

IntimateBond[™] Osteoblast

Quick Summary

The Problem IntimateBond™ Solves

Immune System Attack compromises the fixation and performance of every Biocompatible Orthopedic Implant. Biocompatibility does not stop the attack.

Immune attack most often results in fibroblast encapsulation, death of osteoblasts surrounding the implant, and a failure to trigger Osteoblast production and proper healing. The result is a gap between the implant and healthy bone and all the problems that result.

How Can That Problem be Solved?

The problem can be solved by applying immuno-compatible and immuno-optimized surfaces to the implants.

Immuno-compatibility

is essential in moderating immune attack and preventing long-term inflammation, fibroblast encapsulation and formation of a gap around the implant.

Immuno-optimization

triggers the biological cascade that produces osteoblasts and provides a surface to which osteoblasts will attach preferentially.

IntimateBondTM Osteoblast

- Is **immuno-compatible** to modulate immune system attack.
- Is **immuno-optimized** to trigger the cascade that starts with protein adsorption and results in osteoblast production and attachment to the implant.
- Is 1 of 6 cp-Titanium implant cell attachment surfaces developed for 6 distinct cell types, such as vascular endothelials.
- Has significant in vitro and in vivo data supporting its performance.
- Has been proven in well over 50,000 implantations.

FDA Clearance

Implant Surfaces has demonstrated the ability to assist new customers in getting Special 510(k) clearance, within 45-60 days, for their devices with **IntimateBond**TM Osteoblast applied without them having to perform any testing of their implants with the surface applied.

Implant Surfaces maintains a Master File at the FDA for IntimateBond.

Implant Surfaces is ISO 13485:2016 Certified.

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