

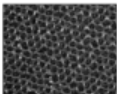
# Mechanical Characteristics of OsteoSyn™ Ti

Site: Medical Research and Development

## Introduction

OsteoSyn™ Ti is a three-dimensional, open-celled titanium scaffold substrate and tissue ingrowth (Figure 1). It is manufactured as a cylindrical ingraft or combined with metal or polymer components to provide a region for bone ingrowth.

Figure 1:



A close-up view of the OsteoSyn Ti substrate.

OsteoSyn Ti has a mean porosity of 76.5%, pore sizes ranging from 120-500  $\mu\text{m}$ , and a mean pore interconnectedity of 127  $\mu\text{m}^2$ . It is manufactured from grade 2 commercially pure titanium utilizing ASTM B37. OsteoSyn Ti can be manufactured in thicknesses of 1 mm and greater. The scaffold thickness for most ingrafts is 1 cm. It is used as a titanium Ti that is machined before or after it is attached to a substrate.

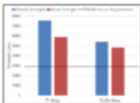
OsteoSyn Ti can be manufacturingly attached to pure Ti, Ti alloy, or CoCr alloy substrates using a proprietary diffusion bonding process. OsteoSyn Ti also can be combined with a polymer via injection or compression molding.

## 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: Applying Force or Bone Contact". The scaffold and scaffold/substrate interface must satisfy a static strength of 30 MPa in both tension and shear, and the scaffold must be capable tested to 10 million cycles. Figure 2 displays the static strength results of OsteoSyn Ti when combined with different metal substrate types as tested per ASTM defined methods<sup>1,2</sup>.

Due to fixture failure rather than sample failure during some of these tests, these reported strengths are lower than the actual titanium Ti substrate strength. Still, all results satisfied FDA requirements. Likewise, 10 million cycle fatigue testing for each of these scaffold/substrate Ti combinations exceeded 10 MPa, a strength level reported for the porous coating on a hip ingraft already cleared by the FDA<sup>3,4,5</sup>.

Figure 2:



Static strength of OsteoSyn 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 strength. Even so, all strengths satisfied FDA requirements.

## Corrosion

Implant corrosion was assessed for the case when OsteoSyn Ti is diffusion bonded to a titanium substrate of CoCr<sup>3,4,5</sup>. Long-term and accelerated soak tests based on the methods outlined by Mullis were performed<sup>6,7</sup>. To summarize, OsteoSyn Ti was diffusion bonded to either titanium or pure CoCr substrates. These specimens were then submerged in simulated Ringer's solution for either a minimum of 6 months at 37°C and/or a minimum of 3 months at 50°C. Throughout the soak test, the specimens were removed from the tanks periodically and inspected for signs of corrosion. Corrosion was not detected on any specimens at any point, whether at the interface between the CoCr substrate and OsteoSyn Ti scaffold or within the OsteoSyn Ti scaffold. This was the case regardless of specimen type, soak test conditions, or manufacturing history of the parts.

<sup>1</sup> Also included in Refs. 10 and 11 and 12.