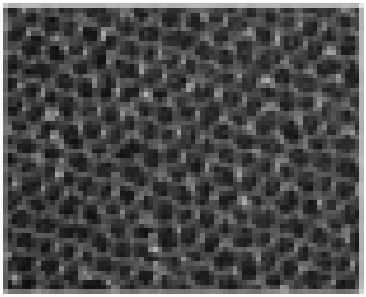
Mechanical Characteristics of *OsteoSync*™ *Ti*

Stinz Medical Research and Development

Introduction

OsteoSync™ Ti is a three-dimensional, open-celled titanium scaffold for bone and tissue ingrowth (Figure 1). It can be used as a standalone implant or combined with metal or polymer components to provide a region for bone ingrowth.

Figure 1:



A close-up view of the *OsteoSync* Ti microstructure.

OsteoSync Ti has a mean porosity of 59.8%, pore sizes ranging from 650-860 µm, and a mean pore interconnectivity of 229 µm[1]. It is manufactured from grade 1 commercially pure titanium satisfying ASTM F67. *OsteoSync* Ti can be manufactured in thicknesses of 0.5 mm and greater. The standard thickness for most implants is 1 mm. If desired, *OsteoSync* Ti can be machined before or after it is attached to a substrate.

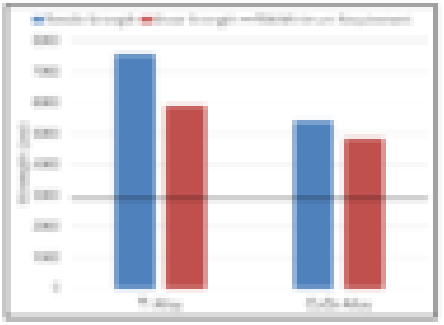
OsteoSync Ti can be metallurgically attached to pure Ti, Ti alloy, or CoCr alloy substrates using a proprietary diffusion bonding process. *OsteoSync* Ti also can be combined with a polymer via injection or compression molding.

Mechanical Strength

Strength requirements for metallic scaffolds are specified in the FDA's 1994 guidance document "Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement"[2]. The scaffold and scaffold/substrate interface must satisfy a static strength of 50 MPa in both tension and shear, and the scaffold must be fatigue tested to 10 million cycles. Figure 2 displays the static strength results of *OsteoSync* Ti when combined with different metal substrate types as tested per ASTM-defined methods[3,4].

Due to fixture failure rather than sample failure during some of these tests, these reported strengths are lower than the actual *OsteoSync* Ti substrate strengths. With all results satisfied FDA requirements. Likewise, 10 million cycle fatigue testing for each of these substrate/*OsteoSync* Ti combinations exceeded 10 MPa, a strength level reported for the porous coating on a hip implant already cleared by the FDA[5,6,7].

Figure 2:



Static strengths of *OsteoSync* Ti when combined with various metal substrates. Due to fixture failure rather than sample failure during some of these tests, these reported strengths are lower than the actual sample strengths. Even so, all strengths satisfied FDA requirements.

Corrosion

Implant corrosion was assessed for the cases where *OsteoSync* Ti is diffusion bonded to a electrolyte substrate (CoCr)[8,9]. Long-term and accelerated weak acid based on the methods outlined by Shultz were performed[3]. To summarize, *OsteoSync* Ti was diffusion bonded to cobalt strength or cast CoCr substrates. These specimens were then submerged in mononuclear Ringer's solution for either a minimum of 6 months at 37±1°C and or a minimum of 3 months at 50±2°C. Throughout the soak tests, the specimens were removed from the tanks periodically and inspected for signs of corrosion. Corrosion was not detected on any specimen at any point, whether at the interface between the CoCr substrate and *OsteoSync* Ti scaffold or within the *OsteoSync* Ti scaffold. This was the case regardless of specimen type, soak test condition, or manufacturing history of the parts.

[1] Also marketed as *BioSync* 350 and *PorstiCoat*®