less than 0.2%.
2. The electroplated part according to claim 1, wherein the content of organic residues in the electroplated layer is less than 0.1%; the content of organic residues in the electroplated layer is less than 0.05%; the content of organic residues in the electroplated layer is less than 0.019%.
3. The electroplated part according to claim 1, wherein a ratio of a thickness of the electroplated layer at the thickest place to a thickness at the thinnest place on the substrate is (1-30): 1; the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is (1-20): 1; the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is (1-15): 1; the ratio of the thickness of the electroplated layer at the thickest place to the thickness at the thinnest place on the substrate is (1-12): 1.
4. The electroplated part according to claim 1, wherein an average thickness of the electroplated layer is 0.5-5 µm; a thickness of the electroplated layer at the thickest place on the substrate is (1, 7.5] times the average thickness; a thickness of the electroplated layer at the thinnest place on the substrate is [0.25, 1) times the average thickness.
5. The electroplated part according to claim 1, wherein a thickness of the electroplated layer at the thinnest place on the substrate is 0.25-4.25 µm; the thickness of the electroplated layer at the thinnest place on the substrate is 0.375-3.2 µm; the thickness of the electroplated layer at the thinnest place on the substrate is 0.6-3.2 µm; the thickness of the electroplated layer at the thinnest place on the substrate is 0.6-2.5 µm.
6. The electroplated part according to claim 1, wherein a thickness of the electroplated layer at the thickest place on the substrate is 1.1-15 µm; the thickness of the electroplated layer at the thickest place on the substrate is 1.1-9.75 µm; the thickness of the electroplated layer at the thickest place on the substrate is 1.1-7.5 µm; the thickness of the electroplated layer at the thickest place on the substrate is 1.2-5 µm.

7. The electroplated part according to claim 1, wherein the electroplated layer covers more than 99% of a surface of the substrate; the electroplated layer is a pure metal layer or an alloy layer; the content of zinc in the electroplated layer is not less than 50%; the content of zinc in the electroplated layer is more than 99%. 5
8. The electroplated part according to claim 1, wherein a medical device comprises a vascular stent, a non-vascular endoluminal stent, an occluder, an orthopedic implant, a heart valve, a spacer, an artificial vessel, a dental implant device, a vascular clamp, a dental implant, a respiratory implant, a gynecological implant, an andrological implant, a suture, and a bolt; the substrate is made of a degradable metal or a degradable non-metal material; the substrate comprises at least one of pure iron, an iron alloy, pure zinc, a zinc alloy, pure magnesium, and a magnesium alloy. 10
9. The electroplated part according to claim 1, wherein a mass-to-volume ratio of the electroplated part is 0.001-10 g/cm³; the mass-to-volume ratio of the electroplated part is 0.001-5 g/cm³; the mass-to-volume ratio of the electroplated part is 0.001-0.4 g/cm³; an iron alloy comprises at least one of a low alloy steel or an iron-based alloy having a carbon content of no more than 2.5 wt.%. 15
10. A preparation method of the electroplated part according to claims 1-9, wherein the electroplated part is placed in an electroplating solution and moves relative to an anode at a certain amplitude and frequency with a fixture, wherein a length of a motion trajectory of the electroplated part relative to the anode during an electroplating process is 2-980 times a width of the anode; and/or auxiliary cathodes are connected to the electroplated part. 20
11. The preparation method according to claim 10, wherein the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 2-540 times the width of the anode; the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 2-400 times the width of the anode; the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 2-240 times the width of the anode; the length of the motion trajectory of the electroplated part relative to the anode during the electroplating process is 2-150 times the width of the anode. 25
12. The preparation method according to claim 10 or 11, wherein the width of the anode is ≥ 0.1 cm; the amplitude of swing of the electroplated part relative to the anode is 0°-180°; the auxiliary cathodes are connected to two ends of the electroplated part in a long axis direction or in a direction parallel to an anode surface. 30
13. The preparation method according to claim 10, wherein the amplitude of swing of the electroplated part relative to the anode is 0°-160°; the frequency of motion of the electroplated part relative to the anode is 0.1 s-20 s/cycle. 35
14. The preparation method according to claim 10, wherein an area of the auxiliary cathode is 30%-70% of an area of a cathode; the auxiliary cathode has a length of 0.5 mm-20 mm; the auxiliary cathode has a length of 0.5 mm-10 mm; the auxiliary cathode is of any shape; the auxiliary cathode comprises at least one of a linear type, an annular type, a ring type, a prismatic type, a pyramidal type, a spiral type, a wheel type, a cylindrical type, and a corrugated type. 40
15. The preparation method according to claim 10, wherein a cross-sectional area of the auxiliary cathode in a direction perpendicular to an anode surface or a long axis direction of the electroplated part is larger than a cross-sectional area of a short axis of the electroplated part; the auxiliary cathode is connected to the electroplated part through a linkage or a point. 45
16. The preparation method according to claim 15, wherein the linkage is one of a straight line or a non-straight line; the linkage is at least one of a linear type, an S type, a ω type, or a Ω type; the linkage is fixedly or detachably connected to the electroplated part, the fixture, and the auxiliary cathode. 50
17. The preparation method according to claim 10, wherein the electroplated part is subjected to a force of the fixture during the electroplating process; the magnitude of the force applied to the electroplated part by the fixture during the electroplating process is 1×10^{-3} N-0.5 N. 55
18. The preparation method according to claim 10, wherein a contact area between the electroplated part and the fixture is not more than 0.1 mm².
19. The preparation method according to claim 10, wherein a temperature of the electroplating solution during the electroplating process of the electroplated part is 10°C-50°C; the current density during the electroplating process of the electroplated part is 1 A·dm²-20 A·dm²; the electroplating time during the electroplating process of the electroplated part is 10-300 s.

20. The preparation method according to claim 10, wherein each component in the electroplating solution is an inorganic substance.
21. The preparation method according to claim 10, wherein when zinc is contained in a plated layer, the electroplating solution comprises 3.4-4.5 wt.% of a zinc-containing component and 2.1-3.1 wt.% of a pH adjusting agent; or the electroplating solution comprises 1.5-3.0 wt.% of the zinc-containing component and 6.5-8.8 wt.% of the pH adjusting agent;
- the zinc-containing component is at least one of zinc chloride, zinc sulfate, and zinc oxide;
- the pH adjusting agent is at least one of boric acid, sodium borate, potassium borate, calcium borate, sodium hydroxide, and potassium hydroxide.
22. The preparation method according to claim 21, wherein the electroplating solution further comprises 15.5-19.5 wt.% of a chloride salt; the chloride salt is at least one of sodium chloride, potassium chloride, and ammonium chloride.
23. A fixture, configured to fix an electroplated part in an electroplating bath and drive the electroplated part to move relative to an anode.
24. The fixture according to claim 23, comprising a connecting portion and clamping portions perpendicularly connected to the connecting portion, wherein the clamping portion is parallel to a long axis direction of the electroplated part; an end of the connecting portion near the electroplated part has at least two connecting rods, and at least one clamping portion is connected to each connecting rod.
25. The fixture according to claim 24, wherein a distance between two connecting rods is [0.6, 0.98] times a distance between corresponding contact points of the electroplated part and the connecting rod.
26. The fixture according to claim 24, wherein a ratio of a distance between any two points connected by a straight line on a cross section of the clamping portion perpendicular to a length direction of the electroplated part to an inner diameter of the electroplated part is 1: 1-1: 20; the clamping portion has a length of 0.16 mm-7 mm.
27. The fixture according to claim 24, wherein more than 95% of a surface of the fixture is covered with an insulating layer; or more than 25% of the surface of the fixture is covered with the insulating layer.
28. The fixture according to claim 24, wherein a fixing part is further connected to an end of the connecting portion away from the electroplated part.
29. An electroplating apparatus, comprising the fixture according to claims 23-28, and further comprising a power supply, an electrolytic bath, and anodes, wherein the fixture is connected to the electroplating apparatus through a supporting rod.
30. The electroplating apparatus according to claim 29, wherein the number of the anodes is greater than or equal to 2; a center position of the two or more anodes coincides with a center position of a motion trajectory of an electroplated part.
31. The electroplating apparatus according to claim 29, a width of the anode is ≥ 0.1 cm; the electroplating apparatus further comprises a component configured to control and drive relative motion of the fixture and the anode.
32. The electroplating apparatus according to claim 29, further comprising a display screen.

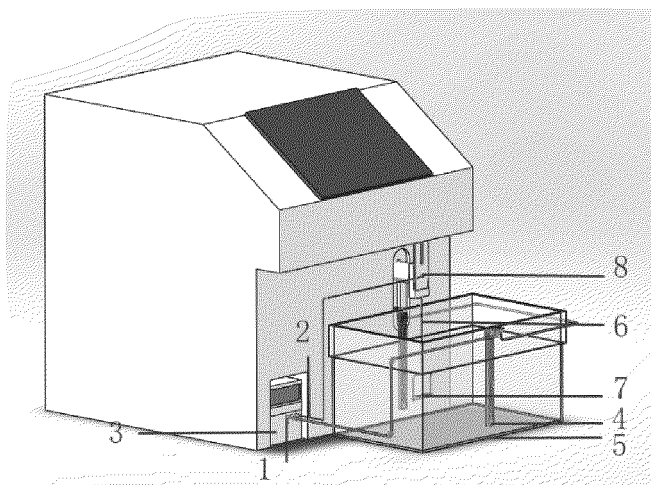


FIG. 1

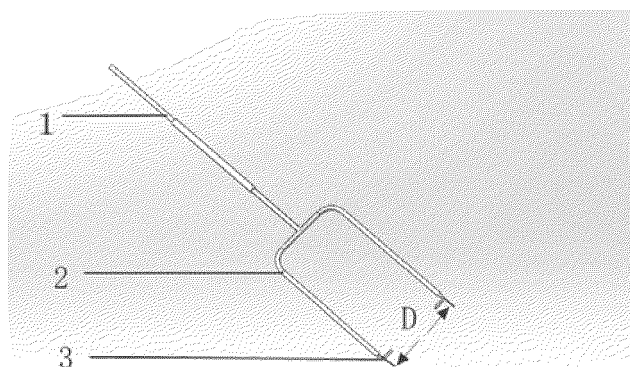


FIG. 2

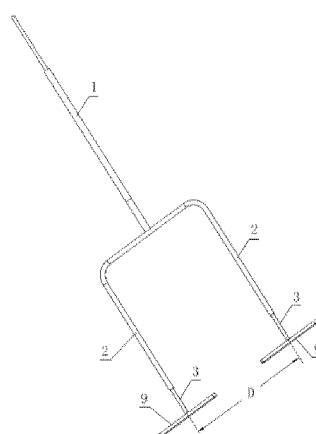


FIG. 3

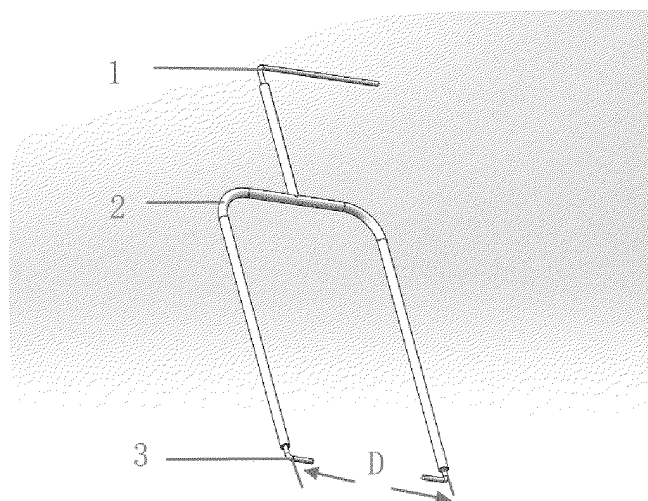


FIG. 4

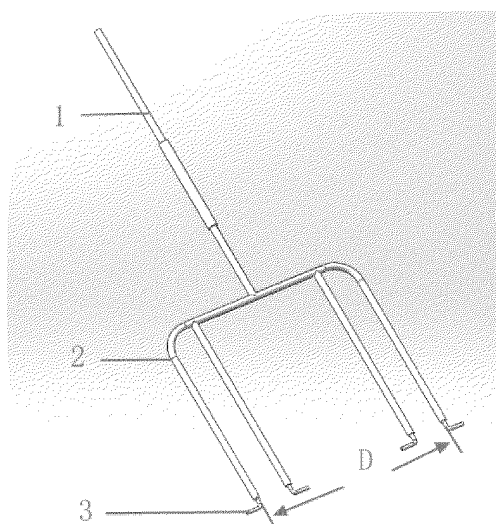


FIG. 5

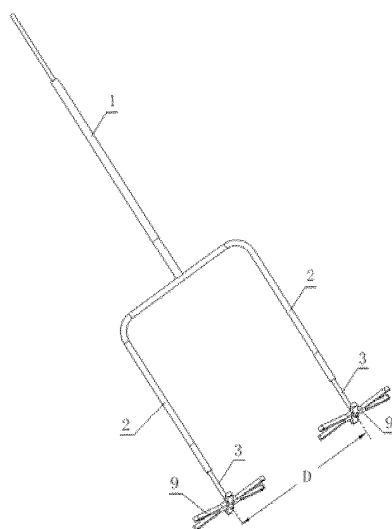


FIG. 6

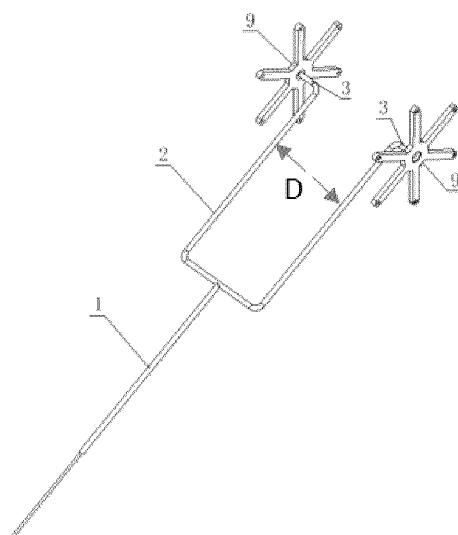


FIG. 7

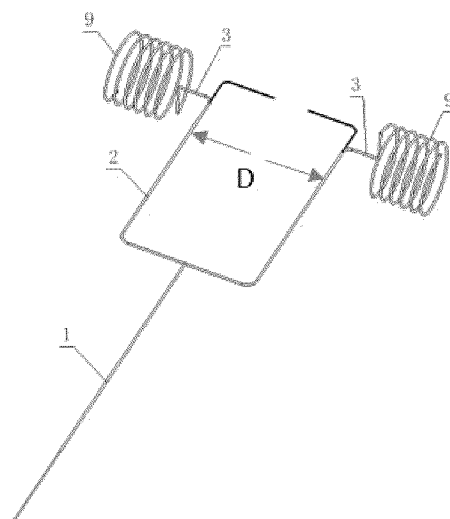


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2023/110250

A. CLASSIFICATION OF SUBJECT MATTER

C25D15/02(2006.01)i; C25D13/02(2006.01)i; C25D7/00(2006.01)i; C25D17/06(2006.01)i; C25D17/08(2006.01)i; C25D19/00(2006.01)i

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)

IPC:C25D15/-, C25D13/-, C25D7/-, C25D17/-, C25D19/-

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

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

CNTXT, DWPI, CNKI, STN, ISI: 电解, 电镀, 有机, 含碳量, 残留, 残余, 夹具, 阳极, 运动, 医疗, electrolysis, electroplating, organic, carbon content, C content, amount of carbon, residual, clamp, anode, medical

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0633329 A1 (SUMITOMO METAL INDUSTRIES, LTD.) 11 January 1995 (1995-01-11) description, page 3, lines 9-22, page 6, lines 7-20, and page 7, lines 7-22	1-9
Y	EP 0633329 A1 (SUMITOMO METAL INDUSTRIES, LTD.) 11 January 1995 (1995-01-11) description, page 3, lines 9-22, page 6, lines 7-20, and page 7, lines 7-22	10-22
X	KR 20150087502 A (DAEDUCK ELECTRONICS CO., LTD.) 30 July 2015 (2015-07-30) description, paragraphs 0016-0020, and figure 2	23-32
Y	KR 20150087502 A (DAEDUCK ELECTRONICS CO., LTD.) 30 July 2015 (2015-07-30) description, paragraphs 0016-0020, and figure 2	10-22
X	JP 2001040498 A (N.E. CHEMCAT CORP.) 13 February 2001 (2001-02-13) description, embodiment 1	1-9
A	JP 2001040498 A (N.E. CHEMCAT CORP.) 13 February 2001 (2001-02-13) description, embodiment 1	10-32
X	JP H07108644 A (SUMITOMO METAL INDUSTRIES, LTD.) 25 April 1995 (1995-04-25) claims 1-5	1-9

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

* Special categories of cited documents:

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“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

30 October 2023

Date of mailing of the international search report

03 November 2023

Name and mailing address of the ISA/CN

China National Intellectual Property Administration (ISA/
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Authorized officer

Telephone No.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2023/110250

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C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP H07108644 A (SUMITOMO METAL INDUSTRIES, LTD.) 25 April 1995 (1995-04-25) claims 1-5	10-32
A	CN 210458402 U (SHENZHEN LIWEI PLASTIC HARDWARE PRODUCTS CO., LTD.) 05 May 2020 (2020-05-05) entire description	1-32

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/CN2023/110250

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JP 2001040498 A	13 February 2001	None	
JP H07108644 A	25 April 1995	None	
CN 210458402 U	05 May 2020	None	