

Biosteon®

HA/PLLA Interference Screws

Biologically Inspired Fixation



Introduction

Searching For a Better Option

Bioabsorbable polymers such as PLA and PGA have been used in bodily implants due to their radiolucency for MRI and CT imaging, as well as, for their degradation properties. Polymers degrade through simple hydrolysis into materials that can be metabolized by the body¹. However, bioabsorbable polymers are not osteoconductive, have no bone bonding ability and have little potential to be replaced by bone when resorbed^{2,3-5}. Polymers are also susceptible to autocatalytic degradation which can result in acidosis and sterile abscess formation at the site^{6,7}.

Researchers have continued to search for a better option. The focus was to find a material that would mimic the biological function of human bone. Since it was understood that calcium phosphate ceramics are osteoconductive^{8,9}, and calcium phosphates are slightly alkaline, acting to buffer the acidic breakdown products of the polymers, calcium phosphate was added to the polymer to create a composite material.

Materials

Biosteon (HA/PLLA)

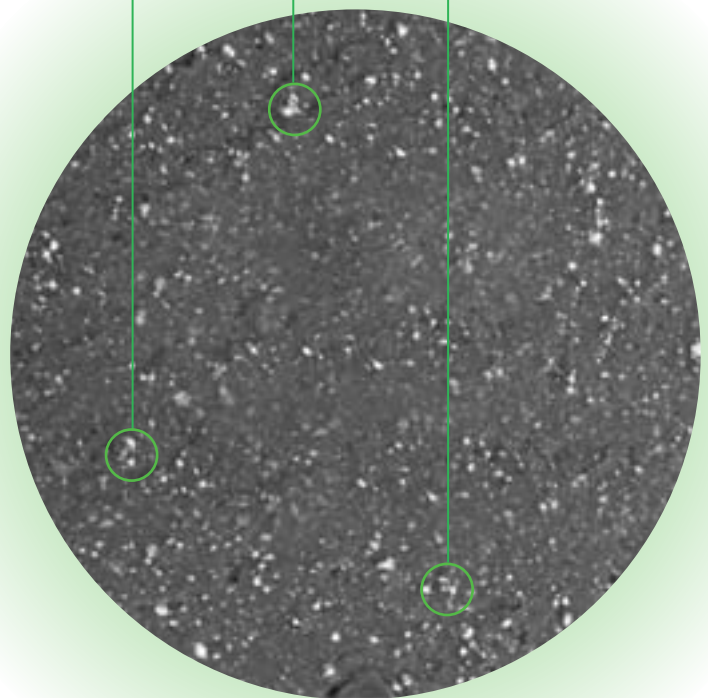
Biosteon is a composite of hydroxyapatite (HA) and non-crystalline poly-L-lactide (PLLA).

25 % HA

HA is dispersed throughout the Biosteon material providing an osteoconductive material similar to the mineral element of bone^{8,9}. The HA particles have a buffering effect on the acidic (lactic acid) degradation product of the polymer⁴, which helps prevent 'autocatalytic' degradation and premature loss of strength.

75% Amorphous PLLA

The amorphous PLLA in Biosteon provides structural integrity, biocompatibility and a controlled degradation rate¹⁰.



Design

Biosteon (HA/PLLA)

Wedge Shape

The wedge shaped design of Biosteon allows for easier insertion and excellent fixation¹¹.



Rounded Threads

Biosteon's rounded thread design helps provide graft protection during insertion.



Cruciate Driver

The cruciate driver design allows for an even distribution of force and a thicker screw wall¹².

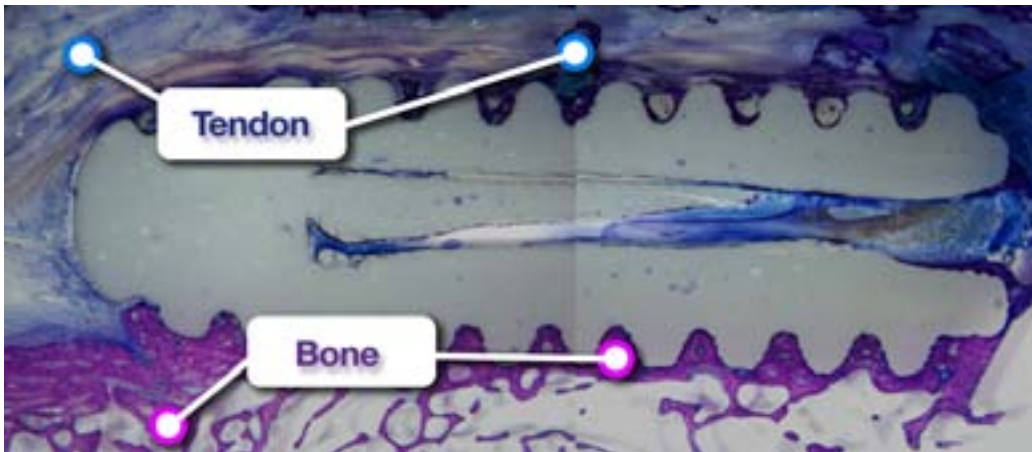


Evidence

Biocompatibility

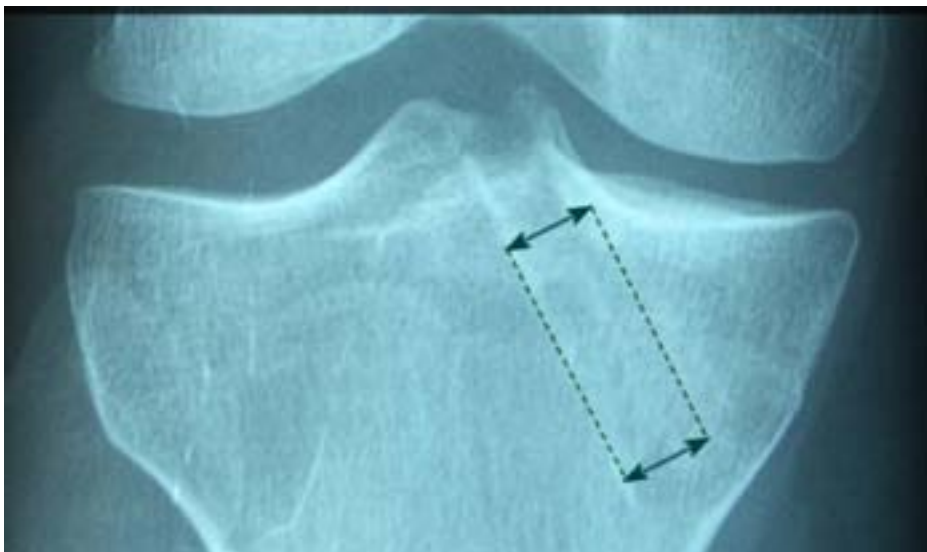
Biosteon HA/PLLA screws have been shown to support bone apposition rather than fibrous tissue formation¹³.

The picture below shows an example of a hard tissue response using the Biosteon HA/PLLA interference screw. In vivo, 6 months post-implantation, new bone has formed into the contours of the Biosteon screw¹³.



Implant/Bone Integration

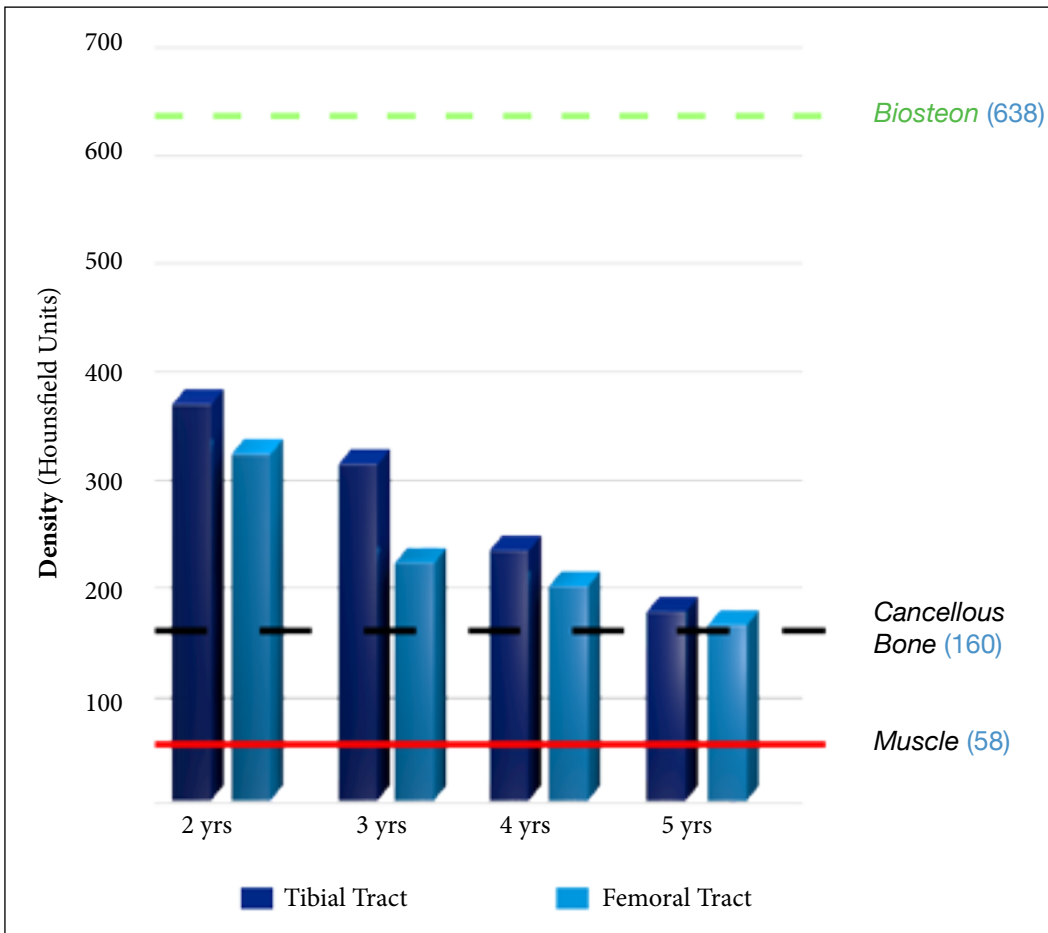
Use of Biosteon screws have been shown to improve the implant/bone integration by reducing tunnel widening¹⁴.



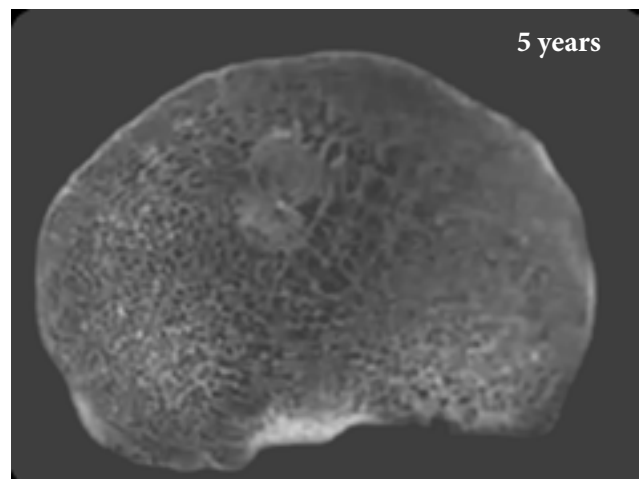
Clinical Evidence of Remodeling¹⁵

Biosteon has been clinically shown to have excellent strength, proven biocompatibility, predictable resorption, osteoconductivity, and remodeling of the screw tract.

The graph below shows the density in the screw tract has become the same as cancellous bone over the course of the remodeling process.



The CT images below show the density of the screw tract at 2 and 5 years. The Biosteon screw is designed to maintain structural integrity and fixation strength during the healing process and remodel over time.



BioSteon Screws

PART NUMBER	DESCRIPTION
234-010-160	6MM X 23MM BIOSTEON SCREW
234-010-161	7MM X 23MM BIOSTEON SCREW
234-010-162	8MM X 23MM BIOSTEON SCREW
234-010-163	9MM X 23MM BIOSTEON SCREW
234-010-164	7MM X 28MM BIOSTEON SCREW
234-010-165	8MM X 28MM BIOSTEON SCREW
234-010-166	9MM X 28MM BIOSTEON SCREW
234-010-167	10MM X 28MM BIOSTEON SCREW
234-010-168	6MM X 28MM BIOSTEON SCREW
234-010-170	10MM X 23MM BIOSTEON SCREW
234-010-172	11MM X 28MM BIOSTEON SCREW
234-010-173	12MM X 28MM BIOSTEON SCREW
234-010-177	9MM X 35MM BIOSTEON SCREW
234-010-178	10MM X 35MM BIOSTEON SCREW
234-010-179	11MM X 35MM BIOSTEON SCREW
234-010-180	12MM X 35MM BIOSTEON SCREW

BioSteon Instrumentation

PART NUMBER	DESCRIPTION
234-010-068	EASY-OUT BIOABSORBABLE ACL SCREW
234-010-090	TAP 6MM BIOSTEON ACL SCREW
234-010-091	TAP 7MM BIOSTEON ACL SCREW
234-010-092	TAP 8MM BIOSTEON ACL SCREW
234-010-093	TAP 9MM BIOSTEON ACL SCREW
234-010-094	TAP 10MM BIOSTEON ACL SCREW
234-010-083	TUNNEL NOTCHER BIOABSORBABLE ACL SCREW
234-010-235	DRIVER SHAFT, TRINKLE 23/28/35MM BIOSTEON ACL SCREW
234-020-117	RATCHETING DRIVER HANDLE
234-020-158	MULTI-PURPOSE IMPACTOR
234-020-234	23MM BIOSTEON SCREW DRIVER
234-020-235	23/28/35MM BIOSTEON SCREWDRIVER
234-030-027	1MM X 14IN NITINOL GUIDE WIRE
234-020-121	BIOSTEON INSTRUMENT TRAY

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