METHOD OF SURFACE HARDENING ORTHOPEDIC IMPLANT DEVICES

This is a continuation of application Ser. No. 07/609/269, filed Nov. 5, 1990, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates generally to titanium orthopedic implant devices and, more particularly, to a surface hardening process applicable to such devices, wherein surface hardness and wear resistance properties of the implant are enhanced with minimal loss in fatigue strength.

Commercially pure titanium and titanium alloys are used for orthopedic applications because of their strength, corrosion resistance, and biocompatibility. However, the tribological behavior of titanium and its alloys is characterized by a high coefficient of friction and poor wear performance, resulting in a tendency for titanium and its alloys to seize or gall under conditions of wear. Therefore, in those orthopedic applications requiring enhanced wear resistance properties, the surface of a titanium implant must be hardened. In the past, surface hardening of orthopedic implants has been achieved either by depositing a nitride coating on the surface of an implant, or by forming a layer of titanium nitride (TIN) on the surface of a titanium substrate.

A TiN layer is produced on the surface of a titanium implant by various nitriding methods, including gas nitriding, chemical salt bath nitriding, plasma or ion nitriding, and ion implantation. Of these alternatives, gas nitriding is believed to be the earliest method used for hardening titanium, and still exhibits advantages over the other methods in terms of cost and ease of manufacture. For instance, gas nitriding permits efficient batch processing of many parts concurrently in a furnace chamber; whereas, the plasma nitriding and ion implantation methods require line-of-sight bombardment of the workpiece, thereby limiting the number of parts that may be processed concurrently.

Gas nitriding of titanium and its alloys has historically been performed at elevated temperatures in the range of 700° C. to 200° C. (1292° F. to 2192° F.) U.S. Pat. No. 4,768,757 discloses a method for nitriding the surface of a titanium dental cast, wherein it is stated that the temperature generally used for the nitriding treatment falls in the range of 700° C. to 880° C. because nitriding generally begins to proceed in the neighborhood of 700° C. and the heat distortion or phase transition point of titanium is about 882° C. Characteristic of virtually all gas nitriding processes is the formation of a relatively thick TiN layer on the surface of the titanium, caused by a scaling reaction. Essentially, successful nitriding of a titanium orthopedic implant for the purpose of providing a hardened surface is defined by the observance of a distinct and measurable TiN layer achieved by elevated temperatures, as taught by the prior art.

It has now been discovered that the aforementioned gas nitriding process, as applied to a titanium orthopedic implant device, may produce several undesirable changes in the physical and mechanical properties of the device. Notwithstanding increases in overall surface hardness, the TiN layer formed on the surface of the device by gas nitriding at elevated temperatures tends to be brittle and exhibits increased surface roughness, both of which cause losses in the fatigue strength of the implant. Also, temperature induced changes in the dimensions of the titanium orthopedic implant device may occur.

Potential losses in the fatigue strength and increases in the surface roughness of a titanium orthopedic implant device are of particular concern in orthopedic applications involving load bearing prostheses in articulating contact with bone or polymers. For instance, under conditions of sliding or articulation of the nitrided implant against other surfaces, particularly bone and polymers, the increased surface roughness may produce wear debris that can act as an abrasive medium. Consequently, it is desirable to reduce the possibility of wear debris and its potential impact on the stability of orthopedic implants by enhancing the surface hardness of the titanium material without substantial losses in fatigue strength or wear resistance properties.

SUMMARY OF THE INVENTION

Generally, the present invention provides a process for surface hardening an orthopedic implant device made of pure titanium or a titanium alloy, wherein the surface hardness of the device is enhanced while maintaining wear resistance and fatigue strength. The invention also encompasses orthopedic implant devices in accordance with the claimed process.

Generally, the process of the present invention enhances the surface hardness of the titanium implant device by thermal reaction of nitrogen gas at low temperatures. Consequently, surface hardness and wear properties are enhanced with minimal loss in fatigue strength. More specifically, the use of a low process temperature prevents the formation of a measurable TiN layer on the surface that tends to increase surface roughness and diminish wear resistance properties in orthopedic implant applications involving articulating joint surfaces.

An advantage of the surface hardening method of the present invention is that the surface of an orthopedic implant device made of titanium is hardened without substantially affecting the mechanical and physical properties of the material.

Another advantage of the surface hardening method of the present invention is that the method is particularly adapted for use on load bearing prostheses that contact with bone or polymers, due to a significant improvement in wear resistance coupled with a minimal loss in fatigue strength.

A further advantage of the surface hardening method of the present invention is that it permits batch processing of orthopedic implant devices, as opposed to individual processing by prior art plasma nitriding processes requiring a "line of sight" to the parts for ion bombardment.

Yet another advantage of the surface hardening method of the present invention is that formation of a TiN layer and its attendant surface roughness is substantially eliminated by the use of a relatively low process temperature, thereby improving wear resistance properties of the treated surface.

The invention, in one form thereof, provides a method of manufacturing an orthopedic implant device having enhanced surface hardness and wear resistance properties. The method includes several essential steps, including an initial step of providing a titanium substrate in the form of an orthopedic implant device, or component thereof. A surface hardening step is then performed. Specifically, the surface of the titanium substrate is hardened by exposure to an atmosphere of