

hardening of the titanium alloy. The solid solution hardening elements in this case are nitrogen, oxygen, and carbon. This region extends several microns from the surface of the device. The SIMS and ISS analyses indicate that the hardened surface layer and hardened diffusion region together constitute the desired hardened surface. Specifically, metallurgical changes on the surface of the treated titanium implant device include the presence of titanium nitride (Ti<sub>2</sub>N), titanium oxide, titanium carbide, and solid solution of nitrogen in titanium, all of which together produce the desired hardening effect.

While the surface hardening process of the present invention is particularly applicable to orthopedic applications involving load bearing prostheses in articulating contact with bone or polymers, e.g., hip, knee, ankle, elbow, shoulder, wrist, finger, and toe joints, it may also be used to treat all titanium and titanium alloy fracture fixation devices as well.

It will be appreciated that the foregoing description of a preferred embodiment of the invention is presented by way of illustration only and not by way of any limitation, and that various alternatives and modifications may be made to the illustrated embodiment without departing from the spirit and scope of the invention.

What is claimed is:

1. A method of manufacturing a titanium orthopedic implant device having enhanced surface hardness and wear resistance properties, comprising the steps of:
  - providing a titanium substrate in the form of an orthopedic implant device; and
  - hardening the surface of said titanium substrate by exposing said titanium substrate to an atmosphere of undiluted molecular nitrogen gas at a process temperature within the range of 750° F. to 1300° F. for a process time duration sufficient to achieve a hardened surface region characterized primarily by solid solution hardening of the surface of the titanium substrate by dissolution of nitrogen in said titanium substrate.
2. The method of claim 1 in which said titanium substrate comprises commercially pure titanium (CP-Titanium).
3. The method of claim 1 in which said titanium substrate comprises a titanium alloy.
4. The method of claim 3 in which said titanium alloy is Ti-6Al-4V (ELI).
5. The method of claim 1 in which said process temperature is approximately 1100° F. and said process time is approximately eight hours.
6. The method of claim 1 in which said hardened surface region exhibits a peak nitrogen concentration within the range of 10 atomic percent to 50 atomic percent at a depth between 0.01 and 0.10 μm (100 and 1000 Å) below the surface of said titanium substrate.
7. The method of claim 1 in which said hardened surface region includes a hardened surface layer limited in thickness to a depth of approximately 0.20 μm (2000

Å) and a hardened diffusion region underneath said hardened surface layer, said surface layer comprising titanium nitride (Ti<sub>x</sub>N<sub>y</sub>), titanium oxide (Ti<sub>x</sub>O<sub>y</sub>), and titanium carbide (Ti<sub>x</sub>C<sub>y</sub>), and said hardened diffusion region comprising a solid solution of nitrogen, oxygen, and carbon in said titanium substrate.

8. A method of manufacturing a titanium orthopedic implant device having enhanced surface hardness and wear resistance properties, comprising the steps of:

- providing a titanium substrate in the form of an orthopedic implant device; and
- exposing said titanium substrate to an atmosphere of undiluted molecular nitrogen gas at a process temperature and for a process time duration sufficient to cause nitrogen dissolution in said titanium substrate without measurable formation of titanium nitride (TiN) on the surface of said titanium substrate, thereby enhancing the surface hardness and wear resistance properties of said titanium substrate without increasing surface roughness that would diminish the wear resistance properties.

9. The method of claim 8 in which said titanium substrate comprises commercially pure titanium (CP-Titanium).

10. The method of claim 8 in which said titanium substrate comprises a titanium alloy.

11. The method of claim 10 in which said titanium alloy is Ti-5Al-4V (ELI).

12. The method of claim 8 in which said process temperature is in the range of 750° F. to 1300° F.

13. The method of claim 12 in which said process temperature is approximately 1100° F.

14. The method of claim 8 in which said process time is approximately eight hours.

15. The method of claim 8 in which said process temperature is approximately 1100° F. and said process time is approximately eight hours.

16. The method of claim 8 in which said atmosphere of molecular nitrogen gas is provided at a process pressure within the range of 1 psig to 2 psig.

17. A method of increasing the surface hardness and wear resistance properties of an orthopedic implant device that is fabricated from a titanium material, comprising the steps of:

- providing a substrate of titanium material in the form of an orthopedic implant device; and

- exposing said substrate to an atmosphere of undiluted molecular nitrogen gas at a process temperature and for a process time duration sufficient to enhance both surface hardness and wear resistance properties of said substrate by nitrogen dissolution in said substrate without increasing surface roughness and thereby diminishing wear resistance properties by the measurable formation of TiN on the surface of said substrate.

18. The method of claim 17 in which said process temperature is in the range of 750° F. to 1300° F.

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